List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 73.43 [Amended]

R–4305 Lake Superior, MN [Amended]

By removing ''Time of Designation. Intermittent by NOTAM, 12 hours in advance,'' and substituting ''Time of designation. Intermittent by NOTAM, 4 hours in advance.''

Issued in Washington, DC, on February 7, 1997.

Jeff Griffith,

Program Director for Air Traffic Airspace Management.

[FR Doc. 97–4068 Filed 2–18–97; 8:45 am]

BILLING CODE 4910–13–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: Interim final rule with comment period.

SUMMARY: In accordance with section 205 of the Health Insurance Portability and Accountability Act of 1996, this final rule establishes a new part 1008 in 42 CFR chapter V to address the new OIG advisory opinion process. Specifically, these regulations set forth the specific procedures by which the Office of Inspector General, in consultation with the Department of Justice, will issue advisory opinions to outside parties regarding the interpretation and applicability of certain statutes relating to the Medicare and State health care programs.

DATES: Effective Date: This rule is effective on February 21, 1997.

Comment Period: To assure consideration, public comments must be delivered to the first address provided under **ADDRESSES** by no later than 5 p.m. on April 21, 1997. Comments will be available for public inspection March 5, 1997 at the second address provided under **ADDRESSES** on Monday through Friday of each week from 8:00 a.m. to 4:30 p.m., (202) 619–0089.

ADDRESSES: Please mail or deliver your written comments to the following address: Office of Inspector General, Department of Health and Human Services, Attention: OIG–10–IFC, Room 5246, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OIG–10–IFC.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. The Medicare Anti-Kickback Statute

Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a–7b(b)) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under the Medicare or State health care programs. The offense is classified as a felony, and is punishable by fines of up to $25,000 and imprisonment for up to 5 years.

This provision is quite broad. The types of remuneration covered specifically include kickbacks, bribes, and rebates, whether made directly or indirectly, overtly or covertly, or in cash or in kind. In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or State health care programs.

Since the statute on its face is so broad, concern has been expressed for many years that some relatively innocuous commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution.

B. Safe Harbors and Fraud Alerts

As a response to the above concern, the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93, specifically required the development and promulgation of regulations, the so-called ''safe harbor'' provisions, designed to specify various payment and business practices which, although potentially capable of inducing referrals of business under the Medicare and State health care programs, would not be treated as criminal offenses under the anti-kickback statute (section 1128B(b) of the Social Security Act; 42 U.S.C. 1320b(b)) and would not serve as a basis for a program exclusion under section 1128(b)(7) of the Social Security Act; 42 U.S.C. 1320a–7(b)(7).

The OIG safe harbor provisions have been developed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. Health care providers and others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement action under the anti-kickback statute or program exclusion authority. The 13 final safe harbor provisions, which specify practices which are expressly made legal, are codified at 42 CFR 1001.952.

In addition, the OIG has also periodically issued Special Fraud Alerts to give continuing guidance to health care providers with respect to practices the OIG regards as unlawful. Eight individual Special Fraud Alerts were published in the Federal Register on December 19, 1994 (59 FR 65372), August 10, 1995 (60 FR 40847) and June 17, 1996 (61 FR 30623). Thus, for many years the OIG has been publishing substantial guidance indicating what practices are lawful and what practices the OIG considers unlawful under the anti-kickback statute.

C. Advisory Opinions: Section 205 of Public Law 104–191

The Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, effective August 21, 1996, now requires the Department to provide additional formal guidance regarding the application of the anti-kickback statute and the safe harbor provisions, as well as other OIG health care fraud and abuse sanctions. Among the provisions set forth in section 205 of Public Law 104–191 is the requirement that the Department, in consultation with the Department of Justice (DoJ), issue written advisory opinions to particular 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, or established by regulation, for activities which do not result in prohibited remuneration; (3) what constitutes an inducement to

reduce or limit services under section 1128A(b) of the Act to Medicare or Medicaid program beneficiaries [1]; 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 will be issued with regard to the provisions authorizing the Department to exclude individuals and entities from participation in Medicare and the State health care programs. Section 1128 of the Act authorizes exclusion in a wide variety of circumstances, for example, conviction of health care related offenses, State licensure action, and submission of claims in excess of usual charges or for services which fail to meet professionally recognized standards of health care. Similarly, the civil money penalty provisions of section 1128A of the Act authorize penalties and exclusion for a variety of acts, for example, presentation of a Medicare or Medicaid claim that is false or fraudulent, and hospital payments to physicians to induce the physician to reduce or limit care to any Medicare or Medicaid beneficiary under the physician's direct care. The Department will also provide advisory opinions regarding the criminal provisions of section 1128B of the Act which includes the anti-kickback statute.

(On December 31, 1996, the OIG, in accordance with section 205 of HIPAA, published a notice in the Federal Register (61 FR 69060) that solicited proposals and recommendations for developing new and modifying existing safe harbor provisions under the Medicare and State health care programs' anti-kickback statute, as well as for developing new OIG Special Fraud Alerts. We specifically indicated in that notice our intention of publishing separate rulemaking addressing the procedures and process for accepting and issuing advisory opinions and soliciting public comments and recommendations in this area.)

In accordance with the statute, requests for advisory opinions must be accepted for agency review on or after February 21, 1997. While the President's fiscal year 1998 budget submission proposes a repeal of section 205, the OIG and the Department are proceeding to implement these statutory obligations in accordance with existing law.

[1] Public Law 104–191 cited this provision as section 1128B(b) of the Act. We believe the correct reference is section 1128A(b).

