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Health, Education and Human Services Division

B-270093

March 18, 1996

The Honorable Fortney H. (Pete) Stark
Ranking Minority Member
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Stark:

On March 15, 1996, you asked us to review the fraud and abuse provisions of House Rule (H.R.) 3063, the Health Coverage Availability and Affordability Act of 1996. Specifically, you asked whether the comments that we had provided to you on October 7, 1995, about the fraud and abuse provisions of H.R. 2425, the Medicare Preservation Act of 1995, were applicable to H.R. 3063. You also asked that we review the provisions of H.R. 3063 regarding (1) an exception for managed care organizations to the Social Security Act's anti-kickback criminal provision and (2) a requirement that the Department of Health and Human Services (HHS) provide binding advisory opinions on whether certain health care arrangements are subject to sanction under the Social Security Act. To respond to your request, we reviewed the relevant sections of H.R. 3063; we did not review the remainder of that bill.

APPLICABILITY TO H.R. 3063 OF GAO COMMENTS ON H.R. 2425

In our earlier review of the fraud and abuse provisions of H.R. 2425 related to health programs under the Social Security Act[1] (enclosed is a copy of our response), we commented on sections that would (1) make obtaining convictions harder under the Medicare anti-kickback law, (2) curtail enforcement of civil monetary penalties under Medicare, (3) make administration of antifraud and antiabuse programs more difficult with the resources available by adding duties for HHS, and (4) reduce savings from Medicare's physician self-referral prohibition.

[1]Fraud and Abuse Provisions in H.R.2425 (GAO/HEHS-96-37R, Oct. 7, 1995).

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Regarding our first concern, H.R. 3063 does not include a provision like that in section 15212(c) of H.R. 2425 that would have made it more difficult to prove the facts necessary to establish criminal liability for making kickbacks for referrals for services. Therefore, our first concern about H.R. 2425 does not apply to H.R. 3063.

Section 232(a) of H.R. 3063 is identical to section 15212(a) of H.R. 2425, and we continue to believe that this section would significantly curtail enforcement under Medicare's civil monetary penalty provisions because those submitting claims would no longer be held to the due diligence standard. Pages 2 through 4 of our October 7, 1995, letter to you present the details of our analysis.

As H.R. 2425 would have done, H.R. 3063 places a number of new responsibilities on HHS and its components related to administering the Social Security Act's fraud and abuse provisions. In commenting on H.R. 2425, we expressed concern that the additional duties would adversely affect antifraud and antiabuse activities because that bill did not provide resources for carrying out the new responsibilities. However, H.R. 3063 would establish an account for fraud and abuse control and appropriate for and transfer funds to it. These funds are to be used for current fraud and abuse investigation and control activities as well as many of the new duties that would flow from H.R. 3063. The funding provisions of H.R. 3063 lessen our concerns about the adequacy of resources for carrying out the additional duties required under the bill.

Finally, H.R. 3063 does not contain the provisions that would have reduced savings from the prohibition against physician self-referrals that were the subject of our fourth comment on H.R. 2425. Thus, that concern about H.R. 2425 does not apply to H.R. 3063.

MANAGED CARE EXCEPTION TO ANTI-KICKBACK PROVISION

Section 216 of H.R. 3063 would establish an exception to the criminal liability for giving or receiving remuneration for referrals under the Social Security Act's health programs. Individuals or entities would not be liable if they are "at substantial financial risk" for the health services or items in question or if such services or items are furnished under a written agreement with a health maintenance organization or competitive medical plan eligible for a contract under section 1876 of the Social Security Act. Substantial financial risk is not directly defined but "withhold, capitation, incentive pool, per diem payment, or any other similar risk arrangement" are listed

as the types of arrangements that could qualify as falling under the substantial financial risk rubric.

The goal of the anti-kickback provision is to discourage the furnishing of unnecessary items or services that increase program costs and to punish those who do so. Concern about the unnecessary provision of items or services is certainly lower when individuals or entities are at risk for the costs of those items or services. However, the range of risk under the types of arrangements listed in section 216 runs from nonexistent to very high. A hospital that agrees to provide all needed inpatient services for a fixed monthly payment would have a high level of risk, assuming the payment rate is not set at an excessive level, and would seek to minimize the services provided. However, a hospital being paid a per diem rate does not have a financial incentive to minimize the number of days of care furnished, unless the rate is below costs, because revenues increase with each day of care. Thus, the existence of one of the listed arrangements may not guarantee a financial incentive not to provide unnecessary items or services. On the other hand, it does not seem likely that the Medicare program would pursue a criminal kickback investigation against an entity that has a legitimate risk agreement with a health maintenance organization with a Medicare risk contract.

