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Report to Congressional Committees

December 2004

MEDICARE

Advisory Opinions as a Means of Clarifying Program Requirements

GAO-05-129

December 2004

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Highlights

Highlights of GAO-05-129, a report to congressional committees

MEDICARE

Advisory Opinions as a Means of Clarifying Program Requirements

Why GAO Did This Study

Health care providers are concerned about the quality of Medicare guidance issued by the Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS). Specifically, they have reported that (1) they receive unclear guidance on program requirements and (2) because policies and procedures change frequently, they may rely on obsolete guidance, resulting in billing errors.

Some government agencies issue advisory opinions in response to specific questions from requesters. These opinions permit agencies to apply law and regulation to a particular set of facts and provide requesters with specific guidance.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed GAO to determine the appropriateness and feasibility of establishing in the Secretary of Health and Human Services authority to issue legally binding advisory opinions to interpret Medicare regulations. GAO (1) identified factors relevant in establishing an advisory opinion process and (2) assessed the role such a process could play in clarifying program requirements. GAO examined four federal agencies' advisory opinion processes and interviewed officials from organizations representing Medicare stakeholders to learn how such a process might address their concerns.

www.gao.gov/cgi-bin/getrpt?GAO-05-129.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Leslie G. Aronovitz at (312) 220-7600.

What GAO Found

GAO identified five common elements in the way four agencies—CMS, the Employee Benefits Security Administration (EBSA) of the Department of Labor, the Internal Revenue Service (IRS), and HHS's Office of Inspector General (HHS-OIG)—set up their advisory opinion processes. While the processes at the four agencies reflected differences in the agencies' respective constituencies and responsibilities, each agency cited five key factors as critical. These were (1) establishing criteria for submitting advisory opinion requests, to define the scope of their processes, (2) developing alternative ways of responding to advisory opinion requests, such as providing other forms of written communication, (3) determining the time frame for issuing advisory opinions, (4) considering anticipated workload, staffing requirements, and user fees as a means of offsetting expenses incurred by the government, and (5) creating internal review and external coordination procedures with other federal agencies with a stake in the outcome of an issued opinion. These five factors and lessons learned from other agencies that issue advisory opinions may be useful in structuring a process for Medicare.

Most of the representatives of provider organizations GAO contacted agreed that an advisory opinion process would partially address their concerns, for example, by providing them with reliable, written responses to their Medicare-related questions. However, they recognized that an advisory opinion process would not address all their concerns and that it is one of several approaches that could improve Medicare guidance. For example, refining existing forms of guidance would also be of value.

In commenting on a draft of this report, HHS stated that a more formal advisory opinion process for Medicare would be costly to implement, not provide quick answers to providers' questions, and have limited applicability. HHS acknowledged that the Medicare program and its implementing regulations are inherently complex and underscored its efforts to improve stakeholders' understanding of the program's complexities.

Advisory Opinion User Fees at Four Agencies in Fiscal Year 2004

Agency	User fee	Charges per opinion
CMS	$75 per hour for staff costs, with a $250 nonrefundable deposit required when the request is made	$250[a]
EBSA	Not applicable	No charge
HHS-OIG	$86 per hour for staff costs, with a $250 nonrefundable deposit required when the request is made	Ranged from $301 to $3,784
IRS	$6,000, based on average cost to agency, with special rate for qualifying requesters	$6,000[b]

Sources: Interviews with CMS, EBSA, HHS-OIG, and IRS officials.

[a]In fiscal year 2004 CMS issued four advisory opinions for which it charged $250 for each opinion. CMS anticipates that charges for future advisory opinions could be higher.

[b]Some taxpayers may be eligible for reduced user fees, depending on the issues involved and the taxpayers' specific circumstances.

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Abbreviations

APA	Administrative Procedure Act
CMS	Centers for Medicare & Medicaid Services
EBSA	Employee Benefits Security Administration
ERISA	Employee Retirement Income Security Act of 1974
FTE	full-time equivalent
HHS	Department of Health and Human Services
HHS-OIG	Department of Health and Human Services-Office of Inspector General
IRS	Internal Revenue Service
MAC	Medicare Appeals Council

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United States Government Accountability Office
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December 8, 2004

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

The Honorable Joe Barton
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable Bill Thomas
Chairman
The Honorable Charles B. Rangel
Ranking Minority Member
Committee on Ways and Means
House of Representatives

The Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS), administers Medicare—the federal health insurance program that serves the nation's aged and certain disabled individuals. In fiscal year 2003, Medicare paid over $271 billion for the health care of approximately 41 million beneficiaries. More than 1 million providers submitted about 950 million claims during that year. As part of its responsibilities, CMS issues regulations to implement Medicare laws that govern the participation of beneficiaries, physicians, hospitals, medical suppliers, and other stakeholders in the Medicare program. Because of Medicare's size and complexity, its regulations are written to cover a variety of situations. Although it is critical that stakeholders understand how the program operates, it may be difficult for them to interpret Medicare's many regulations and apply them to their own unique circumstances. CMS—with the assistance of the claims

administration contractors[1]—routinely issues various forms of guidance to beneficiaries and health care providers. CMS and its contractors also respond to questions from interested parties to further help them understand program requirements.

