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An appropriate amendment to 39 CFR 111.3 will be published to reflect these changes.

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Chief Counsel, Legislative.

[FR Doc. 98-19017 Filed 7-15-98; 8:45 am]

BILLING CODE 7710-12-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1008

RIN 0991-AA85

Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996, this final rule sets forth the specific procedures by which the Department, through the Office of Inspector General (OIG), in consultation with the Department of Justice (DoJ), will issue advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to the Federal and State health care programs. The procedures for submitting a request and obtaining an advisory opinion from the OIG were established through interim final regulations published in the **Federal Register** on February 19, 1997. In response to public comments received on these interim final regulations, this final rule revises and clarifies various aspects of the earlier rulemaking.

EFFECTIVE DATE: This rule is effective on July 16, 1998.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, (202) 619-0089, OIG Regulations Officer.

SUPPLEMENTARY INFORMATION:

I. Background

A. Section 205 of Public Law 104-191

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, specifically required the Department to provide a formal guidance process to requesting individuals and entities regarding the application of the anti-kickback statute, the safe harbor provisions, and other OIG health care fraud and abuse sanctions. In accordance with section 205 of HIPAA, the Department, in

consultation with the DoJ, issues written advisory opinions to parties with regard to: (1) what constitutes prohibited remuneration under the anti-kickback statute; (2) whether an arrangement or proposed arrangement satisfies the criteria in section 1128B(b)(3) of the Social Security Act (the Act), or established by regulation, for activities which do not result in prohibited remuneration; (3) what constitutes an inducement to reduce or limit services to Medicare or Medicaid program beneficiaries under section 1128A(b) of the Act¹; and (4) whether an activity or proposed activity constitutes grounds for the imposition of civil or criminal sanctions under sections 1128, 1128A, or 1128B of the Act. Thus, advisory opinions may be issued with regard to the criminal provisions of section 1128B of the Act, which includes the anti-kickback statute, as well as the provisions of section 1128 of the Act, which authorizes the Department to exclude individuals and entities from participation in Federal and State health care programs. Exclusions are authorized in a wide variety of circumstances, including, for example, conviction of health care related offenses, State licensure action, and submission of claims in excess of usual charges or for services that fail to meet professionally recognized standards of health care. In addition, advisory opinions are available regarding the civil money penalty provisions of section 1128A of the Act, which authorizes penalties for a variety of acts, including, among others, presentation of a false or fraudulent Medicare or Medicaid claim and hospital payments to physicians to induce them to reduce or limit care to any Medicare or Medicaid beneficiary under their direct care.

B. OIG Interim Final Regulations

Because HIPAA required that specific procedures and final regulations on the advisory opinion process be in place by February 21, 1997, the Secretary determined that it was both impracticable and contrary to the public interest to first issue regulations in proposed rulemaking form. As a result, on February 19, 1997, the OIG published interim final regulations (62 FR 7350) establishing a new part 1008 in 42 CFR chapter V addressing the various procedural issues and aspects of the advisory opinion process. Specifically, the interim final rule set

forth (1) the procedures to be followed by parties applying for advisory opinions and by the OIG in responding to these requests; (2) the time frames pursuant to which the OIG will receive and respond to requests; (3) the type and amount of fees to be charged to requesting parties; and (4) the manner in which the public will be informed of the issuance of any advisory opinions.

The interim final rule also set forth a 60-day public comment period for specific comments and recommendations for refining the advisory opinion process.

C. Summary of the Interim Final Rule

The establishment of a new part 1008 in 42 CFR chapter V specifically addressed, among other provisions, the following procedural aspects of the advisory opinion process:

1. Responsibilities of Outside Parties

Section 1008.15 of the interim final rule indicated that any individual or entity may submit a request for an advisory opinion, but that the arrangement in question must, at the time of the request for an opinion, either be in existence or be an arrangement into which the parties have a good faith intention to enter in the future.² Section 1008.15(b) stated that requests presenting general questions of interpretation, posing hypothetical situations, or seeking an opinion about the activities of third parties would not qualify for advisory opinions. Section 1008.11 stated that the OIG would not provide advisory opinions to persons not involved directly in the arrangement. In addition, §§ 1008.53 and 1008.55(b) of the rule stated that an advisory opinion would be legally binding on the Department and the requesting party only with respect to the specific conduct of the requesting party; it would not be legally binding with respect to third party conduct, even if such conduct appears similar to the conduct of the initial requestor.

Section 1008.36 of the interim final rule indicated that a request for an advisory opinion must be submitted to the OIG in written form and must present all facts relevant to the subject matter for which the opinion is being requested. Section 1008.37 provided that all parties and potential parties to the arrangement must be identified.

² Any individual or entity may submit a request for an advisory opinion. However, we anticipate that most requests will apply to health care business arrangements. Therefore, for purposes of this discussion, we will generally use the term "arrangement" to refer to the factual circumstances about which an advisory opinion is requested, even though we realize that some requests will involve facts not related to a business arrangement.

¹ Public Law 104-191 erroneously cited this provision as section 1128B(b) of the Act. Section 4331(a) of the Balanced Budget Act of 1997, Public Law 105-33, corrected this citation to section 1128A(b) of the Act.

Section 1008.38 of the regulations required the requesting party to certify to the truth, correctness, and completeness of all information submitted to the OIG, to the requestor's best knowledge. It also required a requesting party seeking an advisory opinion about a proposed arrangement to certify its good faith intent to enter into the arrangement upon receipt of a favorable advisory opinion.

Section 1008.18 of the interim final rule provided that requestors may contact the OIG directly to inquire about the type and scope of information needed to process their requests, and that the OIG could provide requestors with a list of suggested preliminary questions to aid in formulating their requests. As set forth in § 1008.39, at any time after the preliminary request for an advisory opinion, the OIG may request additional information that the OIG deems necessary to address the advisory opinion request.

2. Fees To Be Charged

In accordance with HIPAA, subpart C of 42 CFR part 1008 of the regulations addressed fees for the cost of advisory opinions. Specifically, § 1008.31 of the regulations stated that the OIG will charge a fee to the requestor (payable to the U.S. Treasury) equal to the costs incurred by the Department in responding to the request. The regulations stated that the fees will factor in the salary, benefits, and overhead costs of attorneys and others who work on analyzing the request and writing the advisory opinion. Because processing fees will vary according to the complexity of the request and the time needed to prepare the response, the rule did not establish specific processing costs in advance. The interim final rule's preamble discussion, however, contains broad estimates of costs and staff time to aid prospective requestors.

3. Responding to the Advisory Opinion Request

Subpart E of the interim final rule addressed the obligations and responsibilities of the OIG in accepting and issuing formal advisory opinions. Section 1008.41 specifically indicated that the OIG would promptly examine the request for an advisory opinion upon receipt and determine whether additional information would be required. The regulations established that within ten (10) working days of receiving the request, the OIG would notify the requestor in writing that (i) it was formally accepting the request, (ii) it was declining to accept the request, or

(iii) it needed additional information to process the request.

In accordance with § 1008.43(c) of the rule, once sufficient information is provided to the OIG, the OIG will consult with DoJ and issue an advisory opinion within sixty (60) days after formally accepting the advisory opinion request. Section 1008.45 of the regulations addresses the OIG's right to rescind an advisory opinion after its issuance in limited circumstances.

4. Dissemination of Advisory Opinions

Section 1008.47 of the interim final rule addressed the circumstances under which the OIG may disclose information submitted by requestors, including making copies of issued opinions available for public inspection and on the OIG's Internet web site.³

II. Response to Comments and Summary of Revisions

As indicated above, the interim final rule established a 60 day comment period for soliciting relevant public comments on the scope and applicability of the provisions set forth in 42 CFR part 1008. We received a total of twenty (20) timely-filed public comments from various health care associations and organizations and from several State and professional medical societies. The comments included both broad concerns about the issuance of advisory opinions in general and more detailed comments on specific aspects of the advisory opinion process. In addition, based on informal discussions with potential requestors and experience gained in reviewing and processing advisory opinion requests since issuance of the interim final rule, the OIG is using this opportunity to clarify portions of the regulations consistent with the statute and the intent of this procedural rulemaking. Set forth below is a synopsis of the various comments received and a summary of the specific revisions and clarifications being made to the regulations in 42 CFR part 1008.

A. General Comments

Comment: Many commenters welcomed the prospect of advisory opinions and expressed general support for the advisory opinion process established by the interim final rule. One commenter indicated that the interim final rule is an attempt "to develop an effective advisory opinion process as a method of bringing clarity to the current Federal fraud and abuse statutory and regulatory system." Another commenter stated that the

interim final rule was a "positive step in the right direction." A third commenter, reflecting the view of several, stated that "the best deterrent to fraud and abuse in the health care industry is clear guidance from the Government concerning its view of the applicable requirements."

The general support of these remarks notwithstanding, these commenters and others expressed concerns about the advisory opinion process. Several commenters viewed the regulations as overly restrictive and complex. Commenters stated that the requirements for submitting substantial amounts of supporting information would dissuade parties from seeking advisory opinions. One commenter stated that other agencies rendering advisory opinions have less onerous requirements, citing the DoJ Antitrust Division Procedures for Business Review Letters, 28 CFR 50.6, and the Federal Trade Commission (FTC) Advisory Opinion Procedures, 16 CFR 1.1 through 1.4. This commenter and others believed that the OIG advisory opinion process could be simplified without compromising the OIG's position. One commenter suggested that the requirements, which it perceived as burdensome, reflect the OIG's opposition to issuing advisory opinions during the legislative process.

Response: The OIG intends to carry out Congress' mandate in good faith and to the best of our ability. We are hopeful that an effective advisory opinion program will further the OIG's fraud-fighting mission by aiding requestors in complying with the fraud and abuse laws. Deterring fraud and abuse in the Federal health care programs continues to be an integral part of that mission. For example, the OIG special fraud alerts and model compliance plans are specifically targeted at deterring fraudulent and abusive activities. Consistent with the OIG mission, we endeavored to develop an advisory opinion process that balances the industry's desire for a process that is not overly burdensome with the OIG's need for full and complete disclosure of facts pertaining to the arrangements under review.

