DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 411

[HCFA–1902–IFC]

RIN: 0938–AI38

Medicare Program; Physicians' Referrals; Issuance of Advisory Opinions

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period incorporates into HCFA's regulations the provisions of section 1877(g)(6) of the Social Security Act (the Act), as added by section 4314 of the Balanced Budget Act of 1997. Section 1877(g)(6) requires that the Secretary issue written advisory opinions to outside parties concerning whether the referral of a Medicare patient by a physician for certain designated health services (other than clinical laboratory services) is prohibited under the physician referral provisions in section 1877 of the Act. Section 1877 not only prohibits certain referrals under the Medicare program, but also affects Federal financial participation payments to States under the Medicaid program for medical assistance consisting of designated health services furnished as the result of certain physician referrals. This final rule sets forth the specific procedures HCFA will use to issue advisory opinions.

EFFECTIVE DATES: The regulations are effective January 9, 1998.

Comment Date: Comments will be considered if we receive them at the appropriate address as provided below, no later than 5 p.m on March 10, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1902–IFC, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments may also be submitted electronically to the following e-mail address: hcfa1902ifc.hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1902–IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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FOR FURTHER INFORMATION CONTACT: Joanne Sinsheimer (410) 786–4620.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative history of section 1877

Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (OBRA'89), Public Law 101–239, enacted on December 19, 1989, added section 1877 to the Social Security Act (the Act). (Unless we indicate otherwise, all references in this document to sections of the law are references to the Act.) In general, section 1877 as it read under OBRA'89 provided that, if a physician (or an immediate family member of a physician) had a financial relationship with a clinical laboratory, that physician could not make a referral to the laboratory for the furnishing of clinical laboratory services for which Medicare might otherwise pay. It also provided that the laboratory could not present or cause to be presented a Medicare claim or bill to any individual, third party payer, or other entity for clinical laboratory services furnished under the prohibited referral. Additionally, it required a refund of any amount collected from an individual as the result of billing for an item or service furnished under a prohibited referral. These provisions were effective for referrals made on or after January 1, 1992.

The statute defined ''financial relationship'' as an ownership or investment interest in the entity providing clinical laboratory services or a compensation arrangement between the physician (or immediate family member) and the entity. The statute provided a number of exceptions to the prohibition. Some of these exceptions applied to both ownership/investment interests and compensation arrangements, while other exceptions applied to only one or the other of these. Additionally, the statute imposed reporting requirements relating to a physician's (or family member's) financial relationships and provided for sanctions.

Section 4207(e) of the Omnibus Budget Reconciliation Act of 1990 (OBRA'90), Public Law 101–508, enacted on November 5, 1990, amended certain provisions of section 1877 to clarify the definitions in section 1877(h), alter the reporting requirements, and to provide an additional exception to the prohibition.

Section 1877 was extensively revised by section 13562 of the Omnibus Budget Reconciliation Act of 1993 (OBRA'93, Public Law 103–66, enacted on August 10, 1993). It modified the prior law to apply to referrals for ten ''designated health services'' in addition to clinical

laboratory services, modified some exceptions, and added new ones. Some of the amendments were retroactively effective to January 1, 1992, while others (such as the expansion to the additional designated health services) did not become effective until January 1, 1995. Section 152 of the Social Security Act Amendments of 1994 (SSA'94), Public Law 103–432, enacted on October 31, 1994, amended the list of designated services, effective January 1, 1995. It also changed the reporting requirements in section 1877(f) and amended some of the effective dates of the OBRA'93 provisions. The amended list of designated health services includes:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

Section 13624 of OBRA'93 extended aspects of the referral prohibition to the Medicaid program, adding a new paragraph (s) to section 1903 of the Social Security Act. This provision denies Federal financial participation (FFP) payment under the Medicaid program to a State for certain expenditures for designated health services. A State cannot receive FFP for designated health services furnished to an individual on the basis of a physician referral that would result in a denial of payment under the Medicare program if Medicare covered the services to the same extent and under the same terms and conditions as under the State Medicaid plan. Section 13624 also specified that the reporting requirements in section 1877(f) and the civil money penalty provision in section 1877(g)(5) (which relates to reporting) apply to a provider of a designated health service for which payment may be made under Medicaid in the same manner as they apply to a provider of a designated health service for which payment may be made under Medicare. Section 1903(s) applies to a physician's referrals made on or after December 31, 1994.

B. Regulations relating to section 1877

On March 11, 1992, we published a proposed rule (57 FR 8588) setting forth the self-referral prohibition and exceptions to the prohibition in section 1877, as enacted by OBRA' 89 and amended by OBRA '90, relating to a physician's referrals for clinical laboratory services.

On August 14, 1995, we published, at 60 FR 41914, a final rule with comment period that incorporated into the Medicare regulations the provisions of section 1877 that relate to the prohibition on physician referrals for clinical laboratory services. The August 1995 final rule contains revisions to the March 11, 1992, proposal based on comments submitted by the public. Further, it incorporates the amendments and exceptions created by OBRA '93 and the amendments in SSA '94 that relate to referrals for clinical laboratory services. It addresses only those changes that had a retroactive effective date of January 1, 1992; it does not incorporate those modifications to section 1877 that became effective for referrals made on or after January 1, 1995. (Even though the August 1995 final rule incorporates OBRA '93 and SSA '94 provisions, it generally only reiterates them without interpreting them. We interpreted the new provisions only in a few instances in which it was necessary to do so in order to implement the statute at all.)

We are publishing elsewhere in this same issue of the **Federal Register** a proposed rule that interprets the OBRA'93 and SSA '94 provisions described above and incorporates and interprets the provisions of section 1877 that became effective on January 1, 1995, and concern the other designated health services. This proposed rule also addresses the application of sections 1877 and 1903(s) to the Medicaid program.

C. Advisory Opinions: Section 4314 of Public Law 105–33

Section 4314 of the Balanced Budget Act of 1997, Public Law 105–33, enacted on August 5, 1997, added section 1877(g)(6) to the Act. This provision requires that the Department provide additional formal guidance to outside parties regarding the application of the physician referral statute.

Section 1877(g)(6)(A) requires that the Secretary issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under the provisions in section 1877. This paragraph states that each advisory opinion issued by the Secretary will be binding on the Secretary and the party or parties who requested the opinion.

Section 1877(g)(6)(B) requires the Secretary, in issuing physician referral advisory opinions, to apply the rules in paragraphs (b)(3) and (4) of section 1128D of the Act, to the extent practicable. Section 1128D was added to the Act by section 205 of the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, effective August 21, 1996. It requires the Secretary, in consultation with the Attorney General, to issue written advisory opinions to particular parties on certain specified matters involved in applying the anti-kickback statute in section 1128B(b) of the Act, the safe harbor provisions in 42 CFR 1001.952, as well as other health care fraud and abuse sanctions handled by the Office of Inspector General (OIG).

Section 1128D(b)(3)(A) prohibits the OIG in its advisory opinions from addressing whether fair market value will be or was paid or received for any goods, services, or property. Section 1128D(b)(3)(B) prohibits the OIG from addressing whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986. As noted above, HCFA is required to apply these provisions ''to the extent practicable.'' We are incorporating these provisions in their entirety into our own advisory opinion rules.

