

Procedures for Advisory Opinions Concerning Physicians' Referrals
And Supporting Regulations in 42 CFR 411.370 through 411.389
OMB NO: 0938-0714

A. **Background**

CMS is requesting OMB re-approval with change for the provisions of the January 9, 1998 interim final rule with comment period and the March 26, 2004 interim final rule with comment period (referenced below—burden accounted for in 0938-0846) that are subject to review under the Paperwork Reduction Act. This final rule with comment requires the Secretary to 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 Social Security Act. In addition, this interim final with comment sets forth the specific procedures CMS uses to issue advisory opinions.

B. **Justification**

1. **Need and Legal Basis**

We are requesting OMB re-approval of the collection of information requirements contained in sections 42 CFR 411.370 through 411.389. Section 4314 of the Balanced Budget Act of 1997, Public Law 105-33, added section 1877(g)(6) of the Social Security Act (the Act), which requires that the Department of Health and Human Services issue advisory opinions 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 of the Social Security Act. Section 1877(g)(6) of the Act requires that the Department of Health and Human Services accept requests for advisory opinions made after November 3, 1997 and before August 21, 2000. Section 543 of the Benefits Improvement and Protection Act of 2001, Public Law 106-554, extended indefinitely the period during which the Department of Health and Human Services accepts requests for these advisory opinions. CMS promulgated 42 CFR 411.370 through 411.389 to comply with this statutory mandate. The collection of information contained in 42 CFR 411.372 and 411.373 is necessary to allow CMS to consider requests for advisory opinions and provide accurate and useful opinions. (OMB previously extended approval for this information collection through November 30, 2007.)

We have attached for your reference section 4314 of Public Law 105-33 and section 543 of Public Law 106-554.

2. **Information Users**

The information is read and analyzed by employees of CMS and the Department to develop and issue an advisory opinion to the individual or entity that submitted the information. The primary office using the information is the Center for Medicare Management, which is responsible for the

issuance of advisory opinions.

3. **Improved Information Technology**

This collection of information requires the submission of information in paper form. In addition, a submission is completely voluntary and each situation for which we receive a request for an advisory opinion is different. Also, the information needed varies greatly among requests, although the required information should be readily available to the requestor in paper form. For these reasons, we do not believe that alternate technological collection mechanisms are appropriate or necessary.

4. **Duplication of Similar Information**

The information requested is not available anywhere else.

5. **Small Businesses**

The only small entities affected by this collection of information are those that voluntarily choose to request an advisory opinion. The information requested is the minimum necessary to enable CMS to issue an advisory opinion.

6. **Less Frequent Collection**

This collection of information is required by section 1877(g)(6) of the Act. Failure to provide this information would prevent CMS from fulfilling its statutory obligation to provide advisory opinions in response to requests filed after November 3, 1997. We can neither reduce the collection of information below the level of one per request nor reduce the burden related to the voluntary requests.

7. **Special Circumstances**

The only special circumstance that may apply to this collection of information is that the requestor may need to provide proprietary trade secrets or other confidential information in order to fully and accurately describe the facts regarding which the advisory opinion is being requested. Submissions accompanying requests for advisory opinions are disclosed to the public to the extent we are required to do so by the Freedom of Information Act (5 U.S.C. 552). The advisory opinions include all information material to the formulation of the opinion. To the extent that confidential information is material to CMS analysis, the advisory opinion includes that information.

8. **Federal Register Notice/Outside Consultation**

A 60-day Federal Register notice was published on June 15, 2007.

A full and complete public comment process was undertaken upon publication of the interim final rule. To implement the provisions in section 1877(g)(6) of the Act in a timely manner, section 1877(g)(6)(C) of the Act authorized us to promulgate regulations that took effect on an interim basis after notice and pending for public comment. We chose to exercise that authority because we believed that the statutory requirement that we accept requests for advisory opinions that are submitted after November 3, 1997, made it imperative that as soon as possible we were to have in place specific procedures to address how we receive and process requests for advisory opinions. We did not receive any public comments concerning any of the provisions. The interim final regulation with comment period published on March 26, 2004 included a 90-day comment period.

9. **Payments/Gifts to Respondents**

This information collection does not involve any payments or gifts to respondents.

10. **Confidentiality**

The only assurance of confidentiality made to requestors was that the documents that they submit would be subject to public disclosure only to the extent that we are required to do so by the Freedom of Information Act (FOIA) (5 U.S.C. 552). We asked requestors to identify information that they believe 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. We do not intend to release any such facts unless we believe it is necessary to do so.

11. **Sensitive Questions**

This collection of information does not include any questions of a sensitive nature.

12. **Burden Estimate (Total Hours & Wages)**

The estimated annual number of respondents for the physician referral advisory opinion provisions in section 1877 of the Act is 50. Many physicians and entities that provide medical services (other than clinical laboratory services) that may be paid for by Medicare or Medicaid could potentially have questions regarding referrals for designated health services about which CMS could issue an advisory opinion. We believe that we have been increasingly successful in creating "bright line" provisions, which reduce ambiguity. Since the first physician referral law was enacted in 1989, CMS has answered telephone inquiries from individuals and entities that participate in Medicare or Medicaid who seek informal guidance with respect to the physician referral provisions. Many inquiries have been of a nature about which the caller might request a written advisory opinion, although most inquiries are related to relatively simple matters that could be researched by private counsel for a relatively minor cost. However, some inquirers are not satisfied with advice of counsel and want an advisory opinion as a "CMS stamp of approval." In addition, three issues are not subject to requests for advisory opinions: issues involving clinical laboratory services; whether a compensation relationship meets any requirements for fair market value; and whether an individual meets the requirements to be considered an employee. Although

consistently we receive about 10 calls per day, in general, we do not receive more than 20 requests for advisory opinions per year. However, once the final rulemaking for the physician referral provisions in section 1877 of the Act has been completed, we expect to receive as many as 50 requests for advisory opinions during each 12-month period.