Our goal is to render meaningful and informed opinions based on a complete and comprehensive understanding of the relevant facts and circumstances of a given arrangement, protecting in the process only those arrangements that pose little or no risk of fraud or abuse to the Federal health care programs. For complex arrangements, this may require relatively extensive submissions by a requestor. We believe that it is difficult to develop bright line rules for the

³ <http://www.dhhs.gov/progorg/oig>

submission of information uniformly applicable to the wide array of arrangements and sanction authorities that may be the subject of advisory opinions.

The Department is in a unique position among agencies of being compelled by statute to provide advisory opinions that bind the Department and the requestors in criminal, as well as civil, matters. The Department must issue these opinions within a sixty (60) day period, regardless of the complexity of the arrangement in question. Accordingly, the OIG has a heightened need to scrutinize arrangements closely to assure that fraudulent or abusive arrangements are not inappropriately granted protection from sanction.

As we gain experience in issuing advisory opinions, we will continue to look for ways to simplify the process. Presently, we are revising these regulations to provide increased flexibility to respond to the circumstances of individual situations. As described in greater detail below, these changes include, among others, expressly permitting submission of requests by counsel; allowing submission of drafts, models, or narrative descriptions of operative documents for proposed arrangements; providing for informal consultation with requestors to aid the OIG's deliberative process; and providing for notice, an opportunity to respond, and a reasonable unwinding period in the unlikely event of termination of a favorable advisory opinion. In addition, these regulations add a procedure for obtaining initial non-binding fee estimates.

Comment: One commenter recommended that the OIG publish generic standards and criteria by which the "case specific" safe harbors afforded by advisory opinions would be granted. The commenter believed that without the promulgation of such standards and criteria, the advisory opinion process could be viewed as arbitrary and capricious.

Response: These regulations are designed to establish procedures for obtaining advisory opinions that will provide the public with meaningful advice regarding the anti-kickback statutes and other OIG sanction authorities as applied to specific factual situations. The statutory and regulatory safe harbors to the anti-kickback statute describe generalized, hypothetical arrangements that are protected. In contrast, an advisory opinion is a means of relating the anti-kickback statute, as well as other OIG sanction authorities, to the facts of a particular arrangement.

There are likely to be factors that make some specific arrangements appropriate for a favorable advisory opinion, even in subject matter areas where a generalized safe harbor may be impractical. Thus, we believe that particularized or "case specific" safe harbor treatment is appropriate where the specific arrangement contains limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused. Our use of the phrase "particularized" or "case specific" safe harbors refers simply to a determination by the OIG, in the exercise of prosecutorial discretion, not to impose sanctions for specific arrangements that may constitute technical violations of OIG authorities.

B. Specific Comments on the Advisory Opinion Process

Section 1008.1, Basis and Purpose

Comment: A number of commenters suggested that requiring a requestor to be a party to the arrangement, or proposed arrangement, that is the subject of a request appears to prevent an attorney from requesting an advisory opinion on behalf of a client.

Response: We recognize that many requesting parties will employ attorneys to assist them in preparing advisory opinion requests. We believe that it is appropriate for an attorney, acting as counsel, to submit an advisory opinion request on behalf of a client, provided that the client is a proper requesting party in all respects under these regulations. This means that the client itself must comply with all requirements for being a proper requesting party under these regulations, including, but not limited to, the requirements under § 1008.36 that the requesting party be specifically identified, and under § 1008.38 that the requesting party provide certain certifications (these certifications must be signed by the client, not by the attorney). Section 1008.1 is being clarified accordingly.

Section 1008.5, Matters Subject to Advisory Opinions

Comment: One commenter requested that we clarify the meaning of the term "authority" as we used it in our preamble to the interim final rule at page 7352. Specifically, the preamble stated:

"To the extent that the subject matter of the request is the requestor's potential liability under one sanction authority, we believe the request should provide a complete description of the facts addressing the elements of that authority. Under these interim final regulations, if the request asks

the OIG to advise on whether an arrangement is subject to sanction under more than one legal authority, we believe the submission should include a complete description of the facts regarding the different sanction authorities in those statutes."

Response: We agree with the commenter that clarification of our use of the term "authority" would be helpful. "Authority," as used in the interim final rule preamble cited above, refers to each separate sanction authority enumerated in sections 1128, 1128A, 1128B of the Act, i.e., each potential ground for exclusion, civil money penalty, or criminal penalty. The section 1128, 1128A, and 1128B sanction authorities cover a wide range of conduct, from kickbacks to false claims to doing business with sanctioned persons. It is unlikely that any one arrangement that is the subject of an advisory opinion would implicate all of the section 1128, 1128A, and 1128B sanction authorities. Because it is most familiar with the circumstances of its arrangement, a requesting party is in the best position, as an initial matter, to identify those authorities that may be implicated in its arrangement and thus expedite processing of its advisory opinion request. Accordingly, when submitting advisory opinion requests, requestors should identify the specific sanction authority or authorities within sections 1128, 1128A, and 1128B of the Act about which they seek an advisory opinion and should describe the facts relevant to each identified authority. Requesting parties may seek an advisory opinion on all sanction authorities they believe may be implicated by their arrangements. However, a blanket designation that a party seeks an advisory opinion on sections 1128, 1128A, and 1128B of the Act, without more specificity, is likely to elicit an OIG request for substantial additional information and delay processing of the advisory opinion. For these same reasons, requestors seeking opinions on compliance with the anti-kickback safe harbors should specify those safe harbors they believe may apply to their arrangements. We have revised the regulations to require designation of the specific sanction authorities about which an advisory opinion has been requested.

Comment: In HIPAA, Congress enacted a new statutory safe harbor to the anti-kickback statute for certain shared-risk arrangements (section 1128B(b)(3)(F) of the Act). This safe harbor is the subject of an on-going negotiated rulemaking process mandated by HIPAA and being

conducted under the auspices of the OIG. The goal of the negotiated rulemaking is the promulgation of regulations governing the safe harbor. One commenter expressed the view that the OIG should not withhold advisory opinions on the shared-risk exception pending the outcome of the negotiated rulemaking.

Response: We discern nothing in HIPAA that permits us to decline to give advisory opinions on the shared-risk safe harbor pending the outcome of the negotiated rulemaking and promulgation of applicable regulations. Accordingly, we will opine on the statute as written. Any advisory opinion issued will be binding on the Department and the requesting parties as provided in these regulations. However, favorable and unfavorable advisory opinions issued before the outcome of the rulemaking process may be subject to modification or termination based on the rule eventually promulgated.

Comment: Two commenters believed that the OIG advisory opinions should address the application of the "Stark amendment" under section 1877 of the Act.

Response: Section 4314 of the Balanced Budget Act of 1997, Public Law 105-33, includes a new requirement that the Department issue advisory opinions on the "Stark" provisions. These opinions will be issued by the Health Care Financing Administration (HCFA) in accordance with regulations issued by the Department. To aid in coordinating both advisory opinion processes, we are modifying our regulations to require requesting parties to notify the OIG if they apply to HCFA for a "Stark" opinion on the same arrangement for which they are seeking an OIG advisory opinion.

Section 1008.15, Facts Subject to Advisory Opinions

Comment: Several commenters suggested that trade associations should be permitted to seek advisory opinions on behalf of their members. These commenters assert that such requests would benefit association members who may not have sufficient resources to obtain an advisory opinion independently. One commenter noted that trade association opinions would be particularly valuable for arrangements involving "national issues." Several commenters also suggested that we issue advisory opinions about "model" arrangements that might be duplicated by many individual entities and that we issue non-binding opinions or business guidance to individual parties and trade

associations similar to advice provided by the FTC and DoJ on antitrust matters.

Response: Section 205 of HIPAA contemplates advisory opinions regarding arrangements currently existing or proposed by specific, identified requestors. This follows from HIPAA's mandate that advisory opinions be binding on the parties, as well as the Department. It is difficult to discern how an advisory opinion issued to a trade association could be made binding for association members or others who later implement an arrangement described in a trade association request. The same difficulty would arise with respect to parties attempting to duplicate protected "model" arrangements. HIPAA's requirements notwithstanding, it is unlikely that a party could precisely duplicate an approved arrangement; invariably, there would be differences, some of which might be significant. Sanction authorities impose liability based on acts by specific people in particular factual circumstances. Thus, a particular arrangement may be legal with respect to one party, but not with respect to another. We believe that it is impossible to identify all hypothetical factors that might lead to different results.

We will continue, however, to offer other industry guidance in the form of safe harbor regulations and special fraud alerts. As part of the OIG's expanded fraud-fighting efforts, we are actively working to finalize the existing proposed safe harbors, to issue new special fraud alerts, and to consider new safe harbors proposed by the public. In accordance with HIPAA, we will formally solicit public comments annually regarding new proposals for safe harbors and special fraud alerts. However, we welcome written comments from the public at any time regarding these topics or other fraud and abuse concerns.

Section 1008.31, Oig Fees for the Cost of Advisory Opinions

Comment: We received several comments regarding the fee provisions of the regulations. A number of commenters objected to the OIG charging a fee for processing an advisory opinion. These commenters believed that a fee would deter some requesting parties and would impose an undue burden on small companies.

Response: Under section 205 of HIPAA Congress directed that the Department charge a fee equal to the costs incurred by the Department in processing an advisory opinion (42 U.S.C. 1320a-7d(b)(5)(B)(ii)).

Comment: Many commenters believed that the amount of the fee charged for an advisory opinion should be limited. These commenters contend that uncertainty about the ultimate fee to be charged for an opinion will be especially problematic for individuals and small entities. Several commenters suggested that the "triggering dollar amount" provided for in the interim final rule, permitting requestors to designate the maximum fee they are willing to incur, does not adequately address the problem of unlimited fees, although some commenters generally supported the concept and advocated its retention. One commenter observed that once the triggering dollar amount is reached, a requesting party "is faced with the untenable decision of paying the triggering dollar amount and receiving nothing to show for its money, or authorizing the OIG to proceed to process the request regardless of the cost." Many commenters suggested that the solution to this dilemma would be for the OIG to provide a fee estimate based on an initial review of the request. Commenters essentially proposed two types of estimates: (1) an initial estimate, with a cap on the final fee equal to a certain percentage above the original estimate (for example, 110% of the original estimate), or (2) a non-binding estimate combined with continued use of the triggering dollar amount designation, which designation could be amended based on the non-binding estimate. Additionally, four commenters suggested that the OIG adopt a fixed fee schedule similar to the one used by the Internal Revenue Service (IRS) for processing private letter rulings.

