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The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Minority Member
Committee on Finance
United States Senate

Subject: Regulatory Issues for Medicare Providers

With services delivered by hundreds of thousands of providers to nearly 40 million beneficiaries and payments of about $220 billion in fiscal year 2000, Medicare is highly vulnerable to fraud, waste, and abuse.[1] The process of enforcing program payment rules, however, has raised concerns that the impact of these safeguard activities has imposed too great a burden on health care providers. Concerns about the regulatory burden facing providers include perceptions of unreasonable or unclear demands for documentation from the Health Care Financing Administration's (HCFA) payment contractors, excessive paperwork, and a belief that Medicare contractors unfairly pursue and investigate physicians who have made innocent billing errors. The Medicare Education and Regulatory Fairness Act (MERFA)—S. 452 and H.R. 868—has been introduced to address some of these concerns. The bills would provide expedited procedures for provider appeals, new options for providers to use in repaying Medicare overpayments, protections for providers who voluntarily return overpayments or ask for a review of their claims, and new requirements for provider education.

This letter responds to your May 16, 2001, request that we provide information on several issues addressed in S. 452. You asked us 18 specific questions about how the proposed legislation would affect Medicare policies and procedures in the following areas: (1) provider education and participation, (2) medical reviews, audits, and appeals, (3) recovery of overpayments, and (4) related legal issues. You also asked that we identify alternative solutions that could address provider concerns while maintaining program integrity.

To address these issues, we collected information from HCFA, the Department of Health and Human Services' Office of the Inspector General (HHS/OIG), and the Department of Justice (DOJ) about their roles and responsibilities. We also compared the proposed legislation to current laws and regulations and examined relevant agency materials. Regarding alternative approaches to these issues, we reviewed suggested modifications to specific provisions of

[1] *High Risk Series: An Update* (GAO-01-263, January 2001).

MERFA from the American Medical Association and Taxpayers Against Fraud.[2] According to the bill's sponsors, these groups have taken the lead in recommending revisions to MERFA. We conducted our review during May and June 2001, in accordance with generally accepted government auditing standards. Enclosure I contains our responses to the 18 specific questions.

A draft of this correspondence was sent to HHS and DOJ for their review. HHS was unable to provide comments in the time allotted. However, program officials informally provided technical comments, which we incorporated where appropriate. In its written comments, DOJ generally agreed with the substance of our report. DOJ indicated that it expects to submit official views on the bills—including MERFA's likely effect on use of the False Claims Act in pursuing Medicare fraud—to the Committee on Finance. DOJ also stated that funds collected and returned to the Medicare Trust Fund are one of the most important measures of the effort to control health care fraud, noting that over $2 billion has been recovered since fiscal year 1997. (See enclosure II.) We incorporated DOJ's technical comments as appropriate.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this letter for 30 days. At that time, we will send copies to the Secretary of Health and Human Services, and others who are interested. The correspondence will also be available on GAO's home page at www.gao.gov. If you would like to discuss the information further, please contact me at (312) 220-7600 or Rosamond Katz, Assistant Director, at (202) 512-7148. Other key contributors to this correspondence were Jenny Grover and Craig Winslow.

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[2]Taxpayers Against Fraud is a nonprofit, public interest organization that promotes the use of the False Claims Act to combat fraud against the federal government.

## INFORMATION RELATED TO S.452

### 1. What educational services are currently offered to Medicare providers and how can providers access these services?

Educational services aim to help providers become more aware of Medicare coverage and billing policies and are provided by the Department of Health and Human Services' (HHS) Health Care Financing Administration (HCFA) and its claims administration contractors—known as fiscal intermediaries and carriers--and by HHS' Office of Inspector General (OIG).[3] HCFA offers information on its website and has also established the web-based Medicare Learning Network (MedLearn) to provide information about Medicare coverage and payment policies. Agency officials also identify provider education needs and develop training materials to be used by contractors.

Medicare claims administration contractors are responsible for planning and conducting most education activities for providers. Examples of these activities include:

- Issuing bulletins. These bulletins are issued at least quarterly and outline changes in national and local Medicare policy and payment, report upcoming training events, inform providers of billing system changes, and address frequently asked questions. Bulletins are mailed to every enrolled provider and are also available at the contractors' web sites.

- Organizing planned events. Contractors conduct seminars, workshops, and teleconferences to educate providers on billing and service issues. They also work closely in a partnership with professional and specialty societies or state agencies to deliver training.

- Responding to individual provider inquiries. Since fiscal year 2000, HCFA has required contractors to maintain toll-free telephone lines for health care providers. Although many calls relate to claims status, contractors also answer questions pertaining to Medicare regulations, billing, and local medical review policies. If a provider inquiry may be more appropriately answered by another entity, the contractors are expected to refer the provider to the appropriate source of information. For example, a coding question regarding the American Medical Association's (AMA) clinical classification of services would be referred to the AMA.

The HHS/OIG's primary education effort for providers has been the development (with industry input) of written guidance on compliance with Medicare program

[3]HCFA has contracted with about 50 insurance companies to serve as fiscal intermediaries (that process part A claims) and carriers (that process part B claims).

billing requirements.[4] In addition, it issues fraud alerts, advisory bulletins, and advisory opinions. It also makes presentations to industry groups on areas of suspected fraud and abuse.