In recent years, Medicare providers have become increasingly concerned about the quality of guidance issued by CMS. For example, they have criticized CMS for a lack of clarity in regulations and related guidance on a variety of program issues ranging from the determination of medical necessity for services covered to the proper use of billing codes. Providers have also expressed concern that because Medicare policies and procedures change frequently, program guidance on which they rely may be obsolete. Consequently, they worry that they may make billing errors that could trigger a range of possible adverse consequences.[2]

Like other federal agencies, HHS currently issues advisory opinions as part of its guidance framework. HHS has two separate advisory opinion processes for specific provisions of Medicare law, but neither process covers the wide range of regulations that govern the Medicare program. Advisory opinions are typically written responses to specific questions that address whether a requester's action or proposed action is in compliance with applicable laws and regulations. The purpose of advisory opinions is generally to permit people engaging in complex or unprecedented transactions to act with some confidence that their actions will not later be found to have been illegal. In general, advisory opinions (1) are issued to a requesting party, (2) interpret or apply law and regulation to a specific set of facts, such as an ongoing or proposed business arrangement, and (3) are legally binding, if at all, only with respect to the requesting party, the

[1] Among other things, the claims administration contractors assist CMS by processing and paying claims and by communicating billing guidance to the provider community and Medicare beneficiaries.

[2] Adverse consequences may include having submitted claims denied or subjected to additional scrutiny, which could delay payment. In addition, providers are concerned that even when their billing errors are inadvertent, they may be subjected to legal action under the False Claims Act (31 U.S.C. §§ 3729-3733 (2000)), which imposes substantial financial liability for "knowingly" submitting improper claims. The statute defines "knowingly" to mean that a person has actual knowledge of the false claim or acts in deliberate ignorance or reckless disregard of its truth or falsity; the statute states that no proof of specific intent to defraud is required.

specific set of facts described, and the extent set out in the advisory opinion.[3] An advisory opinion provides the party who requested it with assurance that, should the party proceed consistent with the opinion, the agency will not take adverse action against that party to the extent set out in the advisory opinion. Because advisory opinions may be published, other interested parties may readily look to them as guidance.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 directed us to determine the appropriateness and feasibility of establishing in HHS the authority to provide legally binding advisory opinions on the appropriate interpretation and application of regulations to carry out the Medicare program.[4] As we discussed with the committees of jurisdiction, we (1) identified factors relevant to the establishment of such an advisory opinion process and (2) assessed the role such a process could play in clarifying Medicare regulations.

To identify factors relevant to the establishment of an advisory opinion process, we selected four federal agencies that have such processes in place and reviewed the policies and procedures each has instituted to manage the processes. We obtained information on the workload and staffing levels related to the advisory opinion process at each agency. In addition, we obtained information on the user fees charged by these agencies to those requesting advisory opinions. The information we obtained was the most current available at the time we performed our work. We also interviewed officials involved with issuing advisory opinions at all four agencies. In selecting agencies, we chose the two agencies within HHS—CMS and HHS's Office of Inspector General (HHS-OIG)—that issue opinions on provisions of Medicare law, and two other federal agencies—the Internal Revenue Service (IRS) and the Employee Benefits Security Administration (EBSA) of the Department of Labor—that administer complex programs governed by numerous laws and regulations affecting large constituencies. In addition, we met with two experts on administrative law and two private sector attorneys to discuss advisory

[3] The extent to which an agency considers itself legally bound by an advisory opinion it provides may be stated in the advisory opinion itself. An advisory opinion provided under a statutory requirement for an agency to provide binding advisory opinions is likely to be accorded considerable weight by courts, at least with respect to the party who requested it. Emphasizing facts similar to those at issue in the advisory opinion, others may argue that the advisory opinion should govern agency actions involving them as well.

[4] Pub. L. No. 108-173, § 904, 117 Stat. 2066, 2377.

opinion processes and factors relevant to the establishment of a new process at HHS to interpret Medicare regulations.

To assess the role an advisory opinion process might play in clarifying Medicare regulations, we interviewed officials from 15 organizations representing various Medicare stakeholders, with an emphasis on organizations representing providers, including one hospital that we visited. (See app. I.) We conducted our work from May 2004 through November 2004 in accordance with generally accepted government auditing standards.

Results in Brief

We identified five factors that are critical to the establishment and management of an advisory opinion process. Officials at each of the four agencies whose processes we examined consistently cited these factors as critical to their processes. First, all four agencies have defined the scope of the advisory opinion process by establishing criteria for submitting advisory opinion requests. For example, none of the four agencies will provide advisory opinions for requests that are based on hypothetical situations. In addition, two of these agencies—IRS and EBSA—have further restricted the scope of their processes by identifying topics on which they will not provide opinions. Second, all four agencies use alternative ways of responding to advisory opinion requests. For example, these agencies may decide that a request concerning a straightforward question that is already clearly addressed in other published guidance does not necessitate an advisory opinion. In such cases, the agencies may opt instead to respond through a letter or by telephone. Third, addressing the issue of a time frame for responding to requests was viewed as essential. Statutory requirements drive such time frames at CMS and HHS-OIG. However, IRS and EBSA have devised their own approaches. IRS has set its own deadline of responding to requests within 4 to 6 months. Conversely, EBSA has not established a deadline. Instead, in determining when to respond to a requester, it considers the significance of the issue addressed by the request and also takes into account whether the request involves a time-critical matter. Fourth, the four agencies had to consider their anticipated workload, staffing requirements, and appropriate user fees. An advisory opinion process was viewed as needing an adequate number of staff with appropriate backgrounds, such as attorneys and individuals with program expertise. Fifth, the agencies stressed that creating internal review and external coordination procedures with other federal agencies that may have a stake in the outcome of any given opinion was important to their programs.