Response: In light of our limited experience with the advisory opinion process, at this time we believe that a binding estimate with a percentage cap would be contrary to section 205 of HIPAA, which requires recovery of actual costs incurred. We do not have enough experience to estimate actual costs with sufficient reliability to make such estimates binding. Similarly, it is not possible at this time to develop fee schedules that would reflect actual costs. As the OIG gains experience, we may be able to provide binding estimates or fee schedules; nothing in these regulations precludes us from revising these proposals at a later date if circumstances warrant.

Until such time, we believe that providing an initial, non-binding estimate is reasonable and feasible. Accordingly, we are revising the regulations to provide for a non-binding, good faith estimate, if requested, based on an initial review of an advisory

opinion request. This initial estimate will be provided at the time an advisory opinion is accepted. However, we will toll processing of the advisory opinion request from the date of acceptance of the request until the requesting party authorizes us in writing to continue the processing. This tolling will enable requesting parties who find that the estimated fee is more than they wish to spend to withdraw their requests before incurring additional costs. We are retaining the triggering dollar amount designation procedures and providing for revised designations in response to our non-binding fee estimates. We note that fees for advisory opinions issued to date generally have been in the range of \$1,500 to \$3,000, with several costing considerably less.

Comment: Some commenters believed that not all requestors may be able to afford advisory opinions. One commenter suggested that the OIG use a sliding fee schedule based on after-tax net profits of the requestor. Further, one commenter believed that the \$250 deposit was excessive for individuals and small entities making simple requests for which the costs might not total \$250, i.e., requesting confirmation of the applicability of an existing opinion to a new participant in the arrangement. Another commenter urged the OIG to notify the requestor prior to processing an advisory opinion if the processing costs are likely to exceed the designated triggering dollar amount to permit requestors who do not wish to pay more than the designated amount to withdraw their requests before incurring costs.

Response: Section 205 of HIPAA contains no financial hardship exception to the mandate that the Department collect a fee equal to the costs incurred by the Department. Even if there were such an exception, the proposal for a sliding scale based on a requestor's after-tax net profits strikes us as impractical to calculate and administer. It is unclear how such a system would apply to individual requestors or non-profit organizations. The \$250 initial deposit represents the OIG's reasonable assessment of the minimum processing costs for advisory opinion requests. Every request for an advisory opinion takes time to read and analyze to ensure that the OIG has an accurate understanding of the facts submitted and the application of the fraud statutes to those facts. The OIG must then consult with DoJ and write the actual advisory opinion. Our experience thus far demonstrates that it is unlikely that even the simplest advisory opinions will cost the agency less than \$250. Where possible, we will

try to notify requestors informally if, as an initial matter, we believe that their designated triggering dollar amounts are likely to be exceeded.

Comment: One commenter suggested that the OIG notify requestors if experts for which costs will be incurred will be required.

Response: Section 1008.33 of the interim final rule provided for notice to requestors, with an estimate of costs, if expert opinions are required. For purposes of clarity, that provision is being moved to § 1008.31(e). We are further revising the rule to clarify that requestors will be responsible for payment of the actual costs of expert opinions and that the expert's work and opinion will be subject to the sole direction of the OIG regardless of the source of payment.

Section 1008.33, Expert Opinions From Outside Sources

Comment: One commenter suggested that requestors should be permitted to review and comment on expert opinions from outside sources, and should be given an opportunity to provide their own expert opinions.

Response: Nothing in the regulations precludes a requestor from submitting an expert opinion if they so desire. In addition, the OIG can solicit a requestor's views on expert opinions if the OIG believes such input would aid its deliberative process. However, we do not believe that it is necessary or cost-efficient to require the OIG to consult with requestors regarding expert opinions in all cases.

Subpart D, Submission of a Formal Request for an Advisory Opinion

Comment: Subpart D of these regulations enumerates the information requestors must submit with their advisory opinion requests. A number of commenters found the requirements of this subpart overly burdensome and likely to dissuade parties from seeking advisory opinions. These commenters expressed the view that the advisory opinion process was not intended as a preliminary enforcement tool by which the OIG could collect large quantities of information about providers and other health care entities.

Response: The procedural requirements set forth in this subpart are intended to ensure that the OIG has a complete record on which to base its advisory opinion, which will bind the Department and the parties. An advisory opinion serves as an individualized safe harbor against criminal and civil penalties; therefore, it is incumbent upon the OIG to conduct a thorough review.

Section 1008.36, Submission of a Request

Comment: Several commenters stated that requesting parties should not be required to provide extensive information about potential participants in an arrangement who are not actual requestors. One commenter expressed the view that the focus of an advisory opinion should be on the factual circumstances of an arrangement, not on the identities of the parties.

Additionally, several commenters believed that sometimes it would be impossible or highly impractical to identify all potential participants to an arrangement. According to their concerns, some arrangements might involve hundreds or even thousands of parties. One commenter cited as an example a request involving all network providers in a managed care plan. The commenter explained that there might be practical difficulties in identifying all such providers; moreover, the problem could be further complicated if the roster of providers were subject to change as a direct result of implementation of the arrangement.

Response: We believe that the identity of parties is sometimes important to rendering an informed decision about an arrangement. There may be different implications under the sanction authorities for different parties in similar factual circumstances. For example, the analysis of a proposed joint venture arrangement under the anti-kickback statute may depend on whether or not the proposed investors are potential referral sources or have other business relationships. Furthermore, identification of parties helps the OIG to determine if the arrangement in question or a similar arrangement is the subject of any ongoing investigation or is, or has been, the subject of a governmental proceeding. As stated in § 1008.15 of these regulations, the OIG will not opine on any matters under investigation.

Section 1008.36(b)(1) requires disclosure of participants to the extent known to the requestor. We agree that there may be situations in which it is not possible or practical to identify all potential participants in an arrangement. In many of these select cases, the OIG may be able to render an informed opinion without knowing the identities of all participants. The managed care network described above might be one such case. Another example might be a proposed pricing arrangement affecting hundreds or thousands of potential customers. In

these types of circumstances, requesting parties should make clear in their requests the reasons why the identities of all potential participants cannot be provided. If it appears to the OIG that the identities of potential participants are reasonably available, the OIG may decline to process the request or may accept the request subject to the subsequent receipt of the identities of potential participants. An advisory opinion issued in such circumstances will be binding only on the requesting party. The requesting party may not be protected by an advisory opinion if the material facts about the unidentified parties differ from the material facts described in the request. For example, if a requestor seeking an advisory opinion about a pricing arrangement describes potential customers as hospitals and the character of the customers is material, a favorable advisory opinion would not be binding on sales to non-hospital customers. Parties joining an arrangement after issuance of an advisory opinion may seek a separate advisory opinion in their own right.

Comment: Several commenters recommended that requestors be permitted to submit anonymous requests, identifying themselves only when it appeared that the OIG would issue a favorable opinion.

Response: Early identification of requestors helps the OIG determine whether the party making the request is under investigation or is involved in proceedings involving the Department or other governmental agencies that would preclude issuance of an advisory opinion under § 1008.15. By making this determination as early in the process as practicable, the OIG can minimize processing fees incurred by requestors.

Comment: Several commenters objected to the required disclosure of the identities of non-requesting parties. Commenters were concerned that such disclosures could undermine the business and competitive interests of all parties to an arrangement. One commenter explained that non-requesting parties may not want to identify themselves in the early planning stages of a transaction, before they are assured that the proposed transaction passes fraud and abuse muster. This is especially true, according to some commenters, because the anti-kickback statute reaches mere offers of prohibited remuneration. Further, they believe there may also be proprietary business reasons for non-requesting parties to withhold their identities. For example, they may be engaged in preliminary discussions and not want to risk being disadvantaged by competitors who may discover their

identity. For these reasons, some commenters believed that the OIG should permit generic descriptions of non-requesting parties to the transaction.

Response: For reasons previously stated, we believe that the identities of parties can be essential to rendering an informed opinion about an arrangement. We recognize that some proposed arrangements may be presented to us at an early stage before all parties are fully committed to participate in the arrangement. For example, a group of surgeons planning an ambulatory surgical center may not have commitments from all prospective investors. Requestors in such circumstances run the risk that the OIG response may be rendered meaningless by subsequent changes in the identities of the parties, i.e., a non-referral source party is replaced in an arrangement by a potential referral source. As set forth in § 1008.53, advisory opinions are operative and binding only for requestors. If parties desire protection, they must be identified as requestors. Non-requesting parties seeking protection after the advisory opinion is issued would need to submit a new request for an advisory opinion.

We are mindful that the risk of disclosures of proprietary information may be troublesome from a business perspective. The OIG is subject to the Freedom of Information Act (FOIA), 5 U.S.C. 552, and the Department's FOIA regulations set forth in 45 CFR part 5. The OIG will endeavor to protect submissions of proprietary information to the extent and in the manner permitted by these authorities.

Comment: Several commenters suggested that the OIG not require requestors to provide complete copies of all operative documents. Instead, these commenters advocated permitting detailed descriptions of such documents. In addition, some commenters noted that operative documents may not be available for proposed arrangements and that requiring their preparation would impose significant costs for arrangements that might never be implemented. Commenters also expressed concerns regarding the potential for disclosure of operative documents under FOIA. One commenter asked that the OIG clarify the meaning of the term "operative documents."

Response: As used in these regulations, "operative documents" broadly encompasses all written documents relevant to the organization or operation of the arrangement in question. These may include, but are

not limited to, contracts, leases, lease guarantees, deeds, loan documents (promissory notes, loan agreements, guarantees, mortgages, etc.), employment agreements, court documents and records, settlement agreements, licenses, permits, corporate and partnership organizational documents (articles of incorporation, bylaws, partnership agreements, operating agreements, etc.), and any documents related to these documents. The specific documents required for review of a particular arrangement will depend on the nature of the arrangement.