**2. How much is currently spent on Medicare provider education programs by HCFA and its fiscal intermediaries and carriers? Would S. 452, section 301(b), designate education funding for all Medicare providers or only a selected group?**

Funding for Medicare provider education comes from two sources. In fiscal year 2000, about $43 million was allocated for provider education from HCFA's regular program management appropriation and about $12 million came from the Provider Education and Training component of the Medicare Integrity Program (MIP).[5] Although HCFA's Center for Health Plans and Providers also supports provider education, the vast majority of these funds are passed on to Medicare contractors. Table 1 shows the amounts and proportions of Medicare fiscal intermediary and carrier funds devoted to provider education.

Table 1: Medicare Contractor Spending for Provider Education and Training Activities, Fiscal Years 2000 and 2001

| | Fiscal year 2000 | | Fiscal year 2001 | |
|---|---|---|---|---|
| | **Millions of dollars** | **Percent of contractor expenditures** | **Millions of dollars** | **Percent of budgeted funds** |
| Carriers | $37.3 | 3.7 | $37.9 | 3.7 |
| Fiscal intermediaries | 17.5 | 3.1 | 19.4 | 3.4 |
| **Total** | **54.8** | **3.5** | **57.3** | **3.6** |

Source: HCFA

S. 452, section 301(b), would amend current law to require that at least 10 percent of MIP funds must be designated to educate physicians, providers of ambulance services, and other providers covered in the bill. As applied to the fiscal year 2001 MIP budget, the new levels would represent a significant increase in provider education spending—from $16.1 million (2.9 percent) to $60.7 million (10 percent). Section 301(b) would also establish minimum spending requirements for contractors' provider education programs. Overall, 1 percent of total fiscal intermediary funds and 2 percent of total carrier funds would have to be used for provider education. As shown in table 1, the bill's target levels are actually below current spending by contractors—3.4 percent for fiscal intermediaries and 3.7 percent for carriers.

S. 452, section 301(b), would apply to the funding of educational programs for certain groups. These include physicians, providers of services (hospitals, critical access hospitals, skilled

[4]To date, compliance guidance has been issued for hospitals, hospices, Medicare+Choice organizations offering coordinated care plans, nursing facilities, individual and small group physician practices, durable medical equipment suppliers, clinical laboratories, home health agencies, and third-party billing companies.

[5]Established by the Congress as part of the Health Insurance Portability and Accountability Act of 1996, MIP provides dedicated funding for Medicare program safeguard activities. Total MIP funding was $539.1 million in FY 2000 and $606.7 million in fiscal year 2001.

nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, and hospice programs), and providers of ambulance services. However, there are other entities that provide services or supplies to Medicare beneficiaries that are not included in these groups, such as occupational and physical therapists, nurse practitioners, psychologists, laboratories, facilities providing treatment for end-stage renal disease, and suppliers of durable medical equipment.

**3. What proportion of Medicare claims were billed correctly in fiscal year 2000 and how does this compare with previous years?**

HCFA data on part A and part B claims processed during fiscal year 1999 indicate that about 81 percent of claims processed were paid as "clean" claims. (HCFA defines a clean claim as one that did not require the contractor to request additional information from the provider prior to payment.) In further analysis of part B denied claims from that year, HCFA found that over 70 percent were denied because they were duplicate, incomplete, or for services that were not medically necessary or covered by Medicare.

Although some claims are not paid the first time they are processed, other claims are paid that should not be. Contractors have made payments in error for claims that lack appropriate documentation, are incorrectly coded, are not for Medicare covered services, or are for services that were deemed not to be medically necessary. As part of its audit of HCFA's annual financial statements, the HHS/OIG estimates a national overpayment error rate from all claims processed for a sample of Medicare beneficiaries. In fiscal year 2000, the HHS/OIG found that $11.9 billion, or 6.8 percent of the $173.6 billion in Medicare fee-for-service payments, were paid improperly. This error rate compares with rates for fiscal years 1998 and 1999 of 7.1 percent and 7.9 percent, respectively.

We have previously reported that the HHS/OIG error rate does not distinguish between benign paperwork mistakes and abusive billing practices, nor does it identify the volume of erroneous payments at each contractor.[6] Because the HHS/OIG methodology generally assumes that medical records received for review are valid, and thus represent actual services provided, improper payments supported by falsified documentation may go undetected. Furthermore, the claims identified as improperly paid had successfully passed through contractors' automated claims processing systems because they were valid on their face. They were disputed only after the underlying medical records were obtained from providers and reviewed in detail or providers failed to supply those records.

**4. What are the implications for program integrity of having Medicare contractors disclose claims processing screens as part of provider education?**

Prior to payment, all Medicare claims are screened by two sets of computerized medical review edits. The first set of edits—completed with no manual review by contractor staff—allows claims to be denied automatically for coverage or coding reasons. The second set of edits—which identify claims for manual review by contractor staff—focuses on questionable billing patterns for individual providers, groups of providers, or specific services. (These manual review edits change often.)

[6] *Medicare Improper Payments: While Enhancements Hold Promise for Measuring Potential Fraud and Abuse, Challenges Remain*, (GAO/AIMD/OSI-00-281, Sept. 15, 2000).