D. Waiver of Proposed Rulemaking

In developing and publishing these regulations as an interim final rule, the Secretary has determined that for good cause it is both impracticable and contrary to public interest to first issue these regulations in proposed rulemaking form. We believe that the statutory requirement that final regulations addressing the advisory opinion process be in effect no later than February 17, 1997, makes it impracticable to develop such procedures with the necessary inter-governmental collaboration and initial public comment usually required in such rulemaking by the statutory deadline.

In addition, we believe that it is imperative that we have in place specific procedures by February 21, 1997, to address the receipt and processing of advisory opinion requests. It would be against the public interest to proceed to receive and process advisory opinions without setting forth procedural guidance. However, we believe that the 60-day period for public comments being set forth in this interim final rule will serve to protect the public's interest in this rulemaking process by allowing for an opportunity for additional input and recommendations, without unduly delaying the intent of these regulations. We will respond to all appropriate and relevant public comments received during the 60-day comment period, and make any necessary revisions to these regulations through a revised final rule to be issued, if possible, within 9 months of the close of the comment period. Accordingly, we believe this interim final rule approach will achieve the dual purpose of issuing a rulemaking consistent with statutory time frames while soliciting and benefiting from the public comment process.

II. Provisions of the Interim Final Rule

Anti-kickback Statute Advisory Opinions: ''Case specific'' Safe Harbors

These interim final regulations establish a new 42 CFR part 1008 that is designed to establish procedures for advisory opinions that will provide the public with meaningful advice regarding the anti-kickback and other OIG sanction statutes regarding specific factual situations. With respect to the anti-kickback statute, these procedures contemplate particularized or ''case specific'' safe harbors. In establishing the regulatory safe harbors in § 1001.952, the OIG first considered the full scope of factual circumstances potentially subject to the anti-kickback statute, that is, generally all types of arrangements that could potentially involve an intentional payment of remuneration to induce the referral of Medicare business. Next, we proceeded to ''limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial or innocuous arrangements.'' (56 FR 35952, July 29, 1991). Thus we sought to specify particular safe harbors that, despite the potentially unlawful intent, would protect non-abusive relationships. To accomplish this objective, each safe harbor contains limitations and controls that provide adequate assurance that the programs will not be abused. The actual intent of the parties is entirely irrelevant to this analysis. The OIG has designed 13 final safe harbors that describe practices that are sheltered from liability, even though unlawful intent may be present, and is continuing to finalize 8 additional safe harbor provisions.

The OIG views the advisory opinion process with a means of analysis similar to the safe harbor provisions, with one major exception. Where the safe harbors describe generalized, hypothetical arrangements which are protected, we view an advisory opinion as a means of relating the anti-kickback statute to the particular facts of a specific 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 can not be abused.

These regulations are designed to avoid the potential pitfalls of advisory opinions on intent-based statutes, such as the anti-kickback statute. First, it is not practical for the agency to make an independent determination of the subjective intent of the parties based only upon written materials submitted by the requestor. While requestors are required to submit a complete written description of the transaction, along with copies of the documents that establish the arrangements in question, these materials do not afford a satisfactory basis upon which to make a reliable determination of subjective intent. In anti-kickback cases, the intent issue is whether one purpose of the remuneration in question is intended to induce the referral of Federal program business. In anti-kickback cases under investigation, the determination of this

issue requires substantial independent investigation of all facts and circumstances surrounding the transaction, usually including extensive interviews. It is most unlikely that written materials prepared by the requestor could encompass all the information necessary to enable the OIG to make a reliable determination of the subjective intent of the parties.

The second potential pitfall is that advisory opinions are capable of being misused by persons *not* a party to the transaction in question in order to inappropriately escape liability. While the safe harbors are intended to create exemptions that apply generally, advisory opinions are intended to address the facts of a particular arrangement. A third party may implement an arrangement that appears similar to the arrangement described in the advisory opinion, but the third party may introduce additional factors that may make a difference in the outcome of an advisory opinion. Thus, advisory opinions are binding upon and may legally be relied upon only by the requestor(s).

We believe that these regulations provide for meaningful guidance to the public on the statutes for which advisory opinions are authorized, while avoiding the potential pitfalls described above.

As set forth, these interim final regulations have been developed primarily to address: (1) The procedures to be followed by a party applying for advisory opinions; (2) the procedures to be followed by the OIG in responding to these requests; (3) the time frames under which the OIG will receive and respond to requests for advisory opinions; (4) the type and amount of fees to be charged to the party requesting an advisory opinion; and (5) the manner in which the general public will be informed of the issuance of any advisory opinions by the OIG.

These regulations do not address the substance or the content of advisory opinions by the OIG.

Responsibilities of Outside Parties Seeking Advisory Opinions

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

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

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

Similarly, we do not believe it is appropriate to provide advisory opinions on hypothetical or generalized arrangements for several reasons. First, the anti-kickback statute and the other OIG sanction statutes impose liability with respect to acts by specific people in particular factual circumstances, i.e., the context in which prosecutive decisions are made. Anti-kickback cases are almost never alike in all material respects. In addition, especially with intent-based statutes like the anti-kickback statute, it is often not possible to determine that a particular general practice is invariably good or bad. An arrangement may be legal under the anti-kickback statute with respect to one party, but not with respect to a second party. Such differing results can be a function of the different intentions of the two parties, or a function of the introduction by a party of additional factors that would make a material difference in the resulting opinion. We believe it would not be possible for an advisory opinion reliably to identify all the possible hypothetical factors that might lead to different results.