We are clarifying the regulations to provide that for proposed arrangements, draft or model documents or detailed descriptions of material terms to be contained in such documents may be provided in lieu of operative documents. We caution requestors that material differences between the drafts, models, or descriptions provided and the final operative documents, including changes or omissions, may affect the enforceability of their options. Accordingly, requestors are encouraged to provide full, complete, and accurate information regarding material terms of operative documents for proposed arrangements.

We are further revising these regulations to permit parties to submit initially only those portions of documents relevant to the arrangement at issue. Parties submitting partial documents must clearly identify and describe in general terms those portions that have been withheld. For example, a diversified corporation may elect to submit only those portions of its business plan relating to health care items or services that are the subject of the request. Nothing in these regulations precludes the OIG from subsequently requesting copies of the withheld portions (and from tolling the processing time in accordance with § 1008.39 pending receipt), if the OIG deems those portions necessary in order to render an informed opinion. The ultimate determination of the relevancy of operative documents, or portions thereof, rests in the sole discretion of the OIG.

Comment: One commenter proposed eliminating the requirement that requesting parties provide Medicare and Medicaid provider numbers.

Response: We agree that provider numbers are not necessary in every case. We are eliminating the requirement for submitting these numbers, but reserve the right to request provider numbers, or other identifying information, if we determine that they are necessary in particular circumstances. We have

determined, however, that the Debt Collection Improvement Act of 1996 (section 31001 of Public Law 104-134) requires agencies to collect the Taxpayer Identification Number (TIN) from all persons or business entities "doing business with a Federal agency" (see 31 U.S.C. 7701(c)). We believe that requesting, receiving and paying for the OIG's 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 requestor's TIN. 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.

Comment: Five commenters stated that requiring requestors to provide detailed and highly specific information regarding existing or prospective arrangements raises questions about the requesting and non-requesting parties' exposure to sanction in the event of an unfavorable opinion. These commenters considered this potential exposure to be a disincentive to using the advisory opinion process. One commenter explained, for example, that if the OIG determines that an arrangement violates the anti-kickback statute, the requester will have given the OIG much, if not all, of the information necessary to prosecute. This commenter suggested that the OIG adopt a "grace" period to allow parties found to be in violation to terminate or restrict an arrangement without risk of prosecution.

Response: There is an unavoidable risk in submitting a request for an advisory opinion regarding the potential applicability of a criminal statute to an existing arrangement. A thorough and detailed understanding of arrangements about which advisory opinions are sought is necessary for the OIG to render an informed opinion. To the extent the arrangement does not qualify for a "safe harbor" or a favorable advisory opinion, it is subject to scrutiny and potential investigation. Otherwise, we believe unscrupulous parties could use the advisory opinion process to immunize themselves from prosecution. In most instances, however, we believe the risk to be minimal. First, most requests will be about arrangements that are not yet operative. Second, in seeking an advisory opinion, most requesting parties presumably will have reviewed the arrangement and determined that it poses little risk of fraud and abuse to Federal health care programs. Third, the failure to obtain a favorable advisory opinion does not mean that an arrangement is illegal; it means only

that the arrangement may pose some risk of fraud and abuse.

As we have observed in the past, the fact that an arrangement does not qualify for a safe harbor or for a favorable advisory opinion does not mean that the anti-kickback statute has been violated or that an enforcement action is appropriate. For example, in an enforcement proceeding, whether an arrangement in fact constitutes a violation of the anti-kickback statute would depend on a showing of requisite intent to solicit, receive, offer, or pay remuneration to induce referrals or business covered by a Federal health care program.

Comment: We indicated in the preamble to the interim final rule that because of the wide diversity of arrangements about which the OIG might be asked to opine, we could not detail in the regulations all of the information a particular requestor would need to submit. Instead, we provided for the use of suggested preliminary questions, which we would provide, and permitted potential requestors to contact us for further guidance about what information to submit. We specifically solicited comments regarding this approach. One commenter agreed that the information necessary to issue an advisory opinion depends on the nature of the request, and that it is not feasible to set hard and fast rules regarding the specific types of information required to issue an advisory opinion.

Response: We are leaving in place the provision regarding the use of the preliminary questions. Moreover, we will continue to permit potential requestors to contact us in writing for guidance on the specific types of information that might be needed for their particular requests.

Section 1008.37, Disclosure of Ownership and Related Information

Comment: One commenter opposed the requirement that requesting parties disclose ownership and related information on the ground that such requirement is burdensome.

Response: We are not persuaded that this requirement is burdensome. The majority of requestors will likely already be providing this information to HCFA through required filings of HCFA form 1513. A copy of a requestor's current HCFA form 1513 will satisfy this requirement.

Section 1008.38, Signed Certifications by the Requestor

Comment: We solicited comments regarding the certification process

outlined in the interim final rule. This process requires requesting parties to certify to the truthfulness of their submissions, including their good faith intent to enter into proposed arrangements. Several commenters viewed the certification requirement as an unnecessary and burdensome requirement not contemplated by section 205 of HIPAA. These commenters stated that the certification requirement is unnecessary because the OIG is not bound by an advisory opinion if it later discovers that a requestor did not fully and accurately disclose information. One commenter suggested that we replace the certification requirement with a provision stating that the protection afforded by an advisory opinion would be applicable only to the arrangement as described in the request and only to the extent implemented by the requestor in accordance with the facts represented in the request. Another commenter believed that certifications were unnecessary, because the advisory opinion process itself is a complicated and costly procedure adequate to deter providers from seeking advisory opinions on arrangements that are hypothetical or not under serious consideration.

Response: The required certifications help ensure that the OIG's time and resources are spent addressing real concerns of legitimate requestors. In particular, the requirement that requestors seeking advisory opinions about proposed arrangements certify to a good faith intent to enter into the proposed arrangement safeguards against abuse of the advisory opinion process by requestors seeking opinions about competitor's practices or hypothetical questions. We are not persuaded that our ability to invalidate an opinion upon later discovery of discrepancies in the facts or implementation is a sufficient or efficient means of protecting against improper or inappropriate requests. In addition, we are not convinced that the advisory opinion process is so costly or complex as to thwart misuse of the process.

As a practical matter, our experience suggests that the certification requirement benefits requesting parties as well. The requirement serves as an incentive to requestors to focus on the completeness and accuracy of their presentations and to research

thoroughly and document their arrangements before submitting their requests or submitting additional information. We believe that this keeps costs down and expedites issuance of opinions by reducing our need to request clarifications and additional information. Additionally, enhanced diligence should reduce the need for ancillary opinions after issuance of the original advisory opinion when new facts or understandings surface that were not fully investigated or considered by the requestor at the time of the initial request. Consequently, we believe that certifications will help ensure more meaningful and informed opinions.

We are clarifying the certification requirements in § 1008.38 in two ways. First, we are adding a provision, inadvertently omitted from the interim final rule, designating the appropriate signatory on behalf of requestors that are limited liability companies. Second, we are clarifying that each requesting party must provide the required certification. These certifications must be signed by the requesting party, not by its attorney.

Comment: Several commenters objected to the requirement for certification of a good faith intent to enter into an arrangement upon receipt of a favorably advisory opinion. These commenters argue that there may be legitimate business reasons, unrelated to the fraud and abuse determination, that an arrangement is not consummated. For example, seeking an advisory opinion may be part of the parties' initial feasibility determinations. Commenters explained that in the fluid and changing health care marketplace, many legitimate business factors may arise between the time a request is filed and the advisory opinion is issued would cause the parties to abandon their proposed arrangements. One commenter questioned what action the OIG would or could take if an arrangement described in a favorable advisory opinion is not implemented. Several commenters urged that failure to implement an approved arrangement should not subject a requestor to any adverse action or inference.

Response: We continue to believe that requiring a good faith intent to enter into a transaction is a reasonable safeguard against misuse of an advisory opinion process. The certification requirement as set forth in these regulations does not preclude abandonment of a proposed arrangement for legitimate business reasons (i.e., an investor withdraws, financing becomes unavailable) that were not reasonably foreseeable at the time the certification was signed.

Comment: One commentor requested that we revise § 1008.38 to accommodate a change in the individual signing additional certifications if, for example, the requestor hires a new chief executive officer while the advisory opinion is pending.

Response: The person signing certifications on behalf of a requestor should be the person occupying the position listed in § 1008.38(c). We are clarifying this section to make clear that changes of the type described by this commentor are allowed.

Section 1008.40, Withdrawal

Comment: Three commenters suggested that all documents submitted in support of a withdrawal request should be returned to the requestor.

Response: We do not believe that requesting parties have a right to the return of documents voluntarily submitted to the Government. In particular, there is no right to the return of potential evidence of a violation of law, and the Government would be remiss in returning such information. In addition, it may be necessary to retain submitted materials to document the workings of the advisory opinion process. Nevertheless, although the OIG reserves the right to retain documents submitted by requestors, nothing in these regulations precludes the OIG from returning documents in its discretion to the extent allowed by law. Parties should note that as part of OIG's required consultation with DoJ, copies of requests and related documents may be sent to DoJ. The OIG can make no representation as to return of such documents to DoJ.

Section 1008.41, Oig Acceptance of the Request

Comment: We requested comments on the process for screening requests for advisory opinions. One commenter suggested that instead of screening and rejecting incomplete requests, such requests should be accepted contingent on receipt of the missing information, and the processing time should be tolled until the missing information is submitted. This commenter explained that in the dynamic health care marketplace, all information may not be available at the time of the request. Another commenter maintained that § 1008.41(b)(3), which provides for formally declining a request, is unnecessary and should be deleted.

Response: We disagree that § 1008.41(b)(3) is unnecessary. There may be circumstances in which a request must be declined in accordance with section 205 of HIPAA, for example, where it seeks a determination of fair

market value or asks whether a physician is an employee of a hospital for purposes of qualifying for the employee safe harbor to the anti-kickback statute. However, nothing in these regulations precludes the OIG, in appropriate circumstances, from accepting incomplete requests conditionally, and we have done so in practice.

Comment: One commentor suggested that the OIG should provide a written statement of reasons for declining a request.

Response: In order to make the advisory opinion program meaningful, it has generally been our practice to inform requestors of the bases for declining to issue a requested advisory opinion, particularly in situations where the requestor may be able to correct or modify a request so as to make it acceptable. Section 1008.15 sets forth certain circumstances under which advisory opinions will not be issued. We are taking this opportunity to clarify in the rule that the circumstances set forth in § 1008.15 preclude both acceptance and issuance of advisory opinions. In addition, requests will not be accepted if they fall outside the scope of the advisory opinion process, as set forth in § 1008.5, or otherwise fail to satisfy the technical requirements of these regulations.