S. 452, section 202, would amend current law to require that all edits used to identify or flag claims for medical review be included in education programs for physicians, providers of services, and providers of ambulance services. HCFA officials noted that, although the agency has not disclosed most automated review edits in the past (those resulting in automatic denials), it would not be opposed to doing so. However, HCFA, HHS/OIG, and the Department of Justice (DOJ) agreed that manual review edits (used to identify aberrant providers for more focused review of their claims) should not be shared. The HHS/OIG noted that revealing such edits would give dishonest providers information to avoid detection and exploit the Medicare program. Program integrity would be at risk if unscrupulous providers were alerted to the safeguards being used and could therefore target their efforts accordingly.

In its proposed modifications to the bill, the AMA suggested eliminating the requirement that all medical review edits, per se, be disclosed to providers. Rather, it stated that information about medical review edits should be used more generally to create education programs on Medicare policy and proper coding. This modification would reduce the risk to HCFA's program integrity activities while improving the focus of provider education efforts.

**5. Is there evidence that physicians are cutting back their participation in the Medicare program?**

Although HCFA officials acknowledge reports that physicians are considering leaving the Medicare program, they noted that their data do not support such a trend. As shown in table 2, relative to the number of physicians nationwide, the number of participating physicians in fee-for-service Medicare has increased in each of the past several years.[7] However, it is unclear whether some physicians have decided to no longer accept new Medicare beneficiaries. Furthermore, HCFA cannot say whether access problems exist for beneficiaries in specific geographic areas.

Table 2: Fee-for-Service Physicians in the Medicare Program, 1996-2000

| Fiscal year | Participating physicians[a] as a percent of all physicians | Physicians[b] per 1,000 fee-for-service Medicare beneficiaries |
|---|---|---|
| 1996 | 74.8 | 14.5 |
| 1997 | 77.5 | 15.0 |
| 1998 | 80.4 | 15.4 |
| 1999 | 82.3 | 15.7 |
| 2000 | 86.3 | [c] |

[a]Includes fee-for-service physicians who accept assignment on claims for Medicare payment.
[b]Includes all fee-for-service physicians who bill Medicare.
[c]Data are not available.
Source: HCFA

**6. What proportion of Medicare providers were subject to medical review in fiscal year 2000 and how has this percentage changed over the past 3 years?**

HCFA guidance to Medicare contractors notes that a provider should be placed on manual prepayment review (which results in payments being delayed while claims are examined)

[7]Participating providers agree to accept assignment for all services provided to Medicare patients. Such providers accept the Medicare payment and agree not to charge the patient any additional amount.

only when data suggest a pattern of billing problems. Data are not available on the number of providers under review each year. HCFA conducted a one-time limited survey of contractors to determine the number of physicians subject to complex medical review—a small subset of all manual reviews—in fiscal year 2000.[8] It found that 1,891, or 0.3 percent of all physicians who bill the Medicare program, were under complex medical review that year.

HCFA provides contractors with direction as to the rates of manual medical review they are expected to perform. The suggested rates of review vary by contractor type and type of review. Table 3 shows HCFA's goals for manual review levels as a percentage of total claims processed, for fiscal year 2000.

Table 3: Manual Medical Review Goals for HCFA Contractors, Fiscal Year 2000

| | Percent of claims by type of contractor | | | |
|---|---|---|---|---|
| **Type of review** | **Carriers** | **Fiscal intermediaries** | **Durable medical equipment regional carriers[a]** | **Regional home health intermediaries[b]** |
| Prepay routine | 4.8 | At least 2.05 (combined) | Up to 14.0 (combined) | At least 2.05 (combined) |
| Prepay complex | 0.35 | | | |
| Prepay random | 0.01 to 0.02 | 0.01 to 0.02 | 0.01 to 0.02 | 0.01 to 0.02 |
| Postpay | 0.04 | 0.04 | 0.1 | 0.04 |

[a]Four health insurance companies that make payments to durable medical equipment suppliers.
[b]Four fiscal intermediaries that make payments to home health agencies and hospices.
Source: HCFA

**7. Under current procedures, are there limits on the length of time a provider may be subject to prepayment review?**

Medicare contractors analyze aggregate claims data to identify potential billing problems, such as claims for services that are not covered by Medicare or for services that are not coded correctly. When data analysis indicates that a limited problem may exist (that is, billing errors by a small group of providers), the contractor conducts a review of a small number of claims from that group, on either a prepayment or postpayment basis. A more comprehensive prepayment claims review may be conducted if a pattern of billing problems is identified. In this case, for a certain period of time, contractor staff review a portion (or all) of a provider's claims prior to payment.

Currently, HCFA guidance to contractors does not set a specific time limit on how long prepayment review can continue. Instead, HCFA specifies that contractors must "remove

[8]HCFA requires that clinically trained staff carry out complex medical reviews based on examination of medical records. In contrast, routine medical review may be carried out by nonclinical staff and does not involve review of patient records.

providers from medical review as soon as possible when they demonstrate compliance with Medicare billing requirements."[9] However, HCFA's guidance to contractors goes on to state that "we recognize that some providers may remain on medical review for long periods of time . . . . In the case of extended medical review activities, provide written notification [to the provider under review] at least every 6 months."

S. 452, section 202, would amend current law to limit the duration of prepayment reviews except when a referral has been made to the HHS/OIG or DOJ. Under the provision, prepayment reviews must end whenever a fiscal intermediary or carrier finds that claims for the same services that were the basis for instituting the prepayment review are proper over a specified time period (180 days) or for a specified volume of claims processed (at least 75 percent of the number of claims received in the full month preceding the start of the prepayment review).