Section 1128D(b)(4)(A) states that the OIG advisory opinions are binding on the Secretary and the party or parties requesting the opinion. Section 1128D(b)(4)(B) provides that if a party fails to seek an advisory opinion, this fact may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A, or 1128B. We are also required to apply these provisions ''to the extent practicable.'' We are incorporating section 1128D(b)(4)(B) in its entirety. However, we are not incorporating section 1128D(b)(4)(A) because we believe that it is redundant with our own advisory authority in section 1877(g)(6)(A). This provision states that each advisory opinion issued by the Secretary will be binding on the Secretary and on the party or parties requesting the opinion.

Section 1877(g)(6)(B) also requires us to take into account the regulations promulgated by the OIG to cover advisory opinions, issued by the OIG under the authority of section 1128D(b)(5). We believe that ''take into account'' means that we should use the OIG regulations as our model, but that we are not bound to follow them. We have attempted to follow the OIG

regulations as closely as possible in each instance in which we believed that it was reasonable to do so.

Section 1128D(b)(5)(A) states that the OIG's regulations must provide for—

- The procedure to be followed by a party applying for an advisory opinion;
- The procedure to be followed by the Secretary in responding to a request for an advisory opinion;
- The interval in which the Secretary will respond;
- The reasonable fee to be charged to the party requesting an advisory opinion; and
- The manner in which advisory opinions will be made available to the public.

Under section 1128D(b)(5)(B), the OIG is required to issue an advisory opinion to a party by not later than 60 days after receiving the request for the opinion and to charge the requesting party a fee that is equal to the costs the Secretary incurs in responding to the request.

The OIG's procedures for advisory opinions are set forth in 42 CFR part 1008. They were published as an interim final rule with comment period on February 19, 1997 (62 FR 7350). In section III. of this preamble, we discuss each of the elements required by section 1128D(b)(5)(A) (for the OIG's regulations). Many of our procedures are based on those articulated in the OIG regulations.

II. Provisions of the Interim Final Rule with Comment Period

A. Overview of the advisory opinion requirement

This interim final rule with comment period creates regulations at sections 411.370 through 411.389 that establish procedures for the advisory opinions described in section 1877(g)(6). These advisory opinions will provide the public with meaningful advice regarding whether, based on specific facts, a physician's referrals for a designated health service (other than a clinical laboratory service) are prohibited by the referral provisions in section 1877. The advisory opinion process will be meaningful to any parties who are interested in learning whether a particular business arrangement involving a physician (or a physician's immediate family member) will result in the physician being prohibited from making certain referrals under the Medicare program. This process also could prove significant to parties who are interested in the status of a physician's referrals under the Medicaid program. That is because the FFP provision in section 1903(s) of the Act depends upon whether a physician's referrals would be prohibited under the Medicare rules if the Medicare program covered a designated health service in the same manner as it is covered under the State Medicaid plan.

In an advisory opinion, we will restate the material facts known to us, present our analysis, and provide conclusions about how we believe the law applies to the facts presented. We will base our analysis on our interpretation of the provisions in section 1877.

Section 1877(g)(6) requires advisory opinions only on the issue of whether a referral relating to designated health services (other than clinical laboratory services) is a prohibited referral under section 1877. If a physician has an unexcepted financial relationship with an entity, as defined by the statute and our regulations, then that physician's referrals for designated health services for a Medicare patient would be prohibited, regardless of the intent of any of the parties involved in the arrangement. Thus, our advisory opinions will be fact-based, and will contain no discussions about what we believe the parties knew when they entered into the arrangement or what they may have intended.

While section 1877 is primarily a payment ban that is effective regardless of the intent of the parties involved, there are additional sanctions under section 1877(g)(3) and (g)(4) that include elements of knowledge or intent. Section 1877(g)(4), in fact, imposes a penalty for certain referrals that might not otherwise be prohibited, if the parties involved in an arrangement have a particular purpose in mind. This provision applies to any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) that the physician or entity knows or should know has a principal purpose of ensuring referrals by the physician to a particular entity that, if the physician directly made referrals to that entity, would be in violation of section 1877. Sanctions under this provision include potentially significant civil money penalties and possible exclusion from the Medicare and other health care programs.

We do not believe that section 1877(g)(6) requires us to express any opinion about what the parties to an arrangement knew or intended, for purposes of any of the sanctions in section 1877(g) (3) and (4). Even if we wished to comment on any intent-based aspect of the referral provisions, we believe that it is not practical for us to make an independent determination of the subjective intent of the parties based only upon written materials that have been submitted by the requestor. While we expect requestors to submit complete written descriptions of their arrangements and transactions, along with relevant portions of documents, these materials do not afford a satisfactory basis upon which we could make a reliable determination of subjective intent.

Section 1877(g)(6)(A) states that an advisory opinion shall be binding on the Secretary and on the party or parties requesting an opinion. It is also our view that an advisory opinion may legally be relied upon only by the requestors.

We believe that advisory opinions are capable of being misused by persons *not* a party to the transaction in question in order to inappropriately escape liability. Advisory opinions are intended only to address the facts of a particular arrangement. A third party may implement an arrangement that appears similar to the arrangement described in the advisory opinion, but the third party may introduce *additional* factors that may make a difference in the outcome of an advisory opinion.

As set forth below, this interim final rule with comment period has been developed primarily to address the following issues:

- The procedure to be followed by a party applying for an advisory opinion.
- The procedure we will follow in responding to a request.
- The interval within in which we will respond to a request for an advisory opinion.
- The reasonable fee we will charge to the party requesting an advisory opinion.
- The manner in which we will make advisory opinions available to the public.

This final rule with comment period does not address the substance or the content of advisory opinions issued by us.

B. Responsibilities of outside parties seeking advisory opinions

1. Who can request an advisory opinion

Any individual or entity may submit a request to us for a written advisory opinion about whether a physician's referral relating to a designated health service, other than a clinical laboratory service, is prohibited under section 1877. We anticipate that most requests will involve financial relationships that involve health care business arrangements. Therefore, for purposes of this discussion, we will generally use the term ''arrangement'' to refer to the factual circumstances that are involved

in a request for an advisory opinion, even though some requests might involve facts that are not related to a business arrangement.

As indicated above, the advisory opinion process is designed to provide authoritative guidance to participants in particular arrangements. Therefore, the arrangement in question must either be in existence at the time of the request for an advisory opinion or, with respect to prospective arrangements, there must be a good faith intention to enter into the described arrangement in the near future. (With respect to prospective conduct, we are stating that the requestor can declare the intention to enter into the arrangement contingent upon receiving a favorable advisory opinion from us or from both us and the OIG.)

Requestors who are not individuals are required to disclose certain ownership information, so that we can check to ensure that the matter which is the subject of the advisory opinion request is not under current investigation. We are also requiring that requestors inform us, to the best of their knowledge, about whether the arrangement involved in the request is the subject of any current investigations.