Moreover, the OIG already has in place a process for offering guidance on the application of the OIG's legal authorities to hypothetical or generalized factual circumstances—the safe harbor provisions and Special Fraud Alerts. As indicated above, the OIG has promulgated 13 final safe harbor provisions in § 1001.952, and has proposed several others specifying generalized payment practices that will not be subject to sanction under the Medicare and Medicaid anti-kickback statute. Members of the public may also now under section 1128D(a) of the Act submit proposals for additional safe harbor regulations to the OIG. Further, in accordance with section 1128D(c) of the Act, if a member of the public is aware of a practice that may be suspect or of particular concern under Medicare or a State health care program, they may request the OIG to issue a Special Fraud Alert regarding the practice.

Requestors who are not individuals are required to disclose certain ownership and control information, so that the appropriate checks can be made to ensure that the matter which is the subject of the advisory opinion request is not under current investigation.

Initiating the Process for an Advisory Opinion

To initiate the advisory opinion process, we are indicating in part 1008 that the requestor must submit a written request for an advisory opinion. The request must clearly and thoroughly present a complete description of the facts for which an advisory opinion is being requested. 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. To the extent that the necessary information is provided in a clear and orderly manner, the OIG will be better able to process the request.

The regulations are requiring any submission to include copies of all relevant documents, such as contracts, leases, employment agreements and court documents, as well as descriptions of any other understandings that may affect the documents. In addition, the submission should include a narrative description of the arrangement. As

indicated in § 1008.36, in making the request, the identities (including names and addresses) of the requestor and all other actual and potential parties, to the extent known to the requestor to the arrangement that is the subject of the request to the advisory opinion must be included. In addition, the requestor must identify a designated contact person who will be available to communicate with the OIG.

We are requesting comments on the certification process being adopted. Under these regulations at this point we are requiring two certifications to be made in a request for an advisory opinion. The certifications must be signed by the individual (if an individual requestor), the Chief Executive Officer, or comparable officer of the company (if a corporate requestor), or the managing partner (if a partnership is the requestor). The responsible individual must 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 the knowledge of the requestor. Where the request relates to prospective conduct, the regulations state that the request must also include a certification that the requestor intends in good faith to enter into the arrangement described in the request. This certification may be made contingent upon receipt of a favorable advisory opinion.

Under these interim final regulations, while all submissions should include the above information, because of the wide variety of activities upon which the OIG must issue advisory opinions, we cannot detail at this point all of the information a requestor must provide. We are requesting public comment and input on the type of information to be provided by the requesting party and will address this point further in any revised final rulemaking. In the interim, prior to submitting a request for an advisory opinion, the requestor is advised to contact the OIG to inquire about the information needed by the OIG to process a request of the type the requestor intends to submit. Inquiries should be made in writing and sent to the Office of Inspector General, Office of Counsel to the Inspector General, Industry Guidance Branch, Room 5246 Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. 20201. (Any changes to this address regarding inquiries will be posted on the OIG home page at http://www.sba.gov/ignet/internal/hhs/hhs.html.) The OIG may, depending on the subject matter of the inquiry, provide the requestor with preliminary questions designated to elicit the factual information necessary to facilitate an OIG response to the request. These questions should be (but are not required to be) answered in the request for an advisory opinion.

If the information needed by the OIG is in the preliminary submission, we will be better able to render a prompt, concise and appropriate advisory opinion. We welcome comments on this approach.

Fees Charged to Requesting Parties

Section 1128D(b)(5)(B)(ii) of the Act requires that requestors be charged a fee equal to the costs incurred by the Department in responding to the request. The fee must be paid into the general fund of the U.S. Treasury.

Section 1008.31 of these regulations indicates that the actual costs of responding to requests for advisory opinions will factor in the salary, benefits and overhead costs of attorneys and others who will work on analyzing requests and writing advisory opinions from requesting parties. In light of the breadth of subject matter and possible range of complexities for advisory opinion requests, we do not believe it is possible to calculate or accurately estimate the actual cost of providing an advisory opinion in advance. Indeed, we believe that the statute requires us to calculate the actual costs incurred during the processing of a specific request and charge the requestor for that amount. As set forth in these regulations, at the conclusion of the advisory opinion process, when either the opinion has been issued or the request has been withdrawn, the requestor is responsible for paying the U.S. Treasury an amount equal to the costs incurred by the Government in responding to the request.

Although we cannot reliably project the processing costs in advance, we can make broad estimates that may be of use to prospective requestors. We estimate that the actual cost of processing requests, including salaries, benefits and overhead, will be near $100 per hour. We must include the time of staff attorneys, supervisors and support staff, as well as others who are consulted on various issues. The processing time will vary according to the complexity of the request and the quality of the submission. Simple requests, for example, regarding whether a certain court action is a conviction for the purposes of exclusion in accordance with section 1128 of the Act may take approximately 3 hours to analyze and produce a written opinion. On the other hand, requests involving the application of the anti-kickback statute to large, multiple party, intricate business deals may take in excess of 40 hours or more to fully analyze and produce a written advisory opinion.

We believe that it is reasonable to expect that requests for an advisory opinion will cost at least $250 in initial processing. Every request for an advisory opinion will take time to read and analyze for the OIG to ensure that it has an accurate understanding of all material facts submitted. Following that initial analysis, the OIG is required to consult with the DoJ and write the actual advisory opinion. By its very nature, most of this work will need to be done by the OIG staff attorneys. Accordingly, the regulations are providing for a non-refundable payment of $250 that is to accompany the request for an advisory opinion. Once we have gained experience in the time and staff resources involved in this process, a clearer estimate may need to be made and a re-calculation set forth.

