

HEALTH CARE FINANCING ADMINISTRATION OFFICE OF LEGISLATION

FAX SHEET

From: Marcy Oppenheimer
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To: Devorah Adler
Fax No.: 456-5557
Date: March 9, 1999

Pages:

Message: Attached is the section-by-section analysis prepared by DOJ as well as the proposed statutory language.

cc: Don
Annette
ous: BW

**U.S. Department of Justice****Office of the Deputy Attorney General***Special Counsel for Health Care Fraud**Washington, D.C. 20530***January 12, 1999**

To: Jane Horvath
Office of Legislative Affairs
Department of Health and Human Services

From: John T. Bentivoglio

Subj: Legislative proposals

The Department of Justice is working with the White House Domestic Policy Council on a major crime legislative package, which is scheduled for introduction in the early days of the 106th Congress. I wanted to make sure you are aware of several proposals that we would like to include in the area of health care fraud. I believe all of these were discussed in January 1998 during the preparation for the President's State of the Union address on health care fraud but were not included in the address because we could not reach consensus.

While we recognize that HHS may have some concerns, we would like to revisit these proposals. The congressional environment may be a little more favorable this year. And on the merits, these proposals would address serious gaps in our current enforcement authority.

I am not sure about the timing of the overall anti-crime package. Nonetheless, I would be more than happy to meet with you and/or others from HHS about these proposals.

If you have any questions, please call me at (202) 514-2707.

SECTION-BY-SECTION ANALYSIS

Section__ GRAND JURY DISCLOSURE.

Under existing law, an attorney for the government may not, as a general matter, disclose matters that occur before a Federal grand jury. A violation of this non-disclosure requirement (set forth in Rules 6(e) of the Federal Rules of Criminal Procedure) is punishable as contempt of court. An overriding objective of this prohibition is to protect the integrity of criminal investigations by limiting opportunities to intimidate witnesses, destroy documents or otherwise obstruct justice. The prohibition is also important in protecting the rights and reputations of persons who appear before grand juries.

In 1989, Congress created an exception to Rule 6(e) when it enacted 18 U.S.C. § 3322 ("Disclosure of Certain Matters Occurring Before Grand Jury") (enacted as section 964 of the "Financial Institutions Reform, Recovery, and Enforcement Act of 1989," (Pub. L. 101-73). Under 18 U.S.C. § 3322(a), an attorney for the government who is privy to grand jury information involving a criminal violation of the Federal banking laws may disclose that information to another attorney for the government for use in connection with civil actions commenced to enforce the banking laws. In enacting this provision, Congress recognized that, in this important class of cases, in which both criminal and civil actions are routinely brought against wrongdoers, and in which large amounts of money are at stake, the Rule 6(e) restriction on disclosure needlessly complicated investigations in complex financial institution fraud cases.

The draft bill would merely extend the existing Rule 6(e) exception to Federal health care offenses, as defined in 18 U.S.C. § 24. Enactment of this provision would not make available information to civil prosecutors that is not already available to them. Rather, it would simplify information sharing and would enhance the government's ability to investigate wrongdoing. Such a provision would be very important for the effectiveness of our overall health care anti-fraud effort. In particular, by facilitating the sharing of information between criminal investigators and civil prosecutors, this proposal would enable us to proceed more quickly and efficiently to recover losses to federal health care programs, such as Medicare, Medicaid, CHAMPUS, and the Federal Employee Health Benefit Program and to prevent wrongdoers from dissipating illegally obtained assets before we can take action to recover the government's losses.

SEC.___ AUTHORIZED INVESTIGATIVE DEMAND PROCEDURES.

Under section 248 of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) (enacting new 18 U.S.C. § 3486), the Attorney General or her designee is authorized to issue an administrative subpoena in connection with an

investigation relating to a "Federal health care offense." Under 18 U.S.C. § 24, a "Federal health care offense" is defined to include only criminal offenses. In civil cases, however, the Department's attorneys must rely on subpoenas issued by the Office of the Inspector General (OIG) of the Department of Health and Human Services (which are issued only to OIG agents assigned to a particular case) or upon civil investigative demands (which must be signed personally by the Attorney General). This constitutes a serious limitation on our ability to investigate civil health care fraud cases in an effective and efficient manner. As a consequence, this provision would make it clear that the Attorney General or her designee (e.g., a duly authorized Assistant United States Attorney) would be permitted to issue an administrative subpoena in connection with any health care fraud case, criminal or civil, thus greatly facilitating our ability to pursue wrongdoers.

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SEC. ____ ATTORNEY GENERAL'S INJUNCTION AUTHORITY.

Under existing law (18 U.S.C. § 1345(a)(1)(C)), Federal prosecutors are able to obtain injunctive relief in connection with a wide variety of Federal health care offenses. This authority has proven to be extremely valuable in putting a halt to fraudulent behavior. Unfortunately, however, such relief is not available in connection with kickback offenses under section 1128B of the Social Security Act (42 U.S.C. § 1320a-7b) ("Criminal penalties for acts involving Medicare or State health care programs"). This is a serious omission. Because of the large amounts of money involved in these kinds of cases, it is essential that we have the authority to enjoin kickback schemes while they are in progress. The draft bill would permit us to do so.

SEC. ____ ATTORNEY GENERAL'S AUTHORITY TO SEEK CIVIL PENALTIES.

Section 1128B of the Social Security Act (42 U.S.C. § 1320a-7b) establishes criminal penalties for kickback offenses committed against federal health care programs, such as Medicare and CHAMPUS. There is, however, no direct civil penalty applicable to such offenses. As a consequence, an attorney for the government is forced in cases of this nature to do nothing or pursuing criminal charges – quite possibly in a case that, while meriting government action, might not be appropriate for criminal prosecution. The draft bill would permit the Attorney General to bring civil actions against wrongdoers under the anti-kickback provisions of the Social Security Act. Civil penalties are, in our view, particularly important in the health care fraud, since the complex business arrangements that are often employed in connection with kickback schemes often make it difficult – or impossible – to demonstrate the necessary scienter needed to sustain a criminal prosecution.

SEC. ____ . EXTENSION OF CRIMINAL PENALTIES FOR KICKBACKS.

Under current law (section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b(b)), the anti-kickback provisions apply only to health care plans receiving federal funds, such as Medicare, Medicaid, and CHAMPUS. We are not aware of any justification for limiting sanctions against illegal kickbacks to Federal health care programs. Kickback schemes committed in connection with private health insurance plans result in the loss of millions of dollars each year and are contrary to the best interests of patients and the public. We believe that we should be able to proceed criminally against kickbacks committed against either public or private health plans, and this provision would provide us with the authority to do so.

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SEC. ____ . GRAND JURY DISCLOSURE

Section 3322 of title 18, United States Code, is amended –

(1) by redesignating subsections (c) and (d) as subsections (d) and (e),
respectively; and

(2) by inserting after subsection (b) the following new subsection:

“(c) A person who is privy to grand jury information concerning a
Federal health care offense, as defined in section 24 of this title –

“(1) received in the course of duty as an attorney for the
government; or

“(2) disclosed under rule 6(e)(3)(A)(ii) of the Federal Rules
of Criminal Procedure;

may disclose that information to an attorney for the government to use in
any investigation or civil proceeding relating to health care fraud.”.

SEC. ____ . AUTHORIZED INVESTIGATIVE DEMAND PROCEDURES.

Subsection (a) of section 3486 of title 18, United States Code, is amended by
inserting after “Federal health care offense”, “,or any allegation of health care fraud
(whether criminal or civil),”.

SEC. ____ ATTORNEY GENERAL'S INJUNCTION AUTHORITY.

Section 1128B of the Social Security Act (42 U.S.C. § 1320a-7b) is amended by adding the following new subsection –

“(h) If the Attorney General has reason to believe that a person is engaging about to engage in conduct constituting an offense under this section, the Attorney General may petition an appropriate United States District Court for an order prohibiting that person from engaging in such conduct. The court may issue an order prohibiting that person from engaging in such conduct if the court finds that the conduct constitutes such an offense. The filing of a petition under this section does not preclude any other remedy that is available by law to the United States or any other person.”.

SEC. ____ ATTORNEY GENERAL'S AUTHORITY TO SEEK CIVIL PENALTIES.

Section 1128B(b) of the Social Security Act (42 U.S.C. § 1320a-7b(b)) is further amended by adding the following new subsection –

“(g)(1) The Attorney General may bring an action in the district courts to impose upon any person who carries out any activity in violation of this section with respect to a Federal health care program a civil penalty of \$25,000 to \$50,000 for each such violation, and damages of three times the total remuneration offered, paid, solicited, or received.

“(2) A violation exists under paragraph (1) if one or more purposes of the remuneration is unlawful, and the damages shall be the full amount of such remuneration.

“(3) The procedures for actions under paragraph (1) with regard to subpoenas, statutes of limitation, standards of proof, and collateral estoppel shall be governed by 31 U.S.C. § 3731, and the Federal Rules of Civil Procedure shall apply to actions brought under this section.

“(4) This section does not affect the availability of other criminal and civil remedies that may be available for such violations.”.

SEC. ____ . EXTENSION OF CRIMINAL PENALTIES FOR KICKBACKS

Section 1128B of the Social Security Act (42 U.S.C. § 1320a-7b) is amended by striking “Federal health care program” each place it appears and inserting in lieu thereof “health care benefit program (as defined in 18 U.S.C. § 24(b))”.

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SUBTITLE D – HEALTH CARE FRAUD AND ABUSE.

SEC. 3031. ATTORNEY GENERAL’S INJUNCTION AUTHORITY.

Section 1128B of the Social Security Act (42 U.S.C. § 1320a-7b) is amended by adding the following new subsection –

“(h) If the Attorney General has reason to believe that a person is engaging about to engage in conduct constituting an offense under this section, the Attorney General may petition an appropriate United States District Court for an order prohibiting that person from engaging in such conduct. The court may issue an order prohibiting that person from engaging in such conduct if the court finds that the conduct constitutes such an offense. The filing of a petition under this section does not preclude any other remedy that is available by law to the United States or any other person.”.

SEC. 3032. ATTORNEY GENERAL’S AUTHORITY TO SEEK CIVIL PENALTIES.

Section 1128B(b) of the Social Security Act (42 U.S.C. § 1320a-7b(b)) is further amended by adding the following new subsection –

“(g)(1) The Attorney General may bring an action in the district courts to impose upon any person who carries out any activity in violation of this section with respect to a Federal health care program a civil penalty of \$25,000 to \$50,000 for each such violation, and damages of three times the total remuneration offered, paid, solicited, or received.

“(2) A violation exists under paragraph (1) if one or more purposes of the

remuneration is unlawful, and the damages shall be the full amount of such remuneration.

“(3) The procedures for actions under paragraph (1) with regard to subpoenas, statutes of limitation, standards of proof, and collateral estoppel shall be governed by 31 U.S.C. § 3731, and the Federal Rules of Civil Procedure shall apply to actions brought under this section.

“(4) This section does not affect the availability of other criminal and civil remedies that may be available for such violations.”.

SEC. 3033. GRAND JURY DISCLOSURE.

Section 3322 of title 18, United States Code, is amended –

(1) by redesignating subsections (c) and (d) as subsections (d) and (e), respectively; and

(2) by inserting after subsection (b) the following new subsection:

“(c) A person who is privy to grand jury information concerning a Federal health care offense, as defined in section 24 of this title –

“(1) received in the course of duty as an attorney for the government; or

“(2) disclosed under rule 6(e)(3)(A)(ii) of the Federal Rules of Criminal Procedure;

may disclose that information to an attorney for the government to use in any investigation or civil proceeding relating to health care fraud or false claims.”.

SEC. 3034. AUTHORIZED INVESTIGATIVE DEMAND PROCEDURES.

Subsection (a) of section 3486 of title 18, United States Code, is amended by inserting after “Federal health care offense”, “, or any allegation of health care fraud or false claims (whether criminal or civil),”.

SEC. 3035. EXTENSION OF CRIMINAL PENALTIES FOR KICKBACKS.

Section 1128B(b) of the Social Security Act (42 U.S.C. § 1320a-7b(b)) is amended by striking “Federal health care program” each place it appears and inserting “health care benefit program (as defined in 24(b) of title 18 United States Code).”.

SEC. 3036. STUDY AND REPORT ON HEALTH CARE FRAUD SENTENCES.

(a) DIRECTIVE TO THE UNITED STATES SENTENCING COMMISSION.----Pursuant to its authority under section 994(p) of title 28, United States Code, and in accordance with this section, the United States Sentencing Commission shall review and, if appropriate, amend its guidelines and its policy statements applicable to persons convicted of health care fraud offenses.

(b) REQUIREMENTS.—In carrying out this section, the Sentencing Commission shall:

(1) ensure that the sentencing guidelines and policy statements reflect the serious harms associated with health care fraud and the need for aggressive and appropriate law enforcement action to prevent such fraud;

(2) consider providing increased penalties for persons convicted of health care fraud offenses in appropriate circumstances;

(3) consult with individuals or groups representing health care fraud victims, law enforcement officials, the health care industry, and the federal judiciary as part of the review described in subsection (a);

(4) assure reasonable consistency with other relevant directives and with other guidelines;

(5) account for any aggravating or mitigating circumstances that might justify exceptions, including circumstances for which the sentencing guidelines currently provide sentencing enhancements;

(6) make any necessary conforming changes to the sentencing guidelines;

and

(7) assure that the guidelines adequately meet the purposes of sentencing as set forth in section 3553(a)(2) of title 18, United States Code.

(c) REPORT.----Not later than December 31, 2000, the United States Sentencing Commission shall submit a report to Congress on issues relating to health care fraud. The report shall explain the changes, if any, to sentencing policy made by the Sentencing Commission in response to this section and include any recommendations that the Commission may have for retention or modification of current penalty levels, including statutory penalty levels, for health care fraud offenses.

**SEC. 3037. PROVISIONS PROTECTING THE INTERESTS OF FALSE CLAIMS
ACT MATTERS IN BANKRUPTCY PROCEEDINGS.**

(a). Certain actions not stayed by bankruptcy proceedings. The commencement or continuation of an action under 31 U.S.C. § 3729 et seq. shall not be stayed by section 362(a)(1) or under section 105(a) of title 11, United States Code.

(b). Certain Debts not Dischargeable in Bankruptcy. No debt owed to the United States for violating 31 U.S.C. § 3729 et seq. or under a compromise or other agreement resolving such a debt shall be discharged under title 11, United States Code.

(c). Repayment of Certain Debts Considered Final. No transfer on account of a debt owed to the United States for violating 31 U.S.C. § 3729 et seq. or under a compromise or other agreement resolving such a debt shall be avoided under sections 544, 545, 547, 548, 549, 553(b) or 724(a) of title 11, United States Code.

SEC. 3038. EXTENDING ANTI-FRAUD SAFEGUARDS TO THE FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM.

(a).Section 1128B(f)(1) of the Social Security Act (42 U.S.C. § 1320a 7b(f)(1),) as enacted by section 204(a)(7) of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191; 110 Stat. 2000), is amended by striking “(other than the health insurance program under chapter 89 of title 5, United States Code)”.

SEC. 3039. NURSING HOME RESIDENT PROTECTION ACT.

(a) SHORT TITLE. --This Act may be cited as the “Nursing Home Resident Protection Act of 1999”.

(b) PROTECTION OF RESIDENTS IN NURSING HOMES AND OTHER RESIDENTIAL HEALTH CARE FACILITIES. – Chapter 63 of title 18, United States Code, is amended by adding at the end the following new section:

(1) “SEC. 1349. Pattern of Violations Resulting in Harm to Residents of Nursing Homes and Related Facilities.

“(a) Offense.--Whoever engages in a pattern of knowing and willful violations of Federal laws, regulations, or rules, or State laws governing the health, safety, or care of individuals residing in a residential health care facility or facilities that results in significant physical or mental harm to one or more such residents, shall be punished as provided in section 1347, except that any organization shall be fined not more than

\$2,000,000 per residential health care facility.

“(b) Civil provisions .--

(1) Civil Penalties --The Attorney General may bring an action in a

United States district court to impose on any individual or entity that engages in a pattern of violations of Federal laws, regulations, or rules, or State laws, which violations affect the health, safety, or care of individuals residing in a residential health care facility and where such pattern results in physical or mental harm to one or more such residents, a civil penalty of --

(A) in the case of an individual (other than an owner, operator, officer or manager of such a residential health care facility) up to \$10,000;

(B) in the case of an individual who is an owner, operator, officer or manager of such a residential health care facility up to \$100,000 for each separate facility involved in the pattern of violations under this section; or

(C) in the case of a residential health care facility up to \$1,000,000 for each pattern of violations, and in the case of an entity up to \$1,000,000 for each separate residential health care facility involved in the pattern of violations owned or managed by that entity.

“(2) Other appropriate relief.--If the Attorney General has reason to believe that an individual or entity is engaging in or is about to engage in a pattern of violations of Federal laws, regulations, or rules, or State laws, which violations affect the health, safety, or care of individuals residing in a residential health care facility, and where such

pattern results in or has the potential for resulting in physical or mental harm to one or more such residents, the Attorney General may petition an appropriate United States district court for appropriate equitable and declaratory relief to eliminate the pattern.

"(3) Procedures for this subsection —

(A) A subpoena requiring the attendance of a witness at a trial or hearing conducted under this subsection may be served at any place in the United States.

(B) An action brought under paragraph (1) of this subsection may not be brought more than 6 years after the date on which the violation of this subsection occurred.

(C) The United States shall be required to prove all actions under this subsection by a preponderance of the evidence.

(D) The Civil Investigative Demand procedures set forth in 15 U.S.C. §§ 1311 -14 and regulations promulgated pursuant thereto shall apply to investigations and actions pursued under this subsection.

(E) The filing or resolution of a matter under this subsection does not preclude any other remedy that is available to the United States or any other person.

“(c) Prohibition against retaliation.--Any person who is the subject of retaliation, either directly or indirectly, for reporting conditions that may constitute a violation of this section shall be authorized to bring an action in an appropriate United States district court for damages, attorneys’ fees and other relief.

“(d) Definitions.--For purposes of this section, the following definitions apply:

“(1) ‘Residential health care facility’ means any facility (including any facility

that does not exclusively provide residential health care services) including but not limited to skilled and unskilled nursing facilities and mental health and mental retardation facilities, that receives Federal funds, directly from the Federal government or indirectly from a third party on contract with or receiving a grant or other monies from the Federal government, to provide health care, or that provides health care services in a residential setting and that, in any calendar year in which a violation occurs, is the recipient of benefits or payments in excess of \$10,000 from a Federal Health Care Program.

“(2) ‘Entity’ means any residential health care facility (including facilities that do not exclusively provide residential health care services), any entity that manages a residential health care facility, or any entity that owns, directly or indirectly, a controlling interest or a 50% or greater interest in one or more residential health care facilities, including States, localities and political subdivisions thereof.

“(3) ‘Federal Health Care Program’ means:

(A) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government; or

(B) any State health care program, as defined in section

1320a-7(h) of Title 42, United States Code.

“(4) ‘Pattern of violations’ means multiple violations of a single law, regulation, or rule, or single violations of multiple laws, regulations, or rules, that are widespread, systemic, repeated, similar in nature, or result from a policy or practice.

“(5) ‘State’ means a state of the United States, the District of Columbia, and any common wealth, territory, or possession of the United States.”.

(c) **AUTHORIZED INVESTIGATIVE DEMAND PROCEDURES.** --Section 3486(a)(1) of title 18, United States Code, is amended by inserting after “Federal health care offense”, “or act or activity involving Section 1349 of this title”.

(d) The table of sections for chapter 63 of title 18, United States Code, is amended by adding at the end:

“1349. Pattern of violations resulting in harm to residents of nursing homes and related facilities.”.



**United States
Office of
Personnel
Management**

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From:	Kim Weaver
Subject:	Health Care Fraud Letter
Date:	March 18, 1999
Pages:	3 (including cover sheet)

COMMENTS:

Please call if you need any additional information.



UNITED STATES
OFFICE OF PERSONNEL MANAGEMENT
WASHINGTON, D.C. 20415

OFFICE OF THE DIRECTOR

FEB. 18 1999

Honorable Janet Reno
The Attorney General
Department of Justice
Washington, DC 20530

Dear Madam Attorney General:

At a meeting with Office of Personnel Management Inspector General Patrick McFarland on January 29, 1999, John Bentivoglio, Special Counsel for Health Care Fraud, Office of the Deputy Attorney General, asked whether this agency supports removal of the exclusion of the Federal Employees Health Benefits Program (FEHBP) from certain civil enforcement provisions of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) (HIPAA). I strongly support our inclusion in these anti-fraud provisions, which apply to all other Federal health care programs, particularly since the FEHBP, by expending over \$17 billion per year, is the largest employer-sponsored health care program in the United States.