Section 1008.43, Issuance of a Formal Advisory Opinion

Comment: Several commenters suggested that requestors be given an opportunity to meet with the OIG during processing of requests to answer questions and address any concerns the OIG might have about their arrangements. Commenters proposed that the OIG provide prior notice to requestors if the OIG determines that it is going to issue an unfavorable opinion, thus permitting requestors to withdraw their requests or make changes to their proposed arrangements to address OIG objections.

Response: Our experience with advisory opinions has demonstrated that informal oral consultation with requestors often aids our understanding of the arrangements at issue and better enables us to render meaningful and informed opinions. However, requiring consultation for every request would impose an unwarranted burden on the OIG and, in many cases, serve only to increase costs to requesting parties with no significant benefit to the process. Nothing in these regulations precludes informal consultation, and we intend to continue working with requestors in appropriate circumstances to facilitate the advisory opinion process. During

these informal consultations, we may identify concerns that, if not adequately addressed by the requestor before the advisory opinion is issued, may lead us to render an unfavorable opinion. However, it is not our role to structure business arrangements. We believe that parties needing such assistance should seek private business and legal guidance.

We are aware that some requestors may want an opportunity to address the OIG's concerns about their arrangements in a manner that would enable them to structure acceptable arrangements and avoid, where possible, an unfavorable outcome. A formal notification requirement, however, could permit unscrupulous parties to misuse the advisory opinion process to "test" hypothetical arrangements, as well as lead to inefficient use of the OIG's resources. We believe that the informal consultation process described above is a better approach and will more effectively address the concerns of requestors who may want an opportunity to modify their arrangements in response to the OIG's concerns.

While requestors may request informal consultations, we anticipate that we will initiate most consultations when we determine that the requestor's input would be helpful. If there are facts or issues that a requestor wants us to consider, the requestor should bring those facts or issues to our attention (and provide any desired explanation) either in its request for an advisory opinion or, if the facts or issues arise after the initial request, in a supplemental submission of additional information.

Additional material information provided in the course of oral consultations will need to be submitted in writing and certified in accordance with §§ 1008.38 and 1008.39. For purposes of calculating the time for issuing the opinion, if the additional information substantially changes the arrangement under consideration, the original request will be treated as having been withdrawn and a new request as having been resubmitted as of the date the OIG receives the additional information in writing.

Comment: Several commenters proposed that the OIG be required to explain its analysis and bases for decision in the written advisory opinion, since the analysis and reasoning will serve as useful guidance to the requestors, the Department and the health care industry.

Response: As indicated in the preamble to the interim final rule, advisory opinions will restate the

material facts known to the OIG and will discuss the OIG's analysis and conclusions regarding the legal questions to be applied to the facts presented. We believe that § 1008.43, as written, reflects this intent. We iterate that opinions are only binding upon the specific parties to whom they are issued.

Comment: One commenter suggested that changes made to an arrangement to correct aspects deemed objectionable by the OIG in an unfavorable advisory opinion should not require an additional advisory opinion in order to be protected.

Response: We are not persuaded that this suggestion is workable in practice. We are unwilling to rely on a determination by the parties that modifications or changes they have made to their arrangements correct in all respects those aspects to which we objected. Moreover, we could not be certain, without further review, that modifications or changes made to one aspect of an arrangement would not adversely impact some other aspect of the arrangement. We are mindful, however, that requestors want to minimize costs associated with requesting a second opinion. We will make a good faith effort to control costs of a subsequent advisory opinion by avoiding duplication of effort expended on the first advisory opinion to the extent possible.

Section 1008.45, Rescission

Comment: The OIG received many responses to its solicitation of comments regarding whether § 1008.45 reasonably balances the Government's need to ensure that advisory opinions are legally correct and the requestor's interest in finality of advisory opinions. Most commenters were concerned that the OIG's authority to rescind advisory opinions defeats the main purpose of obtaining an opinion, which is to ensure that an arrangement will not be subject to sanction under the fraud and abuse statutes. Several commenters urged the OIG to identify a narrower standard to be applied in deciding to rescind an advisory opinion than "in the public interest". These commenters indicated that rescission should be limited to changes in law or material facts. Some commenters objected to using good faith reliance on the request as the standard for enforcement proceedings, suggesting instead that the OIG not proceed against a requestor unless the requestor failed to disclose materially adverse facts. One commenter thought that the OIG should not require parties to unwind transactions unless the OIG had not been provided with all relevant

information or the information provided was misleading or inaccurate. If unwinding were to be required, several commenters urged the OIG to permit a reasonable unwinding period during which a requestor would not be subject to sanction. Further, several commenters noted the significant investment of time and money involved in arrangements operating under the protection of advisory opinions. It was suggested that the OIG limit the use of rescinded opinions to putting parties on notice that the OIG has changed its analysis for the future. Another commenter recommended that the OIG's right to rescind an advisory opinion should be limited to one year from the date of the opinion.

Response: In crafting these regulations, we have been mindful of a requestor's significant interest in the finality of an advisory opinion and have endeavored to balance that interest against the government's compelling interest in protecting the integrity of the Federal agencies, including the Federal Trade Commission, the International Trade Commission, the Food and Drug Administration, and the Internal Revenue Service (See, for example, 16 CFR 1.1.3, 19 CFR 211.54(b), 21 CFR 108.5, and 26 CFR 601.201(1).)

Our use of the words "rescind" and "revoke" in § 1008.45 may have led some members of the public to misconstrue the intent of this section. If a requestor has fully and accurately provided all material information regarding an arrangement in its submission to the OIG, its advisory opinion will bind the Department and the parties during the period it is in effect, that is, until it is terminated, if ever. If, on the other hand, the OIG determines that a requestor's submissions did not fully and accurately provide all material information regarding an arrangement, the OIG may rescind the advisory opinion retroactively to the date of issuance. For purposes of clarity, we are substituting the word "terminate" for "revoke" where appropriate in this section, to more clearly distinguish these two concepts. In addition, as discussed below, we are amending § 1008.45 to make clear that in appropriate cases there is a third, intermediate possibility which is modification of an advisory opinion.

Accordingly, for the purposes of part 1008 we are adding definitions in § 1008.45 for the terms "rescind," "terminate," and "modify." To "rescind" an advisory opinion will mean that the advisory opinion is revoked retroactively to the original date of issuance with the result that the

advisory opinion will be deemed to have been without force and effect from the original date of issuance. Rescission will be reserved for those situations where a requestor has not fully, completely and accurately disclosed facts to the OIG that it knew, or should have known, were relevant and material to the subject matter of the advisory opinion. (The OIG will make the determination of whether the requestor had this state of mind following an opportunity for the requestor to comment on this issue.)

To "terminate" an advisory opinion will mean that the advisory opinion is revoked as of the termination date and is no longer in force and effect after the termination date. However, the opinion will have been in effect as originally issued from the date of issuance until the date of termination.

To "modify" an advisory opinion will mean that the advisory opinion is amended, altered or limited, and that the advisory opinion continues in full force and effect in modified form thereafter. However, the opinion will have been in effect as originally issued from the date of issuance until the date of modification.

The regulations reserve the right of the OIG to rescind, terminate, or modify an advisory opinion after its issuance solely in circumstances "where the public interest requires." We expect that rescissions, terminations, and modifications of advisory opinions will be rare, occurring only in limited circumstances, such as when the OIG learns after the issuance of the opinion that the arrangement in question may lead to fraud or abuse, and the potential for such fraud or abuse was not foreseeable at the time the advisory opinion was issued. Situations that might lead to termination or modification of an advisory opinion may include the following circumstances—

- changes in the law or the business operations of the health care industry that make it possible for an arrangement that previously carried little risk of fraud or abuse to result in fraud or abuse in the future;
- changes in medical science or technology that render an arrangement subject to the risk of fraud or abuse;
- material changes in the arrangement during the course of its implementation; or,
- the operation of the arrangement in practice differs from what the OIG anticipated based on the advisory opinion request.

The latter two examples reflect the fact that proposed business arrangements sometimes change in

unexpected ways during and after their implementation.

Prior to any rescission, termination or modification, the OIG will notify the requesting party that it intends to rescind, terminate, or modify the advisory opinion and afford the requesting party a reasonable opportunity to comment in response. An advisory opinion will only be rescinded, terminated, or modified after appropriate consultation with the requesting party. With respect to modifications, if the party does not agree to modifications proposed by the OIG, or does not itself suggest modifications that satisfy the OIG's concerns, the OIG may instead terminate the advisory opinion under this section. In the event of a determination to rescind, terminate, or modify an advisory opinion under § 1008.45, the OIG will notify the requestor and make such final notice available to the same extent as an advisory opinion.

Except as discussed below, the requestor will not be subject to OIG sanction for actions it took prior to the final notice of termination or modification if the requestor (1) acted in good faith reliance on the advisory opinion, and (2) promptly discontinues such actions upon notification of a termination or promptly modifies such actions upon notification of a modification, as the case may be. We recognize that it may be impracticable to discontinue immediately certain complex business arrangements. Accordingly, except in exceptional circumstances or as otherwise described below, a requestor will be afforded a reasonable opportunity to unwind or otherwise disengage from arrangements subject to terminated advisory opinions, provided that the requestor pursues such unwinding or disengagement promptly, diligently and in good faith. A requestor will be afforded a similar reasonable opportunity to implement modifications to an arrangement that is subject to a modified advisory opinion. During any unwinding period, the protection afforded by the advisory opinion will continue in effect.

We are revising § 1008.45 to provide for a reasonable unwinding period set at the discretion of OIG, after consultation with the requestor, based on the facts and circumstances of the arrangement. For example, the unwinding period for a complex business structure may be a period of years, whereas it may be a much shorter period for a simple compensation arrangement. In determining the duration of the reasonable unwinding or modification period, the OIG will take into account

the complexity of the arrangements involved and the impact of unwinding or modification of Federal program beneficiaries. If the OIG determines, however, that the requestor failed to provide material information or provided untruthful information in its submissions to the OIG, the advisory opinion will be deemed to have been without effect from the time it was issued and no unwinding period will be recognized.

