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

Office of the General Counsel

Subject: Advisory Committee Act: Violation by Health Care Financing Administration

File: B-278940

Date: January 13, 1998

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January 13, 1998

The Honorable Bill Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Chairman:

The Health Care Financing Administration created the Technology Advisory Committee to provide it with expert advice concerning whether Medicare should cover specific technologies on a national basis. In your November 7, 1997, letter to this Office, you asked that we provide a description of the responsibilities and operations of the Committee. You also requested that we provide our opinion whether the Committee is in compliance with the requirements of the Federal Advisory Committee Act and, if it is not, that we discuss the legal implications of that violation.

The purpose of the Technology Advisory Committee (the Committee) is to help the Health Care Financing Administration (HCFA) make decisions concerning whether Medicare should reimburse providers on a national basis for new procedures and technologies. Until HCFA makes a decision to provide national coverage, the carriers--the private-sector companies that operate the Medicare program under contract with HCFA--may decide individually whether they will cover a particular technology.

The Committee meets several times a year to consider an agenda established by HCFA. The membership has consisted of both government employees and carrier medical directors. Although it merely provides information in some instances, the Committee has on occasion made recommendations to HCFA.

As it was constituted as of December 31, 1997, the Committee was an advisory committee as defined in the Federal Advisory Committee Act (the Act or FACA), but was not operating in compliance with the Act. The Act requires that meetings of an advisory committee be open, unless a specific exception to that requirement is invoked. Although HCFA promptly publishes a summary of meetings of the Committee after they take place, the meetings are not open to the public, and no exception has been invoked. The Committee has also not been in compliance with

other provisions of the Act. These include the requirements that the head of the agency, in consultation with the Administrator of General Services, make a formal determination that creation of an advisory committee would be in the public interest, that a charter for an advisory committee be on file with the agency using it and with the congressional committees having legislative jurisdiction, and that the committee have an expiration date.

The Act is silent concerning the consequences of non-compliance. A person who can establish that he is adversely affected by the violation can seek relief from the courts, which are free to craft what they consider to be an appropriate remedy. For example, when the complaint is based on failure to hold open meetings, the courts have ordered that the meetings be opened.

HCFA, in commenting on a draft of this letter, acknowledged that the Committee was "likely not in compliance with the requirements of FACA," and indicates that it is taking steps to cure the violation. HCFA points out that the Committee "performs a very important role in augmenting the limited clinical resources available on our staff to review the scientific evidence respecting the appropriateness of extending Medicare coverage to specific health care items and services." HCFA and the Department of Health and Human Services are therefore developing a proposal for a new committee, chartered under the Act, and with broad public membership, that would in effect replace the existing Committee. Pending that decision, HCFA will "reformulate the current committee" with membership limited to federal employees. (We were told that this would be done before the next scheduled meeting of the Committee in February.) A committee so constituted would not be subject to the Act, which excludes from coverage committees consisting entirely of full-time government officers or employees.

We agree with HCFA's course of action. In the short term, it will cure the violations that now exist. In the longer term, HCFA's consideration of a reconstituted committee with broad public representation that will comply with the Act is worthwhile; although we have not analyzed the operation of the Committee in depth, we found no reason to doubt that it performs a useful function for HCFA. Moreover, it seems reasonable that, as HCFA believes, the presence on the Committee of carrier medical directors brings an added valuable perspective to the Committee's deliberations, and that there may be merit to having additional public representation.

A more detailed discussion and a copy of the comments provided by the Health Care Financing Administration on a draft of this letter are enclosed.

As arranged with your office, unless you announce its contents earlier, we plan no further distribution of this letter until 30 days after this date. At that time, we will send copies to the Administrator of HCFA and interested congressional committees. Copies will be made available to others on request.

If you or your staff have any questions, please call me at (202)-512-8203.

Sincerely,

Barry R. Bedrick
Associate General Counsel

Enclosures

ENCLOSURE I

Application of the Federal Advisory Committee Act to
the Technology Advisory Committee of
the Health Care Financing Administration

The Technology Advisory Committee

The Technology Advisory Committee (the Committee) was established by the Health Care Financing Administration (HCFA) to advise it concerning whether new medical techniques and products should be covered under Medicare on a national basis. HCFA has described the functions of the Committee in part as follows:

"[The Committee] serves in an advisory capacity to HCFA's Office of Clinical Standards and Quality (OCSQ). Its major focus is to assist HCFA in its technology assessment efforts, to recommend whether a technology is appropriate for Medicare national coverage policy, and to refer topics to the Agency for Health Care Policy and Research . . . or other technology assessment expert, for a comprehensive technology assessment when appropriate."