Because we do not believe that we can accurately estimate our costs in advance for a particular request, we are attempting to accommodate requestors who may want to limit the costs of receiving an advisory opinion. The regulations provide that a requestor may designate a ''triggering dollar amount'' in their request for an advisory opinion. If the OIG calculates that the cost of processing the request has reached, or is likely to exceed, that triggering amount, the OIG will stop processing the request and promptly notify the requestor. The requestor may then decide to either authorize continued processing or withdraw the request for an advisory opinion. While the OIG intends to be able to more accurately reflect such costs in advance as experience is gained, this triggering mechanism approach should ensure that requestors do not pay costs far in excess of what they expect to incur by their request.

Section 1008.39 of the regulations specifically indicates that while a requestor may withdraw a request for an advisory opinion at any time, he or she will be responsible for any costs incurred in processing the request prior to its withdrawal.

When the advisory opinion has been completed as discussed below, or the request has been withdrawn, the OIG will calculate the total costs incurred in processing the request after taking into account any previous payments, such as the initial $250 fee, associated with the request, and the OIG will then notify the requestor of the amount owed. Once the requestor has paid the full amount owed for the cost of processing the request as required by statute, the OIG will release the advisory opinion to the requestor.

While the OIG believes the above approach for payment and release will

be sufficient for the vast majority of requests for advisory opinions, an additional procedure will be necessary in those cases where the request requires expert advice on non-legal matters. The OIG is particularly concerned about requests for advisory opinions requiring review by medical experts. For example, section 1128(b)(6)(B) of the Act authorizes the OIG to exclude any individual or entity who has furnished services to patients ''substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care.'' In order to determine whether a given factual scenario would form the basis for a sanction under this authority, as stated in § 1008.33 of these regulations, the OIG may make a determination that extensive medical as well as legal analysis is required, and that the medical analysis should be referred to a Peer Review Organization or other entity capable of providing and issuing medical reviews.

Because of the time and expense of such expert reviews, we believe that a request that requires such outside consultation should be treated differently from a standard request involving the application of the governing law to a given set of facts. When the OIG determines that an expert non-legal opinion is required, we will obtain an estimate for the costs of such an opinion and provide the requestor with that estimate. The requestor may then decide whether to pay the estimated cost of the expert review or withdraw the request. If the requestor pays the estimated cost, the OIG will promptly refer the matter to the expert for such review. Once the OIG receives the medical or other review from the outside expert, the advisory opinion process will continue with the OIG applying the expert evaluation to the legal question(s) at issue.

Responsibilities of the OIG in Reviewing the Advisory Opinion Requests

Subpart E of part 1008 discusses the obligations and responsibilities of the OIG in answering requests for advisory opinions. As set forth in these regulations, once the OIG receives a request for an advisory opinion, we will promptly examine it to determine if it appears to contain sufficient information to form the basis for an informed advisory opinion. Generally speaking, the request must contain responses to the preliminary questions posed by the OIG, as discussed above. If the request does not appear sufficient, we will promptly notify the requestor what additional information is required. Conversely, if the request appears to be sufficient, we will accept the request. In all cases, we will either request additional information or accept the request within 10 working days after receiving the request. If we have requested additional information and the requestor resubmits the advisory opinion request, we will assess within 10 working days the resubmission to determine whether it can be accepted or whether we still need further information. At the point when the OIG accepts the request, we will notify the requestor by U.S. mail of the date of acceptance.

We believe that this approach allows the OIG a reasonable amount of time to identify requests that do not contain information sufficient for the OIG to process the request. While we are limiting the time period of this initial assessment to ensure that facially complete requests are promptly processed, we are soliciting public comment on the appropriateness of this method of screening requests for advisory opinions prior to their acceptance.

Notwithstanding the acceptance of a request, the OIG reserves the right to later determine that it needs additional information. If we decide such additional information is necessary, we will notify the requestor in the same manner as we did prior to acceptance. The time period between when we notify the requestor about the additional information we need and when we receive the requested information will not be counted in considering the time for issuance of an opinion.

Because of the fact-intensive inquiry that will be necessary to render most advisory opinions, the OIG anticipates that there may be a need to request additional information from many requestors. In responding, the requestor should provide the OIG with the necessary information and accompany that submission with a certification from the same individual (or one in the same position) who certified the original request for an advisory opinion.

As required by section 1128D(b)(5)(B) of the Act and set forth in § 1008.43, the OIG will issue an advisory opinion within 60 days after the request for the opinion is accepted. Once the OIG receives a request for an opinion that appears to meet the submission criteria, the request for an opinion will be promptly accepted and the 60-day time period for issuance of an opinion will commence. The OIG will send the advisory opinion to the requestor by regular U.S. mail at the conclusion of the 60-day time period and once all required fees have been paid.

We believe that under certain circumstances the running of the 60-day time limit for issuing an opinion should be tolled. The tolling periods will only reflect time when the OIG cannot work on analyzing the request. If the OIG notifies the requestor that the costs have reached, or are likely to exceed, the triggering amount designated by that requestor, the OIG will stop processing the request until the requestor instructs the OIG to continue. Similarly, if the OIG notifies a requestor of the need for, and estimated cost of, an outside expert opinion on a non-legal issue, the regulations state that the OIG will stop processing the request until the requestor pays the estimated cost and the outside expert provides its opinion. Likewise, in those instances when the OIG requests additional information from the requestor that the OIG believes is necessary to issue the advisory opinion, the OIG will stop processing the opinion until the additional information is provided. The time that elapses during these periods when the OIG is not processing the request will not be counted as part of the 60-day period.