Proposals offered by the AMA and Taxpayers Against Fraud (TAF) would provide that the limit on the duration of prepayment reviews would not apply to an act giving rise to liability under the False Claims Act (FCA), even if no referral had yet been made to DOJ or the HHS/OIG. Commenting on this modification, HHS/OIG officials noted that cases where other sanctions may apply (such as monetary and civil penalties and criminal sanctions) should also be covered by this exemption.

**8. What are the respective roles and activity levels of Medicare contractors, DOJ, and the HHS/OIG in conducting Medicare audits and investigations?**

Medicare contractors have lead responsibility for preventing and detecting Medicare overpayments.[10] They have broad discretion in conducting program safeguard activities, which include:

- Medical review. Contractors review claims to identify those that should not be paid because the service provided was not covered or was medically unnecessary. Medical review may be conducted manually or automatically by computer, and it may be done prior to payment or after payment has been made. In fiscal year 1998, 1 in 8 claims were medically reviewed prior to payment, and 1 in 16 were subject to manual prepayment review.

- Medicare secondary payer review. Contractors identify other primary sources of payment for claims, such as employer-sponsored health insurance or third-party liability settlements.

- Audit of provider cost reports. Fiscal intermediaries audit providers' cost reports to determine if the costs cited are allowable and reasonable.

- Fraud unit investigations. Special contractor fraud units identify potential cases of fraud by sampling claims, verifying delivery of services or medical necessity, and analyzing local billing trends. Based on the results of these activities, they may further investigate

[9]HCFA Program Memorandum to Intermediaries/Carriers, Medical Review Progressive Corrective Action, Transmittal AB-00-72, #6, August 7, 2000.

[10]HCFA is supplementing regular contractor oversight activities through agreements with 12 special program safeguard contractors. For a discussion of HCFA's management of these contractors, see *Medicare: Opportunities and Challenges in Contracting for Program Safeguards* (GAO-01-616, May 18, 2001).

or refer cases to law enforcement agencies. Medicare contractors referred over 820 cases annually to law enforcement agencies in 1998 and 1999.

Independent of HCFA, the HHS/OIG conducts investigations, audits and inspections related to the Medicare program. It pursues potential fraud brought to its attention by the contractors and from sources such as beneficiaries, competitors, and *qui tam* (whistleblower) complaints. For example, of the approximately 650,000 physicians participating in the Medicare program, the HHS/OIG investigates roughly 250 to 300 physicians each year. In fiscal year 2000, the HHS/OIG received $119.3 million for its activities related to the Medicare and Medicaid programs, and had 1,003 full-time equivalent staff devoted to such activities.[11]

DOJ primarily investigates cases that have been referred by the HHS/OIG or other sources to determine if health care providers have engaged in fraudulent activity, and it pursues civil actions or criminal prosecutions, as appropriate. In fiscal year 2000, DOJ received $159.5 million for its health care antifraud activities from direct appropriations and the Health Care Fraud and Abuse Control program. Most of these funds were allocated to the Federal Bureau of Investigation ($101.9 million) and DOJ's 94 U.S. Attorney's offices ($38.2 million). That year, DOJ had 1,939 criminal health care matters pending (involving 3,049 defendants), 457 criminal cases filed, and 233 civil cases filed. Department wide, it had 1,228 full-time equivalent staff involved in health care fraud control activities.

**9. What is the status of cases currently in the fee-for-service appeals process? How would S. 542 affect the appeals process and Medicare providers' eligibility for appeals?**

Appeals of denied claims may be made by the provider--on its own behalf or as a representative of the beneficiary—and may be made by the beneficiary directly. In part B appeals (involving claims for physicians and other outpatient provider services), there are two stages of appeal at the carrier level—an informal carrier review and a carrier fair hearing before a hearing officer.[12] For part A appeals (involving claims for inpatient hospital care and skilled nursing care), the sequence of steps is a reconsideration by the fiscal intermediary followed by appeal to an administrative law judge (ALJ), the Departmental Appeals Board (DAB), and federal court. Only about 3 percent of denied claims under both part A and part B were appealed in fiscal year 2000.

[11]HHS/OIG health care fraud and abuse control activities are funded through the Health Care Fraud and Abuse Control Program. This program, under the joint direction of HHS/OIG and the DOJ, coordinates federal, state, and local law enforcement activities with respect to health care fraud and abuse.

[12]Fair hearing decisions may be appealed to an administrative law judge, assigned to the Social Security Administration, then to the Medicare Operations Divisions, where the appeals are decided by Administrative Appeals Judges of the Medicare Appeals Council located within the Departmental Appeals Board, and finally to federal court.

Table 4: Medicare Fee-for-Service Appeals, Fiscal Year 2000

| | All Medicare (millions) | Part A (millions) | Part B (millions) |
|---|---|---|---|
| Claims processed | 899.0 | 154.8 | 744.2 |
| Claims denied | 171.5 | 12.0 | 159.5 |
| Claims appealed | 5.7 | 0.3 | 5.4 |

Source: HCFA

According to HCFA, roughly half of appealed claims are resolved in favor of the provider, and paid, each year. Also, most are resolved at the contractor level. In fiscal year 2000, at the carrier fair hearing level, 965,000 appealed part B claims were bundled into 106,835 cases. In those, 57.6 percent of contractors' decisions were upheld, while the remaining 42.4 percent of cases were overturned, resulting in payment of the claims involved. In fiscal year 1999 (the latest year for which Social Security Administration (SSA) data were available), about 60 percent of the roughly 67,000 part A and part B cases heard at the ALJ level involved the contractor decision being overturned and the claims paid, while in the remainder, the contractor decision was upheld.