Although many Medicare coverage decisions are made locally by the carriers that administer the program under contract, HCFA has an "overall interest in increasing the consistency of coverage policy among carriers and making national policy for coverage issues that are significant."[1] The Social Security Act specifies certain Medicare benefits, but in addition gives the Secretary of Health and Human Services discretion to cover additional items as long as they are "reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." The Committee is used to help HCFA decide which items fall within that definition:

". . . The [Committee] provides interchange between local and national policy and considers when an issue becomes of such prominence that it warrants a national policy. HCFA develops the agenda that the [Committee] will follow to evaluate and make its recommendations. The [Committee] could recommend that HCFA: issue a national coverage policy, refer the issue for assessment by the Public Health Service or other qualified assessment organization, postpone

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[1]Prepared statement, "Medicare Coverage Policy," by Bruce C. Vladeck, Administrator, Health Care Financing Administration, before the Subcommittee on Health, House Ways and Means Committee, April 17, 1997.

the decision until there is more information, or decline to establish a new policy. HCFA can then accept or reject the [Committee's] recommendation."[2]

Membership on the Committee was originally limited to HCFA employees, but was gradually broadened to bring in employees of other components of the Department of Health and Human Services (HHS) as well as of other federal agencies and, eventually, the medical directors of the carriers. At present,[3] the membership of the Committee comprises representatives of HCFA and other agencies within HHS,[4] representatives of the Department of Veterans Affairs and the Department of Defense, and medical directors of the carriers. An official of HCFA's Office of Clinical Standards and Quality serves as chairman.

The expansion of the Committee's membership coincided with an evolution of its functions. Originally the Committee reviewed whether a technology assessment by the Public Health Service was needed and helped to prepare requests for such assessments. Over time, the committee took on additional responsibility and began to make its own assessments. Current practice is for the Committee to discuss the scientific evidence, and for members to express their views on whether that evidence supports Medicare coverage.

Meetings of the Committee are closed, but HCFA has made information on the meetings, including agendas and minutes, publicly available through HCFA's Home Page on the Internet. According to the former Administrator, "[t]his is one of the means by which we hope to increase participation by interested parties."[5]

The published minutes of Committee meetings provide illustrations of its operation. During its August 5-6,1997 meeting, for example, the Committee considered, among other technologies, a test intended to assist clinicians in selecting chemotherapy agents by predicting tumor resistance to specific drug regimens. In determining the chemotherapy regimen for cancer, practitioners typically use the most powerful therapy available. If the first line of treatment fails, the second attempt at tumor control is rarely as successful as the first one. Therefore, it is important to be precise at the onset of treatment. The Committee considered evidence that the new test lets

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[2]Id.

[3]As discussed further below, HCFA is in the process of reformulating the membership of the Committee to bring it into compliance with the Federal Advisory Committee Act. This discussion applies to the Committee as it existed as of December 31, 1997.

[4]The other HHS components represented on the Committee are the Food and Drug Administration and the National Institutes of Health.

[5]Vladeck statement, supra.

physicians avoid administering toxic agents that not only offer no benefit, but that lessen the likelihood that the next treatment will be effective.

The Committee agreed that a test of this kind would be beneficial but was concerned with a lack of data demonstrating clinical utility and acceptance of the particular test under consideration. The committee recommended to HCFA that the test not be covered.[6] (HCFA's coverage decisions do not prevent technologies such as this one from being used; the only issue for HCFA, and the Committee, is whether the technology should be reimbursable under Medicare on a national basis.)

The Federal Advisory Committee Act

In explaining the purpose of the Federal Advisory Committee Act (the Act), the Congress acknowledged that the numerous committees, boards, commissions, and other organizations established to advise the executive branch are frequently a useful and beneficial source of expert advice, ideas, and diverse opinions. At the same time, it found that the need for many then-existing advisory committees had not been adequately established, and that some committees continued in existence after they were no longer useful. The Congress concluded that additional controls were needed over advisory committees, so that it and the public would be kept informed with respect to the number, purpose, membership, activities, and cost of these committees. 5 U.S.C. app. 2 § 2.