2. Matters not subject to an advisory opinion

As explained above, even if a party requests it, we will not address the issue of whether fair market value was, or will be, paid or received for any goods, services, or property or the issue of whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

In addition, we do not believe that it is appropriate to provide advisory opinions to persons *not* involved in the arrangement in question. For example, we believe that a description of a competitor's arrangement is not the proper subject of an advisory opinion since the participants to the particular transaction would not be involved in the request. A party to an actual arrangement—either existing or about to be entered into—is in a position to provide full and complete information regarding the facts in question. By contrast, third parties are not in a position to provide a reliable statement about the facts of a particular arrangement in which the third party is not a participant. In addition, it is unclear who would be bound by an advisory opinion on an arrangement that does not involve the requestor.

Similarly, we do not believe it is appropriate to provide advisory opinions on hypothetical or generalized arrangements. Section 1877(g)(6) requires the Secretary to issue advisory opinions concerning ''whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section.'' (Emphasis added.) We interpret this provision to mean a specific referral involving a physician in a specific situation. We also believe there are reasons to avoid opinions on generalized arrangements. Because of the complexity of the business arrangements that exist in today's health care community, physician referral cases are not likely to be the same in all material respects. The introduction by a party of any *additional* factors could make a material difference in the resulting opinion. We believe it would not be possible for an advisory opinion to reliably identify all the possible hypothetical factors that might lead to different results.

3. Initiating the process for an advisory opinion

A requestor must submit a written request for an advisory opinion in order to initiate the process. The request must clearly and thoroughly present a complete description of the situation that is the subject of the advisory opinion. The request should include all facts that would be relevant in determining whether a particular situation could result in a physician's referrals being prohibited under section 1877. To the extent that the request provides the necessary information in a clear and orderly manner, we will be better able to process it.

We are requiring any submission to include copies of all relevant documents or relevant portions of documents, such as financial statements, contracts, leases, employment agreements and court documents (requestors may withhold irrelevant portions), as well as descriptions of any other arrangements or relationships that may affect the documents or our analysis. In addition, the submission should include a narrative description of the arrangement. In making the request, a requestor must include the identities (including names and addresses) of the requestor and all other actual and potential parties to the arrangement, to the extent known to the requestor. In addition, the request must include the Taxpayer Identification Number (TIN) of the requestor. The Debt Collection Improvement Act of 1996 (section 31001 of Public Law 104–134) requires agencies to collect the TIN from all persons or businesses ''doing business with a Federal agency.'' (See 31 U.S.C. 7701(c).) We believe that requesting, receiving, and paying for our work on an advisory opinion fits into the category of ''doing business with a Federal agency.'' Therefore, a request for an advisory opinion must include the TIN of the requestor. The TIN will be used for purposes of collecting and reporting on any delinquent amounts arising out of the requestor's failure to render proper payment for the advisory opinion. In addition to the above information, we are also requiring the requestor to identify a designated contact person who will be available to communicate with us.

We are also requiring that requestors make two certifications as part of their request for an advisory opinion. If the requestor is an individual, the individual must sign the certification; if the requestor is a corporation, it must be signed by the Chief Executive Officer, or a comparable officer; if the requestor is a partnership, it must be signed by a managing partner; and, if the requestor is a limited liability company, the certification must be signed by a managing member. The responsible individual must certify that all of the information provided as part of the request is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is being sought, to the best of the requestor's knowledge. If the request relates to prospective conduct, the regulations state that the request must also include a certification that the requestor intends in good faith to enter into the arrangement described in the request. A requestor may make this certification contingent upon receiving a favorable advisory opinion from us or from both us and the OIG.

While all submissions should include the above categories of information, we cannot in these interim final regulations provide complete details on exactly what information a requestor must provide. We anticipate that we will receive requests that involve a wide variety of business arrangements, some of which may be quite complex. At a minimum, any request must describe the entities and parties involved in an arrangement, the specific terms of the arrangement, and the direct or indirect relationship between the physician (or a physician's immediate relative) and any entity that furnishes designated health services. Requestors should also include any information they believe demonstrates that the arrangement meets one of the exceptions to the referral prohibition.

We are soliciting public comment and input on any other types of information that a requestor should routinely provide and intend to address this point

further in any revised final rulemaking. In the interim, prior to submitting a request for an advisory opinion, *we strongly advise* that a requestor contact us to inquire about the information HCFA will need to process a request of the type the requestor intends to submit. Inquiries can be made by telephoning Joanne Sinsheimer at (410) 786–4620. We may, depending on the subject matter of the inquiry, informally provide parties with preliminary questions to help them structure their requests. Our goal is to help ensure that the requests include the factual information we will need to respond to them. Requestors should (but are not required to) answer these questions in their requests for an advisory opinion. If the information we need is in the first submission, we will be better able to render a prompt, concise, and appropriate advisory opinion. We welcome comments on this approach.

The regulation also requires that a requestor inform us about whether the parties involved in the request have also asked for or are planning to ask for an advisory opinion on the arrangement in question from the OIG under section 1128D(b) of the Act. We plan to routinely exchange information with the OIG on requests that we receive and on our intended responses. We plan, in particular, to establish a system that will help guarantee adequate coordination when parties have asked for opinions from both us and the OIG.

4. Fees charged to requesting parties

There is no express authority for us to charge a user fee to individuals who request an advisory opinion under section 4314 of the Balanced Budget Act of 1997. However, in the absence of express authority for this particular purpose, we can rely on the authority for collecting such a fee provided by the Independent Offices Appropriations Act of 1952 (IOAA), 31 U.S.C. 9701. That statute generally governs Federal agencies' imposition and collection of user fees. In § 9701(a), the Congress expressed its intent that each service or thing of value provided by a Government agency to a person is to be self-sustaining to the extent possible. Section 9701(b) authorizes agencies to prescribe regulations establishing the fee for a service or thing of value provided by the agency. The fee must be ''fair'' and based on the cost to the government of providing the service or thing, the value of the service or thing to the recipient, public policy or interest served, and other relevant facts. 31 U.S.C. 9701(b).

In 1974, the Supreme Court ruled that the user fee statute must be read narrowly as authorizing not a ''tax'' (which may be levied only by Congress and need not relate to benefits bestowed on the taxpayer), but a ''fee'' for a particular benefit. *National Cable Television Ass'n, Inc.* v. *United States,* 415 U.S. 336 (1974)(FCC had authority to impose fees; costs that inure to the public's benefit should not be included in the fee imposed). In a companion case, *Federal Power Commission* v. *New England Power Company,* 415 U.S. 345 (1974), the Court opined that the Office of Management and Budget (OMB) had properly construed the user fee statute in a 1959 circular, which stated that a reasonable charge ''should be made to each identifiable recipient for a measurable unit or amount of government service or property from which he derives a special benefit.'' *Id.* at 349. The OMB Circular A–25 was revised in 1993, and currently provides under the heading ''General policy'' that a user charge ''will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.'' 58 FR 38142, 38144. The language of currently applicable OMB guidance to agencies about when a ''special benefit'' will be considered to accrue for purposes of imposing a charge is virtually identical to that cited by the Court with approval. *Id.* at 349, fn. 3.