Comment: One commenter requested that the OIG return documents submitted in connection with rescinded opinions. This commenter argued that such documents should be exempted from FOIA as pre-decisional documents.

Response: As indicated in our discussion of § 1008.40, we do not believe that requesting parties have a right to the return of documents voluntarily submitted to the Government, especially where those documents are potential evidence of a violation of law. In addition, retention of submitted materials may be necessary to document the workings of the advisory opinion process. However, the OIG may return such documents at its discretion to the extent allowed by law. While certain documents may have been provided to DoJ in the course of our consultations, the OIG has no authority over the return of such documents by DoJ. The OIG is subject to FOIA and intends to release documents if required by FOIA, in accordance with procedures set forth in 45 CFR part 5.

Section 1008.47, Disclosure

Comment: Several commenters stated that the disclosure provisions of § 1008.47 do not comport with congressional intent in enacting the advisory opinion program. Several commenters expressed concern about our statement that we could use information submitted by requestors for "any governmental purpose." One commenter specifically stated that if "any governmental purpose" means that the OIG can use information submitted with requests as a basis for investigation, the OIG should expressly say so and put parties on notice to that effect. These commenters indicated that the risk of information being used for any governmental purpose would inhibit the industry from seeking guidance, and considered the risk of public disclosure of a requestor's identity and of the result of its advisory opinion as a further deterrent. One commenter believed that such disclosure could adversely impact a requestor's stock prices or general competitiveness.

Response: Our primary purpose under these regulations is to gather and assess information in order to render informed advisory opinions. However, the anti-kickback statute is a criminal statute, and therefore review of arrangements that potentially implicate the statute requires heightened scrutiny. As a law enforcement agency, the OIG cannot ignore information lawfully obtained to further legitimate governmental purposes.

Comment: Several commenters recommended that the OIG redact names and identifying information from published advisory opinions, as the IRS does with its private letter rulings.

Response: Our current practice is to limit public disclosure of names and identifying information, subject to the requirements of FOIA. Unlike the OIG, the IRS has a specific statutory exception (26 U.S.C. 6110) to FOIA that affords it greater latitude in protecting information from disclosure.

Comment: One commenter requested that the OIG not disclose information without first notifying the requestor and obtaining its consent.

Response: The OIG is subject to FOIA and the Department's FOIA regulations set forth at 45 CFR part 5. These regulations provide that the Department will make reasonable efforts to notify submitters—in this case, the requestors—if the Department determines that material that submitters have designated as exempt from disclosure under exemption 4 to FOIA (trade secrets and confidential commercial or financial information) may have to be disclosed in response to a FOIA request. The regulations at 45 CFR 5.65 provide that submitters of records may designate in writing that all or part of the information contained in such records is exempt from disclosure under exemption 4 at the time they submit such records or within a reasonable time thereafter. Under the Department's FOIA regulations, requestors have an opportunity to respond and, if desired, file a court action to prevent disclosure of exempt records. Requesting parties must specifically identify in their requests for advisory opinions any information they reasonably believe is exempt from disclosure under exemption 4.

These advisory opinion regulations have been amended to incorporate more clearly the requirement for designating trade secrets and confidential commercial or financial information with specificity. Information should be designated in the manner described in 45 CFR 5.65(c) and (d). Parties are encouraged to refrain from designating more information than arguably may be

classified as trade secrets or confidential commercial or financial information. Wholesale designations of entire request letters are counterproductive and may make it more difficult for legitimately exempt information to be protected under FOIA. The requestor's assertions about the nature of the information it has submitted are not controlling. Consistent with the OIG's law enforcement responsibilities, we reserve the right to make disclosures other than in response to FOIA requests where the public interest requires, to the extent authorized by law. Unauthorized releases of confidential information would be a criminal violation of 18 U.S.C. 1905 (the Trade Secrets Act).

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 the OIG 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 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 1128D(b) of the Act. Nevertheless, we do not intend to incorporate any such facts into the body of an advisory opinion unless we believe incorporating such information is necessary in order to render an informed opinion. Moreover, where we intend to incorporate into an advisory opinion information designated by the requesting party as confidential proprietary information, we will endeavor to provide the requesting party with reasonable notice and a reasonable opportunity to respond or withdraw its request.

Section 1008.53, Affected Parties

Comment: One commenter suggested that all parties should be required to consent to a request for an advisory opinion and that the requestor should be required to certify that such consent has been obtained.

Response: The crux of this comment appears to center around a concern that one party to an arrangement may submit information to the OIG without the knowledge or consent of another party who may not want such information disclosed. We believe that this is a matter best handled and resolved between the parties. In addition, for reasons set forth above, we believe that it may be impractical, if not impossible, to obtain consent from all potential parties to certain types of arrangements.

Section 1008.55, Admissibility of Evidence

Comment: While several commenters commended the OIG for prohibiting adverse inferences to be drawn from a party's failure to obtain an advisory opinion, other commenters suggested that we delete or clarify § 1008.55(b), which they found confusing with regard to the prohibition on the use of advisory opinions by third parties. One commenter objected to paragraph (b) of this section because an advisory opinion may be probative evidence as to why someone structured an arrangement in a particular way. The commenter questioned whether the OIG has the power to create evidentiary rules that would be binding on courts or administrative law judges.

Response: We agree that § 1008.55(b) was confusing as originally written. Consistent with our original intent to preclude legal reliance by non-requestors, this section is being revised to read as follows: "An advisory opinion may not be introduced into evidence by a person or entity that was not the requester of the advisory opinion to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law." The Department has the authority to create procedural rules applicable in its tribunals (42 CFR 1005, for example). With respect to other tribunals, the OIG believes it is proper to limit the use of documents created by the OIG for a specific purpose. Consistent with HIPAA's statutory directive that advisory opinions bind *only* requesting parties and the Department, it is our intention to preclude legal reliance by non-requestors; it follows necessarily that an advisory opinion may not be introduced into evidence by such non-requestors in any tribunal.

Section 1008.59, Range of Advisory Opinion

Comment: One commenter stated that advisory opinions should be binding on DoJ as well. The commenter believed that it would be unfair if DoJ, which must be consulted during the advisory opinion process, could still instigate enforcement proceedings against a requestor that has a favorable advisory opinion from the Department.

Response: Section 205 of HIPAA requires only that advisory opinions be binding on this Department. The Department lacks the authority to bind DoJ through the Department's rulemaking.

III. Additional Technical Changes

- In § 1008.5(b)(1), the phrase "what the" is being changed to "whether" to

correct a technical error, and the word "and" is being changed to "or" to be consistent with the statutory directive and our intent that we will not opine on questions of fair market value or bona fide employee status.

- In § 1008.31(c), the phrase "to be" in the first sentence is being deleted to be consistent with the intent of the regulation that the OIG will calculate the actual costs incurred by the Department in responding to an advisory opinion request.

- The phrase "from the time the OIG notifies the requestor" is being added in § 1008.31(d)(4) to be consistent with our original intention that the time period in question commences upon the OIG's notice.

- In § 1008.37, the phrase "will" in the first sentence is being replaced by "must" to be consistent with the mandatory nature of the requirement, and the phrase "or entity" is being inserted to be consistent with the usage of the same term at the beginning of the sentence.

- In § 1008.38(c), the phrase "will" is being replaced by "must" to be consistent with the mandatory nature of the requirement.

- In § 1008.43(a), the word "when" is being replaced by "and" to clarify, consistent with our original intent and practice, that an advisory opinion is issued when payment is received and the opinion is dated, numbered, and signed.

- In § 1008.43(b) is being revised to provide internal consistency within the section and to be consistent with our intent that advisory opinions will be based on the information provided by requestors.

- The word "next" appearing in § 1008.43(c)(2) has been repositioned to correct a technical error. In § 1008.47(c), the word "in" is being replaced by the word "by" to correct a technical error.

- Section 1008.59 has been revised to reflect more clearly our intent that the OIG will not provide legal opinions on questions or issues regarding authorities vested in other Federal, State, or local government agencies.

IV. Regulatory Impact Analysis

Executive Order 12866

The Office of Management and Budget (OMB) has reviewed this final rule in accordance with the provisions of Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health, safety, distributive, and equity effects).

As indicated in our preamble discussions, this rule addresses procedural issues involved in processing requests for advisory opinions submitted to the OIG. It sets up the procedures, as required by Public Law 104-191, for obtaining an advisory opinion on whether or not certain activities violate designated fraud and abuse authorities. This rule does not address the substance of the anti-kickback or other sanction statutes. Nor does it address the substance or content of advisory opinions which may be issued in the future. To the extent that advisory opinions affect the behavior of health care providers, that effect is the product of the substantive content of the sanction statutes themselves and the substantive content of the advisory opinions which will be issued on a case-by-case basis in the future. The effect of advisory opinions on health care providers is not a function of the *process* for requesting an advisory opinion.

In addition, the extent to which advisory opinions will result in alteration of future business practices, if any, is impossible to analyze without experience. It would be completely speculative to try to divine to what degree business deals may or may not occur as a result of the substance of advisory opinions issued in the future.

Moreover, we have no way of knowing in advance what the volume of requests for advisory opinions will be. However, we estimate that we will receive approximately 100 requests per year that will generally require between 3 and 60 hours each to process. Accordingly, it would likely cost in the range of \$30,000 to \$600,000 per year to issue advisory opinions.

Regulatory Flexibility Act

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 the fraud and abuse statutes or the substance of advisory opinions which may be issued in the future. It describes the *process* by which an individual or entity may receive an opinion about the application of these statutes to particular business practices. The aggregate economic impact of this rulemaking on small business entities should, therefore, be minimal. There will, however, be costs

involved in filing requests for opinions by OIG. Those costs will vary depending on the complexity of the request.

Compared to the costs of seeking private legal advice, it would appear that fees charged for the OIG's review will not be substantial. Furthermore, the requirement that applicants pay cost-based fees for advisory opinions is not a product of this rulemaking; it is prescribed by statute. This rule merely lays out the procedures for such costs to be paid. 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.