By excluding the FEHBP from HIPAA, investigators from our Office of the Inspector General are denied the following tools that would help in the investigation and prosecution of health care fraud:

- Enhanced sanctions provisions including mandatory exclusion for felony conviction relating to health care fraud or controlled substances and new minimum exclusion periods for certain permissive exclusions. This deters our ability to rapidly remove felons from the FEHBP under our new, independent debarment authority.
- Expanded anti-kickback provisions which would help us prevent FEHBP health care providers from receiving improper gratuities for referrals or related services.
- Enhanced civil monetary penalties (CMPs). HIPAA lowers the standard of proof for fraudulent claims and increases the penalty per false claim from \$2,000 to \$10,000. In addition, HIPAA allows CMPs to be assessed for incorrect coding, medically unnecessary services and offering remuneration to induce business (e.g. waving coinsurance or deductible).
- Full participation in Health Care Fraud and Abuse Control Account which provides agencies with a source of funding to assist them in investigations, prosecutions, audits or evaluations of health care fraud and abuse. While we are authorized to apply for grants

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Honorable Janet Reno

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from this account, since it is funded by criminal fines, civil false claims act recoveries and civil monetary penalties authorized by HIPAA, our restricted ability to collect such penalties makes it impossible for us to participate fully in supporting these efforts.

We need the same tools to fight fraud in the FEHBP as any other Federal health care program. There is no basis for treating our program any differently than any other Government health care program, which can only make it more difficult for us to participate with prosecutors and other agencies' law enforcement officials in cases involving fraud against multiple health care programs.

For these reasons, the Office of Personnel Management has consistently supported this amendment as a major component of our legislative agenda. I will appreciate any support that you can provide toward enactment of this legislation.

Sincerely,



Janice R. Lachance
Director



HEALTH CARE FINANCING ADMINISTRATION

**ADDRESSEE:***Deborah Adler*

PHONE: _____

FROM: *Glenn Norton***OFFICE OF THE ADMINISTRATOR
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WASHINGTON, DC 20201****PHONE:** 202-690-6726**FAX :** 202-690-6262**TOTAL PAGES:****ADDRESSEE'S FAX MACHINE NUMBER:****DATE:***456-5557***REMARKS:***BoJ proposal*

Nursing Home Resident Protection Act of 1999s

Draft -- 1/29/99 -- Draft

SEC. __1. **SHORT TITLE.** This Act may be cited as the "Nursing Home Resident Protection Act of 1999".

SEC. 2. PROTECTION OF RESIDENTS IN NURSING HOMES AND OTHER RESIDENTIAL HEALTH CARE FACILITIES.

Title 18, United States Code, is amended by adding the following new section:

"SEC. 1348. Pattern of Violations Resulting in Harm to Residents of Nursing Homes and Related Facilities.

"(a) Criminal offense.—Whoever knowingly and willfully engages in a pattern of violations of Federal or State law, regulation or rule governing the care of individuals residing in the residential health care facility, and where such pattern results in physical or mental harm to one or more such residents, shall be punished as specified in Section 1347 of this title,¹ except that any organization found guilty of an offense under this section shall be fined not more than \$2,000,000 per residential health care facility, and any individuals found guilty of an offense under this section shall be fined pursuant to the individual fine provisions of Title 18, Section 3571.

"(b) Civil provisions .--

(1) **Civil Penalties** -- The Attorney General may bring an action in a United States district court to impose on any individual or entity that engages in a pattern of violations of Federal or State law, regulation or rule governing the care of individuals residing in the residential health care facility and where such pattern results in physical or mental harm to one or more such residents, a civil penalty of --

(A) in the case of an individual (other than an owner, operator, officer or manager of such a residential health care facility) up to \$10,000;

(B) in the case of an individual who is an owner, operator, officer or manager of such a residential health care facility up to \$100,000 for each separate facility involved in the pattern of violations under this

¹ The elements of such an offence are:

- knowledge and intent to violate law
- pattern of violations
- of federal or state laws or regulations governing nursing homes or other residential health care facilities
- violations resulted in physical or mental harm

(C) The United States shall be required to prove all actions under this subsection by a preponderance of the evidence.

(D) The Civil Investigative Demand procedures set forth in 15 U.S.C. §§ 1311 - 14 and regulations promulgated pursuant thereto shall apply to investigations and actions pursued under this subsection.

(E) The filing or resolution of a matter under this subsection does not preclude any other remedy that is available to the United States or any other person. The Federal Rules of Civil Procedure shall apply to actions brought under this subsection.

"(c) Prohibition against retaliation.-- Any person who is the subject of retaliation, either directly or indirectly, for reporting conditions that may constitute a violation of this section shall be authorized to bring an action in an appropriate United States district court for damages, attorneys' fees and other relief.

"(d) Definitions.-- For purposes of this section, the following definitions apply:

"(1) 'Residential health care facility' is defined as any facility (including any facility that does not exclusively provide residential health care services) including but not limited to skilled and unskilled nursing facilities and mental health and mental retardation facilities, that receives Federal funds, directly from the Federal government or indirectly from a third party on contract with or receiving a grant or other monies from the Federal government, to provide health care, or that provides health care services in a residential setting and that, in any calendar year in which a violation occurs, is the recipient of benefits or payments in excess of \$10,000 from a Federal Health Care Program.

"(2) 'Entity' is defined in this section as any residential health care facility (including facilities that do not exclusively provide residential health care services), any entity that manages a residential health care facility, or any entity that owns, directly or indirectly, a controlling interest or a 50% or greater interest in one or more residential health care facilities.

"(3) 'Federal Health Care Program' is defined as:

(A) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government; or

(B) any State health care program, as defined in section 1320a-7(h) of Title 42, United States Code.

"(4) 'Pattern of violations' is defined as multiple violations that are widespread, systemic, repeated or similar in nature, or result from a policy or practice.³

"(5) 'Whoever' is defined as in 18 U.S.C. § 921(a)(1).

"(6) 'Attorney General' is defined as the Attorney General of the United States or her designee and 'Secretary for the Department of Health and Human Services' is defined as the Secretary for the United States Department of Health and Human Services or her designee.

"(e) The Attorney General and the Secretary for the Department of Health and Human Services shall develop policies and procedures to reduce the negative impact of actions taken under this section on the residents of the residential health care facility."

SEC. 3. DEFINITION OF FEDERAL HEALTH CARE OFFENSE.

Subsection (a)(1) of section 24 of title 18, United States Code, is amended by adding "1348," after "1347,".

SEC. 4. AUTHORIZED INVESTIGATIVE DEMAND PROCEDURES.

Section 3486(a)(1) of title 18, United States Code, is amended by inserting after "Federal health care offense", "or other allegation of fraud or wrongdoing (whether civil or criminal) made in connection with a health care benefit program (as defined in section 24(b) of title 18, United States Code)".

³ Section by section analysis: "The term 'pattern of violations' refers to a repeated violation that is widespread, systemic, repeated, similar in nature, or resulting from a policy or practice. For example, a widespread group of violations, even if not the result of a common policy or practice or not involving the same or similar regulations, could be covered by this section. On the other hand, one or more isolated violations that do not rise to the level of a 'pattern', as described above, would not be covered. The term incorporates a concept of proportionality so that the number of violations required to establish a pattern within an entity operating numerous facilities across the country would be greater than the number of violations required for a single facility. The term also incorporates a concept of severity so that the number of violations required to establish a pattern within a single entity or an entity operating numerous facilities would be fewer, the more severe the harm.



HEALTH CARE FINANCING ADMINISTRATION

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FAX : 202-690-6262****TOTAL PAGES:****ADDRESSEE'S FAX MACHINE NUMBER:****DATE:****REMARKS:**

**TESTIMONY OF
MICHAEL HASH, DEPUTY ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
on
PREVENTING IMPROPER EVICTIONS
OF NURSING HOME MEDICAID RESIDENTS
before the
HOUSE COMMERCE SUBCOMMITTEE ON HEALTH**

February 11, 1999

Chairman Bilirakis, Congressman Brown, distinguished committee members, thank you for inviting us here today to discuss our efforts to improve protections for nursing home residents. The Health Care Financing Administration (HCFA) is aggressively working to improve the oversight and quality of nursing home care. Preventing inappropriate eviction of Medicaid residents is an essential part of this effort.

There have been intolerable situations in which facilities transferred or discharged Medicaid residents on false grounds and without appropriate notice. This creates serious disruptions in care and untold emotional toll on frail beneficiaries we are sworn to protect.

We have taken swift and strong action in these situations, including the imposition of \$10,000 per day of civil money penalties. States have also taken swift and strong action. States and HCFA together have made clear that we are very serious about protecting Medicaid residents from inappropriate transfers and discharges. But we need to do more, and we need legislation to do it.

Chairman Bilirakis, America's nursing home residents need the bill you and Congressman Davis are introducing to be enacted into law. I am proud to say that the Clinton Administration and my agency strongly support your legislation. America's nursing home residents must not live in fear that they will be evicted solely because they rely on Medicaid to pay for their care. We must

enact this bill to prohibit transfers or discharges of Medicaid residents when a nursing home chooses to leave the Medicaid program. I know my staff has provided technical assistance to your staff in drafting the legislation. We look forward to working with you further to ensure passage and to ensure that the goals of this legislation are met. We also may need to address further protection of Medicaid residents when nursing homes decrease the number of beds available to Medicaid residents, and we look forward to working with you on that issue as well.

BACKGROUND

About 1.6 million elderly and disabled Americans receive care in approximately 16,800 nursing homes across the United States. Through the Medicare and Medicaid programs, the federal government provides funding to the States to conduct on-site inspections of nursing homes participating in Medicare and Medicaid and to recommend sanctions against those homes that violate health and safety rules.

Medicaid nursing home participation is voluntary, and current law allows nursing homes to determine and change the extent of their participation. They can designate that only part of their facilities, for example a certain number of beds or certain wings, are available to Medicaid beneficiaries. If a nursing home wants to reduce the portion of its facilities that are available to Medicaid patients, it must give 30 days notice of its intentions to both the State and the affected residents. It also must ensure that any displaced residents continuously receive all necessary care as they are moved to other appropriate facilities.

USING REGULATORY AUTHORITY

We are taking steps to address problems created when facilities curtail service to Medicaid residents with the authority we have now. We recently issued new policy stating that a nursing home may decrease the portion of its facilities that are available to Medicaid or Medicare residents only once per year. We also are considering whether further regulatory changes would

help protect Medicare and Medicaid residents. However, without the legislation Chairman Bilirakis and Rep. Davis are proposing, we do not have authority to prevent evictions of Medicaid patients if nursing homes leave the Medicaid program.

NURSING HOME INITIATIVE PROGRESS

As I said, preventing inappropriate evictions is an essential component of our broad initiative for improving the quality of nursing home care and oversight. These reforms build on progress made since 1995, when we began enforcing the toughest nursing home regulations ever. We have made solid progress since we announced our new initiative last July. We have taken several steps to improve inspections by States, who have the primary responsibility for conducting these on-site inspections and recommending sanctions for care and safety violations. We have:

- ▶ issued new guidance to States to strengthen their nursing home inspection systems;
- ▶ made clear that States will lose federal funding if they fail to adequately perform surveys and protect residents because we can and will contract with other entities, if necessary, to make sure those functions are performed properly;
- ▶ established a new monitoring system to ensure that States identify problems and impose appropriate sanctions;
- ▶ formally reminded States that they must enforce sanctions for serious violations and may not lift them until an on-site visit verifies that problems are fixed;
- ▶ required States to sanction facilities found guilty more than once for violations that harm residents, with no option to avoid penalties by correcting problems during a grace period;
- ▶ required States to conduct more frequent inspections for nursing homes with repeated serious violations while not decreasing their inspections for other facilities;
- ▶ required States to stagger surveys and conduct a set amount on weekends, early mornings and evenings, when quality and safety and staffing problems often occur;
- ▶ instructed States to look at an entire chain's performance when serious problems are identified in any facility that is part of a chain, and begun developing further guidelines for

sanctioning facilities within problem chains;

- ▶ begun developing new regulations to let States impose civil money penalties for each serious incident and repeal current rules that link penalties only to the number of days that a facility was out of compliance with regulations;
- ▶ begun developing new survey protocols to detect quality problems in nursing homes using a systematic, data-driven process, with initial changes to be implemented this year; and
- ▶ secured, with strong support from Congress, a fiscal year 1999 budget with \$171 million for survey and certification activities, including \$4 million earmarked for the new initiative, and requested \$60.1 million for fiscal year 2000 to enable us and other HHS components to fully implement all provisions of the Nursing Home Initiative. This includes \$35 million for HCFA to strengthen State inspection and enforcement efforts, \$15.6 million in mandatory Medicaid money to supplement State inspection and enforcement efforts, and \$9.5 million to ensure adequate resources for timely judicial hearings and court litigation.

We have taken additional steps to help consumers choose facilities, help facilities improve care, and help our law enforcement partners prosecute the most egregious cases. We have:

- ▶ created and begun testing a new Internet site, Nursing Home Compare, at www.medicare.gov, which will allow consumers to compare survey results and safety records when choosing a nursing home;
- ▶ posted best practice guidelines at www.hcfa.gov/medicaid/siq/siqhmpg.htm on how to care for residents at risk of weight loss and dehydration;
- ▶ begun planning national campaigns to educate residents, families, nursing homes and the public at large about the risks of malnutrition and dehydration, nursing home residents' rights to quality care, and the prevention of resident abuse and neglect;
- ▶ begun a study on nursing home staffing that will consider the potential costs and benefits of establishing minimum staffing levels; and
- ▶ worked with the Department of Justice to prosecute egregious cases where residents have

been harmed, and to improve referral of egregious cases for potential prosecution.

Legislative Proposals

The Clinton Administration's fiscal year 2000 budget includes proposals for:

- ▶ requiring nursing homes to conduct criminal background checks of prospective employees;
- ▶ establishing a national registry of nursing-home workers who have abused or neglected residents or misappropriated residents' property; and
- ▶ allowing more types of nursing-home workers with proper training to help residents eat and drink during busy mealtimes.

The cost of conducting background checks and querying the national registry will be financed through user fees. The Administration will put forward additional proposals as needed for additional legislative authority to further improve nursing home quality and safety.

CONCLUSION

We are making solid progress in our efforts to improve the oversight and quality of nursing home care, but there is more that we must do. We are doing what we can with the regulatory authority we now have. We are working to secure passage of the President's legislative initiatives to further protect nursing home residents.

The legislation that Chairman Bilirakis and Congressman Davis are introducing today to prevent inappropriate Medicaid evictions is another crucial piece that we need to protect nursing home residents. We thank you for your hard work on this matter. We look forward to working with you to secure passage of your bill and the President's proposals. And I am happy to answer your questions.

#

Stock analysts question future of Vencor, Ventas

By HAROLD J. ADAMS
The Courier-Journal

Former Louisville Fortune 500 darling Vencor Inc. and spinoff Ventas Inc. took a beating on Wall Street this week that has analysts wondering about the companies' future.

Stocks for both companies closed at new lows yesterday. Only days before, some analysts had speculated about Vencor's filing bankruptcy and the subsequent fallout for Ventas.

Yesterday, after huge trades of Ventas' stock the previous two days, the New York Stock Exchange asked company executives to issue a statement about any developments that might have triggered the activ-

ity. But Ventas did not respond. Ventas chief executive officer Debra Cafaro, named to that post Monday, told The Courier-Journal that the company had no comment on the unusual trading, which resulted in a 36 percent decline in the company's share price since Thursday. Ventas is a Louisville real estate company formed in a spinoff from Vencor last May that owns most of the nursing homes and hospitals Vencor operates.

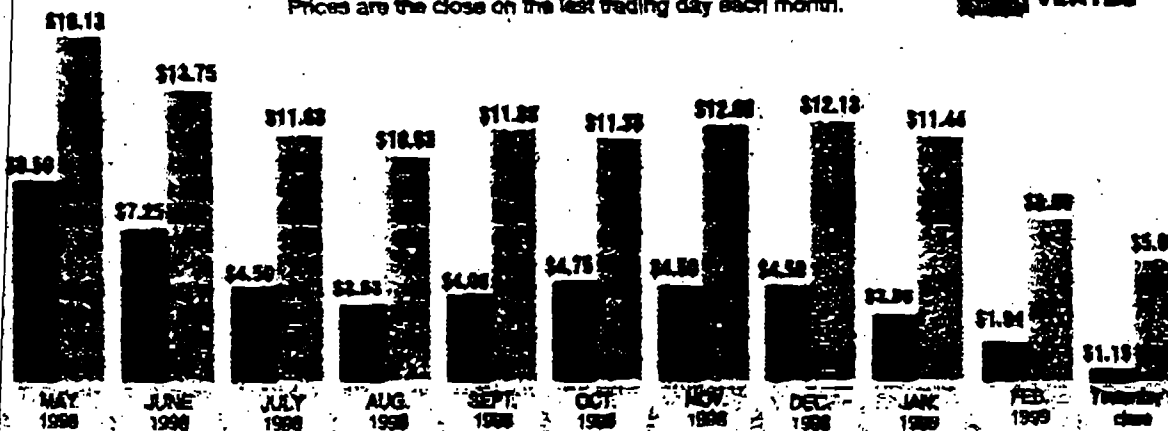
More than 2.7 million shares of Ventas stock were traded yesterday on the heels of 2.6 million shares the day before —

See ANALYSTS
Page 8, col. 4, this section

NE / KENTUCKY • SATURDAY, MARCH 13, 1999

**VENCOR
AND VENTAS**

A look at the two companies' stock prices since they began trading separately last May 1. Ventas was spun off last year and owns Vencor's real estate. Prices are the close on the last trading day each month.



BY WES KENDALL, THE COURIER-JOURNAL

Analysts ponder future of Vencor, spinoff as stock values plunge

Continued from Page One:

more than 12 times the company's average daily trade volume of about 206,000 shares. The totals were boosted by large single trades of 1.8 million shares Thursday and 1.6 million yesterday.

After closing at \$8.12 Monday — Cafaro's first day on the job — Ventas' stock tumbled to close at \$5.06 yesterday, a loss of 37.7 percent for the week.

Meanwhile, analysts have begun speculating about a potential bankruptcy filing by Vencor. The nursing home and hospital operator is in the process of renegotiating \$800 million in credit after the company's value fell below the level required by its lenders.

It also has announced that it expects to post a big loss in its 1998 fourth-quarter earnings report, which is being delayed until negotiations with the banks are complete.

Vencor shares lost more than 23 percent of their value Thursday and



Debra Cafaro, who became Vencor spinoff Ventas' CEO this week, declined to comment yesterday on unusual trading that resulted in a big decline in the stock's share price.

yesterday to close the week at \$1.19. The fates of the two companies are closely tied because more than 98 percent of Ventas revenue comes from lease payments from Vencor.

"Should Vencor declare bankruptcy, Ventas would continue to have a senior position, receiving its lease payments even before senior debt holders receive their interest payments," Hilliard Lyons analyst John Roberts wrote in a recent newsletter to clients.

Although Vencor's problems are dragging down Ventas' share price,

Roberts was recommending that "more aggressive income-oriented investors" buy Ventas shares for their long-term potential.

But amid yesterday's turmoil, brokerage J.C. Bradford downgraded Ventas stock to hold from buy.

John Ransom of Raymond James and Associates, speculating on the drop in Ventas, said: "I would think the bank groups at both Ventas and Vencor are concerned. If that concern has led to any decisions or activity and that activity has gotten into the market, I would think that might be the catalyst."

Some analysts have speculated that Ventas will have to lower Vencor's lease payments if both companies are to escape the current quagmire.

But Cafaro said yesterday, "We don't see that to be the case in our analysis."

Calls to Vencor headquarters yesterday were not returned.

Staff writer Wayne Tompkins contributed to this story.

DATE: 3/18

**U.S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES**

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OFFICE: _____

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Chris. any problem w/ this amend. to
Supplemental to fund DAB NF backlog
w/ DoL unemploy training #? I've
Sent to Dan M @ OMB also. Have
Someone call me or Sharon Clarkin
@ 690 7450 Thanx.