The Act achieves these ends through a set of requirements that apply to the formation and operation of advisory committees.[7] Advisory committees must have written charters on file with the head of the agency that created them, and with the congressional committees with legislative jurisdiction over the agency. 5 U.S.C. app. 2 § 9(c). They must announce and hold open meetings unless one of several specific exceptions applies. Id. § 10. They must cease operation within two years of their creation, unless expressly renewed. Id. § 14. Advisory committees must keep publicly available records of expenditures. Id. § 12. Requirements of the Act are implemented in regulations of the General Services Administration. Id. § 7; 41 C.F.R. Subpart 101-6.10.

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[6]This account is drawn from the summary of the meeting that HCFA posts on its Internet site.

[7]The Act provides different treatment in some respects for advisory committees created by statute, or created or utilized by the President. This discussion applies to advisory committees created by executive agencies.

The Committee is Subject to the Federal Advisory Committee Act

The Act covers the Committee. As defined in the Act, "advisory committee" includes "any committee . . . which is . . . established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for . . . one or more agencies or officers of the Federal Government . . . ." 5 U.S.C. app. 2 § 3. The Committee is established and used by HCFA in the interest of obtaining advice or recommendations.

There are several exceptions in the law from the general definition in the preceding paragraph, but none applies to the Committee as it is currently organized. Two of the exceptions are for specific organizations; the third is for committees "composed wholly of full-time officers or employees of the Federal Government." 5 U.S.C. app. 2 § 3(2)(C). As it was originally constituted, the Committee was composed wholly of full-time government officers or employees and therefore came within the latter exception. However, once the carrier medical directors became Committee members, that exception was no longer available.[8]

The Committee is not in compliance with the Act. Among the most fundamental of the requirements with which the Committee does not comply is that meetings must be open and, subject to reasonable limitations, interested persons must be permitted to attend, appear before, or file statements with any advisory committee. 5 U.S.C. app. 2 § 10(a). Meetings of the Committee have been closed in the past. In addition, the Committee was not established based on a formal determination by the head of the Department of Health and Human Services, after consultation with the Administrator of General Services, that its creation would be in the public interest (Id. § 9(a)(2)), and does not have a charter on file with the Department and the authorizing congressional committees (Id. § 9(c)). The Department of Health and Human Services does not keep records of costs and activities of the Committee. Id. § 12. The Committee has continued in operation for more than two years despite not having been renewed by the Department. Id. § 14.

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[8]We understand that it has been suggested that the Committee might fall within the third exception on the theory that the carrier employees should be regarded as federal employees based on the unique and close relationship between the carriers and the federal government. However, this theory is untenable: carrier employees do not meet the legal requirements for status as officers or employees of the United States. Cf. Ass'n. of American Physicians and Surgeons v. Clinton, 813 F. Supp. 82 (D.D.C. 1993); rev'd. 997 F.2d 898 (D.C. Cir.); remand 837 F. Supp. 454.

Consequences of Violation

The Act does not prescribe remedies or penalties for violations, nor does it specify who may bring suit to challenge alleged violations. This in effect leaves it to the courts to decide who may bring suit and to craft remedies for violations.

Because the Act does not create a right to sue for violations, those seeking to challenge the operation of an advisory committee must first establish that they are directly affected in some fashion by the alleged impropriety concerning the committee. This establishes the requisite "standing" to sue.

In those cases where a plaintiff has been found to have standing, legal challenges under the Act have generally focused on two of its requirements. One of these is balance; that is, the plaintiff argues that the constitution of the committee unfairly weights it in favor of one point of view, in violation of the requirement that the membership of an advisory committee "be fairly balanced in terms of the points of view represented . . . ." 5 U.S.C. app. 2 §§ 5(b)(2), (c). The other requirement that commonly forms the basis for a challenge is openness; plaintiffs allege that they have not been permitted to attend meetings, or that they have been denied access to information about the operations of the committee. Id. §§ 8(b), 10(a)-(d).

Although there is no statutory penalty for violations of the Act, a plaintiff can ask a court to order appropriate relief. Courts have generally responded to violations of the openness requirement by ordering that the committee's proceedings be opened.[9]

In one instance where an order to open the meetings of the committee would have had no effect because the committee had completed its work before the lawsuit concluded, a federal appellate court upheld an order to the agency not to use the product of the committee's deliberations "for any purpose whatsoever, directly or indirectly."[10] The court reasoned that "to allow the government to use the product of a tainted procedure would circumvent the very policy that serves as the foundation of the Act." It is not clear whether courts in the other federal circuits would take the same approach.

