

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) for a proposed or existing arrangement 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. On September 5, 2007, we published in the Federal Register a final rule entitled, “Medicare Program: Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)”; (Vol. 72, 51012, 51098). In that final rule we revised 42 CFR 411.370(a) to remove the sunset provision that formerly applied to our authority 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 January 31, 2011.)

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, which is responsible for the issuance of advisory opinions.

3. **Use of Information Technology**

We have explored various methods of information collection; however, due to the unique and variable nature of the actual or potential arrangements, we have concluded that electronic only completion and submission of the documentation is not feasible. Therefore, requestors will be required to submit, in paper format, the original and two copies of the complete request and relevant documentation. In addition to sending the documents by mail, requestors should send an electronic copy of all documents by email. 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 Efforts**

This information collection requested does not duplicate any other effort and the information cannot be obtained from any other source.

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 August 20, 2010; Vol. 75, No. 161, pg. 51462. No public comments were received.

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 (Hours & Wages)

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. Also 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.

The estimated annual number of respondents for advisory opinion related to the physician referrals provisions in section 1877(g)(6) of the Act is 25. This estimate reflects a decrease from the previous estimate but is based upon a review of the requests received to date. In fact, we have not received more than 20 requests for advisory opinions per year. However, at least one provision of the Patient Protection and Affordable Care Act (ACA) may have some bearing on the number of future requests for an advisory opinion. Specifically, section 6409 of the Patient Protection and Affordable Care Act (ACA) enacted on March 23, 2010 mandates the Secretary to develop and publish a Medicare self-referral disclosure protocol (“SRDP”) that sets forth a process for providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute (Section 1877 of the Social Security Act). We anticipate that the development of the SRDP may impact the number of advisory opinions submitted, as some requestors may choose to use the SRDP to determine whether an existing arrangement is in compliance with 1877 of the Act. However, it is difficult to assess the impact the SDRP will have on the number of advisory opinion requested. Therefore, we are proceeding with our estimate of 25 requests for advisory opinions during each 12-month period. Again, this estimate is based upon a historical review of requests received to date.

We believe that the burden of preparing requests for advisory opinions will vary widely because of differences in size and complexity. 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 proposed or existing arrangements (e.g. 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.

We estimate that the average cost to a respondent will be \$93.00 per hour. We estimate that the average burden for each submitted request for an advisory opinion will be in the range of 5 to 40 hours. Therefore, we estimate that the total annualized cost to each respondent will be \$465 (\$93 x 5 hrs.) to \$3,720 (\$93 x 40 hrs.). We estimate the average hours per request would be 20 hrs. Therefore the average cost would be \$1,860 (20 hrs x \$93).

In summary, we estimate that the total annualized burden to the 25 requestors would range from \$11,625 (\$465 x 25 requests) to \$93,000 (\$3,720 x 25 requests). We estimate the average burden to be \$46,500 (\$1,860 x 25 requests). CMS is presenting a much higher burden estimate and cost with this PRA package than that which was approved in 2007. CMS believes that this 2010 package contains the realistic burden and costs for the submission of an advisory opinion requests as we relied on more current BLS data.

13. **Capital Costs**

There are no capital costs associated with this collection.

14. **Cost to the Federal Government**

CMS anticipates the receipt of 25 Advisory Opinions per year. 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. In order to implement this provision, 42 CFR 411.375(a) requires that requestors must include with each request for an advisory opinion a check or money order for \$250. Section 411.375(c) also provides that by submitting a request for an advisory opinion, the requestor agrees to pay all costs the department incurs in responding to the request for 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. **Changes to Burden**

There are no program changes. (The requirements from the March 26, 2004 rule are accounted for in 0938-0846). The estimated annual number of respondents for advisory opinion related to the physician referrals provisions in section 1877(g)(6) of the Act is 25. This estimate reflects a decrease from the previous estimate but is based upon a review of the requests received to date.

16. **Publication/Tabulation Dates**

Advisory opinions are made available to the public through our website . However identifying information, including names and tax identification numbers, and other information protected by the Privacy Act are redacted and not included in the published 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.