(INCLUDING COVER): 5

REMARKS:

AMENDMENT TO BE OFFERED BY SENATOR GRASSLEY
TO S.544 MAKING SUPPLEMENTAL EMERGENCY APPROPRIATIONS
For the Purpose of Expediting Adjudication of Civil Monetary Penalties
By the Department of Health and Human Services Appeals Board

AMENDMENT

On page 29, Insert after line 10:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
GENERAL DEPARTMENTAL MANAGEMENT

For an additional amount for "general departmental management", \$1,400,000, to reduce the backlog of pending nursing home appeals before the Departmental Appeals Board.

On page 42, line 8, strike \$3,116,076,000 and insert \$3,114,676,000

On page 42, line 9, strike \$164,933,000 and insert \$163,533,000.

EXPLANATION AND JUSTIFICATION

This amendment provides an additional \$1,400,000 for the Department of Health and Human Services Appeals Board. The amendment would require that this sum be used by the Appeals Board to reduce a backlog of appeals by nursing facilities of civil monetary penalties levied by the Health Care Financing Administration for infractions of the Nursing Home Reform Act of 1987.

The Department of Health and Human Services Departmental Appeals Board hears and decides cases on appeal from program units of the Department. Lack of sufficient resources to handle a rapidly increasing case load has lead to a large backlog of pending cases. The major contributor to this backlog is a substantial increase in appeals of civil monetary penalties levied by HCFA on nursing facilities. Appeals of CMPs have increased at an accelerating rate each year since 1995. The rate of increase has accelerated further since January, 1999, reflecting the enhanced oversight and enforcement of nursing facilities undertaken by HCFA following a Presidential initiative and hearings by the Special Committee on Aging. The backlog of appeals subverts the purpose and effect of civil monetary penalties, delaying corrective action and improvements in the quality of care by nursing facilities. Delay in adjudication of appeals is also a burden to nursing facilities.

ADMINISTRATION BUDGET PROPOSAL FOR FY 2000

The Clinton Administration proposed an increase of \$2.8 million for FY 2000 for the Departmental Appeals Board. This amendment would speed up provision of those funds the Appeals Board could effectively use before the end of this fiscal year and thus and permit the Appeals Board to begin immediately to take steps to reduce the backlog of appeals by nursing facilities.

DETAILS FOR HCEA NURSING HOME CASELOAD

<u>Year</u>	<u>Cases Received</u>	<u>Closed No Decision</u>	<u>Closed With Decision</u>	<u>Pending</u>
1996	335	101	22	212
1997	441	160	25	468
1998	483	303	22	626
1999 ¹	196	117	4	701

Note that, although the number of new cases received each year has increased, the number of cases decided has not, indicating lack of resources sufficient to keep up with the increasing annual number of new cases. Currently, the Appeals Board is receiving about 25 new cases per week. In earlier periods 8 to 10 new cases per week were being received.

¹As of January 22, 1999

29

1 DEPARTMENT OF AGRICULTURE

2 FOREST SERVICE

3 WILDLAND FIRE MANAGEMENT

4 Of the funds made available under this heading for
5 fire operations in previous Acts of Appropriation (exclusive
6 of amounts for hazardous fuels reduction), \$100,000,000
7 shall be transferred to the Knutson-Vandenberg fund es-
8 tablished pursuant to Section 3 of Public Law 71-819 (16
9 U.S.C. 576 et. seq.) within 10 days of passage of this Act.

10 CHAPTER 4

11 RELATED AGENCY

12 CORPORATION FOR PUBLIC BROADCASTING

13 For an additional amount for the Corporation for
14 Public Broadcasting, to remain available until expended,
15 \$18,000,000: *Provided*, That such funds be made available
16 to National Public Radio, as the designated manager of
17 the Public Radio Satellite System, for acquisition of sat-
18 ellite capacity.

15.2

19 CHAPTER 5

20 DEPARTMENT OF DEFENSE

21 MILITARY CONSTRUCTION, ARMY NATIONAL GUARD

22 For an additional amount for "Military Construction,
23 Army National Guard" to cover the incremental costs aris-
24 ing from the consequences of Hurricane Georges,

1

CHAPTER 6

2

DEPARTMENT OF LABOR

3

EMPLOYMENT AND TRAINING ADMINISTRATION

4

STATE UNEMPLOYMENT INSURANCE AND EMPLOYMENT

5

SERVICE OPERATIONS

6

Under this heading in section 101(f) of Public Law

7

105-277, delete "\$3,132,076,000" and insert

8

"\$3,116,076,000"; and delete "\$180,933,000" and insert

9

"\$164,933,000".

10

DEPARTMENT OF HEALTH AND HUMAN

11

SERVICES

12

ADMINISTRATION FOR CHILDREN AND FAMILIES

13

TEMPORARY ASSISTANCE FOR NEEDY FAMILIES

14

(DEFERRAL)

15

Of the funds made available for grants to States for

16

Temporary Assistance for Needy Families under section

17

403(a)(1) of the Social Security Act, \$350,000,000 shall

18

not become available for obligation until October 1, 2001,

19

in amounts bearing the same proportion to \$350,000,000

20

as such unobligated balance for such State bears to the

21

sum of such unobligated balances for all States.

3,114,676,000
 163,533,000

HEALTH CARE FINANCING ADI

Devorah Adler

456-5557



URGENT

estimates as to how
much this may increase—
current funds or oth.

ADDRESSEE:

Devorah
Adler/Chris
Jennings

PHONE: _____

FROM:

Maria Martindale

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456-5557

DATE:

3/12/99

REMARKS:

Devorah —

~~The~~ The GAO response will probably
be substantially revised — but this
is the direction we are going.

Also — State Survey Agency letter.

Dear State Survey Agency Director,

The purpose of this letter is to focus upon and clarify our expectation for the collection, review, investigation and reporting of complaints of improper care or treatment against a Medicare, Medicaid or CLIA certified facility.

Since becoming Administrator of the Health Care Financing Administration, I have become increasingly concerned about the effectiveness of current processes for collecting, investigating, resolving and reporting complaints received by the State survey agency from individuals or their representatives. Reports from consumer groups, the media and outside auditors, as well as our own internal assessments, have highlighted failures in complaint investigation, enforcement and reporting. This has been particularly true for complaints received about care provided in nursing homes, psychiatric hospitals and intermediate care facilities for the mentally retarded. In order to assure that all our beneficiaries receive the protections they deserve, we are initiating a series of short and longer term improvements to the complaint process.

Investigation and resolution of complaints are a critical certification function. HCFA, the State survey agency and the State Medicaid Agency (SMA) are all responsible for ensuring that participating facilities continually meet Medicare and Medicaid requirements. This requires prompt review and, where necessary, on-site investigation by the State survey agency on reports alleging noncompliance. Any complaint investigations resulting in deficiency citations must be submitted to the HCFA regional office and/or the SMA.

The State Operations Manual (SOM) at section 3281 outlines processing instructions for certification-related complaints. It requires that any allegation involving an immediate and serious threat to patient health and safety be investigated by the State survey agency within 2 working days of receipt. It defers to existing State agency procedures for prioritizing and investigating other certification-related complaints. However, based on reports from numerous sources, we are concerned that the requirement for 2 working day investigations of immediate and serious threat allegations is not being adhered to universally and all States are not adhering to their own guidelines for responding to complaints that are less serious. In addition, some State agencies do not adequately address complaints which cause actual harm.

For the well-being of beneficiaries, it is essential that all State agencies comply with the existing federal requirements for scheduling immediate and serious threat investigations and State guidelines for processing other complaints. Furthermore, we recognize that more guidance from HCFA on prioritizing and scheduling of other complaints is necessary. To assure that this additional guidance on scheduling complaint investigations is implemented consistently, my staff are committed to working with the Association of Health Facility Survey Agencies to expand on this guidance where necessary and to provide appropriate training programs.

Based on the concerns I have outlined, HCFA is taking action in four separate arenas. Our short-term improvements include the following two changes.

1. **Scheduling of Complaint Investigations**

Effective immediately, any complaint that alleges actual harm to an individual in a certified facility must be investigated within 10 work days of receipt. Where investigations reveal noncompliance with conditions or requirements for participation, the HCFA regional office and/or SMA must be notified. If this expectation creates competing and conflicting priorities for the State agency, it will be necessary to resolve the matter with the HCFA regional office.

2. **Data Entry**

Another criticism of the current complaint process is the failure of some State survey agencies to enter complaint data into the Online Survey, Certification and Reporting system (OSCAR) complaint subsystem. The State Operations Manual, sections 3281-3284, requires and provides instructions for encoding the results of all complaints resulting in citations of deficiencies. The Federal deficiency must be entered into OSCAR even if it is also going to be entered into a State licensure system. Since this information is essential to the effective management of the survey and certification program, it is important that any State not entering comprehensive complaint data into OSCAR do so **immediately and continue to do so**. In addition, it is essential that all backlogged complaint forms be entered OSCAR immediately.

On a longer-term basis we will undertake the following:

1. **Complaint Improvement Project (CIP)**

In addition to the short term measures discussed above, we are planning longer range projects for improving the complaint process. The CIP will address a wide range of issues related to complaints in nursing homes. These include: informing consumers of their right to make complaints and the procedure for filing a complaint; reviewing the complaint intake process including prioritizing and scheduling of complaints; the investigative process; the resolution of complaints and enforcement actions; administrative hearing processes; the interaction of the complaint investigator with various State organizational components and the legal system; the coordination between Federal systems for complaint processing; and, a review of the reporting requirements and tracking systems. Initially, we will work closely with the State survey agencies and then expand our discussion to include consumer groups and other interested parties on the CIP. Our goal is to further improve our ability to assure that allegations of our failure to protect the health and safety of beneficiaries from individuals are treated timely and effectively.

2. **OSCAR Redesign**

HCFA is also working on the redesign of the OSCAR system which will include a new complaint module. This redesign will focus on developing a more user friendly, integrated

system that will allow for better management of the complaint process.

These are ambitious but critical efforts. I recognize that there may be budget implications. We will work with the Association of Health Facilities Survey Agencies to assess and resolve any budget issues. I believe that by working together to assure that all complaints are investigated and resolved in a timely manner and that all results of complaint investigations are promptly entered into OSCAR, we will be making major strides toward an improved complaint process and more importantly, in ensuring the health and safety of our beneficiaries.

Sincerely yours,

Nancy Ann Min-DeParle

3/12/99

**COMMENTS OF THE HEALTH CARE FINANCING ADMINISTRATION
ON THE GENERAL ACCOUNTING OFFICE (GAO) DRAFT REPORT,
NURSING HOMES: COMPLAINT INVESTIGATION PROCESSES
INADEQUATE TO PROTECT RESIDENTS**

In July 1998, the Clinton Administration announced a broad and aggressive new initiative to improve enforcement of nursing home regulations. A recent General Accounting Office (GAO) draft report ("Additional Steps Needed to Strengthen Enforcement of Federal Quality Standards") This General Accounting Office (GAO) report, which examines conditions in nursing homes over a period from July 1995 to October 1998 (just after the new initiative was launched), underscores the need for this initiative and will help sharpen our focus on areas that need to be addressed. We generally concur with the report's four specific recommendations, and are already taking actions to address them.

There has been substantial improvement in nursing home quality since 1995, when the Clinton Administration began enforcing the nation's toughest-ever enforcement regulations. However, our July 1998 Report to Congress and a July 1998 GAO report made clear that more needed to be done. That is why, building on the earlier reforms, the President in July 1998 unveiled an aggressive initiative to further strengthen enforcement and assure quality care.

we are troubled by what the GAO found in its report and
~~We are pleased that this the current GAO report recognizes our efforts to address problems both~~
~~we and the GAO identified last year. We agree that further refinements to our enforcement~~ *complaint process*
~~initiative are needed. And we remain committed to taking appropriate steps to ensure that nursing~~
~~home residents are safe and receive quality care, and we will continue to work with the States,~~
~~Congress, residents and their families, resident advocacy groups, and nursing home providers to~~
~~advance this essential mission. We would like to note that, since the time period analyzed in this~~
~~the current GAO report, we have implemented many aspects of our new enforcement initiative;~~ *but*
recognize that more work needs to be done in the complaint area.
Faster Remedies

As part of the President's nursing home initiative, and as mentioned in this report, HCFA has expanded its definition of the type of facility for which HCFA would take an immediate enforcement action without a grace period (i.e., an opportunity for the facility to correct before sanctions are imposed). We previously labeled these facilities as "poor performing facilities (PPFs)". However, we are now revising our guidance to remove this label, and provide, in its place, direction about when facilities will be given an opportunity to correct. The guidance will make the assumption that unless a facility has no actual harm on the current survey it would not automatically be given an opportunity to correct before sanctions are imposed. Because facilities have no right to a period of correction prior to the imposition of sanctions, there could be other instances where facilities would not be given such an opportunity; for example, where a facility's pre-termination history indicated no commitment to achieve and maintain compliance with

before we address the specific findings and elements in this GAO report, we would like to note some of our accomplishments in other areas in nh.

participation requirements, we believe it would be appropriate to impose sanctions immediately.

Enhanced Enforcement Training

HCFA has been vigorous in encouraging States to apply appropriate sanctions for the noncompliance identified in the President's initiative. We will be providing training and guidance to States beginning this Spring on the nursing home initiatives including enforcement, use of quality indicators in the survey process, survey tasks in the areas of medication review, pressures sores, dehydration, weight loss, and abuse prevention.

Enhanced Oversight of Selected Facilities

HCFA has identified facilities in each State for more frequent inspection and intense monitoring. In selecting these special focus facilities (SFFs), HCFA scored each nursing home based on the results of its most recent annual inspection and any substantiated complaints during the past 2 years. HCFA presented each State survey agency with the names of those homes that generated the highest scores. States selected two facilities and have begun to monitor them more frequently.

Baseline data has been collected on each facility and monthly status reports are required. The monthly status report includes any survey outcomes, complaint investigations, enforcement actions, or press attention for each facility. The purpose of more intense monitoring of these facilities is to determine whether or not closer scrutiny and imposition of immediate remedies will have a lasting effect on these homes, i.e., whether the "yo yo" compliance history is affected. HCFA will conduct systematic analysis to determine if more intense monitoring is effective and if there are innovations with monitoring these facilities which can be used in the overall program.

Stronger Federal Oversight

HCFA has initiated a national program for improving the accuracy and consistency of State survey results. In October 1998, a standardized system for evaluating State survey performance was implemented. The Federal Oversight and Support Survey (FOSS) is a structured protocol for HCFA staff to use onsite in assessing the State survey teams' adherence to Federally mandated procedures and policies. Where training needs or corrective actions are identified, HCFA staff works with the State to assure that the necessary changes are implemented. We expect that this more standardized and aggressive approach to oversight will improve national consistency in the performance of nursing home surveys.

Quality of Care Enhancements

HCFA is in the process of implementing a wide range of initiatives to improve its ability to detect and prevent bed sores, dehydration, and malnutrition in nursing homes. In conjunction with national experts in nursing home care and quality indicator development, HCFA is developing a systematic data driven process for assessing quality problems in nursing homes. This data driven surveillance system will use indicators of potential care problems for facility residents to identify a sample for more in-depth on-site assessment including a larger sample to review for weight loss and pressure sores. National roll outs of this systematic approach are expected to be completed by the end of 2000 with an interim enhancement to the survey process implemented in 1999. In addition, HCFA staff are working with the American Dietetic Association, clinicians, consumers and nursing homes to share best practices for residents at risk for weight loss, dehydration, and

pressure sore development. This includes better guidance and training for surveyors on standards of care practices. A national campaign to educate residents, families, other consumers, and nursing home staff about the risks of malnutrition and dehydration as well as nursing home residents' rights to quality care in nursing homes will begin this year.

Abuse Prevention Campaign

Over the past 8 months, HCFA has concentrated efforts on the reduction of abuse and neglect in facilities. A national abuse and neglect forum consisting of representatives from groups concerned with the frail elderly and disabled has been formed. A survey protocol developed through the forum workgroup for evaluating nursing homes' abuse and neglect prevention processes will be implemented nationally by July 1999. A national consumer education campaign on prevention and detection will also be inaugurated in 1999.

Management Information System

HCFA is in the process of a major redesign and enhancement of its information system for nursing home quality. The goal is to implement in stages a system that is both user friendly for HCFA, State survey agencies, providers and consumers, and includes information necessary for nursing home quality of care evaluation and improvement. In June 1998 the first segment of this information system began with the development of State and national repositories with resident-specific data on declines and improvement (Minimum Data Set (MDS) longitudinal data). In July 1999, HCFA will start using quality indicators developed by national experts to analyze MDS data and identify domains of potential care problems. These quality indicator reports will be available to HCFA and State survey agencies for enhancing the survey system as well as to providers for internal quality improvement activities. In addition, in July 1999, an improved system for information collection, consolidation, and integration will be available to State survey agencies. State staff and managers will be able to generate, for individual facilities, tables that include relevant survey results as well as quality indicator information. This improved information system will enhance States' ability to assess the overall performance of an individual nursing home and to better manage survey resources. Future stages of the improved information system on facility quality will include: enhancement to the State systems on enforcement actions; major revisions to the current On-line Survey, Certification and Reporting (OSCAR) system to provide better and more integrated national information in a more user friendly environment; consumer information on quality indicators; updated quality indicators; and better national enforcement data. HCFA will proceed as quickly as possible with development of its improved information system for nursing home quality although there will be some delays attributable to Y2K priorities.

Consumer Information

HCFA is working to make survey results more accessible to the public. HCFA's new internet site -- Nursing Home Compare -- gives families and consumers direct Internet access to comparative information about nursing homes as well as provides incentives for nursing homes to improve the quality of care. Since the site was established last September, approximately 826,000 pages have been viewed and we are working with consumers, industry and others to make it more useful to consumers and their families. These and other such projects reflect HCFA's commitment to improving care in nursing homes through better information, education and enforcement.

Budget

In support of the nursing home initiatives, Congress appropriated \$4 million to the \$118.7 million in Medicare survey and certification funds requested for fiscal year (FY) 1999. And in order to ensure adequate funding of these efforts, the Clinton Administration intends to reprogram \$4 million from other activities so that a total of \$126.7 million will be directed to the nursing home related survey, certification and enforcement initiatives for FY99. These funds are being used primarily to support key improvements in state survey processes, including:

- staggering the beginning of at least 10% of the annual surveys during the morning and evening hours and on weekends;
- providing enhanced monitoring of those nursing homes who past compliance and complaint survey records indicate a poor history of compliance;
- revising the definition of and targeting nursing homes in which actual harm was found in the current survey and in either the last standard survey or an intervening complaint survey and;
- altering the survey protocol and resident sample selection in a way that identifies residents more susceptible to abuse and to having health problems associated with the lack of proper nutrition and hydration.

The Administration has proposed to expand its nursing home survey, certification and enforcement related funding in the FY2000 budget request to \$135.9 million, an increase of \$9.2 million over the FY 1999 funding. With the approval of this funding, HCFA envisions making significant gains in improving the care of beneficiaries and in providing the oversight necessary to assure that all are working toward this common goal.

Complaint Investigation Processes

We have long viewed complaints as a valuable and unique source of information about the health and safety of nursing home residents. In addition, we have been aware of inadequacies in the ~~entire system of responding~~ ^{problems} appropriately to nursing home complaints from residents, their families, nursing home staff, and other sources. Two HCFA-sponsored study by Abt Associates (A Study of the Variation Among State Long Term Care Complaint Investigation Processes: Complaint Investigations in Long Term Care Facilities/Results of a Survey of State Ombudsmen) identified extensive state variations in complaint investigation procedures and reporting, including many of the problems noted in the GAO report. In response to these identified problems, we created a workgroup to develop formal complaint guidelines for states. Unfortunately, devising universal standards and procedures that recognized the resource constraints in responding with an on-site investigation to every complaint as well as the permitting states to develop unique but effective procedures proved to be a formidable challenge; draft guidelines never were developed ~~for~~ ^{which} were appropriate for implementation. However, from this effort a set of investigatory protocols were developed and sent to the regional offices for distribution to the states. Yet many problems remain, as noted in the GAO report. We generally concur with the report's three specific recommendations, and have already taken actions to address them.