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

While the OIG intends to issue advisory opinions within 60 days of the receipt of the request, we do not believe that the 60-day time period should include delays in the processing of the request that are not within the control of the OIG. With the exception of the delay while waiting for a needed outside expert opinion, all of the possible tolling events are under the exclusive control of the requestor, and as such, since for what we believe will be the vast majority of advisory opinion requests, the 60-day period will only be tolled for those periods during which the requestor has not paid a required fee or has not provided information necessary to the processing of the request.

As required by section 1128D(b)(1) of the Act, the OIG will consult with DoJ when responding to requests for advisory opinions, and will issue an advisory opinion to the requestor after considering the complete description of all facts provided to it by the requestor. The opinion will restate the material facts known to the OIG and discuss the OIG's analysis and conclusion regarding the legal question(s) to be applied to the facts presented.

Dissemination of Advisory Opinions

Section 1128D(b)(5)(A)(v) requires these regulations to describe the manner in which advisory opinions will be made available to the public. As set forth in subpart E of these regulations, once the OIG issues an advisory opinion to a requestor, the OIG will promptly make a copy of that opinion available for public inspection at the OIG headquarters and the DHHS/OIG web site. We also anticipate that advisory opinions will likely be made widely available to interested members of the public through commercial publishers and trade groups. Public comments and additional suggestions regarding the dissemination of advisory opinions to the public will be welcomed.

Documents submitted to the OIG related to requested advisory opinions, and internal government documents related to such opinions, will be available to the extent authorized by the Freedom of Information Act (FOIA) (5 U.S.C. 552). To the extent that a requestor provides information it believes is not subject to disclosure under FOIA, such as items that the requestor believes are trade secrets or privileged and confidential commercial or financial information, the requestor should identify such information in the manner described in 45 CFR 5.65 (c) and (d). The requestor's assertions about the nature of information, however, are not controlling.

In addition, although a document may be exempt from disclosure under FOIA, facts reflected on that document may become part of the advisory opinion that will be provided to the public. The material facts of the arrangement in question will be described in the body of each advisory opinion, all of which will be fully available to the public.

Rescission of an Advisory Opinion

Section 1008.45 of the regulations addresses the rescission of an advisory opinion by the OIG. The regulations reserve the right of the OIG to rescind an advisory opinion after its issuance in limited circumstances, such as when the OIG learns after the issuance of the opinion that the arrangement in question may lead to fraud and abuse. In such an instance, the OIG will notify the requestor of the rescission and make such notice available to the same extent as an advisory opinion. Unless the OIG establishes that the requestor failed to provide material information in its submissions to the OIG, the requestor would not be subject to OIG sanction for actions it took prior to the notice of rescission if the requestor acted in good faith reliance on the advisory opinion. We are specifically soliciting comments on whether this approach reasonably balances the Government's need to ensure that advisory opinions are legally correct and the requestor's interest in finality.

Scope and Effect of Advisory Opinions

Subpart F of part 1008 of these regulations addresses the scope and effect of advisory opinions. An advisory opinion issued under this process is legally binding on the Department (including the OIG) and the requestor, but only with respect to the specific conduct of the particular requestor. In other words, in accordance with section 1128D(b)(4)(A) of the Act with respect to the issuance of advisory opinions, the Department is not legally bound with respect to the conduct of third parties, even if the conduct of that party appears similar to the requestor. We believe that no third parties are bound nor may they rely on an advisory opinion since each advisory opinion will apply legal standards to a set of facts involving certain known persons who provide specific statements about key factual issues. A third party may implement a look-alike arrangement with *additional* characteristics that would lead to an unfavorable opinion. Therefore, by their very nature, advisory opinions, unlike the safe harbor regulations, cannot be applied generally.

We believe the receipt of an advisory opinion regarding a certain arrangement does not totally prevent the Government from commencing an action against a party to the arrangement where, for example, a requestor failed to disclose a material fact. In any such action under sections 1128, 1128A or 1128B of the Act, an individual or entity who has requested and received an advisory opinion from the OIG regarding the arrangement in question may seek to introduce the advisory opinion into evidence in the proceeding. We believe that the court must then determine whether the requestor of the advisory opinion was justified in relying on the opinion. This determination must be made by examining all relevant circumstances, including whether the requestor fully and accurately described the arrangement in its submissions to the OIG.

III. Regulatory Impact Analysis

Executive Order 12866

The Office of Management and Budget (OMB) has reviewed this interim 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 section II of this preamble, this rule deals primarily with the procedural issues involved in the receipt, review and response to requests for advisory opinions by 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. It does not 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 500 requests per year that will generally require between 3 and 40 hours each to process. Accordingly, it would likely cost in the range of $150,000 to $2,000,000 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 a 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 as to 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 would 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 that such fees be paid by those requesting advisory opinions. 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.

IV. Paperwork Reduction Act

In order to provide appropriate advisory opinions, the OIG will need certain information from the parties who request advisory opinions. Sections 1008.18, 1008.36(b) and 1008.37 through 1008.40 of this interim final rule contain information collection requirements that require approval by OMB. We are required to solicit public comments under section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. Specifically, comments are invited on (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility and clarity of the information collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

We are seeking emergency OMB approval for the collection of information contained in this rule. In a separate Federal Register notice, containing a 60-day public comment period, we will solicit public comment on these requirements, thereby initiating the normal Paperwork Reduction Act clearance.

Title: OIG Advisory Opinion Procedure.