More recent appellate court decisions addressing agencies' authority to impose user fees similarly examine the extent to which there is a ''*specific* service that confers a *special* private benefit on an *identifiable* beneficiary.'' *Seafarers Int'l Union of N. Am.* v. *Coast Guard,* 81 F.3d 179, 184 (D.C. Cir. 1996) (emphasis in original). *See, also, Engine Mfrs. Ass'n* v. *EPA,* 20 F.2d 1177 (D.C. Cir. 1994) and *Central & Southern Motor Freight Tariff Ass'n* v. *United States,* 777 F.2d 722 (D.C. Cir. 1985). We believe that the advisory opinions we must provide under section 4314 fall squarely into this category. That is, they are an ''extra'' service that an interested party can request from the Secretary, they relate to the party's own, unique situation, and they are binding on the Secretary and the requesting party alone, with no general application.

Section 411.372(b)(9) requires that a requestor make payment for an advisory opinion directly to us. We believe that HCFA has the authority to both collect and retain the fees. Annual appropriations acts have since 1996 authorized our retention of otherwise authorized user fees, and this authority would apply to all user fees we are authorized to collect. The retention language appears in the most recent appropriations act, enacted on November 13, 1997, Public Law 105–78, in the paragraphs covering appropriations for our program management. This language states that, in carrying out titles XVIII and XIX of the Act, the Secretary is authorized to use a specific amount of money that will be transferred from the Federal Hospital Insurance and the Federal Supplementary Medical Insurance Trust Funds, together with ''such sums as may be collected from authorized user fees and the sale of data, which shall remain available until expended, * * *.''

Since section 1877(g)(6) of the Act requires that we take into account the OIG regulations implementing section 1128D(b)(5), we have modeled our user fee on the fee that appears in those regulations. Under section 1128D(b)(5)(A)(iv), the OIG regulations must provide for a ''reasonable fee'' to be charged to the party requesting an advisory opinion. Section 1128D(b)(5)(B)(ii) requires that requestors be charged a fee equal to the costs incurred by the Department in responding to the request.

We have adopted the ''actual cost'' fee from the OIG regulations. Section 411.375(b) of our regulations indicates that in determining the actual costs, we will factor in the salary, benefits, and overhead costs of policy analysts, attorneys, and others who may work on analyzing requests and writing advisory opinions, including administrative and supervisory support for these individuals. Because we expect that requests may range widely in their complexity, we do not believe it is possible to calculate or accurately estimate the cost of providing an advisory opinion in advance. In fact, the OIG has interpreted section 1128D(b)(5)(B)(ii) to require a fee that represents the *actual* costs that it has incurred in processing each individual request. We are also reflecting this concept in our regulations.

We have included in our regulations the OIG's requirement that, once the advisory opinion process is complete, either because we have issued the opinion or the request has been withdrawn, the requestor is responsible for paying an amount equal to the costs incurred by the Government in responding to the request.

Although we cannot reliably project the processing costs in advance, we can make broad estimates that may be of use to prospective requestors. We estimate that, currently, the actual cost of processing a request, including salaries, benefits and overhead, would be approximately $75 an hour. We must include in our estimate the time of

technical staff, attorneys, supervisors, and support staff, as well as others with whom we may consult on various issues.

The time it will take us to process a request will depend on the complexity of the request and the quality of the submission. Simple requests might only take a few hours. For example, a request concerning whether a physician can refer patients to his wife, who works for a physical therapy facility, may take approximately 3 hours to analyze and produce a written opinion. On the other hand, a request involving the application of the physician referral rules to a large, multi-party, intricate business arrangement may take us in excess of 40 hours to fully analyze and produce a written advisory opinion.

We believe that it is reasonable to expect that requests for an advisory opinion will, at present, cost at least $250 for initial processing. It will take time for us to carefully read and analyze every request for an advisory opinion and to ensure that we have accurately understood all the material facts in each request. Accordingly, the regulations provide for a nonrefundable payment of $250 that must accompany any request for an advisory opinion that we receive through the end of 1998. Once we have gained experience in estimating the resources we will need and have factored in any inflation in our costs, we may need to revise our initial fee through a program issuance. We expect to revise the fee periodically after December 31, 1998.

Because we do not believe that we can accurately estimate our costs in advance for a particular request, we intend to try to accommodate requestors who may want to limit the costs of receiving an advisory opinion. The regulations provide that requestors may designate a ''triggering dollar amount'' in their requests for an advisory opinion. If we calculate that the cost of processing a request has reached, or is likely to exceed, that triggering amount, we will stop processing the request and promptly notify the requestor. The requestor may then decide to either authorize us to continue or withdraw the request. We believe we will be able to more accurately reflect costs in advance once we have gained experience. In the interim, this triggering mechanism should be useful in helping to ensure that requestors do not pay costs far in excess of what they expect to pay when they submit their requests.

Section 411.375(c)(4) of the regulations specifically indicates that, while a requestor may withdraw a request for an advisory opinion at any time, he or she will be responsible for any costs we incurred in processing the request before it was withdrawn.

When we have completed the advisory opinion as discussed below, or the requestor has withdrawn the request, we will calculate the total costs that we incurred in processing the request. In calculating this amount, we will take into account any previous payments associated with the request, such as the initial $250 fee, and then notify the requestor of the amount he or she still owes. Once the requestor has paid the full cost, we will release the opinion to the requestor.

We believe that our approach for payment and release will be sufficient for the vast majority of requests for advisory opinions. However, we also believe that we need an additional procedure for cases in which the request will necessitate that we acquire expert advice. We may, for example, need to consult with accountants or with business professionals in order to better understand complex financial relationships.

Because such expert reviews will entail additional time and expense, we believe that we should treat differently any request that requires outside consultation rather than just a standard application of the governing law to a given set of facts. If we determine that we require an expert opinion, we will obtain an estimate for the costs of the opinion and provide the requestor with that estimate. The requestor may then decide to either pay the estimated cost of the expert review or withdraw the request. If the requestor pays the estimated cost, we will promptly refer the matter to the expert for review. Once the outside expert has provided us with the review, we will continue the advisory opinion process by applying the expert evaluation to the legal questions at issue. If the expert evaluation ultimately costs more than the estimated cost, we will bill the requestor for the additional expense as part of the Department's overall costs in responding to the request. These additional costs will be included when we determine whether we are approaching a requestor's ''triggering dollar amount.''

We intend to begin processing requests as soon as we receive them. However, although we will be charging user fees for the cost to the Government for responding to these requests, we will not be adding staff until we determine the volume of requests and the complexity of the legal issues and fact patterns. Once we have had some experience processing requests for advisory opinions, we intend to reconsider the method described in this section for calculating fees. We are specifically soliciting comments on our methodology for determining costs.

C. HCFA's responsibilities

1. Reviewing requests for advisory opinions

Once we receive a request for an advisory opinion, we will promptly examine it to determine if it appears to contain sufficient information for us to form the basis for an informed advisory opinion. (Generally speaking, a request is most likely to be sufficient if the requestor sought our advice before submitting a formal request, and the request contains responses to any preliminary questions we may have posed at that time.) If a request does not appear to us to be sufficient, we will promptly notify the requestor about the additional information we need. On the other hand, if the request appears to be sufficient, we will accept the request. In all cases, we will either ask for additional information or accept the request within 15 working days after we receive the request. If we have requested additional information and the requestor resubmits the advisory opinion request, we will assess the resubmission within 15 working days to determine whether it can be accepted or whether we still need further information. At the point when we accept the request, we will notify the requestor by U.S. mail of the date of our acceptance.