BINDING ADVISORY OPINIONS

Section 205 of H.R. 3063 would require HHS to issue advisory opinions, binding on HHS and the parties seeking opinions, about the legality of arrangements or activities that could be subject to criminal or civil penalties under certain antifraud and antiabuse provisions of the Social Security Act. HHS would render advisory opinions concerning, among other things, whether a proposed activity constitutes grounds for the imposition of a sanction under sections 1128, 1128A, and 1128B of the Social Security Act. Whether an activity is prohibited under these laws depends in many cases on intent. Section 1128B, for example, makes it a crime to knowingly and willfully solicit or receive remuneration for referring an individual to a provider for services or items reimbursable under Medicare.

We share the concern expressed by the HHS Inspector General and the Department of Justice about similar proposed legislation introduced last year, that the government cannot advise meaningfully on the legality of a proposed action when that determination depends on the state of mind of the person taking the action. The only evidence HHS may have of intent is the presentation by the person proposing the action, which may be self-serving, and investigating

such requests independently may not be practical given the 30-day response limit in the bill.

The advisory opinion provision in the bill is also inconsistent with the current practice of basing criminal prosecution decisions on governmentwide policies, administered by the Department of Justice. To authorize HHS to render opinions that would in effect immunize individuals from prosecution by the Department of Justice is to decentralize what until now has been a single authority for enforcing the criminal laws.

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We will make copies of this letter available to others on request. If you have any questions about the matters discussed in this letter, please contact Tom Dowdal, Assistant Director, on (202) 512-6588.

Sincerely yours,

Sarah F. Jaggar

Sarah F. Jaggar
Director, Health Financing
and Public Health Issues

Enclosure

ENCLOSURE 1

GAO's COMMENTS ON H.R. 2425

GAO

United States
General Accounting Office
Washington, D.C. 20548

Health, Education and Human Services Division

B-270093

October 7, 1995

The Honorable Fortney H. (Pete) Stark
Ranking Minority Member
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Stark:

Your letter of October 4, 1995, asked us to review the fraud and abuse provisions of H.R. 2425, especially two provisions changing requirements of the anti-kickback and civil monetary penalty sections of the Social Security Act. You also forwarded comments you had received from the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG) and the Department of Justice on H.R. 2389.[1] These agencies expressed serious concerns about the two provisions. Because of the limited time available, we concentrated on these two provisions and have not fully analyzed the other provisions in H.R. 2425.

PROPOSED CHANGE TO MEDICARE ANTI-KICKBACK LAW

Section 1128B(b)(2) of the Social Security Act[2] establishes criminal liability for "[w]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person" to refer persons to them for medical services covered by Medicare or certain other health programs. In our experience, such arrangements are often disguised to appear to provide compensation for professional services or as returns on investments. Even when a physician performs a service for the money received, the inducements for referrals can result in unnecessary payments from Medicare.

[1]H.R. 2389 was incorporated, with some changes, into H.R. 2425.

[2]42 U.S.C. 1320a-7b(2).

ENCLOSURE 1

As the HHS OIG pointed out, courts have interpreted section 1128B(b)(2) to find liability whenever it is proven beyond a reasonable doubt that one purpose of a payment was to induce a referral.[3]

Section 15212(c) of H.R. 2425 would substitute for these judicial interpretations by amending the last part of the quoted material to read "to any person for the significant purpose of inducing." We are not convinced that the use of the modifier "the significant" would mean, as the OIG indicated, that 51 percent of the motivation for a payment would have to be to induce referrals in order to establish liability. However "the significant" can only be read to mean that prosecutors would have to prove beyond a reasonable doubt that the primary or most compelling motivation for the payment was to induce referrals.

Proving knowledge is always very difficult because it requires determining what was in the mind of an individual or individuals. Because it is not scientifically possible to prove knowledge directly, doing so requires marshalling a convincing argument based solely on circumstantial evidence. We agree that, as you surmise, this amendment will make proving the facts necessary to establish liability much more difficult. Moreover, the effect could well be to make it easier to disguise the intent behind kickback arrangements, or make disguises currently used more effective in evading prosecution. The result would be greater potential for fraud, with its negative financial effect on Medicare.

PROPOSED CHANGE TO CIVIL MONETARY PENALTY LAW

Section 1128A(a)(1) of the Social Security Act[4] authorizes civil monetary penalties, for example, for anyone who submits claims to Medicare and "knows or should know" that a claim is for services not actually rendered; for services that are false or fraudulent; for physicians' services not actually rendered by a physician; or for services performed by someone excluded from participating in the program.

The phrase "or should know" was substituted for "or has reason to know" by section 4118(e)(1) of the Omnibus Budget

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[3]For example, U.S. v. Bay State Ambulance and Hosp. Rental Serv., 874 F.2d 20, 29-30 (1st Cir. 1989).

[4]42 U.S.C. 1320a-7a(1).