Summary of the collection of information: Section 205 of Public Law 104–191 requires the Department to provide advisory opinions to the public regarding several categories of subject matter. The Department must opine on requestor's potential liability under sections 1128, 1128A, and 1128B of the Act. These regulations provide the procedures under which members of the public may request advisory opinions from the OIG. Because all requests for advisory opinions are purely voluntary, respondents will only be required to provide information regarding facts about which they have decided to request an opinion from the OIG.

In order to ensure a useful advisory opinion process, the OIG must receive information sufficient to determine whether the arrangement in question is subject to sanction. The information provided by the requestor will be applied by the OIG to the legal question posed in the request for an advisory opinion. In general, we are requiring a complete description of all facts relevant to the inquiry, including all related documents.

The general requirements in this rulemaking may be supplemented by voluntary preliminary questions we have developed that correspond with each sanction authority in sections 1128, 1128A, and 1128B of the Act as appropriate. These more specific information collection requirements are being made available for public review and comment by a separate Federal Register notice. The preliminary questions will be designed to elicit the specific information that will enable the OIG to provide the most accurate and timely opinion possible. For example, if a request is made for an advisory opinion on whether a given arrangement will violate the anti-kickback statute, one question may relate specifically to how much remuneration is paid to various parties to the arrangement. Although requestors will be under no obligation to answer the preliminary questions, we believe that the questions will provide requestors with valuable guidance about what information we will need to answer their inquiry. A request for an advisory opinion that includes complete answers to the preliminary questions corresponding to the issue(s) raised by the requestor should contain most, if not all, of the information that we will require to issue an advisory opinion. Even though we believe that the questions will aid requestors, the answering of these questions is purely voluntary in nature and we will process advisory opinion requests regardless of whether the preliminary questions are answered.

The following discussion relates the aggregate effect of the collections of information included in the text of this interim final rule and in the preliminary questions.

Respondents: The ''respondents'' for the collection of information described in these regulations will be self-selected individuals and entities that choose to submit requests for advisory opinions to the OIG. We anticipate that the respondents will include health care providers of many types, 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 Inspector General Division of the Office of the General Counsel 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, that is, the self-referral provisions of section 1877 of the Act. Furthermore, we believe that most of the inquiries have been of a nature that the caller would be unlikely to request a written advisory opinion on the subject matter. Many inquiries related to relatively simple matters that could be researched by private counsel at relatively minor expense. Nevertheless, the rate of these telephone inquiries may form a starting point for estimating the number of advisory opinion requests. We estimate that we received an average of 6 telephone inquiries per day over the past several years. Of these, we believe that an average of two per day could potentially have been the subject of an advisory opinion. Using that history as a rough guide, we estimate an annual number of 500 requests. Obviously, the actual number of requests could be larger since, for the first time, formal written opinions are available. Conversely, the numbers could be smaller for a combination of many unquantifiable reasons, such as the desire not to subject an arrangement to official scrutiny.

Estimated number of responses per respondent: 1.

Estimated total annual burden on respondents: We believe that the burden of preparing requests for advisory opinions will vary widely because of differences in size and complexity of the

business transaction in question. We estimate that the average burden for each submitted request for an advisory opinion will be in the range of 2 to 40 hours. We further believe that the burden for most requests will be closer to the lower end of the range, with an average burden of 10 hours per respondent. Total burden for this proposed information collection is estimated to be 5000 hours.

We are requiring requests for advisory opinions to involve existing conduct, or conduct in which the requestor intends to engage. We anticipate that most requests will involve business arrangements into which the requesting party intends to enter. Because the facts will relate to business plans, 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, the requestor will most likely simply need to compile already collected information for our examination. In some cases, however, the requestor may need to expend a more significant amount of time in preparing a submission related to a complex arrangement involving a large number of parties.

In addition to the hour burden discussed above, some respondents may incur additional 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 submission. The outside assistance cost burden estimate is based on an estimate of 10 hours per request at $200 per hour. Thus, the cost burden for these outside functions is estimated at $1,000,000.

Comments on this information collection should be sent to both:

Cynthia Agens Bauer, OS Reports Clearance Officer, ASMB Budget Office, Room 503–H, Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201, FAX: (202) 690–6352

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.

Comments on these paperwork reduction requirements may be submitted to the above-cited individuals within two days following the Federal Register publication of this interim final rule.

List of Subjects in 42 CFR Part 1008

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

Accordingly, 42 CFR chapter V, subchapter B is amended by adding a new part 1008 as set forth below:

TITLE 42—PUBLIC HEALTH

CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 1008—ADVISORY OPINIONS BY THE OIG

Subpart A—General Provisions

Sec.
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Subpart B—Preliminary Obligations and Responsibilities of the Requesting Party

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Subpart F—Scope and Effect of OIG Advisory Opinions

1008.51 Exclusivity of OIG advisory opinions.
1008.53 Affected parties.
1008.55 Admissibility of evidence.
1008.59 Range of the advisory opinion.

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

Subpart A—General Provisions

§ 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.

(b) An individual or entity may request an advisory opinion from the OIG regarding on any of 5 specific subject matters described in § 1008.5 of this part.

(c) The requesting party must provide a complete description of the facts as set forth in subpart B of this part, and pay the costs to the OIG of processing the request for an advisory opinion as set forth in subpart C of this part.

(d) Nothing in this part limits the investigatory or prosecutorial authority of the OIG, DoJ or any other agency of the Government.

§ 1008.3 Effective period.

The provisions in this part are applicable to requests for advisory opinions submitted on or after February 21, 1997, and before August 21, 2000, and to any requests submitted during any other time period for which the OIG is required by law to issue advisory opinions.