We believe that this approach will provide us with a reasonable amount of time to identify requests that do not contain sufficient information. We are limiting the time period for this initial assessment in order to ensure that we promptly process requests that appear to be complete. We are interested in public comments on whether we have developed an appropriate method for screening advisory opinion requests before we accept them.

Even in situations in which we have accepted a request, we reserve the right to later determine that we need additional information. If we decide that additional information is necessary, we will notify the requestor in the same manner as we would notify a requestor before accepting a request. The time period between when we notify the requestor about the additional information we need and when we receive the requested information will not be counted as part of the time within which we must issue an opinion.

Because we believe that we may need to make fact-intensive inquiries in order to render many advisory opinions, we

anticipate that we may need to request additional information from many requestors. In responding, the requestor should provide us with the necessary information and include with it a certification from the same individual who certified the original request for an advisory opinion (or, if the requestor is an entity, from an individual who is in a comparable position).

2. Timeframe for issuing advisory opinions

Section 1128D(b)(5)(B) of the Act requires that the OIG issue an advisory opinion within 60 days after it has received the request for the opinion. The OIG has reflected this timeframe in its regulations at 42 CFR 1008.43. Because section 1877(g)(6) does not impose any deadline, we have established our own 90-day timeframe for most requests. In addition, for requests that we determine, in our discretion, involve complex legal issues or highly complicated fact patterns, we reserve the right to issue an advisory opinion within a reasonable timeframe. We have created this timeframe based upon our perception that we will receive many requests for advisory opinions and that a large percentage will involve complex fact patterns. This perception is based on the quantity and the nature of phone calls we have received, on a daily basis, over many years. We believe that the number of requests will be affected by the fact that the referral provisions in section 1877 apply to many parties because they can be triggered regardless of the intent of the parties. In addition, if an arrangement involves a physician who has a problematic financial relationship with an entity that furnishes designated health services, the parties must know that the arrangement meets an exception before that physician can refer. We have also based our timeframe on staffing limitations.

Although we will be charging user fees for the cost to the Government for responding to these requests, we will not be adding staff until we determine the volume of requests and the complexity of the legal issues and fact patterns.

Once we have had some experience processing requests for advisory opinions, we intend to reevaluate the timeframe to ensure that it is fair and to determine whether more staff is necessary. We are specifically soliciting comments on this issue.

We intend to begin processing requests as soon as we receive them. Once we receive a request that appears to meet all the submission criteria, we will promptly accept the request and our 90-day period for issuing an opinion will begin. We will send the advisory opinion to the requestor by regular U.S. mail by the end of the 90-day period and once the requestor has paid all the required fees.

We believe that under certain circumstances the running of our 90-day period for issuing an opinion should be tolled (suspended). The suspended periods will only reflect time when we cannot work on analyzing the request. If we notify a requestor that the costs have reached, or are likely to exceed, the triggering amount designated by that requestor, we will stop processing the request until the requestor instructs us to continue. Similarly, if we notify a requestor of the need for, and estimated cost of, an outside expert opinion on a nonlegal issue, the regulations state that we will stop processing the request until the requestor pays the estimated cost and the outside expert provides its opinion. Likewise, in those instances in which we request additional information from the requestor that we believe is necessary for us to issue the advisory opinion, we will stop processing the opinion until we receive the additional information.

The time period for issuing an advisory opinion does not include the time after we notify the requestor that the advisory opinion is complete and the requestor must pay the full balance due for the cost of the opinion.

While we intend to issue advisory opinions within 90 days of receiving the request, we do not believe that the 90-day time period should include delays in the processing of the request that are not within our control. With the exception of the delay that occurs while we wait for a necessary outside expert opinion, all of the possible events that can suspend the period are under the exclusive control of the requestor. We believe that for the vast majority of advisory opinion requests, the 90-day period will only be suspended for those periods during which the requestor has not paid a required fee or has not provided the information we need to process the request.

We will issue an advisory opinion to the requestor after we have considered the complete description of all the facts the requestor has provided to us. In the opinion, we will restate the material facts known to us, present our analysis, and provide conclusions about how we believe the law applies to the facts presented to us.

3. Dissemination of advisory opinions

Section 1128D(b)(5)(A)(v) requires that the OIG's regulations describe the manner in which advisory opinions will be made available to the public. We have adopted the OIG's policy as follows: As set forth in § 411.384(b) of these regulations, once we issue an advisory opinion to a requestor, we will promptly make a copy of that opinion available for public inspection (in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC (phone: 202–690–7890)) during our normal hours of operation and on our web site (http://www.hcfa.gov/regs/aop/). We also anticipate that commercial publishers and trade groups are likely to make advisory opinions widely available to interested members of the public. We welcome public comments and additional suggestions about disseminating advisory opinions to the public.

We will make available documents that are related to a request for an advisory opinion and have been submitted to us and any related internal government documents, to the extent we are required to do so by the Freedom of Information Act (FOIA) (5 U.S.C. 552). If a requestor provides information it believes is not subject to disclosure under FOIA, such as items that the requestor believes are trade secrets or privileged and confidential commercial or financial information, the requestor should identify this information in the manner described in 45 CFR 5.65 (c) and (d). The requestor's assertions about the nature of the information, however, are not controlling.

In addition, although a document may be exempt from disclosure under FOIA, facts reflected in that document may become part of the advisory opinion that HCFA will provide to the public. We will describe the material facts of the arrangement in question in the body of each advisory opinion, which will be made fully available to the public. To the extent that it may be necessary to reveal specific facts that could be regarded as confidential information, we believe we have the authority to do so under sections 1106(a) and 1877(g)(6) of the Act. We do not intend to release any such facts unless we believe it is necessary to do so.

4. Rescission of an advisory opinion

Section 411.382 reserves our right to rescind or revoke an advisory opinion after we issue it, in limited circumstances. For example, we can rescind an opinion if we learn after issuing it that the arrangement in question may lead to fraud and abuse. In such a situation, we will notify the requestor that we have rescinded and make the notice available to the same extent as an advisory opinion. The

requestor would not be subject to sanctions for any actions it took prior to the notice of rescission, if the requestor relied in good faith on the advisory opinion (unless we establish that the requestor failed to provide us with material information when it submitted the request for the opinion) and where the parties promptly discontinue the action upon receiving notice that we have rescinded or revoked our approval. We would also allow the parties to discontinue the action within what we believe is a reasonable ''wind down'' period, if we believe that the business arrangement is one that cannot be discontinued immediately. We are specifically soliciting comments on whether this approach reasonably balances the Government's need to ensure that advisory opinions are legally correct and the requestor's interest in finality.

5. Scope and effect of advisory opinions

Section 411.387 of these regulations addresses the scope and effect of advisory opinions. When we issue an advisory opinion under this process, it is legally binding on the Department and the requestor, but only with respect to the specific conduct of the particular requestor. Section 1877(g)(6)(A) requires only that an advisory opinion issued by the Secretary be binding upon the Secretary and the party or parties requesting the opinion. In light of this provision, the Department is not legally bound with respect to the conduct of a third party, even if the conduct of that party appears similar to the conduct of the requestor. Thus, under these regulations, no third parties are bound by nor may they rely upon an advisory opinion. Each advisory opinion will apply legal standards to a set of facts involving certain known persons who provide specific statements about key factual issues. A third party may create a look-alike arrangement, but any *additional* characteristics could lead to an unfavorable opinion. Therefore, by their very nature, advisory opinions cannot be applied generally.