?

fully as an
 Although we concur with the GAO's recommendations, we think these recommendations are ~~narrowly conceived and do~~ we think the problems are more extensive than recognized in the report, and the solutions more difficult than acknowledged. The report does not address our concern with the complaint process to be responsive to beneficiaries and their families. Even if a complaint is totally groundless, we think it important that a beneficiary (or their family) have timely acknowledgment of their complaint and its resolution in plain language. Accordingly, we have taken steps to initiate a Complaint Improvement Project (CIP) which will incorporate ~~resident and consumer concerns (see description below)~~ *we also will work with both HCFA and GAO* and more effective integration with the GAO *concerns*

spell out
AoA's Ombudsman program The CIP will also develop solutions to some of the problems identified in the GAO report that are not specifically addressed in their recommendations. For example, while it is important to ensure that "... serious complaints alleging situations that may harm residents but are categorized as less than immediate jeopardy" are investigated promptly, there is no ~~apriori~~ already known right way to do this. Ultimately, this involves priority setting and the most cost-effective way of meeting this objective, ~~is unknown; hence, the need for our~~

determining
 CIP

Complaint Improvement Project

HCFA is in the final stages of initiating currently conducting a project on how to strengthen the complaint investigation process, including how HCFA can more effectively monitor and support state efforts. The project will identify model practices for complaint investigation, encompassing all the key elements of the process. This includes: (1) how consumers are informed of their right to make complaints and how to do so; (2) the complaint intake process, including how complaints are received, classified and scheduled for investigation; (3) the investigation process, including the training, knowledge, attitudes, and case load of investigators; (4) the resolution process, by which the determination is made about whether a complaint is substantiated; (5) the administrative hearing process, including back-log of cases; (6) the compliance or response process for addressing substantiated complaints, including the range and actual use of remedies and back-log of actions; and (7) interaction of the complaint investigation process with the licensure and certification systems, the legal system, and facility-level grievance or continuous quality improvement processes.

From this, HCFA will identify federal minimum standards for complaint investigation and the resource and program implications of different levels of increased standards. In addition, HCFA will produce a manual for the states that describes each element of a model complaint investigation process, how states have implemented these processes, and the resource implications in terms of such factors as staffing levels and training. ~~In addition, the project will specify~~ measures HCFA can use to strengthen federal monitoring/audits of state performance, including the elements that should be included in a federal complaint investigation reporting system and database. We will also explore other changes needed to strengthen HCFA's oversight in order to enhance the responsiveness of the complaint investigation process and ensure the welfare of beneficiaries.

Throughout this project, the concerns of beneficiaries, their families, consumer representatives, and representatives from AoA's Ombudsman program will be solicited and incorporated into the

since these are unknown, we need solutions the results on the CIP to formulate some options to solve these problems

design and final work products**GAO Recommendations**

"... we recommend that the HCFA Administrator revise federal guidance and ensure state agency compliance through the following actions:

- Develop additional standards for the prompt investigation of serious complaints alleging situations that may harm residents but are categorized as less than immediate jeopardy.

HCFA Comment

We concur. However, these standards will may have definite serious resource implications, and the most cost-effective way of proceeding is unknown; hence, the need for assessment and recommended procedures that will emerge from our Complaint Improvement Project (CIP).

Although the design and implementation of appropriate standards will emerge from our CIP, we think that some very helpful interim steps can be implemented immediately. Accordingly, the states with respect to scheduling of complaint investigations have been instructed to investigate within 10 days of receipt any complaint that alleges serious harm to an individual in a certified facility to be investigated.

we have drafted a letter to all states with the timeframe to be met for any complaint that

- Strengthen federal oversight of state complaint investigations, including monitoring states practices regarding priority-setting, on-site investigation, and timely reporting of serious health and safety complaints."

HCFA Comment

We concur. We have already taken actions to address this problem and other steps will be initiated:

- Enhanced federal oversight of state complaint investigations will be accomplished by the redefinition of the validation survey to include the expansion of a complaint survey to a standard survey. In essence, this reallocates the 5% look behind surveys to include full FMS surveys that are generated by complaints.
- One component of the nursing home initiatives that were announced in July, 1998 is directed to improve federal oversight of state performance. Consistent with this objective, we have initiated a new process that is focused exclusively on state performance with respect to nursing home survey and certification, independent of the SAQUIP process. This new process is evaluative, designed to improve state accountability, and not CQF-ish includes responsiveness to complaints as a performance measure. We are also concerned about the backlog of complaints for several states that are not entered into our OSCAR database and will also include this as a performance measure.

- ▶ It is true that HCFA's regional offices are required to maintain a log of complaint information reported by the states. If we confirm that these logs are not being maintained, as reported by the GAO, we will take immediate steps to reemphasize the requirement and correct this omission.
- ▶ Our Complaint Improvement Project will assess a number of options and make recommendations, consistent with the GAO recommendation.
- *"Require that the substantiated results of complaint investigations be included in federal data systems or be accessible by federal officials."*

HCFA Comment

We concur. Under our present guidelines, states are required to report this information. If the current complaint form is not adequate, as suggested by the GAO report, this can be corrected with interim improvements and states more closely monitored to ensure that the information currently required is actually entered into HCFA's database. Ultimately, an adequate complaint management system may require more extensive changes that will emerge as recommendations from the CIP, as recommended by the CIP. These long-term changes will be incorporated into the redesign of the OSCAR system. Unfortunately, due to FY2K priorities, we cannot begin work on these improvements until FY2000. Specifically, the following interim steps will be implemented now:

- ▶ Clearer instructions will be issued for completing the current complaint form;
- ▶ States will be required to determine the size of their backlog of complaints not entered into OSCAR and provide a timetable for becoming current. As noted above, their responsiveness to this requirement will be one element of their performance evaluation.
- ▶ Substantiated complaints that are cited under State licensure should also be cited under the federal requirement that facilities be in compliance with all local and state requirements. Hence, we will issue instructions to the states that this federal tag should be cited even when a citation and possible enforcement action is to be taken under state licensure authority. [Helene/Cindy - do you want to include this in the letter?]

Finally, while we think devising a cost-effective solution to the problems noted in the GAO report are more complex than acknowledged in the report, we do agree that some important improvements can be made now and that some states already appear to have developed effective practices.

DATE: 3/17/99**U.S. DEPARTMENT OF HEALTH AND HUMAN
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FAX: 452-5557**FROM:**☐ JANE HORVATH☐ HOLLY BODE☐ SHARON CLARKIN☐ BOB GUIDOS☐ GREG JONES☐ ANDREA LEVARIO☐ ROGER MCCLUNG☒ TANISHA PARKER☐ JON RETZLAFF☐ MARC SMOLONSKY☐ STEPHANIE WILSON☐

(INCLUDING COVER): _____

REMARKS: _____

March 17, 1999

TO: The Deputy Secretary

**Through: COS _____
ES _____**

**FROM: Rich Tarplin
Assistant Secretary for Legislation**

SUBJECT: DOJ 21st Century Law Enforcement and Public Safety Act (Crime bill)

The White House is planning an event around the DOJ 21st Century Law Enforcement and Public Safety Act (Crime bill) for Monday, March 22. The bill currently is under formal review and clearance within the Department. Comments are being collected by the Office of General Counsel (Legislation) and are due back to OMB by March 18.

HHS and its agencies have raised several serious concerns about the legislation since receiving an advance version of portions of the bill in mid-February. Specifically, concerns have been raised that several sections will be viewed as anti-research and development, anti-managed care, and plainly unworkable. Moreover, several agencies have complained that objections raised with DOJ have been ignored, and provisions identified by HHS as unacceptable to the Department have been included in the bill. Sections of particular concern include:

(1) Expansion of the Biological Weapons Statute (Section 6131)

Would criminalize the possession (as opposed to receipt and transfer) of "select agents," if such possession is not reported in advance to the Secretary of HHS.

CDC non-concurs because the provision:

- *Markedly expands CDC regulatory role, requiring CDC to do individual background checks on persons who seek to secure such agents. In addition to making CDC a law enforcement agency, the process will create an adversarial environment with researchers as opposed to the collaborative environment that currently exists.*
- *Will deter legitimate research since prison sentences are contemplated for even negligent non-compliance with reporting obligations.*

We believe the scientific community will oppose this section because it will have a negative

impact on legitimate research, it criminalizes current common practices, and because scientists have had no opportunity to offer their view on this new regimen.

CDC has reviewed previous versions of this provision last year, but DOJ ignored their comments. CDC, ASPE, and ASL have requested over the past several weeks, to no avail, that DOJ modify this provision or remove it from the bill.

(2) Nursing Home Resident Protection Act (Section 3039)

Authorizes DOJ to bring suit seeking criminal or civil penalties for a pattern of harm to nursing home residents or injunctive relief for a potential pattern of harm. Referral by HHS is not a precondition of DOJ taking action. Actions may be brought against nursing homes, nursing home chains, management companies, and individuals.

HCFA's objections include:

- *The proposed legislation would overlap much of HCFA's authority to remedy nursing home noncompliance, enabling DOJ to initiate proceedings on its own without referral from HCFA. It is inevitable that there will be conflicts - - some played out publicly, as in past instances - - where HCFA is required by its jurisdictional statutes to act, perhaps to close down a persistently non-complying facility, that DOJ wants to continue in operation while a US Attorney gathers evidence to build his/her case.*
- *The draft bill would likely lead to the development of conflicting standards with which facilities would be compelled to comply.*

HHS, DOJ, and the White House have had many discussions regarding our objections with this provision and HHS proposes that split, rather than overlapping authority will yield much better outcomes for beneficiaries and for quality of care enforcement.

(3) Amendments Concerning Temporary Emergency Scheduling (Section 4021)

Contrary to present practice, the provision would permit the Drug Enforcement Administration to temporarily emergency schedule a drug not presently scheduled, including drugs that are the subject of an Investigational New Drug application.

FDA does not concur because:

- *This amendment would significantly burden and jeopardize the investigation and development of new drugs and there is no evidence that the amendment is necessary to*

prevent the illicit diversion of drugs from legitimate scientific research. There is not one instance of evidence of diversion from an FDA-approved research project to illicit trafficking.

FDA, HHS, and DOJ have had discussions regarding this provision over the past two years. FDA has said that the current version retreats on some of the headway that has been made in those discussions.

(4) Extension of Criminal Penalties for Kickbacks (Section 3035)

Potentially expands anti-kickback provisions (similar to those under Medicare) to the private insurance industry at large. Apparently, DOJ's rationale for expanding these provisions where Federal dollars are not directly involved grows out of a patient protection argument that medical decisions should be based on medical considerations rather than financial ones.

HCFA has raised concerns about:

- *Criminalizing what is common (and perhaps legitimate) industry practice in the commercial insurance sector. It is not clear that DOJ has informed their proposal by surveying current industry standards.*
- *The applicability of criminal penalties for kickbacks to managed care in all its forms in the commercial market. Although the line between indemnity and capitated programs is pretty clear in Medicare, it is considerably more blurry in the commercial market. As a result, the Medicare analogy does not clearly work for what DOJ proposes.*
- *Medical considerations and financial considerations are not necessarily mutually exclusive concepts, so this aspect of the proposal needs attention.*
- *The complexity of this undertaking; one of the lessons learned from Stark II is that these types of provisions can be extremely complicated, and any legislative proposal should seek to avoid complicating implementation factors, if possible.*
- *The inclusion of this language within the Social Security statute; the authority to pursue private sector arrangements has no relationship to the authority found in this statute.*

In discussions between HCFA and DOJ, DOJ has shown some acceptance of our ideas to scale back the provision to apply only to Federal Employee Health Benefits Program (FEHBP) and to move the provision out of the Social Security Act, but has not made any movement on this section in the draft that OMB is circulating. (Instead, DOJ has added Section 3038 on Extending Anti-Fraud Safeguards to the FEHBP, while leaving Section 3035 intact)

(5) Improving Efficiency Through Improved Medical Payment Rules in Prisons and Related Facilities (Section 7024)

Section 7024 would prohibit Medicare participating providers (physicians and hospitals) from charging more than the DOJ rate for treatment of prisoners and detainees in the custody of the Attorney General. The Social Security Act already requires our hospitals to accept DoD and VA rates for their patients, (SS Act, Section 1866(a)(1)(J) and (L)). The DOJ proposal is modeled on the DoD/VA provision.

HCFA has raised concerns about:

- *Creating a condition of participation for physicians where we currently have none.*
- *Forcing both hospitals and physicians to treat prisoners in order to maintain Medicare provider status.*
- *The language being interpreted to force providers to pay for the security costs associated with treating prisoners. Medicare payments do not cover these costs.*

HCFA and ASL have discussed this provision with the Bureau of Prisons and the U.S. Marshalls and DOJ has shown willingness to accommodate our concerns. A draft of HCFA's suggested amendment is attached which would 1) exclude physicians; 2) make clear that the hospitals are not required to see prisoners, but that if they do, they must accept Medicare rates; and 3) require DOJ, not hospitals, to pay any security-related costs.

(6) Reauthorization of Violence Against Women Act

OMB has requested that HHS provide language to reauthorize VAWA using the Crime bill as a vehicle. These provisions are not in the version of the Crime Bill that is currently in circulation from OMB. When the Department has cleared the language, it will be sent over to OMB for final inclusion in the Crime Bill. Tentative language to be provided to OMB includes provisions regarding Battered Women's Shelter grants (\$102,300,000 -- ACF), the Domestic Violence Hotline grant (\$1.2 million -- ACF), and Grants for Community Initiatives (\$ as may be necessary -- CDC). All appropriations are through 2004.

ATTACHMENT 1**SEC. 7024. EXTENSION OF DOD AND VA ACCESS TO MEDICARE HOSPITAL RATES TO DEPARTMENT OF JUSTICE.**

(a) IN GENERAL. Section 1866(a)(1) (42 U.S.C. 1395cc(a)(1)) is amended

(1) at the end of subparagraph (S), by striking the period and inserting a semi-colon, and

(2) by inserting the following subparagraph at the end of the first sentence:

"(T) in the case of hospitals which furnish inpatient hospital services for which payment may be made under this title, if such hospital furnishes services to patients for whom payment for such services may be made under chapter 301 of title 301, United States Code, to be a participating provider of medical care under such chapter, in accordance with such admission practices and such payment methodology and amounts as are prescribed under joint regulations, issued by the Secretary and by the Attorney General in implementation of such chapter, which shall include full payment by the Attorney General of any security costs associated with treatment of such patients.".

(3) EFFECTIVE DATE. The amendments made by subsection (a) apply to services furnished or after January 1, 2000.

(b) as proposed by DOJ (provision to amend title 18)

HEALTH CARE FINANCING ADMINISTRATION



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5557

URGENT

first response



ADDRESSEE:

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Adler/
Chris Jennings

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3/12/99

REMARKS:

DoJ legislation + Analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administratio

Office of the Administrator
Washington, D.C. 20201

SEP 11 1999

To: Kevin Thurm
Deputy Secretary

From: Nancy-Ann Min DeParle *Nancy-Ann DeParle*
Administrator
Health Care Financing Administration

Subject: Nursing Home Resident Protection Act of 1999

As you know, in addition to the many enforcement activities undertaken in conjunction with our work on the President's nursing home initiative, HCFA has been working collaboratively with the Department of Justice (DoJ) on a number of law enforcement efforts aimed at identifying fraud and abuse in nursing homes, particularly fraud and abuse that may result in harm to patients. Thus far, our discussions with the DoJ have centered primarily on ensuring that appropriate cases for prosecution under federal and state law are referred to the proper authorities in a consistent and timely manner; and ensuring that enforcement and/or prosecution efforts by these various authorities are fully coordinated and in the best interests of patient health and safety.

A few weeks ago, HCFA was asked to review a draft legislative proposal -- "the Nursing Home Resident Protection Act of 1999" -- that was written by the DoJ and that the White House is interested in using for an upcoming announcement on nursing home enforcement and quality of care related activities. In our discussions with the DoJ and HHS Office of General Counsel (OGC), serious concerns have surfaced regarding the potential for this legislation to duplicate HCFA's own enforcement authority and to impede our efforts to pursue enforcement activities under current law. We have outlined below a summary of the legislation and our specific concerns with this proposal.

Main Points of the Proposed Legislation

The draft bill would give DoJ three new weapons to combat nursing home failures (and the failures of other residential health care facilities) to treat residents properly. First, it would create criminal sanctions for organizations or individuals who knowingly and willfully engage in a pattern of violations that result in a pattern of physical or mental harm to residents. Second, it would create civil penalties that could be imposed on individuals, facility chains, or management companies if they engaged in conduct that resulted in a pattern of physical or mental harm to residents. Third, it would authorize

DoJ to seek injunctive relief against these same entities or individuals whenever DoJ has reason to believe that these entities or individuals are engaging in a "pattern" of violations (as few as two) that results in, or has the potential to result in, physical or mental harm to one or more residents. The draft bill would require DoJ to "consult" with the Secretary when it invokes its authority to seek injunctive relief.

Significant Issues

In conjunction with OGC staff, we have reviewed the proposal and have the following concerns:

- ▶ *The proposed legislation would overlap much of HCFA's authority to remedy nursing home noncompliance.*

HCFA While we had hoped that whatever legislation DoJ might propose would serve to complement the authority already provided by statute (such as would be the case if the draft bill were aimed only at nursing home chains or management companies), DoJ's draft bill instead sets out sweeping independent authority that would enable it to take enforcement action against nursing homes virtually any time that HCFA or the States might choose to do the same thing. As drafted, the only area of facility noncompliance that would not pose the problem of overlapping authority for both agencies would be those kinds of cases where violations are fairly minimal or where the harm to residents is isolated.

Although the draft bill does not contain a provision that would require the Secretary to defer to DoJ whenever DoJ insists this be the case, the fact remains that there would be enormous pressure brought to bear on HCFA regional offices to back off enforcement activity if DoJ has an interest in acting itself on the same facts that underlie HCFA's enforcement action. It may often be the case that where DoJ asserts pressure of this sort, conflicts will arise since HCFA has a mandate under the Medicare and Medicaid statutes to protect resident health and safety, and DoJ's timetable for action may not coincide with HCFA's need to act swiftly where needed. We have experienced lately an example of the considerable tensions that can be generated between DoJ and HCFA when the two agencies are intent on taking action against the same facility under different statutory authorities. We believe that this kind of conflict is apt to surface far more frequently should DoJ succeed in obtaining vastly expanded authority to enforce nursing home noncompliance.

Along these same lines, HCFA can expect that DoJ would use its new enforcement authority as a means to significantly increase the number of civil money penalty (CMP) cases that it requires HCFA to suspend or drop. Under the current statute,

CMPs may only be imposed as approved by DoJ. Since the implementation of the nursing home enforcement regulation in 1995, DoJ and HCFA have been operating under a memorandum of understanding that defines the circumstances under which DoJ may ask HCFA to not proceed with CMPs in favor of a DoJ investigation against the same facility. Because of the broad expansion to DoJ's authority in this area represented by the draft bill, we can expect a sharp increase in the numbers of cases in which HCFA's CMP efforts will be curtailed. In light of the pending "per instance" CMP regulation, which is being developed pursuant to the President's nursing home initiative, and which will make it far easier for HCFA and the States to impose CMPs, this draft bill poses a potential obstacle to the use of this new enforcement option.

- ▶ *The proposed legislation would enable DoJ to initiate proceedings on its own without referral from HCFA.*

Under the President's nursing home initiative, HCFA is to refer to appropriate law enforcement agencies "egregious" cases of nursing home noncompliance so that these agencies may consider taking action against the facility. Currently, HCFA referrals are made to the HHS Office of Inspector General (OIG) which in turn may refer cases to the DoJ. The DoJ draft bill, however, would enable DoJ to initiate prosecutions in cases of its own choosing without regard to HCFA's enforcement objectives. We believe that, apart from the likelihood that the exercise of this new authority would create unnecessary overlap in the two agencies' jurisdiction, it would be inconsistent with the program announced by the President last summer that contemplates HCFA as the initiator of enforcement efforts against nursing homes that provide poor quality of care (with referral of only the most egregious cases to law enforcement). This proposed new authority could also create situations where the pursuit of fraud may occur at the expense of quality of care for patients.

- ▶ *The draft bill would likely lead to the development of conflicting standards with which facilities would be compelled to comply.*

Just as DoJ prosecutes False Claims Act cases through the use of experts who determine what standards facilities must abide by, we would expect the same process to unfold under this draft bill where DoJ initiates prosecutions of its own. The difficulty we see is that DoJ experts are certain to establish what they view as essential criteria for proper care that may or may not coincide with the standards set out in Federal certification requirements for the Medicare and Medicaid programs. To the extent that this is the case, facilities may find themselves having to comply with one set of rules to satisfy HCFA and State agencies, and another set of rules developed on a case by case basis by DoJ in the course of its

prosecutions. Thus, what it is that a facility has to do with respect to restraints, or hydration therapy, or bed sores may not harmonize with HCFA's requirements in these areas leaving facilities in the unenviable position of having to figure out how to satisfy both, and perhaps conflicting, sets of requirements.