HCFA noted that the vast majority of contractor appeals are processed on a timely basis. However, the agency has identified appreciable short-term claims appeals backlogs at two carriers (for example, more than 1,000 cases with reviews pending for over 60 days) and has taken steps to allocate available funds to these carriers to reduce these backlogs. In addition, there continue to be substantial long-term backlogs at the higher levels of the claims appeals process—the ALJ and DAB. The most recent data available from the SSA's Office of Hearings and Appeals indicate that the average adjudication time for a Medicare appeal is 382 days at the ALJ, with even longer delays at the DAB.

The Medicare appeals process was revised by section 521 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). BIPA imposes deadlines at each step of the appeals process, with the right to bypass most appeals steps if the deadlines are not met. The following revisions are scheduled to take effect October 1, 2002:

- Generally, initial determinations of a claim must be concluded within 45 days from the date of claim.
- If the individual requests a redetermination, it must be completed within 30 days of receipt of the request.
- If still dissatisfied, the individual has 180 days from receipt of notice of redetermination to request reconsideration through a qualified contractor independent of any organization under contract to make initial determinations. This contractor would have 30 days to conclude the reconsideration.
- If a timely decision is not made and the amount at issue is $100 or more, the individual may then request a hearing by the Secretary (before an SSA ALJ). Such hearings must be held and decisions issued within 90 days.

- If the 90-day limit is not met, individuals may go directly to the DAB. The Medicare Appeals Council of the DAB must conduct a review of an ALJ decision on an escalated appeal within 90 days, or individuals may go directly to federal district court.

- If the dispute is not satisfactorily resolved through this administrative process, and if contested amounts are $1,000 or more, the individual could request judicial review of the Secretary's final decision.

S. 452 would grant new Medicare appeals rights to physicians and certain other providers. Section 201 would amend current law to provide that a decision by a carrier to not approve or renew a physician's Medicare enrollment would constitute an initial determination subject to the same full appeals process as coverage and payment determinations, including the right to judicial review.[13] In addition, under section 204, physicians, providers of services, and ambulance service providers would be entitled to appeal claims determinations on behalf of deceased beneficiaries where no substitute party is available.

Section 102(b) of S. 452 would modify the Medicare appeals process that applies to nursing homes, home health agencies, or other health care institutions or agencies. Currently, a nursing home or home health agency may challenge a determination by HHS to deny its Medicare participation. The bill would subject such hearings to new timelines.[14]

Section 102(b) would also establish a new right to appeal deficiencies identified in inspections prior to the imposition of a sanction. It would also provide a right to a formal hearing or reconsideration before any corrective action or other type of sanction could be imposed on a nursing home or home health agency found out of compliance with any standard or condition of participation. This requirement appears to apply even in cases where a patient's health is found to be in immediate jeopardy.

In commenting on S. 452, section 102(b), the HHS/OIG noted that the DAB and federal courts are not well equipped to develop the facts of such cases and are accustomed to having a full record upon which to review an agency's decision. HCFA officials were similarly concerned that the courts would decide disputes that otherwise would have been resolved at the administrative level by officials most knowledgeable about the subject matter.

**10. How many providers were prosecuted for fraud in fiscal year 2000 and how has this number changed over the past 3 years?**

DOJ is primarily responsible for Medicare fraud prosecutions, including the application of civil or criminal actions, fines, civil money penalties, or other restitution. Criminal health care fraud cases are most often referred to DOJ by the HHS/OIG. As shown in Table 5, the number of civil health care fraud cases filed more than doubled from fiscal year 1998 to 2000. Over the same period, the number of criminal cases filed rose 43 percent and the number of defendants increased by 53 percent. A total of 467 defendants were convicted for health care

[13]During fiscal year 2000, over 3,300 individuals and entities were excluded from participation in Medicare, Medicaid, and other federal health care programs.

[14]Under the bill, unless waived by the appealing party, ALJs would be required to decide appeals within 90 days. ALJ decisions could be appealed to the DAB, which must issue a decision or remand the case within 90 days. If an ALJ did not meet the initial 90-day decision deadline, the matter could be directly appealed to the DAB for determination of the facts and decision within 60 days.

fraud-related crimes in fiscal year 2000. (DOJ does not maintain data on the proportion of providers convicted of fraud who were participating in Medicare.)

Table 5: Civil and Criminal Health Care Fraud Enforcement Actions at DOJ, Fiscal Years 1998-2000

| | Fiscal year 1998 | Fiscal year 1999 | Fiscal year 2000 |
|---|---|---|---|
| **Civil cases filed** | 107 | 91 | 233 |
| **Criminal prosecutions filed** | | | |
| Cases | 319 | 371 | 457 |
| Defendants | 436 | 506 | 668 |
| **Criminal convictions** | | | |
| Cases | 219 | 263 | 343 |
| Defendants | 326 | 398 | 467 |

Source: DOJ

### 11. In auditing samples of claims from which to extrapolate overpayment amounts, do Medicare contractors always draw statistically valid random samples?