We believe that even if a party has received a favorable advisory opinion from us regarding a particular arrangement, the Government is not totally prevented from commencing an action against a party to that arrangement. For example, this could occur if a requestor has failed to disclose a material fact. In any such action under sections 1128, 1128A or 1128B of the Act, an individual or entity who has requested and received an advisory opinion from us regarding the arrangement in question may seek to introduce the advisory opinion into evidence in the proceeding.

III. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, most hospitals, and most other providers, physicians, and health care suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

This rule establishes procedures for us to receive, review, and respond to requests for advisory opinions on the issue of whether a physician's referrals for certain designated health services are prohibited under section 1877 of the Social Security Act. This rule does not address the substance of section 1877 nor the substance or content of the advisory opinions we may issue in the future. Any effect an advisory opinion may have on the behavior of health care providers is the result of the substantive content of section 1877 and of the advisory opinions themselves, and not this rule.

Parties interested in advisory opinions will incur certain costs in requesting the opinions. However, it is the law that allows us to require that requestors pay cost-based fees for advisory opinions. This rule merely lays out procedures for paying the costs.

Estimated number of respondents: Many individuals and entities that provide certain designated health services that may be paid for by Medicare or Medicaid could potentially have questions regarding the referral provisions in section 1877.

We estimate that, within the last year, we received an average of eight telephone calls each day regarding the physician self-referral provisions. We believe that some percentage of calls involved issues and situations about which the callers would be unlikely to request written advisory opinions. Nevertheless, we believe that we can use the number of inquiries as a basis for estimating the number of requests we are likely to receive for advisory opinions. Using this basis, we estimate that 200 physicians, health care entities, and other entities or individuals will request advisory opinions within the first year following publication of this rule. We also anticipate that the number of requests will decline in subsequent years, unless there are significant changes in the law. The costs to these requestors will vary depending on the complexity of each request. Compared, however, to the costs of seeking private legal advice, we believe that the fees charged for our review will not be substantial, and in many cases will not exceed the $250 minimum payment.

Obviously, the actual number of requests could be larger since, for the first time, formal written opinions are available. Conversely, the numbers could be smaller for a combination of many unquantifiable reasons, such as the desire not to subject an arrangement to official scrutiny.

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), if a rule has a significant economic effect on a substantial number of small businesses, the Secretary must specifically consider the effects of the rule on small business entities and analyze regulatory options that could lessen the impact of the rule. As stated above, this rule does not address the substance of section 1877 of the Act or the substance of advisory opinions that may be issued in the future. It describes the *process* by which an individual or entity may receive an opinion about how section 1877 applies to particular business practices. The aggregate economic impact of this rulemaking on small business entities should, therefore, be minimal.

Thus, we have concluded, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small business entities, and that a regulatory flexibility analysis is not required for this rulemaking.

In accordance with the provisions of E.O. 12866, this regulation was reviewed by the Office of Management and Budget.

IV. Authority for an Interim Final Rule with Comment Period, and Waiver of Delayed Effective Date

We ordinarily publish a general notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. That rule would have included a reference to the legal authority under which we are proposing it, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Further, we generally provide for final rules to be effective no sooner than 30 days after the date of publication unless we find good cause to waive the delay.

In order to implement the provisions in section 1877(g)(6) in a timely manner, section 1877(g)(6)(C) gives us the authority to promulgate regulations that take effect on an interim basis after notice and pending opportunity for public comment. We have chosen to exercise this authority for the following reasons. We believe that the statutory requirement that we accept requests for advisory opinions that are submitted on or after November 4, 1997, makes it imperative that, by that date, we have in place specific procedures to address how we will receive and process advisory opinion requests. It would be contrary to the public interest for us to receive and process advisory opinions without first setting forth procedural guidelines. We also believe that the 60-day period for public comment established by this interim final rule will protect the public's interest in this rulemaking, while providing us with additional input and recommendations, without unduly delaying the advisory opinion process. We are therefore publishing the advisory opinion procedures as an interim final rule with comment period. We also find that for good cause it would be against the public interest to delay the effective date of this rule. We will respond to all appropriate and relevant public comments that we receive during the 60-day comment period, and we will make any necessary revisions to these regulations through a revised final rule.

V. Collection of Information Requirements

In order to provide appropriate advisory opinions, we will need certain information from the parties who request advisory opinions. Sections 411.372, 411.373, and 411.378 of this interim final rule contain information collection requirements that require approval by OMB. We are required to solicit public comments under section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. Specifically, comments are invited on (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

We are requesting an emergency review of this interim final rule with comment period. In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are submitting to OMB the collection of information requirements described below for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320, to ensure compliance with section 1877(g)(6)(D) of the Act, which was added by section 4314 of the Balanced Budget Act of 1997. Section 1877(g)(6)(D) requires us to respond to requests for advisory opinions that are submitted after November 3, 1997. We cannot reasonably comply with normal clearance procedures because of the statutory deadline and public harm is likely to result if the agency cannot provide for advisory opinions.

We are providing a 3-day public comment period from the date of publication of this interim final rule, with OMB review and approval 4 days from the date of publication, and a 180-day approval. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Title: HCFA Advisory Opinion Procedure.

Summary of the collection of information: Section 4314 of Public Law 105–33, in establishing section 1877(g)(6) of the Act, requires the Department to provide advisory opinions to the public regarding whether a physician's referrals for certain designated health services are prohibited under the other provisions in section 1877 of the Act. These regulations provide the procedures under which members of the public may request advisory opinions from HCFA. Because all requests for advisory opinions are purely voluntary, respondents will only be required to provide information to us that is relevant to their individual requests.

The following discussion describes the aggregate effect of the collections of information included in the text of this interim final rule.

Respondents: The ''respondents'' for the collection of information described in these regulations will be self-selected individuals and entities that choose to submit requests for advisory opinions to HCFA. We anticipate that the respondents will include health care providers of many types, from physicians who are sole practitioners to large diversified publicly-traded corporations.

Estimated number of respondents: 200. This estimate is based on the number of telephone calls we have received regarding the physician referral provisions.

Estimated number of responses per respondent: 1.

Estimated total annual burden on respondents: We believe that the burden of preparing a request for an advisory opinion will vary widely depending upon the size and complexity of the business transactions in question. We estimate that the average burden for each submitted request for an advisory opinion will be in the range of 2 to 40 hours. We further believe that the burden for most requests will be closer to the lower end of the range, with an average burden of 10 hours per respondent. Total burden for this proposed information collection is estimated to be 2000 hours.

We are requiring that requests for advisory opinions involve existing conduct, or conduct in which the requestor intends to engage. We anticipate that most requests will involve business arrangements into which the requesting party intends to enter. Because the facts will relate to business plans, we believe the requesting party in many cases will already have collected and analyzed all or almost all of the information we will need in order to review the request. Therefore, in order to request an advisory opinion, the requestor will most likely simply need to compile for our examination information that the requestor has already collected and reviewed. In some cases, however, the requestor may need to expend a more significant amount of time in order to submit information relating to a complex arrangement that involves a large number of parties.