- *The proposed legislation, would, however, fill gaps in current Federal law by providing DoJ authority to take actions against individuals and nursing home chains or management companies.*

Because the draft bill would enable DoJ to take action against both nursing home chains and management companies which operate nursing homes, the bill would add targets that are currently beyond the reach of our authorities. We have consistently agreed with DoJ that there needs to be authority to go after these entities since the government's overall enforcement efforts to improve the quality of care received by nursing home residents would be significantly enhanced by being able to reach these entities that up to now have been immune from enforcement action. Other than criminal sanctions, however, which would be the exclusive purview of DoJ, we believe that HCFA and the Department should decide whether any legislation addressing these issues should give the Secretary the authority to reach chains and management companies since it would pose such a logical extension of our current authority to protect the health and safety of facility residents.

Next Steps

- In our discussions with OGC, HCFA believes that the DoJ should take action on individual nursing home or a nursing home chain only after a referral from HCFA. If we decided to pursue this legislation with the DoJ, it must be significantly narrowed. If we were to agree to it as written, HCFA could possibly lose control of the nursing home survey and certification process -- and its current focus on ensuring the health and safety of vulnerable residents. OGC is working with the DoJ on the issue of referrals.
- HCFA staff continues to work with DoJ staff on a process for ensuring that appropriate cases for prosecution under federal and state law are referred (by HCFA) to the proper authorities and that those efforts are fully coordinated and in the best interests of patient health and safety.

• "Potential" for actual harm → presents risks (injunctive relief).

• Pragmatic OGC agency are not consistent w/ DOJ goals.

JAL

- need DOJ to be more active



HEALTH CARE FINANCING ADMINISTRATION



456-

5557

URGENT



ADDRESSEE:

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FROM:

Marie Martinez

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3/12/99

REMARKS:

DoJ legislation + Analysis.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administratio

Office of the Administrator
Washington, D.C. 20201

FEB 11 1999

To: Kevin Thurm
Deputy Secretary

From: Nancy-Ann Min DeParle *Nancy-Ann DeParle*
Administrator
Health Care Financing Administration

Subject: Nursing Home Resident Protection Act of 1999

As you know, in addition to the many enforcement activities undertaken in conjunction with our work on the President's nursing home initiative, HCFA has been working collaboratively with the Department of Justice (DoJ) on a number of law enforcement efforts aimed at identifying fraud and abuse in nursing homes, particularly fraud and abuse that may result in harm to patients. Thus far, our discussions with the DoJ have centered primarily on ensuring that appropriate cases for prosecution under federal and state law are referred to the proper authorities in a consistent and timely manner; and ensuring that enforcement and/or prosecution efforts by these various authorities are fully coordinated and in the best interests of patient health and safety.

A few weeks ago, HCFA was asked to review a draft legislative proposal -- "the Nursing Home Resident Protection Act of 1999" -- that was written by the DoJ and that the White House is interested in using for an upcoming announcement on nursing home enforcement and quality of care related activities. In our discussions with the DoJ and HHS Office of General Counsel (OGC), serious concerns have surfaced regarding the potential for this legislation to duplicate HCFA's own enforcement authority and to impede our efforts to pursue enforcement activities under current law. We have outlined below a summary of the legislation and our specific concerns with this proposal.

Main Points of the Proposed Legislation

The draft bill would give DoJ three new weapons to combat nursing home failures (and the failures of other residential health care facilities) to treat residents properly. First, it would create criminal sanctions for organizations or individuals who knowingly and willfully engage in a pattern of violations that result in a pattern of physical or mental harm to residents. Second, it would create civil penalties that could be imposed on individuals, facility chains, or management companies if they engaged in conduct that resulted in a pattern of physical or mental harm to residents. Third, it would authorize

DoJ to seek injunctive relief against these same entities or individuals whenever DoJ has reason to believe that these entities or individuals are engaging in a "pattern" of violations (as few as two) that results in, or has the potential to result in, physical or mental harm to one or more residents. The draft bill would require DoJ to "consult" with the Secretary when it invokes its authority to seek injunctive relief.

Significant Issues

In conjunction with OGC staff, we have reviewed the proposal and have the following concerns:

- ▶ *The proposed legislation would overlap much of HCFA's authority to remedy nursing home noncompliance.*

While we had hoped that whatever legislation DoJ might propose would serve to complement the authority already provided by statute (such as would be the case if the draft bill were aimed only at nursing home chains or management companies), DoJ's draft bill instead sets out sweeping independent authority that would enable it to take enforcement action against nursing homes virtually any time that HCFA or the States might choose to do the same thing. As drafted, the only area of facility noncompliance that would not pose the problem of overlapping authority for both agencies would be those kinds of cases where violations are fairly minimal or where the harm to residents is isolated.

Although the draft bill does not contain a provision that would require the Secretary to defer to DoJ whenever DoJ insists this be the case, the fact remains that there would be enormous pressure brought to bear on HCFA regional offices to back off enforcement activity if DoJ has an interest in acting itself on the same facts that underlie HCFA's enforcement action. It may often be the case that where DoJ asserts pressure of this sort, conflicts will arise since HCFA has a mandate under the Medicare and Medicaid statutes to protect resident health and safety, and DoJ's timetable for action may not coincide with HCFA's need to act swiftly where needed. We have experienced lately an example of the considerable tensions that can be generated between DoJ and HCFA when the two agencies are intent on taking action against the same facility under different statutory authorities. We believe that this kind of conflict is apt to surface far more frequently should DoJ succeed in obtaining vastly expanded authority to enforce nursing home noncompliance.

Along these same lines, HCFA can expect that DoJ would use its new enforcement authority as a means to significantly increase the number of civil money penalty (CMP) cases that it requires HCFA to suspend or drop. Under the current statute,

CMPs may only be imposed as approved by DoJ. Since the implementation of the nursing home enforcement regulation in 1995, DoJ and HCFA have been operating under a memorandum of understanding that defines the circumstances under which DoJ may ask HCFA to not proceed with CMPs in favor of a DoJ investigation against the same facility. Because of the broad expansion to DoJ's authority in this area represented by the draft bill, we can expect a sharp increase in the numbers of cases in which HCFA's CMP efforts will be curtailed. In light of the pending "per instance" CMP regulation, which is being developed pursuant to the President's nursing home initiative, and which will make it far easier for HCFA and the States to impose CMPs, this draft bill poses a potential obstacle to the use of this new enforcement option.

- ▶ *The proposed legislation would enable DoJ to initiate proceedings on its own without referral from HCFA.*

Under the President's nursing home initiative, HCFA is to refer to appropriate law enforcement agencies "egregious" cases of nursing home noncompliance so that these agencies may consider taking action against the facility. Currently, HCFA referrals are made to the HHS Office of Inspector General (OIG) which in turn may refer cases to the DoJ. The DoJ draft bill, however, would enable DoJ to initiate prosecutions in cases of its own choosing without regard to HCFA's enforcement objectives. We believe that, apart from the likelihood that the exercise of this new authority would create unnecessary overlap in the two agencies' jurisdiction, it would be inconsistent with the program announced by the President last summer that contemplates HCFA as the initiator of enforcement efforts against nursing homes that provide poor quality of care (with referral of only the most egregious cases to law enforcement). This proposed new authority could also create situations where the pursuit of fraud may occur at the expense of quality of care for patients.

- ▶ *The draft bill would likely lead to the development of conflicting standards with which facilities would be compelled to comply.*

Just as DoJ prosecutes False Claims Act cases through the use of experts who determine what standards facilities must abide by, we would expect the same process to unfold under this draft bill where DoJ initiates prosecutions of its own. The difficulty we see is that DoJ experts are certain to establish what they view as essential criteria for proper care that may or may not coincide with the standards set out in Federal certification requirements for the Medicare and Medicaid programs. To the extent that this is the case, facilities may find themselves having to comply with one set of rules to satisfy HCFA and State agencies, and another set of rules developed on a case by case basis by DoJ in the course of its

prosecutions. Thus, what it is that a facility has to do with respect to restraints, or hydration therapy, or bed sores may not harmonize with HCFA's requirements in these areas leaving facilities in the unenviable position of having to figure out how to satisfy both, and perhaps conflicting, sets of requirements.

- *The proposed legislation, would, however, fill gaps in current Federal law by providing DoJ authority to take actions against individuals and nursing home chains or management companies.*

Because the draft bill would enable DoJ to take action against both nursing home chains and management companies which operate nursing homes, the bill would add targets that are currently beyond the reach of our authorities. We have consistently agreed with DoJ that there needs to be authority to go after these entities since the government's overall enforcement efforts to improve the quality of care received by nursing home residents would be significantly enhanced by being able to reach these entities that up to now have been immune from enforcement action. Other than criminal sanctions, however, which would be the exclusive purview of DoJ, we believe that HCFA and the Department should decide whether any legislation addressing these issues should give the Secretary the authority to reach chains and management companies since it would pose such a logical extension of our current authority to protect the health and safety of facility residents.

Next Steps

- In our discussions with OGC, HCFA believes that the DoJ should take action on individual nursing home or a nursing home chain only after a referral from HCFA. If we decided to pursue this legislation with the DoJ, it must be significantly narrowed. If we were to agree to it as written, HCFA could possibly lose control of the nursing home survey and certification process -- and its current focus on ensuring the health and safety of vulnerable residents. OGC is working with the DoJ on the issue of referrals.
- HCFA staff continues to work with DoJ staff on a process for ensuring that appropriate cases for prosecution under federal and state law are referred (by HCFA) to the proper authorities and that those efforts are fully coordinated and in the best interests of patient health and safety.

• "Potential" for actual harm → presents serious (injunctive relief).

• Programmatic OGC agency are not consistent w/ DOJ goals.

See
- need to be in the national effort

Nursing Home Resident Protection Act of 1999s
Draft - 1/29/99 -- Draft

SEC. 1. **SHORT TITLE.** This Act may be cited as the "Nursing Home Resident Protection Act of 1999".

SEC. 2. **PROTECTION OF RESIDENTS IN NURSING HOMES AND OTHER RESIDENTIAL HEALTH CARE FACILITIES.**

Title 18, United States Code, is amended by adding the following new section:

"SEC. 1348. **Pattern of Violations Resulting in Harm to Residents of Nursing Homes and Related Facilities.**

"(a) **Criminal offense.**—Whoever knowingly and willfully engages in a pattern of violations of Federal or State law, regulation or rule governing the care of individuals residing in the residential health care facility, and where such pattern results in physical or mental harm to one or more such residents, shall be punished as specified in Section 1347 of this title,¹ except that any organization found guilty of an offense under this section shall be fined not more than \$2,000,000 per residential health care facility, and any individuals found guilty of an offense under this section shall be fined pursuant to the individual fine provisions of Title 18, Section 3571.

"(b) **Civil provisions.**—

(1) **Civil Penalties** — The Attorney General may bring an action in a United States district court to impose on any individual or entity that engages in a pattern of violations of Federal or State law, regulation or rule governing the care of individuals residing in the residential health care facility and where such pattern results in physical or mental harm to one or more such residents, a civil penalty of --

(A) in the case of an individual (other than an owner, operator, officer or manager of such a residential health care facility) up to \$10,000;

(B) in the case of an individual who is an owner, operator, officer or manager of such a residential health care facility up to \$100,000 for each separate facility involved in the pattern of violations under this

¹ The elements of such an offence are:

- knowledge and intent to violate law
- pattern of violations
- of federal or state laws or regulations governing nursing homes or other residential health care facilities
- violations resulted in physical or mental harm

section; or

(C) in the case of a residential health care facility up to \$1,000,000 for each pattern of violations, and in the case of an entity up to \$1,000,000 for each separate residential health care facility involved in the pattern of violations owned or managed by that entity.

"(2) Other appropriate relief.— If the Attorney General has reason to believe that an individual or entity is engaging in or is about to engage in a pattern of violations of Federal or State law, regulation or rule governing the care of individuals residing in the residential health care facility, and where such pattern results in or has the potential for resulting in physical or mental harm² to one or more such residents, the Attorney General may petition an appropriate United States district court for appropriate equitable and declaratory relief to eliminate the pattern. In pursuing such equitable or declaratory relief under this subsection, the Attorney General shall consult with the appropriate Federal agencies.

"(3) Procedures for this subsection (subsection 1348(b) of this Title) —

(A) A subpoena requiring the attendance of a witness at a trial or hearing conducted under this subsection may be served at any place in the United States.

(B) An action brought under paragraph (1) of this subsection may not be brought more than 6 years after the date on which the violation of this subsection occurred.

² Section by Section analysis: " Physical harm includes acts or omissions that result in death, hospitalization, medical treatment, external or internal bodily injury, illness, disease, infection, loss of consciousness, interruption in breathing, pain, discomfort, sexual assault, unlawful chemical, physical, or mechanical restraint, adverse reaction to medication, poisoning, self-injurious behavior, suicide attempt, substance abuse, ingestion of dangerous substance or object, or deterioration of skills or in level of functioning. The harm may be temporary or permanent. It includes, but is not is not limited to the following: a fracture, sprain, strain, laceration, damage to an internal or external organ, abrasion, contusion, wound, abrasion, skin irritation, bite, burn, scalding, concussion, swelling, bleeding, strangulation, choking, aspiration, edema, hematoma, exacerbation of symptoms of chronic illness. loss of limb, organ, teeth, or bodily function, malnutrition, dehydration, clinically detrimental weight loss or gain, or pressure sores.

Mental harm includes mental anguish, emotional distress, intimidation, humiliation, loss of dignity, fear, or loss of cognitive functioning. It can be measured by either an objective or subjective standard.

"(4) 'Pattern of violations' is defined as multiple violations that are widespread, systemic, repeated or similar in nature, or result from a policy or practice.¹

"(5) 'Whoever' is defined as in 18 U.S.C. § 921(a)(1).

"(6) 'Attorney General' is defined as the Attorney General of the United States or her designee and 'Secretary for the Department of Health and Human Services' is defined as the Secretary for the United States Department of Health and Human Services or her designee.

"(e) The Attorney General and the Secretary for the Department of Health and Human Services shall develop policies and procedures to reduce the negative impact of actions taken under this section on the residents of the residential health care facility."

SEC. 3. DEFINITION OF FEDERAL HEALTH CARE OFFENSE.

Subsection (a)(1) of section 24 of title 18, United States Code, is amended by adding "1348," after "1347,".

SEC. 4. AUTHORIZED INVESTIGATIVE DEMAND PROCEDURES.

Section 3486(a)(1) of title 18, United States Code, is amended by inserting after "Federal health care offense", "or other allegation of fraud or wrongdoing (whether civil or criminal) made in connection with a health care benefit program (as defined in section 24(b) of title 18, United States Code)".

¹ Section by section analysis: "The term 'pattern of violations' refers to a repeated violation that is widespread, systemic, repeated, similar in nature, or resulting from a policy or practice. For example, a widespread group of violations, even if not the result of a common policy or practice or not involving the same or similar regulations, could be covered by this section. On the other hand, one or more isolated violations that do not rise to the level of a 'pattern', as described above, would not be covered. The term incorporates a concept of proportionality so that the number of violations required to establish a pattern within an entity operating numerous facilities across the country would be greater than the number of violations required for a single facility. The term also incorporates a concept of severity so that the number of violations required to establish a pattern within a single entity or an entity operating numerous facilities would be fewer, the more severe the harm.

(C) The United States shall be required to prove all actions under this subsection by a preponderance of the evidence.

(D) The Civil Investigative Demand procedures set forth in 15 U.S.C. §§ 1311 - 14 and regulations promulgated pursuant thereto shall apply to investigations and actions pursued under this subsection.

(E) The filing or resolution of a matter under this subsection does not preclude any other remedy that is available to the United States or any other person. The Federal Rules of Civil Procedure shall apply to actions brought under this subsection.

"(c) Prohibition against retaliation.— Any person who is the subject of retaliation, either directly or indirectly, for reporting conditions that may constitute a violation of this section shall be authorized to bring an action in an appropriate United States district court for damages, attorneys' fees and other relief.

"(d) Definitions.— For purposes of this section, the following definitions apply:

"(1) 'Residential health care facility' is defined as any facility (including any facility that does not exclusively provide residential health care services) including but not limited to skilled and unskilled nursing facilities and mental health and mental retardation facilities, that receives Federal funds, directly from the Federal government or indirectly from a third party on contract with or receiving a grant or other monies from the Federal government, to provide health care, or that provides health care services in a residential setting and that, in any calendar year in which a violation occurs, is the recipient of benefits or payments in excess of \$10,000 from a Federal Health Care Program.

"(2) 'Entity' is defined in this section as any residential health care facility (including facilities that do not exclusively provide residential health care services), any entity that manages a residential health care facility, or any entity that owns, directly or indirectly, a controlling interest or a 50% or greater interest in one or more residential health care facilities.

"(3) 'Federal Health Care Program' is defined as:

(A) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government; or

(B) any State health care program, as defined in section 1320a-7(h) of Title 42, United States Code.

766170



**UNITED STATES
OFFICE OF PERSONNEL MANAGEMENT**

WASHINGTON, D.C. 20415

OFFICE OF THE DIRECTOR

FEB 18 1999

Honorable Janet Reno
The Attorney General
Department of Justice
Washington, DC 20530

Dear Madam Attorney General:

At a meeting with Office of Personnel Management Inspector General Patrick McFarland on January 29, 1999, John Bentivoglio, Special Counsel for Health Care Fraud, Office of the Deputy Attorney General, asked whether this agency supports removal of the exclusion of the Federal Employees Health Benefits Program (FEHBP) from certain civil enforcement provisions of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) (HIPAA). I strongly support our inclusion in these anti-fraud provisions, which apply to all other Federal health care programs, particularly since the FEHBP, by expending over \$17 billion per year, is the largest employer-sponsored health care program in the United States.

By excluding the FEHBP from HIPAA, investigators from our Office of the Inspector General are denied the following tools that would help in the investigation and prosecution of health care fraud:

- Enhanced sanctions provisions including mandatory exclusion for felony conviction relating to health care fraud or controlled substances and new minimum exclusion periods for certain permissive exclusions. This deters our ability to rapidly remove felons from the FEHBP under our new, independent debarment authority.
- Expanded anti-kickback provisions which would help us prevent FEHBP health care providers from receiving improper gratuities for referrals or related services.
- Enhanced civil monetary penalties (CMPs). HIPAA lowers the standard of proof for fraudulent claims and increases the penalty per false claim from \$2,000 to \$10,000. In addition, HIPAA allows CMPs to be assessed for incorrect coding, medically unnecessary services and offering remuneration to induce business (e.g. waving coinsurance or deductible).
- Full participation in Health Care Fraud and Abuse Control Account which provides agencies with a source of funding to assist them in investigations, prosecutions, audits or evaluations of health care fraud and abuse. While we are authorized to apply for grants

Honorable Janet Reno

2

from this account, since it is funded by criminal fines, civil false claims act recoveries and civil monetary penalties authorized by HIPAA, our restricted ability to collect such penalties makes it impossible for us to participate fully in supporting these efforts.

We need the same tools to fight fraud in the FEHBP as any other Federal health care program. There is no basis for treating our program any differently than any other Government health care program, which can only make it more difficult for us to participate with prosecutors and other agencies' law enforcement officials in cases involving fraud against multiple health care programs.

For these reasons, the Office of Personnel Management has consistently supported this amendment as a major component of our legislative agenda. I will appreciate any support that you can provide toward enactment of this legislation.

Sincerely,



Janice R. Lachance
Director



U.S. Department of Justice

Office of the Deputy Attorney General

Washington, D.C. 20530

FAX TRANSMISSION SHEET

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Special Counsel for Health Care Fraud

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DATE:

10/20/98

NUMBER OF PAGES (including this cover sheet):

4

MESSAGE:

Chris - we sent these to HCFAyesterday and have received no comments.(which ~~is~~ is fine). After the conference,
I'd be happy to brief you on where we
think this is headed.JLB

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

*For the Robert
abuse panel
Paul will give*

will not

**Remarks of Eric H. Holder, Jr.
Deputy Attorney General**

**Nursing Home Quality of Care and Fraud Conference
October 21, 1998**

Welcome

On behalf of the Department of Justice, I want to welcome you to what I know will be a very challenging and important two days. I also want to thank the HHS Inspector General, June Gibbs Brown, and the Administrator of the Health Care Financing Administration, Nancy Ann Min DeParle (DEH-Parl), for their tireless efforts in combatting health care fraud and for their commitment in pulling together this first-ever national conference on nursing home fraud and abuse.