Overall, most of the representatives of provider organizations we spoke with agreed that a process for providing legally binding advisory opinions would partially address their concerns about the guidance that they currently receive from CMS and its contractors. They told us that providers often find it difficult to obtain timely and reliable answers to their questions regarding Medicare from CMS and its claims administration contractors. Most favored the establishment of an advisory opinion process to interpret Medicare regulations, in part because such a process would provide them with accurate, written responses that could offer providers protection from possible adverse actions. At the same time, these groups also generally recognized that a legally binding opinion may not provide an immediate answer. By their nature, advisory opinion processes are not designed to provide requesters with answers within a day or a few weeks. As a result, these groups concurred that, while beneficial, advisory opinions may not address their need to obtain timely responses to their questions. In addition, they noted that improving the clarity and accessibility of other forms of Medicare guidance would remain important to them, regardless of the availability of legally binding advisory opinions.

In commenting on a draft of this report, HHS stated that an enhanced and more formal advisory opinion process for Medicare would not be a successful pursuit at this time. HHS said it would be costly to implement, would not provide quick answers to providers' questions, and would have limited applicability beyond the parties requesting advisory opinions. However, HHS acknowledged that the Medicare program and its implementing regulations are inherently complex and underscored its efforts to improve stakeholders' understanding of the program's complexities.

Background

The process of implementing programs established by federal law often begins with the issuance of rules to guide those who are subject to the law's requirements. The requirements for promulgating rules, set out in the Administrative Procedure Act (APA), usually include the publication of a proposed rule, an opportunity for public comment, and the publication of a final rule after taking into consideration the comments received.[5] Final rules, also referred to as regulations, have the force and effect of law. To explain and clarify the statutory law and implementing regulations, the APA also permits agencies to issue orders, which are the result of an adjudication that resolves a dispute or controversy between the agency and one or more parties. While orders are typically binding only on the parties directly involved, agency officials and program participants often use them for guidance. Because agencies rarely issue regulations or orders that explain every element of the programs they administer, they also produce a wide variety of written guidance, which may include advisory opinions. Although the APA prescribes the process agencies generally must follow to issue rules and orders, it does not prescribe a process for producing advisory opinions. In light of this, agencies generally have discretion in how they can structure their advisory opinion processes, subject to constraints, if any, in other applicable statutes.

[5] 5 U.S.C. § 553 (2000). This process is referred to as informal rulemaking. Agencies are not required to use this process when establishing interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice. In addition, agencies may issue rules without notice and comment when they for good cause find that the process is impracticable, unnecessary, or contrary to the public interest. Also, statutes sometimes require rules to be made "on the record" after the opportunity for an agency hearing. This is referred to as formal rulemaking.

HHS produces written guidance about Medicare in a variety of forms. For example, it issues "rulings" that, according to the agency, provide clarification and interpretation of complex or ambiguous provisions of law or regulations and promote consistency in the interpretation of policy and adjudication of disputes. Although rulings are not issued in response to specific requests, they are binding on CMS and Medicare contractors, among others. In addition, HHS's Medicare Appeals Council (MAC) issues written decisions in disputes over Medicare eligibility and specific Medicare claims.[6] Although MAC is a component of HHS, it functions independently and is not bound by guidance, such as Medicare program instructions or memoranda, issued by CMS. MAC decisions are binding precedent in subsequent disputes and serve as another significant source of Medicare guidance. Furthermore, HHS provides Medicare guidance through reimbursement manuals, program transmittals, coverage determinations, program instructions, CMS publications, program memorandums, fraud alerts, press releases, and other publications.[7] In addition, CMS and its claims administration contractors respond to millions of written and oral questions from providers and beneficiaries annually.

HHS does not issue advisory opinions on the Medicare program except where expressly required by statute.[8] CMS and HHS-OIG have processes that generally focus on two provisions of Medicare law concerning specific

[6] 42 U.S.C. § 1395ff(d)(2) (2000).

[7] Proposed and final rules are published in the *Federal Register* and final rules are incorporated into the *Code of Federal Regulations.* Other forms of HHS written guidance are, for example, posted on the HHS Web site, distributed through mailing lists, or provided only upon request.

[8] Generally, HHS may prescribe statements of policy, interpretative rules, or rules of agency organization, procedure, or practice necessary for the Medicare program. 42 U.S.C. § 1395hh (2000). Experts we consulted, as well as HHS officials, acknowledged that the agency may issue advisory opinions. In 1998, we addressed the potential use of advisory opinions in connection with the False Claims Act and a Medicare rule concerning hospital inpatient costs. We concluded that advisory opinions did not seem necessary or helpful with respect to the False Claims Act generally or the particular rule. B-279893, July 22, 1998.

types of business arrangements.[9] Specifically, HHS-OIG provides advisory opinions in connection with the federal health care antikickback statute,[10] which imposes criminal penalties for knowingly giving, offering, soliciting, or receiving payment for patient referrals, among other things. CMS provides advisory opinions related to the so-called Stark Law,[11] which generally prohibits physicians from referring patients to heath care facilities in which they have a financial interest. Both statutory advisory opinion provisions state that these advisory opinions shall be binding only on the agency and requesting party. The agencies also advise that other parties are not bound by and cannot legally rely on these advisory opinions.

IRS and EBSA differ from CMS and HHS-OIG in the scope, management, and history of their advisory opinion processes. While both CMS and HHS-OIG have developed their advisory opinion processes within the last decade, IRS and EBSA have a long history of providing advisory opinions under their authority to administer federal tax and employee benefits law, respectively. Unlike CMS and HHS-OIG, the processes in IRS and EBSA were initiated by the agencies under their authority to administer laws in these areas rather than in response to specific statutory requirements. IRS established its advisory opinion process in 1953 to answer requests regarding the tax effects of certain acts or transactions.[12] EBSA established its process in 1976 to answer inquiries regarding the Employee Retirement Income Security Act of 1974 (ERISA), which is a federal law governing employee benefit plans.[13] Despite these differences, IRS and EBSA also characterize their advisory opinions as binding on the agency, subject to the agencies' ability to modify or revoke the opinion, as appropriate. The two agencies also advise that the opinions do not apply to other parties and situations.