Comments on this information collection should be sent to both:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attn: HCFA–1902–IFC, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850

and

Allison Herron Eydt, HCFA Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 725 17th Street, NW, Washington, D.C. 20503.

You may also fax comments on these paperwork reduction requirements to the Health Care Financing Administration at (410) 786–1415 and to Ms. Eydt at (202) 395–6974. All comments should refer to file code HCFA–1902–IFC.

To be considered, you must submit comments on these paperwork reduction requirements to the individuals listed above within 3 days after this interim final rule is published in the **Federal Register**.

List of Subjects in 42 CFR Part 411

Administrative practice and procedures, Fraud, Grant programs—health, Health facilities, Health professions, Medicaid, Medicare, Penalties.

42 CFR part 411 is amended as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Sections 411.370, 411.372, 411.373, 411.375, 411.377 through 411.380, 411.382, 411.384, and 411.386 through 411.389 are added to subpart J to read as follows:

§ 411.370 Advisory opinions relating to physician referrals.

(a) *Period during which HCFA will accept requests.* The provisions of §§ 411.370 through 411.389 apply to requests for advisory opinions that are submitted to HCFA after November 3, 1997, and before August 21, 2000, and to any requests submitted during any other time period during which HCFA is required by law to issue the advisory opinions described in this subpart.

(b) *Matters that qualify for advisory opinions and who may request one.* Any individual or entity may request a written advisory opinion from HCFA concerning whether a physician's referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. In the advisory opinion, HCFA determines whether a business arrangement described by the parties to that arrangement appears to constitute a ''financial relationship'' (as defined in section 1877(a)(2) of the Act) that could potentially restrict a physician's referrals, and whether the arrangement or the designated health services at issue appear to qualify for any of the exceptions to the referral prohibition described in section 1877 of the Act.

(1) The request must involve an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. HCFA does not consider, for purposes of an advisory opinion, requests that present a general question of interpretation, pose a hypothetical situation, or involve the activities of third parties.

(2) The requestor must be a party to the existing or proposed arrangement.

(c) *Matters not subject to advisory opinions.* HCFA does not address through the advisory opinion process—

(1) Whether the fair market value was, or will be, paid or received for any goods, services, or property; and

(2) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(d) *Facts subject to advisory opinions.* HCFA considers requests for advisory opinions that involve applying specific facts to the subject matter described in paragraph (b) of this section. Requestors must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in § 411.372.

(e) *Requests that will not be accepted.* HCFA does not accept an advisory opinion request or issue an advisory opinion if—

(1) The request is not related to a named individual or entity;

(2) HCFA is aware that the same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) HCFA believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry.

(f) *Effects of an advisory opinion on other Governmental authority.* Nothing in this part limits the investigatory or prosecutorial authority of the OIG, the Department of Justice, or any other agency of the Government. In addition, in connection with any request for an advisory opinion, HCFA, the OIG, or the Department of Justice may conduct whatever independent investigation it believes appropriate.

§ 411.372 Procedure for submitting a request.

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to HCFA in writing, including an original request and 2 copies. The request must be addressed to: Health Care Financing Administration, Department of Health and Human Services, Attention: Advisory Opinions, P.O. Box 26505, Baltimore, MD 21207.

(b) *Information HCFA requires with all submissions.* The request must include the following:

(1) The name, address, telephone number, and Taxpayer Identification Number of the requestor.

(2) The names and addresses, to the extent known, of all other actual and potential parties to the arrangement that is the subject of the request.

(3) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with HCFA on behalf of the requestor.

(4) A complete and specific description of all relevant information bearing on the arrangement, including—

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including: the purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved) and any entities that provide designated health services; the types of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients;

(ii) Complete copies of all relevant documents or relevant portions of documents that affect or could affect the arrangement, such as personal services or employment contracts, leases, deeds, pension or insurance plans, financial statements, or stock certificates (or, if these relevant documents do not yet exist, a complete description, to the best of the requestor's knowledge, of what these documents are likely to contain);

(iii) Detailed statements of all collateral or oral understandings, if any; and

(iv) Descriptions of any other arrangements or relationships that could affect HCFA's analysis.

(5) Complete information on the identity of all entities involved either directly or indirectly in the arrangement, including their names, addresses, legal form, ownership structure, nature of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect, and as defined in section 1877(a)(2) of the Act and § 411.351), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) A discussion of the specific issues or questions the requestor would like HCFA to address including, if possible, a description of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions to the prohibition the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

(7) An indication of whether the parties involved in the request have also asked for or are planning to ask for an advisory opinion on the arrangement in question from the OIG under section 1128D(b) of the Act (42 U.S.C. 1320a-7d(b)) and whether the arrangement is or is not, to the best of the requestor's knowledge, the subject of an investigation.

(8) The certification(s) described in § 411.373. The certification(s) must be signed by—

(i) The requestor, if the requestor is an individual;

(ii) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(iii) The managing partner of the requestor, if the requestor is a partnership; or

(iv) A managing member, if the requestor is a limited liability company.

(9) A check or money order payable to HCFA in the amount described in § 411.375(a).

(c) *Additional information HCFA might require.* If the request does not contain all of the information required by paragraph (b) of this section, or, if either before or after accepting the request, HCFA believes it needs more information in order to render an advisory opinion, it may request whatever additional information or documents it deems necessary. Additional information must be provided in writing, signed by the same person who signed the initial request (or by an individual in a comparable position), and be certified as described in § 411.373.

§ 411.373 Certification.

(a) Every request must include the following signed certification: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.''

(b) If the advisory opinion relates to a proposed arrangement, in addition to the certification required by paragraph (a) of this section, the following certification must be included and signed by the requestor: ''The arrangement described in this request for an advisory opinion is one into which [the requestor], in good faith, plans to enter.'' This statement may be made contingent on a favorable advisory opinion, in which case the requestor should add one of the following phrases to the certification:

(1) ''if HCFA issues a favorable advisory opinion.''

(2) ''if HCFA and the OIG issue favorable advisory opinions.''

§ 411.375 Fees for the cost of advisory opinions.

(a) *Initial payment.* Parties must include with each request for an advisory opinion submitted through December 31, 1998, a check or money order payable to HCFA for $250. For requests submitted after this date, parties must include a check or money order in this amount, unless HCFA has revised the amount of the initial fee in a program issuance, in which case, the requestor must include the revised amount. This initial payment is nonrefundable.

(b) *How costs are calculated.* Before issuing the advisory opinion, HCFA calculates the costs the Department has incurred in responding to the request. The calculation includes the costs of salaries, benefits, and overhead for analysts, attorneys, and others who have worked on the request, as well as administrative and supervisory support for these individuals.

(c) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (c)(3) of this section, to pay all costs the Department incurs in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If HCFA estimates that the costs of processing the advisory opinion request have reached or are likely to exceed the designated triggering dollar amount, HCFA notifies the requestor.

(3) If HCFA notifies the requestor that the actual or estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, HCFA stops processing the request until the requestor makes a written request for HCFA to continue. If HCFA is delayed in processing the request for an advisory opinion because of this procedure, the time within which HCFA must issue an advisory opinion is suspended until the requestor asks HCFA to continue working on the request.