Many of you traveled quite a distance to participate in these sessions and we are pleased that you were willing to do so; even for those of you whose offices are in the Washington metropolitan area, the trip out to Dulles seems like a distance. This gathering was located out here — away from the bustle of phones, faxes, and day to day business — for a reason: to emphasize the importance of the discussions which will take place and to give the topic the attention and energy it demands.

Health Care Fraud – A Priority

From the beginning of her tenure, Attorney General Reno has made combating health care fraud a top priority of the Department of Justice. We have substantially increased the number of prosecutors and investigators assigned to health care fraud cases, and our caseload has increased to record levels. And some of the most dramatic increases involve allegations of fraud and abuse in nursing homes.

DOJ Statistics

According to a recent survey of DOJ enforcement efforts, the number of new referrals received each year involving nursing homes has jumped substantially. In 1994, we received 5 new referrals; in 1997, we received 54 new referrals – a 10-fold increase. More than one-third of these matters involved charges of substandard care that could pose a risk to individual patients.

Priority within HHS

And I know this area is a top priority for the Department of Health and Human Services. The tough new actions announced by the President and the Secretary of HHS in July demonstrate a commitment to ensuring high-quality nursing home care.

Challenge to Do More

While we are proud of such efforts, I believe we can -- indeed must -- do more. Within the Department of Justice, we have made combating nursing home fraud and abuse -- particularly when it poses a threat to the health and safety of patients -- one of our highest priorities within our overall health care fraud program.

The Task for Conference Participants

I know all of the agencies and offices you represent share our concerns about the many ways that health care fraud schemes harm patients and about the staggering financial losses as well. The many federal, state and local agencies represented today have worked cooperatively on anti-fraud efforts, with impressive results. But that's all I'm going to say about the work we have done -- because we need to turn our attention to what still needs to be done.

Your discussions over the next two days will focus on the effects that health care fraud has on one of the most vulnerable segments of society -- the elderly who are in need of long term, skilled nursing care. Many victims of these offenses are not able to protect themselves from acts of violence or other inappropriate physical contact, not able to get out of bed and go look for a new health care provider who will treat them more appropriately, not able to discern that the appropriate number of floor nurses are not on duty because the facility's owners cut staff levels in order to save money; many of them are not able to even make a verbal complaint about their care or make the degree of their suffering known. That is what makes fraud in the nursing home setting particularly heinous -- the fact that many victims cannot express their outrage. They rely totally on their caregivers for the most basic of needs. And they rely on us to ensure that safeguards are in place to oversee the performance of their caregivers and take timely, effective enforcement action against those who do not provide quality health care.

Call for A Coordinated "Action Plan"

Your job over the next two days is to begin work on an "action plan" for bolstering our current enforcement efforts against fraud and abuse in nursing homes. This plan must ensure that we do business in a manner which prevents and detects these practices, and ensure that we use every possible tool -- civil, criminal, and administrative and the federal, state and local level -- to effectively deal with this conduct.

The Plan -- Ensuring Cooperation

The plan should also look for new and more effective ways to coordinate the efforts of the entire enforcement community -- and I use the term enforcement in the broadest sense. All of us in this room have a role in enforcement. That may require task forces at the local level that bring together the key regulatory, licensing, investigative and prosecutorial agencies. It may

require new approaches for sharing information that allow us to take action against unscrupulous providers and – just as important – take immediate steps to protect the health and safety of patients. And it may require new outreach efforts to patient advocacy groups and others to ensure we receive appropriate “early warning” signs of problems.

The Plan – Use of All Enforcement Tools; Possible Need
for New Tools

On the enforcement side, federal officials cannot simply think about the civil False Claims Act and the criminal mail fraud statute, and state officials cannot confine themselves to considering prosecution for fraud crimes and assault violations. We need to consider all of our options, and bring into our discussions state licensing officials, survey agencies and accreditation bodies who have the ability to affect whether a provider will continue to do business in this manner — or do business at all — and who monitor the provider’s continuing behavior. And we must consider whether we new tools are needed to address gaps in current laws and regulations. Perhaps most importantly, we must all share a common goal — ensuring quality care — and must place that goal above all else.

CHRIS-
IS THIS SOUNDING
LIKE JUSTICE IS
GOING BEYOND
F.C.A?
Too
Aggressive?

Conclusion

As you discuss these difficult issues, I encourage you to “think outside the box” and to expand your knowledge and understanding of the array of remedies which are available to ensure the provision of quality health care in the nursing home setting. Every participant here today was invited to this conference because he or she has specialized expertise in this area; I encourage each of you to participate fully and to share your ideas with each other.

I anticipate that because of the knowledge and experience gathered here, effective strategies will be designed to improve our cooperative enforcement efforts in the context of a truly cooperative federal-state-local initiative to bolster our enforcement efforts.

I look forward to the results of our efforts, and I wish you well in this very important endeavor.

February 21, 1999

Recruiting Beneficiaries to Spot Medicare Fraud

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By ROBERT PEAR

WASHINGTON -- The federal government will begin enlisting millions of **Medicare** beneficiaries in its war against **Medicare** fraud next week, urging them to report billing errors, overcharges and other evidence of possible wrongdoing by their own doctors and hospitals.

The campaign has strong support from lobbyists for the elderly, who see it as a way to educate consumers and save money for **Medicare** and its beneficiaries.

But the effort has provoked outrage among doctors, who say it will drive a wedge into the doctor-patient relationship, undermining the trust needed for effective medical care.

Federal officials will fan out across the country on Wednesday to show **Medicare** beneficiaries how to decipher their medical bills and ferret out fraud.

The secretary of Health and Human Services, Donna Shalala, Attorney General Janet Reno and the director of the FBI, Louis J. Freeh, will speak to beneficiaries at 30 sites linked by satellite. The "fraud fighter rallies" will be held in Washington, New York City, Boston, Miami, Chicago, Dallas, Los Angeles, Seattle and Honolulu, among other places.

"Senior citizens are our first line of defense in the battle against **Medicare** fraud," Shalala said.

June Gibbs Brown, inspector general of the Department of Health and Human Services, estimates that improper **Medicare** payments totaled \$12.6 billion last year. But she said she could not specify how much of this was attributable to fraud, as opposed to unintentional billing errors. **Medicare** finances health care for 39 million people who are elderly or disabled.

The theme of the new campaign is: "Who Pays? You Pay!" The message is that **Medicare** beneficiaries and taxpayers pay more when doctors, hospitals and other health care providers "rip off" the program, in the words of the Federal Health Care Financing Administration, which runs **Medicare**.

The government is offering rewards up to \$1,000 for information that leads to the recovery of **Medicare** money lost to fraud and abuse. Federal officials said

such abuse included billing **Medicare** for services that were never provided or were not medically necessary; billing for services more costly than those actually performed, and billing twice for the same service or supplies.

In recruiting "fraud busters," the government tells **Medicare** patients, "You can join the fight and help stop **Medicare** cheats from stealing your tax dollars."

Leaders of the American Medical Association met recently with **Medicare** officials to complain that the government was using inflammatory language that tends to set patients against doctors.

In a confidential report to AMA trustees, Dr. E. Ratcliffe Anderson Jr., executive vice president of the association, said: "We stated that we could not underscore strongly enough the outrage that physicians feel about these types of beneficiary outreach programs. We expressed physicians' grave concern that this type of rhetoric completely undermines the physician-patient relationship."

But federal officials said patients were often in the best position to spot fraud and abuse.

Medicare contractors say that they receive 130,000 telephone calls about potential fraud and abuse each year, and that 72 percent, or 94,000 calls, are from beneficiaries, many of whom question the propriety of claims filed on their behalf.

The American Association of Retired Persons, a co-sponsor of the new campaign, says, "**Medicare** beneficiaries must become the eyes and ears of law enforcement." The group is urging its members to join a "neighborhood fraud watch," which will scrutinize **Medicare** statements for questionable charges.

In brochures to be disseminated at the kickoff events next week, the AARP says: "Most health care providers are honest, and the questionable charge may be the result of a clerical error. That's why many people call their provider first.

"However, if you're not sure, you don't feel comfortable talking with your provider or your provider's answer is not satisfactory, don't hesitate to report a questionable charge to the **Medicare** fraud hot line at 1-800-447-8477."

The hot line is operated by the inspector general of the Department of Health and Human Services. "Just reporting questionable practices will help keep unethical providers on their toes," the association of retired persons says.

But some doctors are furious. Dr. George J. Petruncio, a family practitioner in Turnersville, N.J., said: "Senior citizens are being drafted to act as agents of the government. This will create an adversarial relationship between the patient and the physician."

Dr. John M. Rainey, who has been caring for cancer patients in Lafayette, La., for more than 20 years, said, "The government is, in effect, asking patients to turn in their doctors." Dr. Jerald R. Schenken, a pathologist in Omaha, said, "Legitimate doctors are very concerned that they will be classified as fraudulent."

Dr. Jeffrey S. Freed, a surgeon in Manhattan, said: "This puts patients in the position of having to police their own physicians. We have a sacred trust to do no harm, but the government now tells patients that we may be doing them financial harm. Patients will be less likely to trust me as their advocate, and less willing to share delicate medical information."

The American Hospital Association has told its members to prepare for a barrage of phone calls from **Medicare** patients. Richard J. Pollack, executive vice president of the association, conceded that hospital bills were "hideously complex and often incomprehensible." But he said that patients overestimated fraud and mistakenly believed that "if you crack down on fraud, you can extend the life of the **Medicare** trust fund forever."

The government is assigning more auditors and investigators to health care cases. In the last four years, more than 8,500 health care providers were excluded from **Medicare** after they were found to have engaged in fraud or professional misconduct. Criminal convictions for health care fraud reached 326 last year, up from 140 in 1994.

Beneficiaries repeatedly say **Medicare** fraud should be eliminated before their benefits are cut or premiums or co-payments are increased.

Although the government pays most **Medicare** bills, older Americans receive statements itemizing the services and equipment for which **Medicare** has been billed. Federal officials and the AARP say that any questionable charge should be investigated.

Specifically, they say, beneficiaries should answer three questions about each charge: Did you receive the service or product for which **Medicare** was billed? Did your doctor order the service or product for you? To the best of your knowledge, is the item relevant to your diagnosis or treatment?

An FBI official said that several complaints about the same provider may indicate a pattern of abuse or a fraudulent scheme.

Besides offering monetary rewards, federal officials note that private citizens may file lawsuits, on behalf of the government, against health care providers who defraud **Medicare**. Under the False Claims Act, the government may impose a civil fine up to \$10,000 for each fraudulent claim and may recover three times the amount of any damages it sustains. The person who filed the original lawsuit may get up to 30 percent of the money recovered.

But doctors say the government must be careful. Dr. William F. Gee, a urologist in Lexington, Ky., said: "**Medicare** patients may not remember what services they received. They may never see the doctors who perform certain services -- the radiologist who reads an X-ray, the pathologist who examines a tissue specimen."

Medicare claims typically are reviewed and paid by Blue Cross and Blue Shield plans or other insurance companies acting as agents for the government. The government recently advised these companies about how to handle complaints of fraud and abuse, saying that patients should not be told simply to "work it out" with their doctors.

Instead, the government said, if a complaint seems to have merit, the contractor should interview a sample of the doctor's patients.

Related Sites

These sites are not part of The New York Times on the Web, and The Times has no control over their content or availability.

- [Department of Health and Human Services.](#)



U.S. Department of Justice

Office of the Deputy Attorney General

Washington, D.C. 20530

FAX TRANSMISSION SHEET

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John T. Bentivoglio

Special Counsel for Health Care Fraud

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DATE:

10/20/98

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Chris - we sent these to HCFA

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**Remarks of Eric H. Holder, Jr.
Deputy Attorney General**

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October 21, 1998**

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According to a recent survey of DOJ enforcement efforts, the number of new referrals received each year involving nursing homes has jumped substantially. In 1994, we received 5 new referrals; in 1997, we received 54 new referrals – a 10-fold increase. More than one-third of these matters involved charges of substandard care that could pose a risk to individual patients.

Priority within HHS

And I know this area is a top priority for the Department of Health and Human Services. The tough new actions announced by the President and the Secretary of HHS in July demonstrate a commitment to ensuring high-quality nursing home care.

Challenge to Do More

While we are proud of such efforts, I believe we can -- indeed must -- do more. Within the Department of Justice, we have made combating nursing home fraud and abuse -- particularly when it poses a threat to the health and safety of patients -- one of our highest priorities within our overall health care fraud program.

The Task for Conference Participants

I know all of the agencies and offices you represent share our concerns about the many ways that health care fraud schemes harm patients and about the staggering financial losses as well. The many federal, state and local agencies represented today have worked cooperatively on anti-fraud efforts, with impressive results. But that's all I'm going to say about the work we have done -- because we need to turn our attention to what still needs to be done.

Your discussions over the next two days will focus on the effects that health care fraud has on one of the most vulnerable segments of society -- the elderly who are in need of long term, skilled nursing care. Many victims of these offenses are not able to protect themselves from acts of violence or other inappropriate physical contact, not able to get out of bed and go look for a new health care provider who will treat them more appropriately, not able to discern that the appropriate number of floor nurses are not on duty because the facility's owners cut staff levels in order to save money; many of them are not able to even make a verbal complaint about their care or make the degree of their suffering known. That is what makes fraud in the nursing home setting particularly heinous -- the fact that many victims cannot express their outrage. They rely totally on their caregivers for the most basic of needs. And they rely on us to ensure that safeguards are in place to oversee the performance of their caregivers and take timely, effective enforcement action against those who do not provide quality health care.

Call for A Coordinated "Action Plan"

Your job over the next two days is to begin work on an "action plan" for bolstering our current enforcement efforts against fraud and abuse in nursing homes. This plan must ensure that we do business in a manner which prevents and detects these practices, and ensure that we use every possible tool -- civil, criminal, and administrative and the federal, state and local level -- to effectively deal with this conduct.

The Plan -- Ensuring Cooperation

The plan should also look for new and more effective ways to coordinate the efforts of the entire enforcement community -- and I use the term enforcement in the broadest sense. All of us in this room have a role in enforcement. That may require task forces at the local level that bring together the key regulatory, licensing, investigative and prosecutorial agencies. It may

require new approaches for sharing information that allow us to take action against unscrupulous providers and — just as important — take immediate steps to protect the health and safety of patients. And it may require new outreach efforts to patient advocacy groups and others to ensure we receive appropriate “early warning” signs of problems.

The Plan — Use of All Enforcement Tools; Possible Need
for New Tools

On the enforcement side, federal officials cannot simply think about the civil False Claims Act and the criminal mail fraud statute, and state officials cannot confine themselves to considering prosecution for fraud crimes and assault violations. We need to consider all of our options, and bring into our discussions state licensing officials, survey agencies and accreditation bodies who have the ability to affect whether a provider will continue to do business in this manner — or do business at all — and who monitor the provider’s continuing behavior. And we must consider whether we new tools are needed to address gaps in current laws and regulations. Perhaps most importantly, we must all share a common goal — ensuring quality care — and must place that goal above all else.

Conclusion

As you discuss these difficult issues, I encourage you to “think outside the box” and to expand your knowledge and understanding of the array of remedies which are available to ensure the provision of quality health care in the nursing home setting. Every participant here today was invited to this conference because he or she has specialized expertise in this area; I encourage each of you to participate fully and to share your ideas with each other.

I anticipate that because of the knowledge and experience gathered here, effective strategies will be designed to improve our cooperative enforcement efforts in the context of a truly cooperative federal-state-local initiative to bolster our enforcement efforts.

I look forward to the results of our efforts, and I wish you well in this very important endeavor.

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**Medicare Reimbursement for
Hospital Beds in the Home**

Prices



**JUNE GIBBS BROWN
Inspector General**

**NOVEMBER 1998
OEI-07-96-00221**

EXECUTIVE SUMMARY

PURPOSE

To determine the reasonableness of Medicare's reimbursement for rental of hospital beds in the home when compared to other Federal, State, private insurance companies, and managed care organizations.

BACKGROUND

Medicare authorizes beneficiaries to obtain hospital beds for use in their home. This is done on the basis of a rental schedule with an option to purchase the bed. Suppliers receive monthly reimbursement from the Medicare Durable Medical Equipment Regional Carriers based upon a fee schedule. This schedule is limited by the Health Care Financing Administration's (HCFA) established national payment ceilings, and is adjusted annually for inflation based upon the Consumer Price Index. The rental fee schedule caps the rental payments at 120 percent of the allowable charge for purchase. In calendar year (CY) 1996, Medicare allowed charges of over \$272 million for the four categories of hospital beds included in this study. Semi-electric beds (code E0260) comprised 86 percent of this total while total electric beds accounted for less than one-half of one percent.

We surveyed sampled entities from Medicare risk managed care organizations, Medicaid State Agencies, the top 50 health insurance companies as ranked by policies in force, and a listing of companies providing national and local coverage in the Federal Employees Health Benefits program. Overall, we achieved an 82 percent response rate.

This is one of two reports examining Medicare's policies and reimbursement for hospital bed equipment. A companion report "*Medicare Reimbursement for Hospital Beds in the Home: Payment Methodology*" OEI-07-96-00222 compares Medicare's rental reimbursement payment methodologies to those of other medical insurance payers.

FINDING

Medicare Rates for Rental of Hospital Beds for Home Use Are Substantially Higher than Rates Paid by Most Other Payers

Comparison of Average Monthly Rental Payments for Semi-Electric Beds

Ninety-seven percent of our respondents pay for rental of hospital beds (72 of 74 respondents). We analyzed the rates for each hospital bed to identify the entities that paid uniform rates for rental and those that paid variable rates which depend on locale and market competition.

Of the 51 entities furnishing information on both the rental rates and the frequency of these payments for the four categories of hospital beds included in this inspection, 37 (72.6 percent) use a uniform monthly rate schedule, and 14 (27.4 percent) pay variable rates.

We found that on average, other payers' uniform monthly rental rates were more than 14 percent lower than the corresponding Medicare monthly rate for semi-electric hospital beds. For entities using a variable rate schedule, their highest rate ranged from 22 percent above to almost 23 percent below the corresponding Medicare average rate for this bed. We found similar results for manual, manual-adjustable, and total-electric hospital beds.

Comparison of Actual Monthly Rental Rates for Semi-Electric Beds

Since Medicare, unlike other entities, pays an enhanced rate for the first 3 months of rental, we also compared their actual rate for months 1 - 3 and months 4 - 15 to the rates of other entities. We found Medicare's rates for months 1 - 3 were from 18 percent to 38 percent higher, and for months 4 - 15 were from 9 percent lower to 18 percent higher.

Maximum Potential Rental Payments

We compared Medicare's rental payments for a semi-electric hospital bed during the maximum potential rental period of 15 months to other payers' maximum rental payments. We found entities paying a uniform rate were on average over 30 percent lower than Medicare's maximum payments. Also, entities who predominately reimburse from their highest variable rate schedule were on average 30 percent lower. Those payers primarily paying from their lowest rate schedule were on average 43 percent lower. Similar results were obtained for manual, manual-adjustable and total-electric hospital beds.

RECOMMENDATION

HCFA Should Take Immediate Steps to Reduce Medicare Payments for In-Home Hospital Beds

Medicare's monthly rates for the four types of hospital beds studied, when considered with total rental payments during the 15 month extended rental period, exceed the rates of other payers by more than 14 percent. The Balanced Budget Act of 1997 provides HCFA with the necessary tools to immediately reduce rates if there is compelling evidence that their rates exceed those generally being paid in the marketplace. We believe that this is the case here. If this authority is exercised for the four types of hospital beds surveyed, we estimate that annual savings at a 12 - 15 percent reduction would be approximately \$32.7 to \$40.9 million. Projected over 5 years, Medicare would save over \$163 to \$204 million.

We also believe that the payment method used by Medicare inappropriately overcompensates for rental use during the first 3 months of each rental period. We discuss this more thoroughly in our companion report, "*Medicare Reimbursement for Hospital Beds in the Home: Payment Methodology*" OEI-07-96-00222. In that report we include a recommendation that HCFA seek legislation to correct that aspect of the problem. Overall, we believe that a combination of both approaches would be best. However, the savings would not be additive.

AGENCY COMMENTS

The HCFA concurs with the intent of our recommendation and is undertaking a comparison of hospital bed rates and a competitive bidding demonstration project as a prelude to making hospital bed rate changes. Appendix F contains the complete text of these comments. We remain available to provide technical assistance to HCFA on this matter.

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**Comparing Drug Reimbursement:
Medicare and
Department of Veterans Affairs**



**JUNE GIBBS BROWN
Inspector General**

**NOVEMBER 1998
OEI-03-97-00293**

EXECUTIVE SUMMARY

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the Department of Veterans Affairs.