[9] In addition, HHS-OIG is required to provide advisory opinions on whether an activity or proposed activity could otherwise trigger certain administrative actions, including civil monetary penalties, as well as criminal penalties. 42 U.S.C. § 1320A-7d(b)(2)(D) and (E) (2000).

[10] 42 U.S.C. § 1320a-7d(b) (2000).

[11] 42 U.S.C. § 1395nn(g)(6) (2000).

[12] IRS uses the term letter rulings to describe its advisory opinions.

[13] 29 U.S.C. §§ 1001 et seq. (2000).

Five Key Factors for Establishing an Advisory Opinion Process

The processes at the four agencies we contacted—CMS, HHS-OIG, IRS, and EBSA—reflect common elements that merit consideration when establishing an advisory opinion process. We identified five key factors related to agency planning efforts and allocation of resources that each of the four agencies addressed in establishing its advisory opinion process. These factors are (1) establishing criteria for submitting advisory opinion requests, (2) developing alternative ways to respond to advisory opinion requests, (3) determining the time frame for issuing advisory opinions, (4) considering anticipated workloads, staffing requirements, and user fees, and (5) creating internal review and external coordination procedures. The structures of the legally binding advisory opinion processes at the four agencies, however, reflect differences in their respective constituencies and responsibilities.

Establishing criteria for submitting advisory opinion requests: All four agencies have defined the scope of their processes by identifying criteria for submitting advisory opinion requests. For example, none of these agencies will provide advisory opinions for requests that are based on hypothetical situations.[14] IRS has identified circumstances under which it will not issue an advisory opinion, such as those concerning issues that it finds frivolous or those that it expects will be resolved following the issuance of pending regulations or anticipated guidance. IRS has also identified circumstances under which it will not ordinarily respond to requests, such as those that involve matters already under examination or audit by IRS, or those that involve pending litigation. Generally, EBSA will not provide advisory opinions for requests where all parties involved are insufficiently identified and described, where material facts or details of the transaction are omitted, or where the requester is seeking an opinion on alternative courses of action. Further, EBSA generally only provides advisory opinions for requests on future actions, rather than actions or transactions that have already occurred. HHS-OIG and CMS also have defined submission criteria for their processes. Specifically, they will not provide advisory opinions for requests dealing with general questions of interpretation, or activities in which the requester is not and does not plan to be involved. In addition, HHS-OIG does not issue opinions on matters

[14] ERISA Procedure 76-1 states that EBSA generally does not issue advisory opinions for hypothetical situations.

where the same, or substantially the same, subject matter is or has been the subject of a government proceeding, or if an informed opinion cannot be made, or could be made only after extensive investigation.[15]

Two of the four agencies, IRS and EBSA, whose advisory opinion processes otherwise involve broad areas of law, have identified substantive issues on which they will not provide advisory opinions. IRS has developed extensive "no-rule" lists of certain domestic and international tax law matters on which the agency will not provide advisory opinions, and EBSA has identified sections of ERISA about which it will not ordinarily provide advisory opinions. By contrast, while the statutory requirements for HHS to provide advisory opinions focusing on specific Medicare provisions set out two substantive restrictions,[16] HHS-OIG and CMS have not identified other substantive areas that would eliminate an advisory opinion request from consideration, provided that the subject of the request falls within the scope authorized by statute.

Developing alternative ways of responding to advisory opinion requests: To have efficient advisory opinion processes, the agencies do not automatically provide an advisory opinion for every request received, and may respond through other means. For example, if an agency decides that a request concerns matters that are not complex, it may find it more appropriate to provide a response during a telephone conversation. Although not legally binding, such a response may provide the requester with a satisfactory and timely answer, prompting the withdrawal of the request for an advisory opinion. The agencies told us that they respond in this manner when requests involve relatively straightforward questions that may have already been addressed through earlier guidance. For example, an official at HHS-OIG told us that the agency may respond orally to a hospital's question on whether a hospital that restocks supplies for local ambulances violates the federal health care antikickback statute by providing incentives to the ambulance companies to direct patients to the hospital. In this case, the HHS-OIG official said the agency could direct the requester to existing guidance on the matter. However, should a requester want an advisory opinion after receiving informal guidance, HHS-OIG will issue an opinion, as required.

[15] 42 C.F.R. § 1008.15(c) (2003).

[16] The restrictions prohibit HHS from providing advisory opinions on fair market value or an individual's status as an employee under federal tax law. 42 U.S.C. §§ 1320a-7d(b)(3) and 1395nn(g)(6)(B) (2000).

IRS and EBSA have also established forms of written correspondence in addition to legally binding advisory opinions to respond to individual requesters. Specifically, both agencies provide information letters, which are written statements that call attention to a well-established interpretation or principle of law without applying it to a specific factual situation. The agencies provide such letters in response to requests that they determine do not merit an advisory opinion and could be addressed by supplying the requester with general information. For example, IRS may decide that an advisory opinion request on a certain income tax deduction is best answered through an information letter describing the general requirements for claiming these deductions. Neither agency publishes all of their information letters.