HCFA requires that contractors validate a provider's potential billing problems by conducting a "probe" review of roughly 20 to 40 claims. If the probe sample indicates improper billing, then one remedy can be the selection of a statistically valid random sample of claims to extrapolate the provider's overpayment amount.[15]

However, overpayment amounts are sometimes based on the probe sample or other small sample which is not statistically representative of a provider's claims. HCFA permits contractors to offer providers the option of entering into a consent settlement, whereby the provider accepts the results of the review and agrees to an extrapolated "potential" overpayment amount based on the small sample.[16] Alternatively, providers may choose to accept the settlement but submit additional documentation on specific claims, to potentially adjust downward the amount of the projected overpayment. A provider that believes that the claims reviewed are not representative of the claims in question may decline a consent settlement and require the Medicare contractor to use a statistically valid random sample to extrapolate the overpayment amount.

Although providers have the option of choosing a statistically valid random sampling of claims, consent settlements are less burdensome for both Medicare contractors and providers, as fewer claims have to be documented and reviewed. However, because the limited sample is not statistically representative of the provider's claims in question, the amount repaid by the provider may not be an accurate representation of the overpayment amount.

[15]HCFA provides guidance to the contractors on how to conduct the statistically valid random sample, including how to draw the sample, how to determine the period of review, and the required criteria for confidence and precision levels.

[16]As part of a consent settlement, the provider also agrees to relinquish the right to appeal the denied claims.

**12. How does the standard of "clear and convincing evidence of fraud" in S. 452, section 103, differ from the standard of proof currently required to determine provider fraud? What impact could this standard have on the ability of the federal government to collect overpayments?**

Because it is a regulatory rather than a law enforcement agency, HCFA does not have the authority to make a legal finding of fraud. Agency officials stated that when a provider is suspected of engaging in egregious activities, contractors suspend payment if there is "reliable evidence of fraud" stemming from an investigation of the provider's billing pattern. Contractors may refer the case to the HHS/OIG or DOJ for further investigation and possible prosecution. In civil fraud litigation, however, the standard of proof established by the False Claims Act (FCA) is a "preponderance of the evidence."[17] That is, the government must show that its characterization of the facts is more likely to be true than not.

S. 452, section 103, would require that the agency prove "clear and convincing evidence of fraud" prior to disallowing the option of extended repayments. This standard is the highest burden of proof used in civil cases and would require the Secretary of HHS to prove its allegations of false claims much more conclusively than is now required.[18] Even where the liability of a provider to repay Medicare funds was satisfactorily established through civil litigation, unless HCFA found there to be clear and convincing evidence of fraud, it would be required to give covered providers up to 3 years to make those repayments through offsets against future Medicare payments or other repayment plan.

An HHS/OIG official told us that this standard may be unworkable. He noted that it would be impractical to apply such a rigorous standard so early in the process, when the facts of the case have not been developed. The DOJ commented that section 103 would require the Secretary of HHS to meet a higher standard of proof to recoup overpayments than the Department of Justice is currently required to show in order to impose treble damages and penalties for the same conduct under the FCA.

In its proposal to modify the bill, the AMA suggested that the standard of "clear and convincing evidence of fraud" be lowered to a standard of "sufficient evidence of fraud to warrant an investigation."

**13. What procedures are currently in place for providers to voluntarily return overpayments? Could S. 452, section 103, allow providers to return only a portion of an overpayment and be held harmless for the remainder?**

HCFA's current procedures generally allow providers to submit voluntary refunds to the fiscal intermediaries and carriers. There are different methods of handling overpayments for part A and part B. If a part A provider is erroneously paid for services not performed or is incorrectly paid for any other reason, overpayments can be resolved through the credit

[17]31 USC section 3731(c). For a discussion regarding the standard of proof applicable under the FCA, see John Terrence A. Rosenthal and Robert T. Atler, "Clear and Convincing to Whom? The False Claims Act and its Burden of Proof Standard: Why the Government Needs a Big Stick", Notre Dame Law Review, Vol. 75, p. 1409 (2000).

[18]Like other criminal violations, criminal fraud convictions related to Medicare require guilt to be proven beyond a reasonable doubt.

balance reports (quarterly reports that identify whether the provider owes Medicare money). Any part B provider that is overpaid must return the money to Medicare within 30 days to avoid interest and penalties.

S. 452, section 202, would amend current law to permit a physician or an ambulance service provider to return an overpayment without penalty or interest within 1 year from the date of receipt of the overpayment, if (1) the fiscal intermediary or carrier has not requested "any relevant record or file," or (2) the case has not been referred before the date of repayment to DOJ or the HHS/OIG. Thus, if a covered provider returned an overpayment within a year from the time it was received, subsequent investigations of claims related to the voluntary repayment would be prohibited. Under this provision, it appears that a provider could return a portion of an overpayment and essentially be held harmless for the remainder.

The AMA and TAF have offered several revisions to this provision. First, they propose an additional circumstance—when an FCA investigation is imminent or has already begun—under which a provider would not be allowed to make a voluntary repayment without incurring penalty or interest. Second, they propose that the overpayment must be returned in full. Finally, the prohibition on investigations would apply to contractors but not to law enforcement agencies.

**14. What are the implications of offering extended provider repayment periods on the federal government's ability to fully recover overpayments?**

When a billing error is detected, Medicare contractors send a letter listing the services at issue, the basis for the overpayment, and the amount being requested as repayment. If the refund is not received within 30 days, a second letter will be sent and the balance due will be satisfied by withholding future claim payments (otherwise known as offset). Contractors commonly recover overpayments automatically through offsets. According to HCFA, contractors allow providers to arrange extended repayment schedules for large overpayments, if a provider demonstrates financial hardship and an ability to repay over the course of the extended repayment schedule.