BACKGROUND

Medicare allowances for prescription drugs totaled almost \$2.3 billion in 1996. In 1997, allowances rose to approximately \$2.75 billion.

Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, under specific circumstances, Medicare Part B covers drugs used with durable medical equipment or infusion devices. Medicare also covers certain drugs used in association with organ transplantation, dialysis, chemotherapy, and pain management for cancer treatment. Additionally, the program covers certain vaccines, such as those for influenza and hepatitis B.

Physicians and suppliers usually bill Medicare directly for the prescription drugs they provide to beneficiaries. Medicare Part B reimburses covered drugs at 95 percent of the drugs' average wholesale prices (AWPs). The beneficiary is responsible for a 20 percent coinsurance payment.

Unlike Medicare, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. There are several purchase options available to the VA, including the Federal Supply Schedule, Blanket Purchase Agreements, and VA national contracts.

We focused our inspection on 34 drug codes, each with over \$10 million in Medicare allowed charges for 1996. We then compared the amount Medicare reimbursed for these drugs to the VA's Federal Supply Schedule acquisition costs during the first quarter of 1998.

FINDINGS

Medicare and its beneficiaries could save \$1 billion in 1998 if the allowed amounts for 34 drugs were equal to prices obtained by the VA.

After comparing the median Medicare allowance with the corresponding median VA acquisition cost for 34 drugs, we estimated that Medicare and its beneficiaries could save \$1.03 billion in 1998 if the Medicare allowed amounts for 34 drugs were equal to prices obtained by the VA under the Federal Supply Schedule.

This savings represents almost half of the \$2.07 billion in reimbursement that Medicare and its beneficiaries paid for these 34 drugs in 1997. The estimated savings for individual drugs ranged from a high of \$276 million for J9217 (leuprolide acetate) to a low of \$16,460 for K0523 (concentrated metaproteranol sulfate).

Medicare allowed between 15 and 1600 percent more than the Department of Veterans Affairs paid for the 34 drugs reviewed.

The Medicare allowance was greater than the VA acquisition cost for every drug reviewed. For 3 of the 34 drugs, Medicare allowed more than 16 times the VA acquisition cost. Eleven drugs had Medicare allowances that were between two and six times higher than the VA cost. For only two drugs was the difference between Medicare reimbursement and VA cost less than 25 percent.

RECOMMENDATIONS

The Department of Veterans Affairs purchases drugs for its healthcare system directly from manufacturers or wholesalers. Conversely, Medicare reimburses doctors and suppliers for drugs which they administer or supply to beneficiaries. We recognize that the Health Care Financing Administration (HCFA) and the VA operate under different statutory constraints. Nevertheless, the fact remains that another Federal agency can get prescription drugs for a drastically lower price than Medicare.

Previous reports of the Office of Inspector General found that actual wholesale prices available to physicians and suppliers are often significantly lower than the Medicare allowed amounts. This report provides additional evidence that the published AWP's used in determining the Medicare allowed amounts for certain prescription drugs can be many times greater than the actual acquisition costs available in the marketplace.

We believe our current findings provide further support for recommendations made in earlier reports. We previously recommended that HCFA reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments as appropriate. The HCFA concurred with this recommendation. We outlined a number of options for implementing this recommendation, including: (1) greater discounting of published average wholesale prices, (2) basing payment on acquisition costs, (3) establishing manufacturers' rebates similar to those used in the Medicaid program, and (4) using competitive bidding.

We continue to support the need for a comprehensive statutory reform of Medicare's prescription drug reimbursement methodology. A number of proposals addressing reform have been offered by both the Administration and members of Congress. However, until legislation can be enacted providing for such reform, we recommend that HCFA utilize the new inherent reasonableness or competitive bidding authorities provided in the Balanced Budget Act of 1997 to reduce Medicare's unreasonably high payments for certain drugs.

AGENCY COMMENTS

The HCFA concurred with our recommendations, stating that it appreciates the OIG's continuous efforts to assist it in obtaining the lowest prices for covered drugs. The HCFA noted that it has made several efforts to reduce excessive reimbursement rates, including using an inherent reasonableness adjustment for albuterol sulfate. The OIG supports these efforts and we believe HCFA should continue to use its inherent reasonableness authority to lower inappropriate payments for other drugs with excessive reimbursement rates.

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

FISCAL INTERMEDIARY FRAUD UNITS

JUNE GIBBS BROWN - INSPECTOR GENERAL

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DEC-02-1550 10:04 HCFA PRESS OFFICE 202 690 7159 P.06/24

EXECUTIVE SUMMARY

PURPOSE

The purpose of this report is to provide national information on fiscal intermediary fraud units.

BACKGROUND

Fiscal intermediaries are companies under contract with the Health Care Financing Administration (HCFA) to administer a major part of the Medicare program. Individual fiscal intermediaries vary in many ways including the amount of claims and payments they process. Likewise, their fraud units differ from one another. But, all must meet requirements outlined in the Medicare Intermediary Manual. Fiscal intermediaries were responsible for \$130 billion, or 75 percent, of total Medicare payments in 1996. The other 25 percent was handled by companies called carriers.

The HCFA requires that fiscal intermediaries and carriers have distinct units to detect and deter fraud and abuse. These units are part of HCFA's overall Medicare integrity program and are monitored by HCFA regional offices. The HCFA is currently planning to separate future anti-fraud functions from other intermediary and carrier operations. These activities will become the purview of a few contractors to be known as program safeguard contractors.

For this report, we surveyed all 41 fiscal intermediary fraud units that were under contract with HCFA in 1996 and still under contract in 1998. We collected fraud unit data for fiscal year 1996.

FINDINGS

Fraud units differed substantially in the number of complaints and cases handled. Some units produced few, if any, significant results.

While one would expect units of different size and resources to handle different size workloads, we found units of similar size and resources handling substantially different workloads.

- ▶ *Fraud units handled between 3 and 1,892 complaints per unit.*
- ▶ *The number of cases handled by each fraud unit ranged from 0 to 625.*
- ▶ *Fraud units referred between 0 and 102 cases to the Office of Inspector General.*

Despite HCFA's expectation that fraud units proactively identify fraud, half of the fraud units did not open any cases proactively.

More than one-third of fraud units did not identify program vulnerabilities.

Key words and terms related to fraud unit work vary in meaning. This hinders HCFA's ability to interpret fraud unit data and measure fraud unit performance.

RECOMMENDATIONS

The HCFA and fiscal intermediary fraud units have significant responsibilities in identifying and deterring fraud in a part of the Medicare program where \$130 billion is at risk. The variation in fraud detection, especially among units with similar resources, raises concern about possible poor performance by some fraud units.

Although HCFA currently conducts performance evaluations of fraud units, we believe there is a need to strengthen the monitoring and oversight of contractors' efforts to identify fraud and abuse. In recent years, HCFA has focused on continuous improvement as a method of evaluating contractor performance. In light of the disparity in fraud detection among contractors, the agency may need to refocus its evaluation efforts to include some type of return on investment analysis.

In order that HCFA may have a better understanding of fraud unit performance, which in turn will lead to making better decisions about fraud unit funding, selecting future contractors, and working collaboratively with other anti-fraud entities, we recommend that HCFA:

- ▶ Improve the contractor performance evaluation system so that it not only encourages continuous improvement, but also holds contractors accountable for meeting specific objectives.
- ▶ 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.
- ▶ 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.
- ▶ 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.
- ▶ Provide opportunities for fraud units to exchange ideas, compare methods, and highlight best practices relating to fraud and abuse detection.

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF
PARTIAL HOSPITALIZATION SERVICES
PROVIDED THROUGH
COMMUNITY MENTAL HEALTH
CENTERS**



JUNE GIBBS BROWN
Inspector General

OCTOBER 1998
A-04-98-02146



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date OCT - 5 1998

From June Gibbs Brown
Inspector General *June G Brown*

Subject Review of Partial Hospitalization Services Provided Through Community Mental Health Centers (A-04-98-02146)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

Attached is a copy of our final report entitled "Reviews of Partial Hospitalization Services Provided Through Community Mental Health Centers." This report provides you with a summary of audit activity on the delivery of mental health services through partial hospitalization programs (PHP) for Medicare beneficiaries at community mental health centers (CMHC) in Florida and Pennsylvania. The Office of Inspector General's (OIG) and the Health Care Financing Administration's (HCFA) work indicated widespread problems in this program. As you know, our offices have worked closely in reviewing this fast growing benefit area. We want to share with you our thoughts on possible actions that can be taken to address this problem issue of partial hospitalization services.

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) authorized Medicare coverage and payment of partial hospitalization services provided by CMHCs that are reasonable and necessary for the diagnosis and active treatment of an individual's mental condition in order to prevent a relapse or hospitalization. Joint reviews between HCFA staff and OIG offices in Florida and Pennsylvania showed that in 14¹ CMHCs:

- ▶ certification requirements to qualify as a CMHC were not always met;
- ▶ most of the beneficiaries were found to be ineligible for PHP services;
- ▶ many of the services provided to beneficiaries were not reasonable and necessary...nor were they eligible PHP services; and
- ▶ provider cost reports contained costs that were not always allowable, reasonable, and necessary.

¹Subsequent to the issuance of our draft report, 6 additional HCFA reviews in Florida disclosed problems similar to those found in the 14 reviews of CMHCs (12 in Florida, 2 in Pennsylvania) reported herein. Five of the six facilities reviewed by HCFA are no longer in business.

Page 2 - Nancy-Ann Min DeParle

Because localized approaches were used between our staffs in reviewing these 14 CMHCs, we are not able to provide an overall average error rate for these above noted error types. However, improper payments on behalf of ineligible beneficiaries or facilities that did not qualify as a CMHC totaled over \$31 million for these 14 providers. The HCFA suspended Medicare payments to all 14 providers and terminated the provider numbers for 10 of the 12 facilities in Florida. Eleven of the 14 providers were referred to the OIG Office of Investigations for further analysis of their activities.

The OIG recently completed a review of PHP services in 5 States, representing about 77 percent of CMHC PHP payments nationally. This review was designed to determine the extent of ineligible beneficiaries enrolled in the program and provide input to HCFA on the reasonableness and necessity of the services provided by the CMHCs. The 5-State review disclosed that a substantial percentage of both claims and services were unallowable or highly questionable. The HCFA also recently completed a provider enrollment initiative in which on-site reviews were conducted at 700 CMHCs in 9 States. With the assistance of your office, we will also continue to target CMHCs around the country for individual reviews for eligibility and the allowability, reasonableness, and necessity of the costs reported on the cost reports.

This report presents our thoughts on changes that could be considered in an effort to eliminate the abusive practices being found in this program. We support: HCFA's efforts to develop a prospective payment system (PPS) for PHP services at CMHCs; the development of proposed rules that address surety bonds for CMHCs and the enrollment/re-enrollment process for CMHCs to participate in the Medicare PHP program; and HCFA's current 9-State enrollment initiative. As a PPS system is developed, we recommend that HCFA determine the costs of unnecessary care and other excessive costs (as shown in reviews completed thus far), and eliminate them from the cost data used to establish the PPS. We also offer the following recommendations for your consideration:

- Concerning the enrollment of ineligible providers, we suggest that HCFA either develop Conditions of Participation or conduct onsite surveys during the enrollment process to address qualifications issues. This would include compliance with laws and regulations including State licensure laws, furnishing appropriate services, and other patient health and safety issues.
- In regard to ineligible beneficiaries and services, we suggest that the fiscal intermediary (FI) perform a detailed review of the first claim for each new beneficiary receiving PHP services, including a review of medical records, and that HCFA, as part of its oversight activities, perform medical reviews of selected PHP claims.



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

Nancy-A DePaul

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.

PRESIDENT CLINTON UNVEILS LEGISLATIVE AND ADMINISTRATIVE PROPOSALS TO FIGHT MEDICARE FRAUD, WASTE, AND ABUSE

December 7, 1998

Today, President Clinton announced additional steps to fight fraud, waste, and abuse in the Medicare program, building on the Administration's longstanding efforts in this area. The President unveiled a legislative package that will save Medicare over \$2 billion. He also announced new administrative measures to crack down on fraud, including efforts to make Medicare contractors more effective and accountable. Today in an event with the Administrator of the Health Care Financing Administration (HCFA), the HHS Inspector General, Senator Tom Harkin, and the Older Women's League, the President:

ANNOUNCED NEW LEGISLATIVE PACKAGE THAT WILL SAVE MEDICARE OVER \$2 BILLION BY COMBATING FRAUD, WASTE, AND ABUSE. President Clinton will send Congress a comprehensive legislative package to fight fraud, waste, and abuse in the Medicare program as part of his FY2000 budget proposal. These proposals, which are consistent with recommendations made by the HHS Office of the Inspector General (OIG) in recent reports and some of which have been recommended to Congress before, will give HCFA more tools to root out fraud, abuse, and waste in Medicare. The proposals include:

- **Eliminating Excessive Medicare Reimbursement for Drugs.** A recent report by the OIG confirmed that Medicare currently pays hundreds of millions of dollars more for 22 of the most common and costly drugs than it would if it used market prices. For more than one-third of these drugs, Medicare paid more than double the average wholesale price, and in one case paid ten times the amount. This proposal would base Medicare payments on the actual acquisition cost of these drugs to the provider, eliminating current mark-ups and thereby substantially reducing Medicare costs.
- **Ending Overpayments for Epogen,** a drug used to treat anemia related to chronic renal failure. An OIG report found that the current reimbursement rate of \$10 per 1,000 units of Epogen exceeds the current cost of the drug by approximately 10 percent. The Administration's proposal reduces Medicare reimbursement to reflect current market prices.
- **Preventing Abuse of Medicare's Partial Hospitalization Benefit.** A recent OIG report found that providers are abusing Medicare by billing for partial hospitalization services that were never given or provided to many fewer patients than were billed for. This proposal would ensure that Medicare reimburses only for services actually given by placing stricter controls on the provision of these services.
- **Ensuring Medicare Does Not Pay for Claims Owed by Private Insurers.** Private insurers of working Medicare beneficiaries are required under law to be the primary payor of health claims. These insurers, however, do not always pay the claims for which they are responsible. This proposal prevents this abuse by requiring private insurers to report all Medicare beneficiaries they insure to HCFA. This proposal also would give HCFA greater authority to fine private insurers, including the authority to recoup twice the amount owed if insurers intentionally allow Medicare to pay claims for which they are responsible.
- **Empowering Medicare to Purchase Cost-Effective High-Quality Health Care.** Medicare now has limited demonstration authority to contract out with institutions that have a track record of providing exceptionally high-quality care at a reasonable price, called centers of excellence. This proposal would expand this authority to urban areas that have multiple providers, thereby enabling the Medicare program to provide higher quality health care at less cost.

- **Requesting New Authority to Enhance Contractor Performance.** HCFA still does not have the authority it needs to terminate more expeditiously contractors who do not effectively perform their duties. This proposal would give HCFA authority to contract with a wider range of carriers to administer the program, and then to terminate them if they fail to perform effectively. The proposal would give HCFA greater authority to oversee contractor performance of such functions as enrolling providers, investigating fraud, and collecting overpayments.

TOOK NEW ACTIONS TO HELP ENSURE MEDICARE CONTRACTORS FIGHT FRAUD, WASTE, AND ABUSE. Today, the President is also unveiling new administrative efforts to ensure contractors are cracking down on fraud and abuse. These include:

- **Contracting with Special Fraud Surveillance Units to Ensure Detection of Fraudulent Activities.** OIG reports have shown that many Medicare contractors do a poor job of investigating fraud, in part because they have a wide variety of other functions, and in part because they have multi-faceted relationships with providers that may create conflicts of interest. The Administration fought to include in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) new authority to contract with specialized fraud, waste, and abuse surveillance units or "fraud fighters," which are better equipped to audit cost reports and conduct activities that are vital to the detection of fraud, waste, and abuse. The first fraud surveillance units will begin their efforts this spring.
- **Implementing the Competitive Bidding Demonstration for Durable Medical Equipment.** The OIG recently found that Medicare rates for hospital beds are substantially higher than rates paid by other payers. HCFA will begin a demonstration this spring that will use competitive bidding to decrease Medicare payment for hospital beds and other durable medical equipment, thereby lowering program costs.
- **Requiring Contractors to Report Fraud Complaints to the Inspector General Right Away.** Many contractors now defer reporting cases of suspected fraud to the OIG when the dollar amounts are low, even though these reports could show significant patterns of fraud. This month, HCFA will send program memorandums to all contractors requiring them to refer suspected fraud to OIG immediately, regardless of the amounts involved.
- **Announcing That A New Comprehensive Plan to Fight Fraud and Abuse Will Be Completed By Early Next Year.** To improve efforts to cut down on fraud and abuse, HCFA will release a new Comprehensive Plan for Program Integrity early next year. This plan will outline new strategies to fight fraud, including enhanced use of audits and improved management tools.

BUILDING ON LONGSTANDING COMMITMENT TO FIGHTING FRAUD, WASTE, AND ABUSE.

The new steps the President took today build on the Administration's longstanding commitment to crack down on fraud, waste, and abuse. Since 1993, the Administration's efforts have saved taxpayers more than \$20 billion, with health care fraud convictions increasing by more than 240 percent. The Administration has assigned more federal prosecutors and FBI agents to fight health care fraud than ever before. HIPAA created, for the first time ever, a stable funding source to fight fraud and abuse, and in FY1997 alone -- the first full year of funding under HIPAA -- nearly \$1 billion in fraud and abuse savings was returned to the Medicare Trust Fund.

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INTRODUCTION

PURPOSE

To compare Medicare allowances for prescription drugs with drug acquisition prices currently available to the Department of Veterans Affairs.

BACKGROUND

Medicare allowances for prescription drugs totaled almost \$2.3 billion in 1996. In 1997, allowances rose to approximately \$2.75 billion. Medicare allowances include both the Medicare payment and the 20 percent copayment made by the beneficiary.

Medicare Coverage and Payment of Prescription Drugs

Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, under specific circumstances, Medicare Part B covers drugs used with durable medical equipment (DME) or infusion devices. Medicare also covers certain drugs used in association with organ transplantation, dialysis, chemotherapy, and pain management for cancer treatment. Additionally, the program covers certain vaccines, such as those for influenza and hepatitis B.

Physicians and suppliers usually bill Medicare directly for the prescription drugs they provide to beneficiaries. Medicare Part B reimburses covered drugs at 95 percent of the drugs' average wholesale prices (AWPs). The beneficiary is responsible for a 20 percent coinsurance payment.

The Health Care Financing Administration (HCFA) contracts with local carriers and four DME regional carriers (DMERCs) to process Part B claims and establish the Medicare allowed amounts for covered drugs. These carriers determine the allowed amount for a drug based on the AWPs as reported in the *Red Book* or similar pricing publications used by the pharmaceutical industry. If a drug has both brand and generic sources available, reimbursement is based on 95 percent of the median AWP for generic sources. However, if a brand name product's AWP is lower than the median generic price, a new median including the brand must be calculated. Beginning in 1999, Medicare will calculate the AWP for multiple-source drugs at the lower of the median generic AWP or the lowest brand-name AWP.

The HCFA and its carriers identify drug products using codes in HCFA's Common Procedure Coding System (HCPCS). The HCPCS codes define the type of drug, and in most cases, a dosage amount. The codes do not identify the specific drug product billed.

Department of Veterans Affairs Payments for Prescription Drugs

Unlike Medicare, the Department of Veterans Affairs (VA) purchases drugs for its healthcare system directly from manufacturers or wholesalers. The VA uses National Drug Codes (NDCs) rather than HCPCS codes to identify drugs products. Each drug manufactured or distributed in

the United States has a unique NDC. The NDCs identify the manufacturer of the drug, the product dosage form, and the package size.

There are several purchase options available to the VA, including the Federal Supply Schedule, Blanket Purchase Agreements, and VA national contracts. The Federal Supply Schedule provides agencies like the VA with a simple process for purchasing commonly-used products in various quantities while still obtaining the discounts associated with volume buying. Using competitive procedures, contracts are awarded to companies to provide services and supplies over a given period of time. Although the General Services Administration awards most Federal Supply Schedule contracts, the VA awards contracts for certain medical items. Agencies are not required to use the Federal Supply Schedule, however, and are able to negotiate prices lower than the Federal Supply Schedule price.