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[9]Ass'n. of American Physicians and Surgeons v. Clinton, 813 F. Supp. 82 (D.D.C. 1993); rev'd. 997 F.2d 898 (D.C. Cir.); remand 837 F. Supp. 454.

[10]Alabama-Tombigbee Rivers Coalition v. Fish & Wildlife Service of U.S. Dept. of Interior, 1993 WL 646410 (N.D. Ala. Dec 22, 1993), aff'd. 26 F.3d 1103 (11th Cir. 1994).

ENCLOSURE II

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration
Office of Clinical Standards & Quality
7500 Security Boulevard
Baltimore, MD 21244-1850

December 22, 1997

Barry R. Bedrick
Associate General Counsel
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Bedrick:

Thank you very much for giving us the opportunity to comment on a draft of your response to Congressman Bill Thomas, who has asked you for a description of the responsibilities and operations of HCFA's technology advisory committee and a legal opinion concerning that committee's compliance with the Federal Advisory Committee Act (FACA).

We believe the committee has been performing a very important role in augmenting the limited clinical resources available on our staff to review the scientific evidence respecting the appropriateness of extending Medicare coverage to specific health care items and services. The committee has also added valuable perspectives to our discussions about these coverage decisions, based on the experience of other agencies faced with similar issues and the experience of our contractors responsible for processing Medicare claims.

As your draft correctly points out, the composition of the committee has evolved since its inception in 1980. It began solely with a group of clinicians who were on the staff of HCFA. Over time, we added representatives of other Federal agencies, both within and outside the Department, and medical directors from some of the Medicare carriers. The functions of the committee have also evolved. The initial purpose was to review whether a technology assessment should be sought from the Public Health Service regarding coverage for a specific item or service and, if so, to help HCFA staff frame the issue properly and review the response from PHS. As the committee grew and gained experience, it began to undertake more extensive discussion of the scientific evidence available regarding the clinical utility of items and services under review and, eventually, the members began to express their views on whether such evidence supported Medicare coverage.

We acknowledge that the committee is likely not in compliance with the requirements of FACA. Although we have publicized the existence of the committee, and now make the agendas and minutes of its meetings available to the public by means of the Internet, we have not made an effort to charter the committee under FACA. Nor have we opened its discussion of the scientific evidence to the general public.

Since the reorganization and reorientation of HCFA in July of this year, we have been reviewing our coverage decision process and the role of this committee. We believe there may be merit in establishing a FACA-chartered committee, with broad public representation, to review and provide counsel on the policies and procedures for coverage policy. We are developing a proposal for such a committee and will be presenting it for review and approval by the Department. It will likely be several months before there is a final decision on such a committee. During this process, we plan to reformulate the current committee, so that it is comprised solely of Federal employees, in order that we can continue to receive the valuable services it provides.

Thank you again for providing us a draft copy of your response and an opportunity to comment.

Sincerely,

/S/

Peter Bouxsein
Acting Director
Office of Clinical Standards and Quality

GAO

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

Office of the General Counsel

B-278940

May 8, 1998

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

Dear Mr. Stark:

The Health Care Financing Administration (HCFA) created the Technology Advisory Committee to provide it with recommendations and advice concerning whether certain medical technologies should be covered nationally by Medicare. Despite the requirement of the Federal Advisory Committee Act that advisory committee meetings be open to the public, the practice of the Committee until recently had been to hold closed meetings. In an opinion issued in January, we found that the Committee was violating the Federal Advisory Committee Act in that and other respects.[1] Because its membership includes officials of private sector companies, the Committee does not fall within the exception in the Act for advisory committees made up wholly of government employees.

In your February 5, 1998, letter, you asked that we provide the dates of changes in the composition of the Technology Advisory Committee (the Committee). You asked in particular that we determine when the Committee first became noncompliant with the Act.

HCFA created the Committee in 1993 through a consolidation of two earlier advisory committees that together had performed essentially the same function now carried out by the Committee. One of those predecessors, the Coverage Policy Technical Advisory Group (the Group), also violated the Act during its existence, from 1983 to 1993, by holding closed meetings and in other respects.

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[1] B-278940, January 13, 1998. In commenting on a draft of our earlier opinion, HCFA made a commitment to cure the violation by the Committee.