In addition, one agency responds to some requests for advisory opinions by publishing guidance with broad applicability. IRS publishes general guidance, which includes revenue rulings that inform the public about IRS's position on a particular issue to ensure its uniform application of guidance. For example, a revenue ruling might conclude that, given a specific set of facts, taxpayers may be entitled to claim certain income tax credits. IRS also publishes revenue procedures, which consist of official statements of internal practices and procedures, such as filing procedures, which affect the rights and duties of taxpayers. For example, a revenue procedure might describe filing procedures that taxpayers must follow to claim certain income tax deductions and credits. IRS officials said that the agency places a higher priority on issuing more broadly focused guidance, such as revenue rulings, than on other, more narrowly focused forms of guidance such as advisory opinions.

Determining the time frame for issuing advisory opinions: The four agencies varied on how they addressed the issue of a time frame for providing advisory opinions. HHS-OIG is required by law to issue advisory opinions within 60 days.[17] CMS's regulations provide for it to issue opinions within 90 days or, for requests that it determines involve complex legal issues or complicated fact patterns, within a reasonable time.[18] IRS does not have any statutory time frame requirements and has its own deadlines. According to IRS officials, the agency's goal is to complete

[17] 42 U.S.C. § 1320a-7d(b)(5)(B) (2000).

[18] 42 C.F.R. § 411.380(c)(1) (2003). HHS-OIG and CMS begin counting these days only after requests have been "formally accepted." 42 C.F.R. §§ 1008.41(e) and 411.379(b) (2003).

more than half of the requests received within 4 months, and about 90 percent of the requests received within 6 months. EBSA officials estimate that they typically provide advisory opinions within 7 to 9 months after receiving requests. However, EBSA has not established any time frames. The agency prioritizes its responses to requests after considering the significance of the issue addressed by a request and whether it involves a time-critical matter, such as a pending financial transaction.

Agencies have identified concerns associated with establishing time frames for issuing advisory opinions. EBSA officials told us that their agency has not developed time frames for issuing advisory opinions because imposing a deadline creates an artificial requirement that bears no relationship to the nature of the request. EBSA prefers to have flexibility because of the uncertainty of the types and number of requests the agency will receive. Although HHS-OIG is required to respond to requesters within 60 days, an agency official told us that it is sometimes difficult to complete all of the research and other necessary steps within the required time frame because of both the complexity of the issues and the other responsibilities held by lawyers issuing the opinions. However, regulations provide for the suspension of time limits in order to compensate for delays that are not within HHS-OIG's control, such as those associated with obtaining additional information from requesters or expert opinions from external third parties.[19]

Considering anticipated workloads, staffing requirements and user fees: All four agencies addressed staffing issues to make their advisory opinion processes effective. For example, EBSA officials told us that EBSA's process needs to be supported by an adequate number of staff with appropriate backgrounds, such as attorneys and individuals with program expertise. As shown in table 1, agencies vary in the size of their workloads and the number of staff they assign to their advisory opinion processes. In fiscal year 2003, EBSA and HHS-OIG provided 17 and 18 opinions, respectively. In contrast, IRS provided about 3,000 advisory opinions and used about 69 full-time equivalent (FTE) staff to respond to requests. Agencies also differed in the number of opinions issued per FTE. At EBSA and HHS-OIG, 1 FTE staff member was required for every 8 to 9 opinions provided, while IRS needed 1 FTE staff member to process 42 opinions on average. Agency variation in the number of advisory opinions generated by an FTE may reflect differences in case complexity as well as in the

[19] 42 C.F.R. § 1008.43(c)(3) (2003).

proportion of requests that are withdrawn prior to issuance of an opinion. For example, an HHS-OIG official estimated that two-thirds of requests submitted to the agency are withdrawn before an opinion is issued. In some instances, the requesters terminated the process after HHS-OIG staff had performed all of the legal research and analysis necessary to issue the opinions.

Table 1: Advisory Opinion Workload and Staffing Levels at EBSA, HHS-OIG, and IRS in Fiscal Year 2003

Agency	Number of opinions provided	Number of FTE staff	Average number of opinions per FTE
EBSA	17	2	8.5
HHS-OIG	18	2	9
IRS	2,919	69	42

Sources: EBSA, HHS-OIG, and IRS.

Note: We excluded CMS from this analysis because it did not issue any advisory opinions during fiscal year 2003.

Despite differences in workload and productivity, all three agencies employ flexible staffing arrangements to process advisory opinions. For instance, IRS selects staff from a pool of approximately 500 to 600 attorneys who, in addition to processing advisory opinions, also provide other guidance to individual taxpayers. Similarly, HHS-OIG draws from a group of staff who are assigned to respond to requests for advisory opinions in addition to other responsibilities. EBSA staffs its advisory opinion processes by assigning personnel to work on opinions on an as needed basis.[20]

Three of the four agencies we contacted charge a fee to process their advisory opinions. These user fees enable the government to recoup some of its costs. CMS and HHS-OIG charge an initial nonrefundable fee to accept a request for an advisory opinion and impose hourly fees for the time staff spend responding to a request for an opinion. IRS has implemented a fee schedule and charges fees that vary depending on the type of requester. The fee is $6,000 with a reduced fee for qualifying

[20] EBSA assigns staff with legal backgrounds and at least 3 years of relevant experience to work on advisory opinions on a part-time basis.

requesters.[21] Table 2 summarizes the user fees charged by the four agencies in fiscal year 2004.

Table 2: Advisory Opinion User Fees at Four Agencies in Fiscal Year 2004

Agency	User fee	Charges per opinion
CMS	$75 per hour for staff costs, with a $250 nonrefundable deposit required when the request is made	$250[a]
EBSA	Not applicable	No charge
HHS-OIG	$86 per hour for staff costs, with a $250 nonrefundable deposit required when the request is made	Ranged from $301 to $3,784
IRS	$6,000, based on average cost to agency, with special rate for qualifying requesters	$6,000[b]

Sources: Interviews with CMS, EBSA, HHS-OIG, and IRS officials.