Under S. 452, section 103, overpayments to providers covered under the bill could not be automatically offset against future payments. Instead, providers would have the option of paying back any overpayment exceeding $5,000 over a 3-year period, even when liability has been established through civil litigation and the provider has the ability to pay. (This would not apply to cases where HHS finds "clear and convincing evidence of fraud or similar fault," a very high standard.) In addition, S. 452, section 104, would protect providers from offset or other repayment during an appeal.

We reported last year that whenever the recovery of Medicare overpayments is delayed, the chances that the amounts will not be fully recovered are increased.[19] HCFA's practice of offsetting overpayments with future payments has given it leverage that accounts for much of its collection success. The HHS/OIG noted that changes under section 103 of S. 452 would most likely result in reduced collections of overpayments, as some providers under extended repayment agreements would file for bankruptcy, leave Medicare, or cease operations—making it unlikely that the amounts due would be collected.

[19] *Medicare: HCFA Could Do More to Identify and Collect Overpayments* (GAO/HEHS/AIMD-00-304, Sept. 7, 2000).

The AMA and TAF have suggested significant changes to this provision. They propose that the option of entering into an extended repayment schedule apply only to providers covered under the bill with 25 or fewer employees. They also clarify that the provider would have to pay interest on the alleged overpayment. Most importantly, this option would not be available in cases where (1) the overpayment was attributed to improper billing under the FCA, (2) there is sufficient evidence of fraud to warrant an investigation, or (3) an offset arrangement is already in place.

**15. What rate of interest does HHS charge providers on outstanding payments and how does this compare with interest rates charged by the Internal Revenue Service (IRS) and other federal agencies? Under S. 452, section 104, would HHS be allowed to assess an interest penalty while an appeal is in process?**

Medicare is required to collect interest on overpayments not satisfied within 30 days of its request for a provider refund. HCFA charges providers and suppliers the higher of the private consumer rate or the current value of funds rate that is in effect on the date of the initial demand for payment.[20] The private consumer rate is historically higher than the current value of funds rate, which is used by many federal agencies. According to HCFA officials, it is also higher than the IRS underpayment rate but lower than some IRS penalty rates. They noted that the private consumer rate is currently 13.75 percent and is adjusted quarterly.

S. 452, section 104, would prohibit HCFA from recovering overpayments or imposing penalties while an appeal is pending. Whether HCFA could assess interest while an appeal is pending would depend on whether such interest would be characterized as a penalty.

**16. How does S.452, section 3, define a "provider of services"? Are there provisions in the bill that provide differential treatment for some Medicare providers?**

The entities covered by the bill include providers of services, physicians and providers of ambulance services. S. 452, section 3, paragraph (9), specifies that "provider of services" has the same meaning as it does in section 1861(u) of the Social Security Act. Under that definition, provider of services includes hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, and hospice programs.

However, it appears that the bill generally would not cover other entities that provide services or supplies to Medicare beneficiaries. For example, occupational and physical therapists, nurse practitioners, psychologists, and other specialized providers of services generally do not appear to be covered by the bill. Most institutional providers are covered under the definition of providers of services, but laboratories and facilities providing treatment for end-stage renal disease are not among them. Suppliers of durable medical equipment are also not covered by the bill.

[20]The requirement that providers of service must pay interest on overpayment amounts is set out in the Social Security Act, section 1815(d).

**17. Is it more difficult to challenge a Medicare regulation in court compared to other federal regulations? How would S.452, section 102, affect an entity's ability to challenge Medicare regulations?**

Parties generally must exhaust administrative remedies and obtain final agency action before going into federal court. Under the Administrative Procedure Act, the promulgation of a final regulation is generally considered a final agency action. Those adversely affected by a regulation often challenge it in federal district court by invoking federal question jurisdiction. Frequently, however, the statute under which a regulation was promulgated establishes different grounds for obtaining judicial review, which must be followed instead.

That is essentially what has happened with respect to challenges to Medicare regulations. The Social Security Act provides for a hearing before an ALJ (and, in some cases, the DAB), as well as subsequent judicial review. However, federal question jurisdiction cannot be invoked in the Medicare context. Thus, Medicare regulations generally cannot be challenged in federal district court until after they have been channeled through the same administrative process followed in other Medicare disputes.[21]

This makes challenging Medicare regulations more cumbersome than it would be if it were possible to invoke federal question jurisdiction and go to federal district court as soon as a regulation is finalized. Under HCFA regulations governing provider payment disputes, parties can pursue judicial review when the sole issue in dispute is the constitutionality of a statute or validity of a regulation.[22] In addition, as noted in question 9, recent amendments in BIPA that take effect October 1, 2002, establish deadlines at each step of the administrative process and permit parties to bypass steps if these deadlines are missed.

S. 452 would make it easier to challenge a Medicare regulation. Essentially, section 102 would amend current law to provide that the administrative process followed in other Medicare disputes would not have to be followed when challenging the constitutionality of a Medicare provision or regulation, or the authority of HCFA to promulgate a regulation. Instead, individuals adversely affected by a regulation could go directly to federal district court to challenge HCFA's application of the good cause exception to promulgate a rule without providing notice and comment.[23] It is also uncertain whether disputes would be resolved more quickly in court than in the sometimes-backlogged administrative appeals process.