The estimated total annual hour burden on respondents after final rulemaking has been completed is 500 hours. We believe that the burden of preparing requests for advisory opinions will vary widely because of differences in size and complexity. 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. We require that requests involve an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. Because the facts will relate to business plans, the requesting party will have already collected and analyzed all or almost all of the information we will need to collect to review the request. Therefore, to request an advisory opinion, the requestor will most likely simply need to compile already collected information for our examination. In some cases, however, the requestor may need to expend a more significant amount of time and cost in preparing a submission related to a very complex arrangement possibly involving a large number of parties.

After final rulemaking has been completed, we estimate that the annualized cost to respondents for their internal information collection of information will be \$43,750. We estimate that the average cost to a respondent for his or her internal information collection activities will be \$87.50 per hour and that internal information collection should average 10 hours. This average reflects the fact that most of the information to be collected should be readily available and collectable by employees who do not have major managerial responsibilities. We estimate that 75 percent of the average hour burden will be attributable to employees with an average cost of \$50 per hour. We believe that a smaller portion of the information collection hours will be attributable to employees compensated at a higher rate. We estimate that 25 percent of the average hour burden will be attributable to employees with an average cost of \$200 per hour.

In addition to the hour burden on respondents, we believe that some respondents will contract out certain collection of information activities. We believe that some respondents may pay law firms or consultants for the preparation of requests for advisory opinions. We believe that the burden related to such outside assistance varies from zero to 40 hours of work per request with an average of 10 hours per request. Furthermore, we estimate the average hourly costs of such purchased services to be \$200. Thus, we estimate that the annual cost for respondents for outside law firms and consultants would be \$100,000.

Therefore, we estimate that the total annual cost to the 50 requestors should be about \$143,750 (\$43,750 for the work of employees + \$100,000 for the work of outside law firms and consultants).

13. **Capital Costs**

There are no capital costs associated with this collection.

14. Cost to the Federal Government

Ultimately, there should be only a relatively small cost to the Federal government because we charge requestors a user fee that is equivalent to CMS's cost and some of the Department's cost. (This is explained at the end of this section.) OMB Circular A-25 currently provides 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. The authority for the provisions in this circular derives from the Independent Offices Appropriations Act of 1952, 31 U.S.C. 9701. Based on a number of court decisions, we believe that the advisory opinions we must provide are subject to user fees. This is because 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. Therefore, we are required to charge requestors a fee equal to the costs incurred by CMS and the attorneys in the Department's Health Care (HCF) Division in the Office of General Counsel, in responding to the request for an advisory opinion.

In the January 9, 1998 advisory opinion final rule with comment period (63 FR 1646), we estimated that the average hourly cost to requestors of processing a request, including salaries, benefits, direct costs (for example, copying), and overhead would be \$75. This estimate reflected the fact that most of the analysis, writing of advisory opinions, and review would be performed by higher graded health insurance specialists and attorneys from the Department (from the CMS Division in the Office of General Counsel). We anticipated that individuals with an average grade level of GS-14 would conduct much of this work. In addition, a manager at grade level of GS-15 would expend some time on supervision and review.

We believe that the costs for creating advisory opinions vary considerably, depending upon the nature of the request and underlying facts. CMS is required to issue advisory opinions on issues that vary greatly in their complexity. We estimated that CMS would spend a minimum of 3 hours in processing, analyzing, and issuing an advisory opinion for the most basic request. For more complex questions, which may involve multiple, large and complex entities and several types of health care providers, CMS may need to expend over 40 hours of work to process the request and issue an advisory opinion. We estimated that the average request would take us 20 hours to process, which would result in a cost to the requestor of approximately \$1,500.

As required by OMB Circular A-25 and the FY 1998 Appropriations Act that applies to the Department (Public Law 105-78), CMS is authorized to retain all user fees that we are authorized to collect for creating an advisory opinion. Although we furnish drafts of advisory opinions to the Department's Office of Inspector (OIG) for its review to determine if there are anti-kickback problems with the planned arrangements, the requestor has not asked for this review and we do not believe that the requestor should or can be charged for this review since the requestor has only asked for an advisory opinion concerning physician referral issues. Therefore, because we do not anticipate any costs to the Federal government other than those incurred by OIG in its anti-

kickback analysis, the net cost to the Federal government should be just the cost incurred by OIG.

15. **Program Changes**

There are no program changes. (The requirements from the March 26, 2004 rule are accounted for in 0938-0846)

16. **Publication and Tabulation Dates**

Advisory opinions are made available to the public. Identifying information, including names and tax identification numbers, and other information protected by the Privacy Act are not included in the advisory opinions. However, to the extent that information provided by the requestor is material to the resulting advisory opinion, that information is included in the advisory opinion. The information collected is not compiled, tabulated, or consolidated. The information is analyzed only in the context of the specific advisory opinion that was requested.

17. **Expiration Date**

This collection does not lend itself to the displaying of an expiration date.

18. **Certification Statement**

There are no exceptions to the certification statement.

C. **COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

This collection of information does not employ statistical methods.