[a]In fiscal year 2004, CMS issued four advisory opinions for which it charged $250 for each opinion. CMS anticipates that charges for future advisory opinions could be higher.

[b]Some taxpayers may be eligible for reduced user fees, depending on the issues involved and the taxpayers' specific circumstances.

Although three of the four agencies charge user fees, only IRS has authority to apply those fees to fund its advisory opinion process.[22] However, although CMS and HHS-OIG do not retain the user fees charged, they may have been able to absorb the costs of issuing opinions because they receive relatively few requests per year. According to legal experts we interviewed, the amount of user fees charged, and an agency's ability to use them to offset costs, could be critical to the success of a large advisory opinion process.

Creating internal review and external coordination procedures: In addition to reviewing its response to an advisory opinion request internally, an agency issuing an advisory opinion may also need to coordinate its response with other federal agencies. The agencies said that this is

[21] Some taxpayers may be eligible for reduced user fees, depending on the issues involved and the taxpayers' specific circumstances.

[22] Treasury, Postal Service and General Government Appropriations Act, 1995, Pub. L. No. 103-329, tit. I, § 3, 108 Stat. 2382, 2388. Current law provides that no fee may be charged with respect to requests after December 31, 2004. Act of Oct. 1, 2003, Pub. L. No. 108-89, sec. 202(a), § 7528(c), 117 Stat. 1131, 1133. In general, agencies may impose user fees to offset the government's cost of providing a service. Without specific authorization, however, agencies may not retain or use fees collected, but must deposit them into the U.S. Treasury as required by section 3302 of Title 31 of the United States Code.

particularly important if those entities have a stake in the outcome—for example, if the advisory opinion involves laws affecting another agency. Internal review and external coordination permit other entities to bring their perspectives to the issue and to raise matters that may not have been previously considered.

All four agencies have developed internal review and external coordination procedures for their advisory opinion processes. Both CMS's and HHS-OIG's internal reviews consist of obtaining comments from one another as well as from the HHS Office of the Secretary and the HHS Office of the General Counsel. In addition, their external coordination includes consultation with the Department of Justice.[23] CMS officials said that, in certain cases, there may need to be additional coordination because it has overlapping jurisdictions with other agencies such as HHS's Public Health Service and Indian Health Service, as well as the Department of Veterans Affairs. EBSA's internal review consists of coordination between the office drafting the advisory opinions and the agency's legal counsel. Depending on the issue and whether it may have relevance to other laws, EBSA may also coordinate with IRS, the Pension Benefit Guaranty Corporation, and the Securities and Exchange Commission. In contrast, IRS has a limited internal review process that usually involves the attorney writing the opinion, a reviewing attorney, and the branch chief of the office issuing the opinion. IRS also rarely coordinates with external entities due to significant limitations in IRS's ability to share taxpayer data.

Medicare Providers Consider Advisory Opinions as a Possible Way to Improve Guidance

Representatives of most provider organizations we spoke with told us that providers seeking clarification of Medicare rules and procedures often find it difficult to obtain reliable or timely written responses to their inquiries. As a result, most of these organizations viewed the establishment of an advisory opinion process to interpret Medicare regulations positively, particularly if the opinions were legally binding. However, representatives for some organizations told us that an advisory opinion process is only one way to address their concerns; improving existing CMS and contractors' guidance was also viewed as important. In addition, some recognized that advisory opinions may not always be appropriate, given that questions related to Medicare regulations may sometimes require a quick response—something that an advisory opinion process may be unable to provide.

[23] With respect to its advisory opinions, HHS-OIG is required to consult with the Department of Justice. 42 U.S.C. § 1320a-7d(b)(1) (2000).

Medicare Providers Are Concerned about Unreliable and Untimely Answers to Their Questions from CMS and its Contractors

Officials from most provider organizations we contacted[24] told us that providers are concerned that they often do not receive reliable or timely responses to their questions. They said that Medicare providers frequently have questions about a variety of issues related to Medicare regulations, including matters relating to billing, coverage of services, medical necessity, and beneficiary eligibility, particularly if a beneficiary is eligible for both Medicare and Medicaid.[25] However, half said that they have difficulty obtaining the necessary clarification. For example, some told us that the claims administration contractors—who are generally the first point of contact for providers with questions—often respond to identical questions from providers with substantially different answers. In addition, about half of the provider organizations we contacted said that providers cannot rely on CMS to respond to their questions in a timely manner, particularly in writing. For example, representatives of one provider organization told us that they have been trying for about a year to obtain guidance from CMS concerning whether physicians in a state that has reduced its Medicaid benefits can bill beneficiaries who are eligible for both Medicare and Medicaid, to compensate for this reduction, without violating federal law. Similarly, officials at the hospital we visited told us that it took CMS about 6 months to reply to the hospital's inquiry about the findings of a recently completed audit by the hospital's claims administration contractor. The audit determined that procedures that the hospital had followed for 12 years—at the instruction of its contractor—were now considered by the contractor to be in violation of Medicare regulations. The hospital requested CMS to clarify whether it would be held liable for its past practices and how it should respond to the contractor's audit findings. We have also recently reported on shortcomings in the way CMS and its contractors communicate with providers. Specifically, we identified problems in both the accuracy and timeliness of CMS's written guidance and in its oral responses to providers who contact call centers operated by contractors with billing-related and other types of policy-oriented questions.[26]

[24] We spoke to representatives of organizations representing providers, suppliers, and billing companies as well as officials from one hospital. For convenience, we have used the term provider organizations to refer to these entities collectively.