(4) If the requestor chooses not to pay for HCFA to complete an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs HCFA has identified as costs it incurred in processing the request for an advisory opinion, up to that point.

(5) If the costs HCFA has incurred in responding to the request are greater than the amount the requestor has paid, HCFA, before issuing the advisory opinion, notifies the requestor of any additional amount that is due. HCFA does not issue an advisory opinion until the requestor has paid the full amount that is owed. Once the requestor has paid HCFA the total amount due for the costs of processing the request, HCFA issues the advisory opinion. The time period HCFA has for issuing advisory opinions is suspended from the time HCFA notifies the requestor of the amount owed until the time HCFA receives full payment.

(d) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in § 411.377.

(2) The time period for issuing an advisory opinion is suspended from the time that HCFA notifies the requestor that it needs an outside expert opinion

until the time HCFA receives that opinion.

§ 411.377 Expert opinions from outside sources.

(a) HCFA may request expert advice from qualified sources if HCFA believes that the advice is necessary to respond to a request for an advisory opinion. For example, HCFA may require the use of accountants or business experts to assess the structure of a complex business arrangement or to ascertain a physician's or immediate family member's financial relationship with entities that provide designated health services.

(b) If HCFA determines that it needs to obtain expert advice in order to issue a requested advisory opinion, HCFA notifies the requestor of that fact and provides the identity of the appropriate expert and an estimate of the costs of the expert advice. As indicated in § 411.375(d), the requestor must pay the estimated cost of the expert advice.

(c) Once HCFA has received payment for the estimated cost of the expert advice, HCFA arranges for the expert to provide a prompt review of the issue or issues in question. HCFA considers any additional expenses for the expert advice, beyond the estimated amount, as part of the costs HCFA has incurred in responding to the request, and the responsibility of the requestor, as described in § 411.375(c).

§ 411.378 Withdrawing a request.

The party requesting an advisory opinion may withdraw the request before HCFA issues a formal advisory opinion. This party must submit the withdrawal in writing to the same address as the request, as indicated in § 411.372(a). Even if the party withdraws the request, the party must pay the costs the Department has expended in processing the request, as discussed in § 411.375. HCFA reserves the right to keep any request for an advisory opinion and any accompanying documents and information, and to use them for any governmental purposes permitted by law.

§ 411.379 When HCFA accepts a request.

(a) Upon receiving a request for an advisory opinion, HCFA promptly makes an initial determination of whether the request includes all of the information it will need to process the request.

(b) Within 15 working days of receiving the request, HCFA—

(1) Formally accepts the request for an advisory opinion;

(2) Notifies the requestor about the additional information it needs, or

(3) Declines to formally accept the request.

(c) If the requestor provides the additional information HCFA has requested, or otherwise resubmits the request, HCFA processes the resubmission in accordance with paragraphs (a) and (b) of this section as if it were an initial request for an advisory opinion.

(d) Upon accepting the request, HCFA notifies the requestor by regular U.S. mail of the date that HCFA formally accepted the request.

(e) The 90-day period that HCFA has to issue an advisory opinion set forth in § 411.380(c) does not begin until HCFA has formally accepted the request for an advisory opinion.

§ 411.380 When HCFA issues a formal advisory opinion.

(a) HCFA considers an advisory opinion to be issued once it has received payment and once the opinion has been dated, numbered, and signed by an authorized HCFA official.

(b) An advisory opinion contains a description of the material facts known to HCFA that relate to the arrangement that is the subject of the advisory opinion, and states HCFA's opinion about the subject matter of the request based on those facts. If necessary, HCFA includes in the advisory opinion material facts that could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) HCFA issues an advisory opinion, in accordance with the provisions of this part, within 90 days after it has formally accepted the request for an advisory opinion, or, for requests that HCFA determines, in its discretion, involve complex legal issues or highly complicated fact patterns, within a reasonable time period.

(2) If the 90th day falls on a Saturday, Sunday, or Federal holiday, the time period ends at the close of the first business day following the weekend or holiday;

(3) The 90-day period is suspended from the time HCFA—

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in § 411.375(c)(2) until HCFA receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until HCFA receives the additional information;

(iii) Notifies the requestor of the full amount due until HCFA receives payment of this amount; and

(iv) Notifies the requestor of the need for expert advice until HCFA receives the expert advice.

(d) After HCFA has notified the requestor of the full amount owed and has received full payment of that amount, HCFA issues the advisory opinion and promptly mails it to the requestor by regular first class U.S. mail.

§ 411.382 HCFA's right to rescind advisory opinions.

Any advice HCFA gives in an opinion does not prejudice its right to reconsider the questions involved in the opinion and, if it determines that it is in the public interest, to rescind or revoke the opinion. HCFA provides notice to the requestor of its decision to rescind or revoke the opinion so that the requestor and the parties involved in the requestor's arrangement may discontinue any course of action they have taken in accordance with the advisory opinion. HCFA does not proceed against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon HCFA's advice under this part, provided—

(a) The requestor presented to HCFA a full, complete and accurate description of all the relevant facts; and

(b) The parties promptly discontinue the action upon receiving notice that HCFA had rescinded or revoked its approval, or discontinue the action within a reasonable ''wind down'' period, as determined by HCFA.

§ 411.384 Disclosing advisory opinions and supporting information.

(a) Advisory opinions that HCFA issues and releases in accordance with the procedures set forth in this subpart are available to the public.

(b) Promptly after HCFA issues an advisory opinion and releases it to the requestor, HCFA makes available a copy of the advisory opinion for public inspection during its normal hours of operation and on the DHHS/HCFA web site.

(c) Any predecisional document, or part of such predecisional document, that is prepared by HCFA, the Department of Justice, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part is exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to HCFA in connection with a request for an advisory opinion are available to the public to the extent they are required to be made available by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section limits HCFA's obligation, under applicable

laws, to publicly disclose the identity of the requesting party or parties, and the nature of the action HCFA has taken in response to the request.

§ 411.386 HCFA's advisory opinions as exclusive.

The procedures described in this subpart constitute the only method by which any individuals or entities can obtain a binding advisory opinion on the subject of a physician's referrals, as described in § 411.370. HCFA has not and does not issue a binding advisory opinion on the subject matter in § 411.370, in either oral or written form, except through written opinions it issues in accordance with this subpart.

§ 411.387 Parties affected by advisory opinions.

An advisory opinion issued by HCFA does not apply in any way to any individual or entity that does not join in the request for the opinion. Individuals or entities other than the requestor(s) may not rely on an advisory opinion.

§ 411.388 When advisory opinions are not admissible evidence.

The failure of a party to seek or to receive an advisory opinion may not be introduced into evidence to prove that the party either intended or did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

§ 411.389 Range of the advisory opinion.

(a) An advisory opinion states only HCFA's opinion regarding the subject matter of the request. If the subject of an advisory opinion is an arrangement that must be approved by or is regulated by any other agency, HCFA's advisory opinion cannot be read to indicate HCFA's views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion that HCFA issues under this part does not bind or obligate any agency other than the Department. It does not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 2, 1997.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: December 30, 1997.

Donna E. Shalala,

Secretary.

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