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[21]For a complete discussion, see John Alysius Cogan, Jr. and Rodney A. Johnson, "Administrative Channeling Under the Medicare Act Clarified: Illinois Council, Section [205(h)], and the Application of Congressional Intent," Annals of Health Law, vol. 9, p. 125 (2000).

[22]See, for example, 42 C.F.R., sections 405.718, 405.853, 405.1842. However, parties must still present a claim for determination prior to pursuing expedited judicial review.

[23]Agencies do not have to provide for notice and comment if they determine that it would be impracticable, unnecessary, or contrary to the public interest.

**18. How might S. 452 affect the federal government's ability to use the False Claims Act in regard to Medicare payments?**

The FCA is the federal government's primary civil remedy for fraudulent claims.[24] It covers only offenses committed with actual knowledge that a claim is false or offenses by providers who demonstrate a reckless disregard of the truth of the claim. The FCA allows for penalties of between $5,500 and $11,000 for each false claim, plus damages of up to three times the amount of the erroneous payment.[25]

S. 452 does not directly address the FCA, but includes a number of provisions that offer health care providers immunity from investigation or other law enforcement activities. These protections may adversely affect the federal government's ability to use the FCA. For example, under section 202, covered providers would be permitted to repay Medicare overpayments for up to 1 year (without penalties or interest) and, in such circumstances, no law enforcement agency would be permitted to initiate an investigation associated with the Medicare claim involved. This would apparently prevent the government from pursuing an investigation under the FCA even if the provider returned only a small portion of a disputed Medicare payment.

S. 452 would also offer protections to covered providers who request written assistance from HCFA or its contractors related to Medicare claims. Specifically, section 301 would disallow extrapolation of overpayment amounts based on claims voluntarily submitted for review, while section 303 would protect providers from future findings that the provider had received an overpayment related to claims submitted.[26] Since the amount of liability under the FCA is often derived through extrapolation, it is unclear to what extent this would affect FCA actions. In addition, HCFA noted that because S. 452, section 105, would prohibit requests for documents from providers without cause and require notification of any postpayment audits, it would make it more difficult to conduct the type of preliminary investigations often necessary before pursing FCA claims.

The modifications proposed by the AMA and TAF would clarify that none of the provisions in S. 452 are intended to limit, or in any way affect, investigations or provider liability under the FCA.

[24]In 1986, amendments to the FCA strengthened the government's ability to identify and recover improper payments by federal programs, including Medicare.

[25]Although an individual claim submitted by a provider to Medicare is not likely to be very large, because providers submit hundreds of claims each year, high-volume providers could potentially incur substantial penalties under the FCA.

[26]This would not apply in cases of fraudulent billing.

Enclosure II

U.S. Department of Justice

*Washington, D.C. 20530*

JUN 8 2001

Ms. Leslie G. Aronovitz
Director
Health Care-Program Administration
And Integrity Issues
U.S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Aronovitz:

On May 31, 2001, the General Accounting Office (GAO) provided the Department of Justice (DOJ) copies of its draft report entitled "Regulatory Issues for Medicare Providers." The draft addresses such issues arising from the proposed Medicare Education and Regulatory Fairness Act (MERFA) S. 452 and H.R. 868. The Department is continuing to review the legislation and hopes to submit official views on the bill - including its likely effect on our ability to use the False Claims Act in pursuing Medicare fraud - to the Chairman of the Senate Committee on Finance in the near future. However, the Department generally agrees with the substance of this report and is providing additional information regarding its workload and the burden of proof in the proposed legislation.

The workload statistics in this report do not adequately reflect the full impact of the work done by the DOJ, in partnership with the U.S. Department of Health and Human Services (HHS), state Medicaid Fraud Control Units, and other federal investigative agencies. While it is instructive to look at the number of cases filed, or defendants convicted, one of the most important measures of the effort to combat health care fraud is the amount of dollars collected and returned to the Medicare program through judgments, settlements, and administrative penalties. Since FY 1997, over $2 billion dollars has been collected and returned to the Medicare program.

Congress has specified the "preponderance of the evidence" standard as the appropriate standard of proof for courts to use in False Claims Act cases. 18 U.S.C. § 3731(c). The "preponderance of the evidence" standard is the normal burden of proof in civil cases generally, and is the standard that the courts will adopt in fraud cases under civil statutes

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unless Congress has specifically provided a different standard. *Grogan v. Garner*, 498 U.S. 279, 286-87 (1991) ("preponderance" held the appropriate standard of proof to apply to bankruptcy fraud cases); *Herman & MacLean v. Huddleston*, 459 U.S. 375, 388-90 (1983) ("preponderance" held the right standard for securities fraud cases). The draft legislation precludes the Secretary from recouping monies paid out improperly from medical providers unless he first finds "clear and convincing evidence of fraud," (Section 103), which is a higher standard of proof than "preponderance," and indeed is the highest standard of proof imposed in any civil case. The bill would thus require the Secretary of HHS to meet a higher standard of proof to recoup overpayments than the Department of Justice is currently required to show in order to impose treble damages and penalties for the same conduct under the False Claims Act.

I hope the comments will be beneficial in completing the final document. If you have any questions concerning the DOJ's comments, you may contact its Audit Liaison Office on (202) 514-0469.

Sincerely,

Janis A. Sposato
Acting Assistant Attorney General
for Administration

(290074)