[25] Medicaid is a jointly funded federal and state program that provides health care coverage for certain individuals and families who meet eligibility criteria. 42 U.S.C. §§ 1396 et. seq. (2000). Medicaid is the largest source of funding for medical and health-related services for people with limited income.

CMS officials acknowledged that because the agency receives thousands of inquiries every year, it is sometimes difficult to respond to all of them in a timely manner. The time it takes the agency to answer can vary based on the nature of the inquiry and the type of reply that is necessary. While basic or routine questions may receive a relatively quick response, more involved and complex questions, such as the one presented by the hospital, require extensive research and internal review, which could delay the agency's response. CMS has taken steps in recent years to improve communications with providers. For example, it has held town hall meetings on new initiatives and developed provider-specific Web pages and listservs. In response to our recommendations to improve the accuracy of information given to providers from call centers operated by contractors, CMS has agreed to create a process to routinely screen, triage, and route provider calls to specialty staff by fiscal year 2005.

Medicare Providers View Advisory Opinions as One of Several Approaches to Enhance Guidance

Overall, representatives from most of the provider organizations we spoke with agreed that an advisory opinion process would partially address their concerns about the guidance that they currently receive from CMS and its contractors. Specifically, most said that such a process would provide them with useful answers that they could rely on to appropriately interpret Medicare regulations. Their reasons included that such a process would establish a central place to submit questions and that they would feel more confident about the accuracy of responses received because an advisory opinion process would, presumably, involve extensive legal research. In addition, written documentation that such a process would provide could later help to protect them from adverse actions if it is subsequently determined that they billed incorrectly or are otherwise found to be noncompliant with program rules. However, representatives recognized that while an advisory opinion process guarantees a response to an inquiry, it may not address providers' need for quick answers. Some said that providers generally seek relatively rapid responses to their questions on Medicare regulations—for example, they told us that for billing questions, providers often need responses within 24 hours. However, CMS officials said that short time frames may be unrealistic because of the extensive research necessary to prepare an advisory opinion.

[26] GAO, *Medicare: Communications with Physicians Can Be Improved*, GAO-02-249 (Washington, D.C.: Feb. 27, 2002) and *Medicare: Call Centers Need to Improve Responses to Policy-Oriented Questions from Providers*, GAO-04-669 (Washington, D.C.: July 16, 2004).

Providers' representatives also noted additional benefits that can be associated with the advisory opinion process. For example, even though these opinions may only be binding to the requesters, if published, they could also provide instructive guidance to the provider community at large. However, 8 of the 12 provider organizations we contacted suggested that, to maximize the usefulness of an advisory opinion process, the process should be structured to also permit an advisory opinion to be applied to similarly situated parties with similar questions, instead of just a single requester. One added that, unlike HHS-OIG's process, which often requires requesters to provide proprietary information that could alert their competitors to their business plans, advisory opinion requests on Medicare regulations are more likely to involve day-to-day activities that are common to many providers. Along the same lines, three organizations suggested that an advisory opinion process also be open to entities representing providers, so that they could submit questions on behalf of larger constituencies. Even though it might not be possible for more broadly applicable advisory opinions to be legally binding, representatives of some provider organizations indicated that such an approach would make the process more efficient and responsive to those participating in Medicare.

Representatives of provider organizations told us that an advisory opinion process should not be used in place of, or precede other efforts, to improve the communication of guidance. They stressed that clarifying existing guidance to address common provider questions is important. They also told us that receipt of reliable and timely written responses to their questions would go far to reduce their interest in an advisory opinion process. While such responses may not carry as much weight as advisory opinions, these representatives said that they would help providers better understand regulations.

Representatives from one provider organization we contacted were opposed to instituting an advisory opinion process because they said such a process might disrupt the effective dialogue that the organization has established with CMS in recent years. Specifically, they were concerned that an advisory opinion process may prevent them from obtaining more informal and timely guidance from the agency on an as needed basis. In addition, officials from a beneficiary advocacy organization expressed concern that an advisory opinion process could negatively affect beneficiaries. Anticipating that providers would be the primary users of an advisory opinion process, this organization was concerned that beneficiaries' interests would not be fully represented.

Concluding Observations

The Medicare program and its implementing regulations are inherently complex. It is critical that Medicare providers receive correct and complete answers to their questions about program rules. An advisory opinion process to interpret Medicare regulations could provide an avenue for providers to receive this information in the form of legally binding answers to complicated questions about their unique circumstances. Although providers have expressed concern about the lack of timeliness of CMS's responses to their questions, it would be unreasonable to expect that advisory opinions could be issued in a matter of a few days or even a few weeks, given the complexity of the questions and the significance of obtaining legally binding responses. However, it is important that the establishment of such a process not preclude CMS or its contractors from responding promptly to providers with relatively straightforward questions that do not necessitate an advisory opinion. If established, an advisory opinion process to interpret Medicare regulations should not serve as a substitute for enhancing existing forms of CMS guidance. In addition, the lessons learned by other federal agencies may be useful in structuring a process for Medicare.

Agency Comments

In written comments on a draft of this report, HHS stated that an enhanced and more formal advisory opinion process for the Medicare program would not be a successful pursuit at this time. Specifically, HHS said such an effort would be costly to implement and noted that fees collected for its advisory opinions are not paid to or retained by HHS, and thus do not offset the costs of the staff time allocated to this work. Further, HHS said that such a process would not provide quick answers to providers' questions, and would have limited applicability beyond the parties requesting advisory opinions. However, HHS acknowledged that the Medicare program and its implementing regulations are inherently complex and underscored its efforts to improve stakeholders' understanding of the program's complexities. HHS also provided us with technical comments, which we incorporated as appropriate. We have reprinted HHS's letter in appendix II.