V. Paperwork Reduction Act

A. Introduction

In order to provide appropriate advisory opinions, the OIG has specified certain information from the parties who request advisory opinions. Under section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are required to solicit public comments and secure final approval from OMB on these information collection requirements. In the interim final regulations published on February 19, 1997, we indicated that §§ 1008.18, 1008.36(b) and 1008.37 through 1008.40, along with a listing of voluntary preliminary questions, specifically contained information collection requirements that required approval by OMB. As a result, the OIG published a Federal Register notice on March 21, 1997 (62 FR 13621) specifically requesting comments on these information collection activities. The information collection requirements set forth in the interim final rule were subsequently approved by OMB in September, 1997 under control number 0990-0213. OMB also approved a set of preliminary questions which provide guidance as to what should be included in a request for an advisory opinion.

B. Discussion of Revised Information Collection Requirements

This final rulemaking is now easing or streamlining a number of these information collection activities in response to public comments received on the interim final regulations. Specifically, as indicated in this preamble, we are revising § 1008.36(b), with respect to the submission of a request, to permit parties to submit only those portions of documents relevant to the arrangement at issue, and describe in general terms those portions of the documents that have been withheld. In

addition, to avoid a blanket designation when a party seeks an advisory opinion, we have revised § 1008.36(b)(3) to indicate that requestors must give explicit designation of the specific sanction authorities about which an advisory opinion has been requested. Also in § 1008.36, we are eliminating the requirement that requesting parties submit their Medicare and Medicaid provider numbers. We are, however, adding a new paragraph (b)(8) to this section to require, in accordance with the Debt Collection Improvement Act of 1996, that requesting parties include their Taxpayer Identification Number when requesting an advisory opinion.

Further, new §§ 1008.36(b)(7) and 1008.39(e) are also being added to require requesting parties to notify the OIG if they apply to HCFA for an advisory opinion in accordance with 42 CFR part 411 on the same arrangement for which they are seeking an OIG advisory opinion. We believe that this change will better aid efforts to address and coordinate both the OIG and the HCFA advisory opinion processes.

Finally, we are revising or clarifying certain requirements in § 1008.38(c) concerning who may sign original (and additional) certifications submitted by requestors. Specifically, this revised section now clearly designates the appropriate signatory on behalf of requestors that are limited liability companies, and clarifies that each requesting party, and not its attorney, must provide the required certifications.

C. Proposed Information Collection Activities

The proposed information collection requirement described below will be submitted to the OMB for review and approval, as required by the Paperwork Reduction Act. In accordance with the Paperwork Reduction Act, we are soliciting public comment on the collection of the information in conjunction with section 205 of HIPAA that are contained in this revised final. Interested persons are invited to send comments regarding burden estimates or any aspect of the collection of information, including (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 agency's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility and clarity of the information to be 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.

Type of information collection request: OIG Advisory Opinion Procedures in 42 CFR Part 1008. Section 205 of HIPAA, Public Law 104-191, requires the Department to provide advisory opinions to the public regarding several categories of subject matter, including the requestor's potential liability under sections 1128, 1128A and 1128B of the Social Security Act (the Act). The OIG published interim final regulations in the **Federal Register** on February 19, 1997 (62 FR 7350), setting forth the procedures under which members of the public may request advisory opinions from the OIG, and a **Federal Register** notice on March 21, 1997 (62 FR 13621) that contained a more thorough discussion of the information collection activities associated with the advisory opinion process. In order to aid potential requestors and the OIG in providing opinions under this process, a series of preliminary questions that may be answered in an advisory opinion request was developed by the OIG. These preliminary questions remain voluntary. The information collection requirements in the interim final rule and the preliminary questions were approved by OMB under control number 0990-0213.

The aggregate information burden for the information collection requirements contained in these revised final regulations is set forth below.

Respondents: The "respondents" for the collection of information described in the OIG rulemaking will be self-selected individuals and entities that choose to submit request for advisory opinions to the OIG. We anticipate that the respondents will include many types of health care providers, from sole practitioner physicians to large diversified publicly-traded corporations.

Estimated number of respondents: 500. Most individuals and entities that provide medical services that may be paid for by Medicare, Medicaid or Federal health care programs could potentially have questions regarding one of the subject matters about which the OIG will issue advisory opinions. In reality, we believe that the number of requestors will be a small fraction of such providers.

Over the past several years, the Office of the General Counsel, Inspector General Division has answered telephone inquiries from individuals and entities seeking informal guidance with respect to the Medicare and State health care programs' anti-kickback statute and other sanction authorities. Many of the inquiries related to authorities outside

the scope of the advisory opinion process, such as the self-referral provisions of section 1877 of the Act. In addition, we believe that most of the inquiries received have been of a nature that the caller or requestor would be unlikely to request a formal written advisory opinion on the subject matter. Many inquiries related to rather simple and straight-forward matters that could have been researched by private counsel at relatively minor expense. Nevertheless, the rate of telephone inquiries form a starting point for estimating point for estimating the potential number of advisory opinion requests.

We estimate that the OIG received an average of six related telephone inquiries per day over the past several years. Using that history as a general guide and benchmark, we estimate an annual number of 500 respondents. Obviously, the actual number of requests could be larger since, for the first time, formal written opinions are available. Conversely, the number of inquiries could be less based on combination of several unquantifiable reasons, including the desire not to have one's arrangement be subject to scrutiny by the OIG (following issuance of the opinion) and the general public.

Estimated number of responses per respondent: One.

Estimated total annual (hour) burden on respondents: 5,000 hours. We believe that the burden of preparing requests for advisory opinions will vary widely depending upon the differences in the size of the entity making the request and the complexity of the advice sought. 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 request will be closer to the lower end of this range, with an average burden of approximately 10 hours per respondent.

The OIG is requiring requests for advisory opinions to involve actual or intended fact scenarios. 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, the requesting party will have collected and analyzed all, or almost all, of the information we will need to collect to review the request. Therefore, in order to request an advisory opinion, in many instances the requestor will simply have need to compile already collected information for our examination. In some cases, the requestor may need to expend a more significant amount of time and cost in preparing a submission related to more complex arrangements

that involve a large number of parties or participants.

Estimated annual cost burden on respondents (in addition to the hour burden): \$1,000,000. In addition to the hour burden on respondents discussed above, some respondents may incur additional information collection costs related to the purchase of outside professional services, such as attorneys or consultants. We believe that the cost burden related to such outside assistance will vary from zero to 40 hours per request, with an average of 10 hours. At the rate of \$200 per hour, this total burden would amount to \$1,000,000.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Interested persons are invited to submit comments regarding this collection of information. Comments on this information collection should refer to the document identifier code OIG-10-F, and should be sent both to: Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201, FAX: (202) 690-6352; and Allison Herron Eydt, OIG Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 725 17th Street, N.W., Washington, D.C. 20053, FAX: (202) 395-6974.

To request more information on the project or to obtain a copy of the information collection plans, please contact the OS Reports Clearance Officer, (202) 690-6207. Written comments should be received by [60 days from date of publication in the Federal Register], but in order to expedite full consideration of any concerns we recommend that comments be submitted as soon as possible within the first 30 days. After due consideration of all timely-filed public comments on these revised information collection activities, we will re-submit these sections to OMB for their approval under the Paperwork Reduction Act. These sections will not become effective until cleared by OMB. In the interim, requestors should rely on the preliminary questions issued by the OIG on which OMB has already granted approval.

List of Subjects in 42 CFR Part 1008

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

Accordingly, the interim final rule adding 42 CFR part 1008, which was published at 62 FR 7350 on February 19,

1997, is adopted as a final rule with the following changes:

PART 1008—[AMENDED]

1. The authority citation for part 1008 continues to read as follows:

Authority: 42 U.S.C. 1320a-7d(b).

2. Section 1008.1 is amended by revising paragraphs (a) and (b) to read as follows:

§ 1008.1 Basis and purpose.

(a) This part contains the specific procedures for the submission of requests by an individual or entity for advisory opinions to, and the issuance of advisory opinions by, the OIG, in consultation with the Department of Justice (DoJ), in accordance with section 1128D(b) of the Social Security Act (Act), 42 U.S.C. 1320a-7d(b). The OIG will issue such advisory opinions based on actual or proposed factual circumstances submitted by the requesting individual or entity, or by counsel on behalf of the requesting individual or entity, provided all other requirements of this part are satisfied (including the requirement that the requesting individual or entity provide the certifications required in accordance with § 1008.38 of this part).

(b) An individual or entity may request an advisory opinion from the OIG regarding any of five specific subject matters described in § 1008.5 of this part.

3. Section 1008.5 is amended by republishing introductory paragraph (b) and by revising paragraph (b)(1) to read as follows:

§ 1008.5 Matters subject to advisory opinions.

(b) *Exceptions.* The OIG will not address through the advisory opinion process—

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

4. Section 1008.15 is amended by revising introductory paragraph (c) and paragraph (c)(3) to read as follows:

§ 1008.15 Facts subject to advisory opinions.

(c) Advisory opinion request will not be accepted, and/or opinions will not be issued when—

(3) An informed opinion cannot be made, or could be made only after

extensive investigation, clinical study, testing, or collateral inquiry.

5. Section 1008.18 is amended by revising paragraph (b) to read as follows:

§ 1008.18 Preliminary questions suggested for the requesting party.

(b) Questions the OIG suggests that the requestor address may be obtained from the OIG. Requests should be made in writing, specify the subject matter, and be sent to the headquarter offices of the OIG.

6. Section 1008.31 is amended by revising paragraphs (c), (d)(1), (d)(2), (d)(3), and (e)(2); by redesignating paragraphs (d)(2) through (d)(5) as paragraphs (d)(3) through (d)(6) respectively; and by adding a new paragraph (d)(2) to read as follows:

§ 1008.31 OIG fees for the cost of advisory opinions.

(c) *Calculation of costs:* Prior to the issuance of the advisory opinion, the OIG will calculate the costs incurred by the Department in responding to the request. The calculation will include the costs of salaries and benefits payable to attorneys and others who have worked on the request in question, as well as administrative and supervisory support for such person. The OIG has the exclusive authority to determine the cost of responding to a request for an advisory opinion and such determination is not reviewable or waivable.