§ 1008.5 Matters subject to advisory opinions.

(a) An individual or entity may request an advisory opinion from the OIG regarding—

(1) What constitutes prohibited remuneration within the meaning of section 1128B(b) of the Act;

(2) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in section 1128B(b)(3) of the Act for activities that do not result in prohibited remuneration;

(3) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in § 1001.952 of this chapter for activities that do not result in prohibited remuneration;

(4) What constitutes an inducement to reduce or limit services under section 1128A(b) of the Act to Medicare or Medicaid program beneficiaries; and

(5) Whether any activity, or proposed activity, constitutes grounds for the imposition of a sanction under sections 1128, 1128A or 1128B of the Act.

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

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

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

Subpart B—Preliminary Obligations and Responsibilities of the Requesting Party

§ 1008.11 Who may submit a request.

Any individual or entity may submit a request to the OIG for an advisory opinion regarding an existing arrangement or one which the requestor in good faith specifically plans to undertake. The requestor must be a party to the arrangement, or proposed arrangement, that is the subject of the request.

§ 1008.15 Facts subject to advisory opinions.

(a) The OIG will consider requests from a requesting party for advisory opinions regarding the application of specific facts to the subject matters set forth in § 1008.5(a) of this part. The facts must relate to an existing arrangement, or one which the requestor in good faith plans to undertake. The plans may be contingent upon receiving a favorable advisory opinion. The advisory opinion request should contain a complete description of the arrangement that the requestor is undertaking, or plans to undertake.

(b) Requests presenting a general question of interpretation, posing a hypothetical situation, or regarding the activities of third parties do not qualify as advisory opinion requests.

(c) An advisory opinion request will not be accepted when—

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

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

(3) An informed opinion cannot be made, or could be made only after extensive investigation, clinical study, testing or collateral inquiry.

§ 1008.18 Preliminary questions suggested for the requesting party.

(a) The OIG may establish and maintain a set of questions corresponding to the categories of opinion subject matter as set forth in § 1008.5(a) of this part as appropriate. The questions will be designed to elicit specific information relevant to the advisory opinion being sought; however, answering the questions is voluntary.

(b) Questions the OIG suggests the requestor to 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.

(c) When submitting a request for an advisory opinion, a requestor may answer the questions corresponding to the subject matter for which the opinion is requested. The extent to which any of the questions is not fully answered may effect the content of the advisory opinion.

Subpart C—Advisory Opinion Fees

§ 1008.31 OIG fees for the cost of advisory opinions.

(a) *Responsibility for fees.* The requestor is responsible for paying a fee equal to the costs incurred by the Department in responding to the request for an advisory opinion.

(b) *Initial payment.* A request for an advisory opinion must be accompanied by a check or money order payable to the Treasury of the United States for $250. This initial payment is non-refundable.

(c) *Calculation of costs.* Prior to the issuance of the advisory opinion, the OIG will calculate the costs to be 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 persons. 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)(3) 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 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.

(3) If the OIG notifies the requestor that the estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, the OIG will stop processing the request until such time as the requestor makes a written request for the OIG to continue processing the request. Any delay in the processing of the request for an advisory opinion attributable to these procedures will toll the time for issuance of an advisory opinion until the requestor asks the OIG to continue working on the request.

(4) If the requestor chooses not to pay for completion of an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs incurred and identified by the OIG attributable to processing the request for an advisory opinion up to that point.

(5) If the costs incurred by the OIG in responding to the request are greater than the amount paid by the requestor, the OIG will, prior to the issuance of the advisory opinion, notify the requestor of any additional amount due. The OIG will not issue an advisory opinion until the full amount owed by the requestor has been paid. Once the requestor has paid the OIG the total amount due for the costs of processing the request, the OIG will issue the advisory opinion. The time period for issuing advisory opinions will be tolled from the time the OIG notifies the requestor of the amount owed until the time full payment is received.

(e) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in § 1008.33.

(2) 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.

§ 1008.33 Expert opinions from outside sources.

(a) The OIG may request expert advice from qualified sources on non-legal issues if necessary to respond to the advisory opinion request. For example, the OIG may require the use of appropriate medical reviewers, such as peer review organizations, to obtain medical opinions on specific issues.

(b) 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. As indicated in § 1008.31(e), the requestor must pay the estimated cost of the expert advice.

(c) Once payment is made for the cost of the expert advice, the OIG will arrange for a prompt expert review of the issue or issues in question.

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

§ 1008.36 Submission of a request.

(a) A request for a formal advisory opinion must be submitted in writing. An original and 2 copies of the request

should be addressed to the headquarter offices of the OIG.

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

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

(2) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request for an advisory opinion with the OIG on behalf of the requestor;

(3) A declaration of the subject category or categories as described in § 1008.5 of this part for which the advisory opinion is requested;

(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) Complete copies of all operative documents, and

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

(5) All Medicare and Medicaid provider numbers used by all parties to the arrangement;

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

(7) 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.

§ 1008.37 Disclosure of ownership and related information.

Each individual or entity requesting an advisory opinion will supply full and complete information as to the identity of each entity owned or controlled by the indivudual, 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. 1320a–3(a)(1)) and part 420 of this chapter.

§ 1008.38 Signed certifications by the requestor.

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

(b) If the advisory opinion relates to a proposed arrangement, the request must also include the following signed certification: ''The arrangement described in this request for an advisory opinion is one that [the requestor] in good faith plans 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) will be signed by—

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

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

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

§ 1008.39 Additional information.