We also provided excerpts of the draft to EBSA and IRS. The excerpt that each agency received consisted only of statements pertaining to its respective advisory opinion processes. We received technical comments from both agencies, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services, the Administrator of CMS, and other interested parties. We will also make copies available to others upon request. In addition, this report will be available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please call me at (312) 220-7600. An additional GAO contact and other staff members who made major contributions to this report are listed in appendix III.

Leslie G. Aronovitz
Director, Health Care—Program
Administration and Integrity Issues

Medicare Stakeholders Contacted

American Ambulance Association
American Association of Family Physicians
American Association of Home Care
American College of Physicians—American Society of Internal Medicine
American Health Information Management Association
American Hospital Association
American Medical Association
Center for Medicare Advocacy
HCPro
Health Care Billing Managers Association
Medical Group Management Association
Medicare Rights Center
National Association of Home Care
National Association of State Medicaid Directors
Northwestern Memorial Hospital

Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Washington, D.C. 20201

NOV 22 2004

Ms. Leslie G. Aronovitz
Director, Health Care—Program
Administration and Integrity Issues
United States Government Accountability Office
Washington, D.C. 20548

Dear Ms. Aronovitz:

Enclosed are the Department's comments on your draft report entitled, "Medicare—Advisory Opinions As A Means of Clarifying Program Requirements" (GAO-05-129). The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department provided several technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

Daniel R. Levinson

Daniel R. Levinson
Acting Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for Government Accountability Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

COMMENTS BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED "MEDICARE: ADVISORY OPINIONS AS A MEANS OF CLARIFYING PROGRAM REQUIREMENTS (GAO-05-129)

The HHS appreciates the opportunity to review and comment on GAO's draft report. We appreciate GAO's efforts to assess the role that a broader advisory opinion process might play in clarifying Medicare regulations.

In its concluding observations on page 21, the draft observes that the Medicare program and its implementing regulations are "inherently complex," and we agree. We do currently engage in numerous efforts to assist stakeholders' understanding of the program's complexities, the most important of which are described below. Included among these efforts are targeted advisory opinion processes conducted by our Office of Inspector General (OIG) and also within our Office of General Counsel. As the draft also acknowledges, however, advisory opinion processes are limited in their ability to provide quick answers to pressing problems. We agree.

We believe that an enhanced and more formal process of developing advisory opinions would not be a successful pursuit at this time. We believe such a process would be costly and just as slow as the current processes, which have been streamlined to the extent possible, given the large volume of pertinent guidance, which is constantly (and necessarily) in flux. Given the complexity and broad scope of the Medicare program, an enhanced effort to provide advisory opinions would require a far larger professional staff than is available under current resource constraints. It is also important to note that current HHS opinions specifically state that they are limited in scope to the specific arrangement described in the request and have "no applicability to other arrangements, even those which appear similar in nature or scope" and "may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion." We believe that the usefulness of a broader set of opinions would be similarly constrained.

Additionally, the GAO draft states that the presence of user fees is among the critical factors in making currently operational advisory-opinion processes effective. It is important to note that fees collected for our advisory opinions are not paid to or retained by HHS, and thus do not offset the costs of the staff time allocated to this work.

We cite the following as important existing sources of the guidance needed by Medicare stakeholders:

- The Center for Medicare and Medicaid Services (CMS)'s customized provider web pages allow physicians, hospitals, ambulances, and other providers quick access to relevant Medicare information. These web pages, found on ***www.cms.hhs.gov/providers***, have associated Listservs that ensure providers will get new information as it becomes available.

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- CMS has a Medicare Coverage Database on the CMS website, ***www.cms.hhs.gov***, that contains all national and local coverage policy and articles produced by contractors that provide additional coverage guidance. CMS has also implemented a new web page, allowing for easier provider and public access to recent Administrator decisions regarding the Provider Reimbursement Review Board and issued by the Office of the Attorney Advisor.

- CMS publishes a *Quarterly Provider Update* on the first business day of each quarter on the CMS web site to inform the public about regulations and major policies currently under development during this quarter; regulations and major policies completed or cancelled; and new/revised manual instructions. This Update, makes it easier for providers, suppliers, and the general public to be aware of impending program changes.

- In fiscal year 2004, CMS implemented an On-Line Manual System, located at ***www.cms.hhs.gov/manuals***, to consolidate and update its manuals, policy and billing instructions, eliminate duplicate policy across manuals, and establish a single source to obtain information on the Medicare and Medicaid programs. Additionally, a related Monthly Bulletin is communicated to Medicare Contractors via email and is posted on the CMS On-Line Manual System.

- In 2001, CMS began an initiative to improve provider communications when the agency required contractors to institute toll-free phone service to answer inquiries from providers who bill for services under fee-for-service Medicare. CMS also now issues nationally consistent provider education materials to accompany contractor instructions that implement new or revised policy. "Medlearn Matters…Information for Medicare Providers" contains educational articles, written in consultation with clinicians, billing experts, and other medical professionals, and tailored in content and language to the specific provider types who are affected by the program change. These articles explain in plain English content of the program instructions, and, more importantly, the specific impact that the change has on the affected providers. The articles are housed in one central, easily accessible location (***www.cms.hhs.gov/medlearn/matters)***.

- CMS has held fourteen individual Open Door Forums and town hall meetings for physicians to discuss new initiatives. CMS has also established a provider partnership network with provider associations and organizations, whereby providers give input on products and CMS information tools, and assist in the dissemination of CMS information.

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GAO Contact and Staff Acknowledgments

GAO Contact

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