New Authorities Provided by the Balanced Budget Act

A provision within the Balanced Budget Act of 1997 allows Medicare to diverge from a statutorily defined payment method if the application results in a payment amount that is not inherently reasonable. Additionally, the Act provides HCFA with the authority to conduct competitive bidding demonstrations. The legislation authorizes up to five of these demonstrations for health care items and services covered by the Medicare fee-for-service program. All demonstrations must be completed by December 31, 2002.

Related Work by the Office of Inspector General

This report is one of several Office of Inspector General (OIG) reports concerning Medicare payments for prescription drugs. In 1997, we released *Excessive Medicare Payments for Prescription Drugs* (OEI 03-97-00290), which found that Medicare allowances for 22 drugs exceeded actual wholesale prices by \$447 million in 1996. In 1996, we released a report entitled *Appropriateness of Medicare Prescription Drug Allowances* (OEI-03-96-00420) which compared Medicare drug reimbursement mechanisms with Medicaid mechanisms and found that Medicare could achieve significant savings by adopting reimbursement strategies similar to those used by Medicaid. The OIG has also released several reports focusing on the cost of inhalation drugs covered by Medicare. *Medicare Payments for Nebulizer Drugs* (OEI-03-94-00390), *A Comparison of Albuterol Sulfate Prices* (OEI-03-94-00392), and *Suppliers' Acquisition Costs for Albuterol Sulfate* (OEI-03-94-00393) all found Medicare allowances for inhalation drugs to be excessive.

METHODOLOGY

We focused our inspection on the HCPCS codes with over \$10 million in Medicare allowed charges for 1996. We then compared the amount Medicare reimburses for these drugs to the VA's acquisition costs during the first quarter of 1998.

We collected data from four sources. We accessed the HCFA National Claims History (NCH) File to get information concerning Medicare allowances and utilization for prescription drugs in 1996 and 1997. We gathered reimbursement rates for specific Medicare drug codes by

contacting several carriers. We obtained drug acquisition costs from the VA. We used the CD-ROM version of the *Red Book* to help us match HCPCS codes to their equivalent NDCs.

Medicare Allowances for Prescription Drugs

To determine total Medicare payments for prescription drugs, we compiled a list of HCPCS codes representing all drugs covered by Medicare in 1996. We selected 1996 because it was the most recent year with complete data in the NCH file. We then determined the Medicare allowance and utilization for each of the more than 400 HCPCS codes using HCFA's Part B Extract Summary System (BESS). Next, we aggregated the individual allowances and utilization to determine the total allowance and utilization for all prescription drugs covered by Medicare in 1996.

We arrayed the HCPCS codes by their allowances and found that 40 codes each had over \$10 million in allowances for 1996. These 40 codes represented just over \$2 billion in allowances for 1996, and comprised 88 percent of the total Medicare allowance for all prescription drugs.

We removed several HCPCS codes from our review. Codes J7699, J7999, and J3490 were removed because they are defined as either "not otherwise classified" or "unclassified" drugs. We also chose not to use code A4646, an iodine product. Two Factor VIII codes (J7190 and J7192) were removed because we knew from previous studies that they were difficult to match to NDCs. Finally, code J9010 (Doxorubicin, 50 mg) is no longer reimbursed by HCFA, and was therefore removed from review.

Several other HCFA coding changes in 1997 and 1998 affected the drugs in our review. Code J1625 was deleted, and replaced with J1626. Inhalation codes J7610 and J7645 were changed to K0503 and K0518 respectively. Finally, HCFA deleted inhalation codes J7620 and J7670 and replaced them with two codes each, one representing a concentrated dose and the other a unit dose form of the drug. Code J7620 was changed to codes K0504 and K0505, while code J7670 was changed to K0523 and K0524. After accounting for these changes, 35 HCPCS codes remained in our review.

Carrier Reimbursement for Prescription Drugs

Because Medicare does not have uniform national allowed amounts for prescription drugs, we had to collect reimbursement information from various carriers. We obtained first quarter 1998 Medicare allowed amounts for the 35 HCPCS codes from five large Medicare carriers: Xact Medicare Services, United Healthcare Insurance Company, Blue Cross and Blue Shield of Texas, Blue Cross and Blue Shield of Florida, and Blue Cross and Blue Shield of South Carolina. We also received Medicare allowed amounts from the four DMERCs. To determine a single Medicare allowed amount, we calculated median prices for each HCPCS code based on this information.

Matching HCPCS Codes to NDCs

Since the VA pays for drugs based on NDCs, we used the 1998 *Red Book* CD-ROM update to determine the specific NDCs that would match the HCPCS code definition for each of the 35 drugs. Whenever possible, we selected NDCs that met the exact dosage delineated in the HCPCS code description. When this was not possible, we chose NDCs with doses for which a conversion factor to the HCPCS definition could be readily determined.

VA Acquisition Costs for Prescription Drugs

To determine the VA's first quarter 1998 acquisition costs for the selected NDCs, we obtained a file from the VA containing contract acquisition costs. We selected the Federal Supply Schedule price for comparison purposes. However, some drugs had lower prices available to the VA based on other contractual methods.

Eleven drugs had only one NDC match in the VA file, while six drugs had more than five matches. One HCPCS code (90724) and its corresponding NDCs did not have any matches in the VA file. This HCPCS code was therefore removed from the study, leaving 34 codes in our review. A list of the final 34 HCPCS codes and their corresponding descriptions is presented in Appendix A.

These 34 HCPCS codes represented 17 single-source, 11 multiple-source, and 6 multiple-brand drugs. A single-source drug has only one brand of drug available. A multiple-source drug has both brand and generic sources available. A multiple-brand drug has more than one brand but no generic versions available. Of the 11 drugs with a single NDC match in the VA file, 8 were single-source drugs.

Comparing Medicare Allowance Amounts to VA Acquisition Costs

Using the *Red Book* and the HCPCS code definitions, we compared product descriptions for the 34 drugs reviewed. For some NDCs, the corresponding HCPCS codes had an equivalent dosage, and therefore the VA cost could be easily compared to the Medicare allowed amount. If the two codes were not equal, we determined a conversion factor to match the NDC dosage and package size to the HCPCS dosage. We then took the Federal Supply Schedule contract price for the NDC and divided it by the conversion factor to determine the pricing of its HCPCS code equivalent.

To compare VA costs to Medicare allowed amounts, we needed to determine a single VA price for each drug. For the 11 drugs with a single NDC match in the VA file, we simply used the Federal Supply Schedule contract price of that NDC. For the 23 drugs with multiple NDC matches in the VA file, we took the median of the Federal Supply Schedule contract prices.

Calculating Potential Medicare Savings

To calculate potential Medicare savings, we used the utilization numbers contained in the 1997 BESS file. Although we used 1998 Medicare allowed amounts, we chose to use 1997 utilization

data for our calculations since the 1998 utilization data was incomplete at the time of our review. Because two HCPCS codes underwent dosage changes between 1997 and 1998, we needed to determine a conversion factor to estimate utilization for the new dosages. In 1998, code J1625 was changed to J1626, with the dosage changing from 1 milligram (mg) to 100 micrograms (mcg). Therefore, we estimated that utilization would increase by a factor of 10 (1 mg = 1000 mcg). Also in 1998, the dosage of J1562 was changed from 500 milligrams to 5 grams (g). Therefore, we estimated that overall utilization would decrease by a factor of 10 at the new dosage (5000 mg = 5 g).

Finally, for each drug, we compared the median Medicare allowed amount to the median VA acquisition cost for the first quarter of 1998. We multiplied the difference by the 1997 utilization of each drug to calculate the potential savings to Medicare if the program reimbursed drugs at VA cost rather than 95 percent of AWP.

FINDINGS

MEDICARE AND ITS BENEFICIARIES COULD SAVE \$1 BILLION IN 1998 IF THE ALLOWED AMOUNTS FOR 34 DRUGS WERE EQUAL TO PRICES OBTAINED BY THE DEPARTMENT OF VETERANS AFFAIRS.

After comparing the median Medicare allowance with the corresponding median VA acquisition cost for 34 drugs, we estimated that Medicare and its beneficiaries could save \$1.03 billion in 1998 if the Medicare allowed amounts for 34 drugs were equal to prices obtained by the VA under the Federal Supply Schedule. The estimated savings represents almost half of the \$2.07 billion in reimbursement that Medicare and its beneficiaries paid for these 34 drugs in 1997.

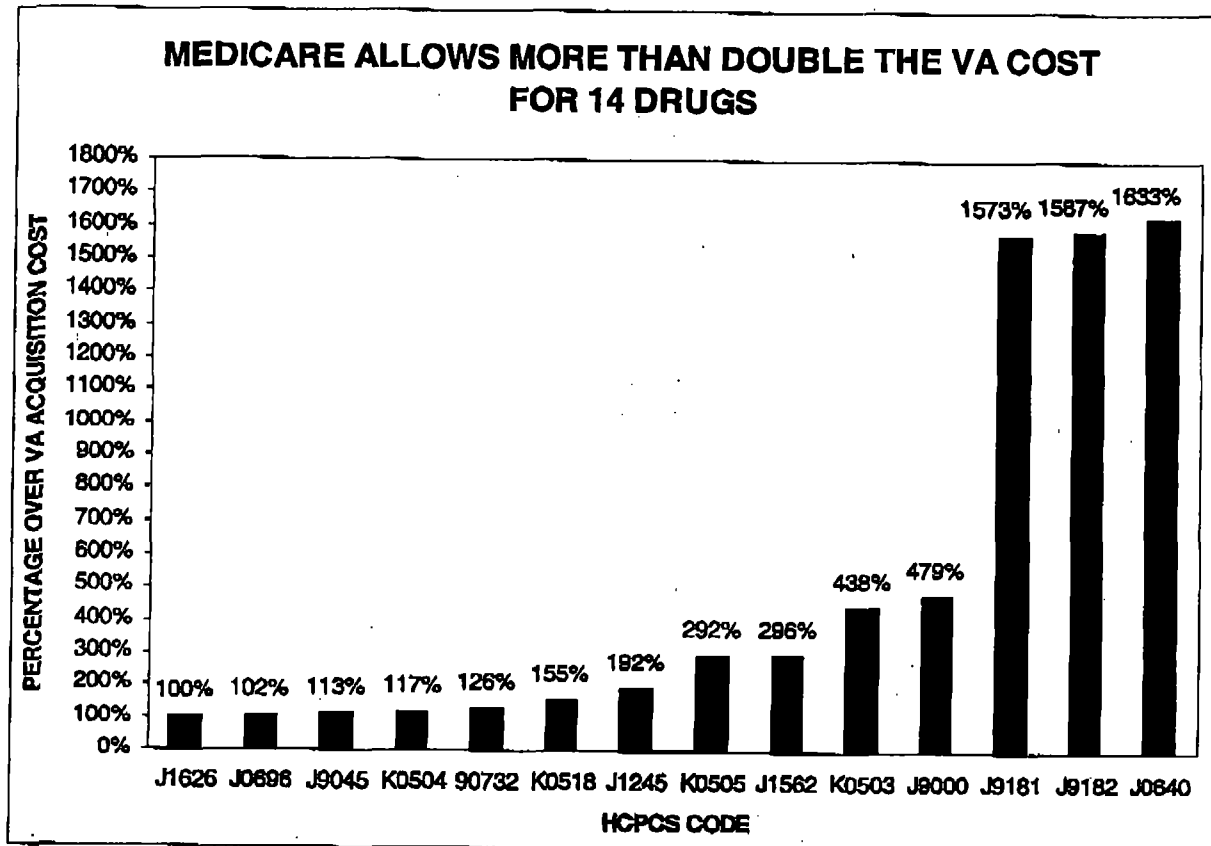
The estimated savings for individual drugs ranged from a high of \$276 million for J9217 (leuprolide acetate) to a low of \$16,460 for K0523 (concentrated metaproterenol sulfate). Drugs with estimated savings greater than \$20 million are listed below. A complete list of the 34 drugs, Medicare and VA median costs, and potential savings is provided in Appendix B.

DRUGS WITH 1998 ESTIMATED SAVINGS OVER \$20 MILLION						
HCPES CODE	GENERIC DRUG NAME	VA MEDIAN	HOPA MEDIAN	DIFFERENCE	NUMBER OF SERVICES	ESTIMATED SAVINGS
J9217	Leuprolide acetate	\$299.38	\$513.60	\$214.22	1,286,664	\$275,629,162.08
K0505	Albuterol sulfate (dose form)	\$0.12	\$0.47	\$0.35	343,627,175	\$120,269,511.25
J9202	Goserelin acetate	\$206.29	\$389.98	\$183.69	329,988	\$60,615,495.72
K0518	Ipratropium bromide	\$1.31	\$3.34	\$2.03	29,505,931	\$59,897,039.93
J9265	Paclitaxel	\$109.36	\$173.50	\$64.14	895,067	\$57,409,597.38
Q0136	Epoetin alpha	\$6.74	\$12.00	\$5.26	10,466,953	\$55,056,172.78
J0640	Leucovorin calcium	\$1.18	\$20.45	\$19.27	2,833,686	\$54,605,129.22
J9045	Carboplatin	\$39.50	\$84.16	\$44.66	982,275	\$43,868,401.50
J1626	Granisetron hcl	\$8.42	\$16.85	\$8.43	4,105,560	\$34,609,870.80
J1562	Immune globulin (5 g)	\$110.83	\$439.38	\$328.55	92,994	\$30,553,178.70
J9182	Etoposide	\$7.84	\$132.25	\$124.41	181,322	\$22,558,270.02
J9000	Doxorubicin	\$7.46	\$43.23	\$35.77	629,236	\$22,507,771.72
J1561	Immune globulin (500 mg)	\$27.71	\$48.65	\$20.94	1,039,526	\$21,767,674.44
J2430	Pamidronate disodium	\$104.39	\$196.90	\$92.51	229,935	\$21,271,286.85

MEDICARE ALLOWED BETWEEN 15 AND 1600 PERCENT MORE THAN THE DEPARTMENT OF VETERANS AFFAIRS PAID FOR THE 34 DRUGS REVIEWED.

During the first quarter of 1998, Medicare allowed amounts were greater than the VA acquisition cost for every drug in our review. However, there was substantial variation in the difference between Medicare reimbursement and VA cost among the 34 drugs.

Fourteen of the drugs in our study (41 percent) had Medicare allowances that were more than double the VA cost. For 11 of these drugs, Medicare allowed between two and six times the VA acquisition cost. For three drugs in our review (J0640, J9181, J9182), Medicare allowed more than 16 times the VA acquisition cost. The chart below illustrates these drugs and their comparative cost to Medicare. Appendix B lists the difference between Medicare reimbursement and VA cost for all 34 drugs.



The remaining 20 drugs in our review also had Medicare reimbursements that were greater than VA acquisition cost. Eighteen of the 20 drugs had Medicare reimbursements between 44 and 93 percent higher than VA acquisition cost. For only two drugs was the difference between Medicare reimbursement and VA cost less than 25 percent.

RECOMMENDATIONS

The Department of Veterans Affairs purchases drugs for its healthcare system directly from manufacturers or wholesalers. Conversely, Medicare reimburses doctors and suppliers for drugs which they administer or supply to beneficiaries. We recognize that HCFA and the VA operate under different statutory constraints. Nevertheless, the fact remains that another Federal agency can get prescription drugs for a drastically lower price than Medicare.

Previous reports of the Office of Inspector General found that actual wholesale prices available to physicians and suppliers are often significantly lower than the Medicare allowed amounts. This report provides additional evidence that the published AWP's used in determining the Medicare allowed amounts for certain prescription drugs can be many times greater than the actual acquisition costs available in the marketplace.

Our current findings provide further support for recommendations made in earlier reports. We previously recommended, and HCFA concurred, that HCFA reexamine its Medicare drug reimbursement methodologies with the goal of reducing payments as appropriate. We outlined a number of options for implementing this recommendation, including: (1) greater discounting of published average wholesale prices, (2) basing payment on acquisition costs, (3) establishing manufacturers' rebates similar to those used in the Medicaid program, and (4) using competitive bidding.

We continue to support the need for a comprehensive statutory reform of Medicare's prescription drug reimbursement methodology. A number of proposals addressing reform have been offered by both the Administration and members of Congress. However, until legislation can be enacted providing for such reform, we recommend that HCFA utilize the new inherent reasonableness or competitive bidding authorities provided in the Balanced Budget Act of 1997 to reduce Medicare's unreasonably high payments for certain drugs.

AGENCY COMMENTS

The HCFA concurred with our recommendations, stating that it appreciates the OIG's continuous efforts to assist it in obtaining the lowest prices for covered drugs. The HCFA noted that it proposed in the President's fiscal year 1998 budget that drugs be reimbursed at the provider's actual acquisition cost. The Congress did not enact the recommendation, and therefore the proposal was again submitted with the fiscal year 1999 budget.

The HCFA further stated that DMERCs have issued inherent reasonableness notices to suppliers which proposed an 11 percent decrease in the reimbursement amount for albuterol sulfate. The HCFA indicated that other drugs may be reviewed for inherent reasonableness adjustments in the future. The full text of HCFA's comments is provided in Appendix C.

OIG RESPONSE

We fully support HCFA's and the Administration's continued efforts to reduce excessive payments for covered drugs. Until comprehensive reforms are enacted, we believe HCFA should continue to use its inherent reasonableness authority to lower inappropriate payments for other drugs with excessive reimbursement rates.

APPENDIX A

DESCRIPTION OF 34 HCPCS CODES

1995 HCPCS CODE	1999 HCPCS CODE	DESCRIPTION	CHANGES
J0732	J0732	Immunization, active; Pneumococcal vaccine	
J0205	J0205	Injection, Alglucerase, per 10 units	
J0505	J0505	Botulinum toxin type A, per unit	Changed 9/96 from per 100 units to per 1 unit
J0610	J0610	Injection, Leucovorin calcium, per 50 mg	
J0696	J0696	Injection, Ceftriaxone sodium, per 250 mg	
J1245	J1245	Injection, Dipyridamole, per 10 mg	
J1110	J1110	Injection, Filgrastim (G-CSF), 300 mcg	
J1111	J1111	Injection, Filgrastim (G-CSF), 480 mcg	
J1551	J1551	Injection, Immune globulin, intravenous, 500 mg	
J1552	J1552	Injection, Immune globulin, intravenous, 5 g	Changed 1/98 from per 500mg to per 5g
J1625	J1625	Injection, Granisetron hydrochloride, per 100 mcg	Changed 1/98 from per 1mg (J1625) to per 100mcg (J1626)
J2405	J2405	Injection, Ondansetron HCl, per 1 mg	
J2450	J2450	Injection, Pamidronate disodium, per 30 mg	
J7610	K0503	Acetylcysteine, unit dose form, per gram	Changed 4/97 from 10%, per ml (J7610) to per gram (K0503)
J7620	K0504	Albuterol sulfate, concentrated form, per mg	Changed 4/97 from .083%, per ml (J7620) to per mg, concentrated form (K0504)
J7620	K0505	Albuterol sulfate, unit dose form, per mg	Changed 4/97 from .083%, per ml (J7620) to per mg, unit dose form (K0505)
J7645	K0518	Ipratropium bromide, unit dose form, per mg	Changed 4/97 from .02%, per ml (J7645) to per mg, unit dose form (K0518)
J7670	K0523	Metaproterenol sulfate, concentrated form, per 10 mg	Changed 4/97 from .4%, per 2.5ml (J7670) to per 10mg, concentrated form (K0523)
J7670	K0524	Metaproterenol sulfate, unit dose form, per 10 mg	Changed 4/97 from .4%, per 2.5ml (J7670) to per 10mg, unit dose form (K0524)
J9000	J9000	Doxorubicin Hcl, 10 mg	
J9001	J9001	BCG, live (intravesical), per installation	
J9015	J9015	Injection, Carboplatin, 50 mg	
J9032	J9032	Injection, Cisplatin, 50 mg	
J9101	J9101	Injection, Etoposide, 10 mg	
J9102	J9102	Injection, Etoposide, 100 mg	
J9115	J9115	Injection, Fludarabine phosphate, 50 mg	
J9202	J9202	Goserelin acetate implant, per 3.6 mg	
J9211	J9211	Interferon alfa-2b, recombinant, 1 million units	
J9217	J9217	Leuprolide acetate (for depot suspension), 7.5 mg	
J9235	J9235	Injection, Paclitaxel, 30 mg	
J9293	J9293	Injection, Mitoxantrone HCl, per 5 mg	
J9300	J9300	Vinorelbine tartrate, per 10 mg	
J9311	J9311	Cyclosporine, oral, 25 mg	
J9336	J9336	Injection, Epoetin alfa, (non-ESRD), per 1000 units	