(a) If the request for an advisory opinion does not contain all of the information required by § 1008.36 of this part, or the OIG believes it needs more information prior to rendering an advisory opinion, the OIG may, at any time, request whatever additional information or documents it deems necessary. The time period for the issuance of an advisory opinion will be tolled from the time the OIG requests the additional information from the requestor until such time as the OIG determines that it has received the requested information.

(b) The OIG may request additional information before or after the request for an advisory opinion has been accepted.

(c) Additional information should be provided in writing, signed by the same person who signed the initial request and certified by this person to be a true, correct and complete disclosure of the requested information in a manner equivalent to that described in § 1008.37 of this part.

(d) In connection with any request for an advisory opinion, the OIG or DoJ may conduct whatever independent investigation they believe appropriate.

§ 1008.40 Withdrawal.

The requestor of an advisory opinion may withdraw the request prior to the issuance of a formal advisory opinion by the OIG. The withdrawal must be written and must be submitted to the same address as the submitted request, as indicated in §§ 1008.18(b) and 1008.36(a) of this part. Regardless of whether the request is withdrawn, the requestor must pay the costs expended by the OIG in processing the opinion, as discussed in § 1008.31(d) of this part. The OIG reserves the right to retain any request for an advisory opinion, documents and information submitted to it under these procedures, and to use them for any governmental purposes.

Subpart E—Obligations and Responsibilities of the OIG

§ 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 of 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—

(1) Formally accept the request for an advisory opinion,

(2) Notify the requestor of what additional information is needed, or

(3) Decline to formally accept the request.

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

(d) Upon acceptance of the request, the OIG will notify the requestor by regular U.S. mail of the date that the request for the advisory opinion was formally accepted.

(e) The 60-day period for issuance of an advisory opinion set forth in § 1008.43(c) of this part will not commence until the OIG has formally accepted the request for an advisory opinion.

§ 1008.43 Issuance of a formal advisory opinion.

(a) An advisory opinion will be considered issued, once payment is received, when 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 known 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 and known to the OIG.

(c)(1) The OIG will issue an advisory opinion, in accordance with the provisions of this part, within 60 days after the request for an advisory opinion has been formally accepted;

[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.

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

(ii) Requests additional information from the requestor until the time the OIG receives the requested information;

(iii) Notifies the requestor of the full amount due until the time the OIG receives payment of the full amount owed; and

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

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

§ 1008.45 Rescission.

Any advice 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 or revoke the action. Notice of such rescission or revocation will be given to the requestor so that the individual or entity may discontinue the course of action taken in accordance with the OIG advisory opinion. The OIG will not proceed against the requestor with respect to any action taken in good faith reliance upon the OIG advice under this part, where all the relevant facts were fully, completely and accurately presented to the OIG, and where such action was promptly discontinued upon notification of rescission or revocation of the OIG approval.

§ 1008.47 Disclosure.

(a) Advisory opinions issued and released in accordance with the provisions set forth in this part will be available to the public.

(b) Promptly after the issuance and release of an advisory opinion to the requestor, a copy of the advisory opinion will be available for public inspection between the hours of 10:00 a.m. and 3:00 p.m. on normal business days at the headquarter offices of the OIG and on the DHHS/OIG web site.

(c) Any pre-decisional document, or part of such pre-decisional document, that is prepared in 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 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 will be available to the public to the extent authorized by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section will limit the OIG's right, in its discretion, to issue a press release or otherwise publicly disclose the identity of the requesting party or parties, and the nature of the action taken by the OIG upon the request.

Subpart F—Scope and Effect of OIG Advisory Opinions

§ 1008.51 Exclusivity of OIG advisory opinions.

The only method for obtaining a binding advisory opinion regarding any of the subject matters set forth in § 1008.5(a) is through the procedures described in this part. No binding advisory opinion, oral or written, has or may be issued by the OIG regarding the specific matters set forth in § 1008.5(a) except through written opinions issued in accordance with this part.

§ 1008.53 Affected parties.

An advisory opinion issued by the OIG will have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion.

§ 1008.55 Admissibility of evidence.

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

(b) An advisory opinion not issued to a person may not be introduced into evidence to prove that person did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

§ 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 agency, such advisory opinion will not be taken to indicate the OIG's views on the legal or factual issues that may be raised before that agency.

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

Dated: December 26, 1996.

June Gibbs Brown,

Inspector General, Department of Health and Human Services.

Approved: January 28, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97–4086 Filed 2–18–97; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 199

[CGD 84–069]

RIN 2115–AB72

Lifesaving Equipment

AGENCY: Coast Guard, DOT.

ACTION: Interim rule, partial suspension; request for comments.

SUMMARY: On May 20, 1996 the Coast Guard published an interim rule revising the lifesaving equipment regulations for U.S. inspected vessels. The interim rule included provisions for vessels not on international routes to comply with certain new requirements by October 1, 1997 and October 1, 2001. The Coast Guard has received comments concerning the regulatory analysis for the interim rule which may lead to changes to the lifesaving requirements in the final rule. To prevent any economic expenditures based on the interim rule which might not be necessary under the final rule, the Coast Guard is suspending the implementation requirements for certain provisions in the interim rule. The Coast Guard requests comments on the economic impacts of the lifesaving requirements covered by the partial suspension.

DATES: The suspension of § 199.10(i)(1)(i), (ii) and (iii) is effective February 19, 1997. Comments must be received on or before April 21, 1997.

ADDRESSES: Mail comments to the Executive Secretary, Marine Safety Council (G–LRA) [CGD 84–069], U.S. Coast Guard Headquarters, 2100 Second