Thus, the violation by the Committee began with its formation in 1993, but also represents a continuation of a violation by its predecessor, the Group, that dates from the creation of the Group in 1983. Although the Committee's functions include some not performed by the Group, there is an underlying continuity of purpose--to provide advice and recommendations to HCFA concerning national coverage under Medicare of new medical technologies--between HCFA's current use of the Committee and its former use of the Group. A detailed explanation follows.

The Federal Advisory Committee Act requires that, unless specific exemptions apply, meetings of an advisory committee must be announced publicly and must be open to the public. The Act imposes various other requirements on the formation and operation of advisory committees. 5 U.S.C. app. 2 (1994). An advisory committee, for this purpose, is "any committee . . . which is . . . established or utilized by one or more agencies in the interest of providing advice or recommendations for . . . one or more agencies or officers of the Federal Government . . . ." However, the Act does not apply to committees "composed wholly of full-time officers or employees of the Federal Government." 5 U.S.C. app. 2 § 3 (1994).

The Technology Advisory Committee, now used by HCFA to advise it on national Medicare coverage of medical technologies, is the product of the merger in 1993 of two organizations, the Physicians Panel (the Panel) and the Coverage/Payment Technical Advisory Group.[2] HCFA created the Panel in 1980, followed by the Group in 1983.

The Panel was not subject to the Act. Its original functions were to decide which Medicare coverage issues to refer to the Public Health Service (PHS), to help frame those issues, and to review the responses from PHS. Later, it also made recommendations on Medicare coverage. However, all Panel members were government employees, which made it exempt from the Act.

The Group, from its creation in 1983 until it was merged into the Committee in 1993, violated the Act by holding closed meetings, and in other respects. The Group did not come under the exemption from the Act that was applicable to the Panel, because the membership of the Group, like that of the current Committee, comprised, in addition to HCFA staff, a Blue Cross representative and officers of the so-called carriers, the private sector companies that administer Medicare under contract with the government.

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[2]The Group was originally called the Coverage Policy Technical Advisory Group, later the Coverage Technical Advisory Group, and finally the Coverage/Payment (or, sometimes, Coverage-Payment) Technical Advisory Group.

HCFA points out that the functions of the Group were more limited than those of the Committee. Despite the inclusion in its name of "coverage" and "policy," the Group did not make national coverage policy recommendations to HCFA, as does the Committee. According to HCFA, the Group focused on--

"a variety of technical issues involved in the implementation of coverage policies and coordination of contractor responsibilities. [The Group] was used to clarify coverage instructions issued by HCFA and to identify concerns that arose in the implementation of those instructions. It also served to alert HCFA about items and services that were being presented to the contractors for resolution that might need a national coverage determination by HCFA. . . . When [the Group] identified an issue for a potential coverage determination, this was referred to the HCFA Physicians Panel. In turn, after the HCFA Physicians Panel made a coverage recommendation, this would often be referred to [the Group] to deal with any technical issues that might arise in the implementation of the coverage determination."

The records we reviewed generally confirm this characterization.[3]

Although its function was different from that of the Committee, the Group was also an advisory committee and was also in violation of the Act. Unlike the Committee, the Group did not make direct recommendations on coverage determinations. However, the Group functioned as a source of consensus recommendations for HCFA on other matters without holding open meetings.[4] In doing so, it acted in violation of the Act.

In 1993, HCFA created the Committee as a "consolidation" of the Group and the Panel. The Committee had the same categories of members as the Group--HCFA employees, carrier medical directors, and a Blue Cross representative--augmented by employees of other government agencies with an interest in Medicare coverage issues. The Committee continued the prohibited practices of its predecessor, the Group, of holding closed meetings, and failed also to comply with other requirements of the Act.

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[3]We read the minutes of all meetings of the Group from its creation to its merger into the Committee, and reviewed an opinion from the Office of General Counsel of the Department of Health and Human Services that describes the functions of the Group.

[4]On some issues, the Group acted as a vehicle for conveying individual members' opinions. A meeting with more than one person for the purpose of obtaining the advice of individual attendees is not an advisory committee. 41 C.F.R. 101-6.1004(i) (1997). However, the Group's typical operation was to deliberate as a group and to provide consensus advice, making it clearly an advisory committee. Id.

We conclude that noncompliance with the Act in connection with HCFA's use of advisory committees to determine national Medicare coverage of medical technologies began in 1983 with the formation of the Group and continued through the creation of the Committee in 1993.

If you or your staff have any questions, please call me at (202) 512-8203.

Sincerely yours,

Barry R. Bedrick
Associate General Counsel