(d) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (d)(4) of this section, to pay all costs incurred by the OIG in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may request a written estimate of the cost involved in processing the advisory opinion. Within 10 business days of receipt of the request, the OIG will notify in writing of such estimate. Such estimate will not be binding on the Department, and the actual cost to be paid may be higher or lower than estimated. The time period for issuing the advisory opinion will be tolled from the time the OIG notifies the requestor of the estimate until the OIG receives written confirmation from the requestor that the requestor wants the OIG to continue processing the request. Such notice may include a new or revised triggering dollar amount, as set forth in paragraph (d)(3) of this section.

(3) In its request for an advisory opinion, the requestor may designate a

triggering dollar amount. If the OIG estimates that the costs of processing the advisory opinion request have reached, or are likely to exceed, the designated triggering dollar amount, the OIG will notify the requestor. The requestor may revise its designated triggering dollar amount in writing in its response to notification of a cost estimate in accordance with paragraph (d)(2) of this section.

* * * * *

(e) *Fees for outside experts.* * * *

(2) If the OIG determines that it is necessary to obtain expert advice to issue a requested advisory opinion, the OIG will notify the requestor of that fact and provide the identity of the appropriate expert and an estimate of the costs of the expert advice.

7. Section 1008.33 is amended by revising paragraphs (b) and (c) to read as follows:

§ 1008.33 Expert opinions from outside sources.

* * * * *

(b) The time period for issuing an advisory opinion will be tolled from the time that the OIG notifies the requestor of the need for an outside expert opinion until the time the OIG receives the necessary expert opinion.

(c) Once payment is made for the cost of the expert opinion, as set forth in § 1008.31(e) of this part, either directly to the expert or otherwise, the OIG will arrange for a prompt expert review of the issue or issues in question. Regardless of the manner of payment, the expert's work and opinion will be subject to the sole direction of the OIG.

8. Section 1008.36 is amended by republishing introductory paragraph (b); by revising paragraphs (b)(1), (b)(3), and (b)(4); by deleting existing paragraph (b)(5); by redesignating (b)(6) and (b)(7) as (b)(5) and (b)(6) respectively and revising them; and by adding new paragraphs (b)(7) and (b)(8) to read as follows:

§ 1008.36 Submission of a request.

* * * * *

(b) Each request for an advisory opinion must include—

(1) To the extent known to the requestor, the identities, including the names and addresses, of the requestor and of all other actual and potential parties to the arrangement, that are the subject of the request for an advisory opinion;

* * * * *

(3) A declaration of the subject category or categories as described in § 1008.5 of this part for which the advisory opinion is requested. To the extent an individual or entity requests

an advisory opinion in accordance with §§ 1008.5(a)(3) or (a)(5) of this part, the requesting individual or entity should identify the specific subsections of sections 1128, 1128A or 1128B of the Act or the specific provision of § 1001.952 of this chapter about which an advisory opinion is sought:

(4) A complete and specific description of all relevant information bearing on the arrangement for which an advisory opinion is requested and on the circumstances of the conduct,¹ including—

(i) Background information,

(ii) For existing arrangements, complete copies of all operative documents,

(iii) For proposed arrangements, complete copies of all operative documents, if possible, and otherwise descriptions of proposed terms, drafts, or models of documents sufficient to permit the OIG to render an informed opinion,

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

(v) If applicable, a designation of trade secrets or confidential commercial or financial information in the manner described in 45 CFR 5.65;

(5) Signed certifications by the requestor(s), as described in § 1008.37 of this part;

(6) A check or money order payable to the Treasury of the United States in the amount of \$250, as discussed in § 1008.31(b) of this part;

(7) A declaration regarding whether an advisory opinion in accordance with part 411 of this title has been or will be requested from HCFA about the arrangement that is the subject of the advisory opinion request; and

(8) Each requesting party's Taxpayer Identification Number. (Approved by the Office of Management and Budget under control number 0990-0213)

9. Section 1008.37 is revised to read as follows:

§ 1008.37 Disclosure of ownership and related information.

Each individual or entity requesting an advisory opinion must supply full and complete information as to the identity of each entity owned or controlled by the individual or entity, and of each person with an ownership or control interest in the entity, as defined in section 1124(a)(1) of the Social Security Act (42 U.S.C. 1302a-3(a)(1)) and part 420 of this chapter.

¹ The requestor is under an affirmative obligation to make full and true disclosure with respect to the facts regarding the advisory opinion being requested.

(Approved by the Office of Management and Budget under control #0990-0213)

10. Section 1008.38 is amended by revising paragraphs (a) and (b), introductory paragraph (c), paragraphs (c)(2) and (c)(3); and by adding a new paragraph (c)(4) to read as follows:

§ 1008.38 Signed certifications by the requestor.

(a) Every request must include the following signed certification from all requestors: "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, the request must also include the following signed certification from all requestors: "The arrangement described in this request for an advisory opinion is one that [the requestor(s)] in good faith plan(s) to undertake." This statement may be made contingent on a favorable OIG advisory opinion, in which case, the phrase "if the OIG issues a favorable advisory opinion" should be added to the certification.

(c) The certification(s) must be signed by—

* * * * *

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

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

(4) The managing member, or comparable person, if the requestor is a limited liability company.

11. Section 1008.39 is amended by revising paragraph (c) and by adding new paragraphs (e) and (f) to read as follows:

§ 1008.38 Additional information.

* * * * *

(c) Additional information should be provided in writing and certified to be a true, correct and complete disclosure of the requested information in a manner equivalent to that described in § 1008.38 of this part.

* * * * *

(e) Requesting parties are required to notify the OIG if they request an advisory opinion in accordance with part 411 of this title from HCFA about the arrangement that is the subject of their advisory opinion request.

(f) Where appropriate, after receipt of an advisory opinion request, the OIG may consult with the requesting parties to the extent the OIG deems necessary.

12. Section 1008.41 is amended by revising paragraph (a); and by republishing introductory paragraph (b) and revising paragraph (b)(3) to read as follows:

§ 1008.41 OIG acceptance of the request.

(a) Upon receipt of a request for an advisory opinion, the OIG will promptly make an initial determination whether the submission includes all of the information the OIG will require to process the request.

(b) Within 10 working days of receipt of the request, the OIG will—

* * * * *

(3) Formally decline to accept the request.

* * * * *

13. Section 1008.43 is amended by revising paragraphs (a), (b) and (c)(2); and by republishing introductory paragraph (c)(3) and revising paragraph (c)(3)(i) to read as follows:

§ 1008.43 Issuance of a formal advisory opinion.

(a) An advisory opinion will be considered issued once payment is received and it is dated, numbered, and signed by an authorized official of the OIG.

(b) An advisory opinion will contain a description of the material facts provided to the OIG with regard to the arrangement for which an advisory opinion has been requested. The advisory opinion will state the OIG's opinion regarding the subject matter of the request based on the facts provided to the OIG. If necessary, to fully describe the arrangement, the OIG is authorized to include in the advisory opinion the material facts of the arrangement, notwithstanding that some of these facts could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1905.

(c) * * * * *

(2) If the 60th day falls on a Saturday, Sunday, or Federal holiday, the time period will end at the close of the next business day following the weekend or holiday;

(3) The 60 day period will be tolled from the time the OIG—

(i) Notifies the requestor that the costs have reached, or are likely to exceed, the triggering amount until the time when the OIG receives written notice from the requestor to continue processing the request;

* * * * *

14. Section 1008.45 is revised to read as follows:

§ 1008.45 Rescission, termination or modification.

(a) Any advisory opinion given by the OIG is without prejudice to the right of the OIG to reconsider the questions involved and, where the public interest requires, to rescind, terminate or modify the advisory opinion. Requestors will be given a preliminary notice of the OIG's intent to rescind, terminate or modify the opinion, and will be provided a reasonable opportunity to respond. A final notice of rescission, termination or modification will be given to the requestor so that the individual or entity may discontinue or modify, as the case may be, the course of action taken in accordance with the OIG advisory opinion.

(b) For purposes of this part—

(1) To *rescind* an advisory opinion means that the advisory opinion is revoked retroactively to the original date of issuance with the result that the advisory opinion will be deemed to have been without force and effect from the original date of issuance. Rescission may occur only where relevant and material facts were not fully, completely and accurately disclosed to the OIG.

(2) To *terminate* an advisory opinion means that the advisory opinion is revoked as of the termination date and is no longer in force and effect after the termination date. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith discontinued in accordance with reasonable time frames established by the OIG after consultation with the requestor.

(3) To *modify* an advisory opinion means that the advisory opinion is amended, altered, or limited, and that the advisory opinion continues in full force and effect in modified form thereafter. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith modified in accordance with reasonable time frames established by the OIG after consultation with the requestor.

15. Section 1008.47 is amended by revising paragraphs (c) and (d) to read as follows:

§ 1008.47 Disclosure.

* * * * *

(c) Any pre-decisional document, or part of such pre-decisional document, that is prepared by the OIG, DoJ, 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 generally will be exempt from

disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to the OIG in connection with a request for an advisory opinion may be available to the public in accordance with 5 U.S.C. 552 through procedures set forth in 45 CFR part 5.

* * * * *

16. Section 1008.55 is amended by revising paragraph (b) to read as follows:

§ 1008.55 Admissibility of evidence.

* * * * *

(b) An advisory opinion may not be introduced into evidence by a person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate the provisions of sections 1128, 1128A or 1128B of the Act or any other law.

17. Section 1008.59 is amended by revising paragraph (a) to read as follows:

§ 1008.59 Range of the advisory opinion.

(a) An advisory opinion will state only the OIG's opinion regarding the subject matter of the request. If the arrangement for which an advisory opinion is requested is subject to approval or regulation by any other Federal, State or local government agency, such advisory opinion may not be taken to indicate the OIG's views on the legal or factual issues that may be raised before that agency. The OIG will not provide any legal opinion on questions or issues regarding an authority which is vested in other Federal, State or local government agencies.

* * * * *

Dated: February 6, 1998.

June Gibbs Brown,

Inspector General, Department of Health and Human Services.

Approved: March 24, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98-18874 Filed 7-15-98; 8:45 am]

BILLING CODE 4150-04-M

**FEDERAL EMERGENCY
MANAGEMENT AGENCY**

44 CFR Part 65

[Docket No. FEMA-7248]

**Changes in Flood Elevation
Determinations**

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the