Reconciliation Act of 1987 (OBRA-87) (P.L. 100-203). This change originated in the House bill for OBRA-87 and was included unchanged in the final version. The relevant House report states that this change was intended to overturn In the Matter of the Inspector General v. Frank P. Silver, M.D., Docket No. C-19 (Apr. 27, 1987).[5] In Silver, the reviewing official held that an employer could not be subject to civil monetary penalties for actions taken by his or her employees within the scope of their employment, and interpreted "reason to know" as imposing a duty on one submitting a claim to investigate the truth of the claim only if he or she had reason to suspect that the information in the claim was erroneous.

Although the interpretation of "reason to know" in Silver is consistent with the discussion of the phrase in the Restatement of Torts, Second, section 12, it troubled the drafters of the OBRA-87 amendment because they understood that it would make it easier for individuals to defraud Medicare by freeing them from a general duty to reasonably ensure the accuracy of the claims submitted. The amended language was expressly intended to "incorporate common law principles" into the civil monetary penalty provision.[6] In other words, under the current language, providers have an affirmative duty to ensure that the claims for payment that they submit, or that are submitted by their employees, are accurate. As pointed out by the OIG, the phrase "should know" is a standard American courts are accustomed to.

Section 15212(a)(2) of H.R. 2425 would require proof that the person acted "in deliberate ignorance" or "in reckless disregard" of the truth or falsity of the information. This would represent a significant change over the due diligence required of those submitting claims under the current standard.

The new definition for "should know" is basically the statutory definition of the terms "knowing" and "knowingly" found in the federal False Claim Act.[7] The result is that the knowledge standard for Medicare civil monetary penalties would be changed, in effect, from "know or should

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[5]H. R. Rpt. No. 391, 100th Cong., 1st Sess., pt. 1, at 533.

[6]The amendment was included under the title "Civil Monetary Penalty and Exclusion Clarifications," 101 Stat. 1330-155.

[7]31 U.S.C. 3729(b).

ENCLOSURE 1

know" to "knowing" or "knowingly." Under the False Claim Act, individuals have been found not liable for innocent mistakes and, in addition, not liable in cases of negligence.[8]

We agree with the OIG that this new definition of "should know" would, as drafted, "significantly curtail enforcement" under the Medicare civil monetary penalty provisions. Assuming that this interpretation would be applied with respect to the virtually identical definition in the Medicare context, proving negligence in the filing of claims would no longer suffice to impose a civil monetary penalty. This would result in imposing a far greater burden on prosecutors. It would constitute a reversal of the action taken in OBRA-87 and reinstate a knowledge standard at least as lenient as the one articulated in Silver.

OTHER CONCERNS

Although we have not fully analyzed the other provisions in H.R. 2425, we noted a few general concerns during our review of the fraud and abuse provisions.

First, a number of additional responsibilities would be placed on HHS, its Health Care Financing Administration, and the HHS OIG. Such responsibilities include soliciting views from and responding to the public on (1) safe harbors, (2) ways to improve the administration of Medicare, and (3) complaints and allegations about fraud and abuse. However, no resources are provided to accomplish these tasks. While any of these provisions might be laudable on its own, in today's budgeting environment we are concerned that additional resources needed for administration might not be available. This could result in anti-fraud and abuse staff being spread more thinly than they are now with negative consequences for fraud and abuse detection and prevention efforts.[9] Further, it could result in insufficient resources to carry out the intent of the legislative provisions.

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[8]See, for example, Wang v. FMC Corp., 975 F.2d 1412, 1420 (9th Cir. 1992).

[9]We have commented on many occasions on the need for adequate resources to effectively perform the tasks that comprise fraud and abuse detection and prosecution.

ENCLOSURE 1

Second, the bill would make a number of changes to Medicare's prohibition on physician referrals to facilities and suppliers in which they have an ownership interest. We, as well as the HHS OIG and others, have conducted a number of studies that identified increased use of services when physicians refer patients to entities they own or in which they have substantial financial interests. Substantial savings were estimated to accrue from enactment of the provisions proposed for modification, and we are concerned that this could increase Medicare costs. We are particularly concerned about repeal of the provision requiring covered providers and suppliers to report to HHS on who their owners are. Without this information, it would be very difficult and expensive for HHS to enforce the prohibition or to identify violations.

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We are sending a copy of this letter to the Chairman, Subcommittee on Health. If you have any questions about the matters discussed in this letter, please contact Tom Dowdal, Assistant Director, on (202) 512-6588.

Sincerely yours,

Sarah F. Jaggar
Director, Health Financing
and Public Health Issues

(106431)

5 GAO/HEHS-96-37R Fraud and Abuse Provisions in H.R. 2425

(108273)

9 GAO/HEHS-96-111R Fraud and Abuse Provisions in H.R. 3063

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