

These regulations will be effective on that portion of Fiesta Bay and Mission Bay, San Diego, California, that is described in Table 1 of 33 CFR 100.1101. Implementation of 33 CFR 100.1101 is necessary to control vessel traffic in the regulated area during the event to ensure the safety of participants and spectators.

Pursuant to 33 CFR 100.1101(a), Commander, Coast Guard Activities San Diego, is designated Patrol Commander for this event; he has the authority to delegate this responsibility to any commissioned, warrant, or petty officer of the Coast Guard.

**DATES:** This section is effective from 7:30 a.m. PDT until 6 p.m. PDT, September 18, 1998, and continues to be effective from 7:30 a.m. PDT until 6 p.m. PDT every day through, and including, September 20, 1998. If the event concludes prior to the scheduled termination date and/or time, the Coast Guard will cease enforcement of this section and will announce that fact via Broadcast Notice To Mariners.

**FOR FURTHER INFORMATION CONTACT:** QMC Michael C. Claeys, U.S. Coast Guard Activities San Diego, California; Tel: (619) 683-6309.

**SUPPLEMENTARY INFORMATION:**

**Discussion of Implementation**

The World Series of Power Boat Racing on Mission Bay is scheduled to occur on September 18 and continues daily through, and including, September 20, 1998. This event, formerly known as the Thunderboat Regatta, consists of racing using high-speed powerboats with a maximum length of 27 feet. Neither the sponsor, nor the date, nor the location of the event has changed since this event was listed as the "Thunderboat Regatta" in Table 1 of 33 CFR 100.1101.

These Special Local Regulations permit Coast Guard control of vessel traffic in order to ensure the safety of spectator and participant vessels. In accordance with the regulations in 33 CFR 100.1101, no persons or vessels shall block, anchor, or loiter in the regulated area; nor shall any person or vessel transit through the regulated area, or otherwise impede the transit of participant or official patrol vessels in the regulated area, unless cleared for such entry by or through an official patrol vessel acting on behalf of the Patrol Commander.

Dated: June 25, 1998.

**J.C. Card,**

*Vice Admiral, U.S. Coast Guard, Commander, Eleventh Coast Guard District.*

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**POSTAL SERVICE**

**39 CFR Part 111**

**Use and Determination of Postage Value of Breast Cancer Research Semi-postal Stamp**

**AGENCY:** Postal Service.

**ACTION:** Final rule; request for comments.

**SUMMARY:** This rule amends the Domestic Mail Manual to establish the terms and conditions for use and determination of value of the Breast Cancer Research Semi-postal Stamp.

**DATES:** Effective July 29, 1998.

Comments must be received on or before August 17, 1998.

**ADDRESSES:** Mail or deliver written comments to the Manager, Mail Preparation and Standards, 475 L'Enfant Plaza, SW, Room 6800, Washington, DC, 20260-2405. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday at USPS Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor N, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Anne Emmerth, (202) 268-2363.

**SUPPLEMENTARY INFORMATION:** The Stamp Out Breast Cancer Act, Pub. L. No. 105-41, 111 Stat. 1119 (1997), directs the Postal Service to make available a Breast Cancer Research Semi-postal Stamp at a special price to enable the public to make contributions to fund breast cancer research. The Act specifies that the price of the special postage stamp is the First-Class Mail single-piece first-ounce letter rate plus a differential not to exceed 25 percent of that rate category. The Act empowers the Governors of the United States Postal Service to establish the price for the stamp. Pursuant to the Act, the Governors have established a price of 40 cents for each Breast Cancer Research Semi-postal Stamp.

Mailers may use the Breast Cancer Research Semi-postal Stamp in place of First-Class Mail single-piece first-ounce letter rate stamps on their mail, if they so choose, in order to make a contribution. The difference between the purchase price of the stamp (40 cents) and the First-Class Mail single-piece first-ounce letter rate (currently 32 cents) less associated costs will be used to fund breast cancer research. Pursuant to the Act, the Postal Service is directed to pay, after deduction for its reasonable costs, 70 percent of the revenue from the differential to the National Institutes of Health, and the remainder to the Department of Defense.

The stamp's dual purposes, namely, as a means of payment of postage and as a device for raising funds for breast cancer research, require that special terms and conditions apply to the use of the stamp. In particular, because the stamp must be made available for a two-year period, and given that the Act does not require that the stamp's price be changed in the event that a change in the First-Class Mail single-piece rate is implemented during the two-year period, the Postal Service has determined that the stamp will be non-denominated. This measure preserves the Governors' option of maintaining the price of the Breast Cancer Research Semi-postal Stamp at 40 cents, even after the First-Class Mail single-piece rate is raised to 33 cents after the stamp's issuance, without the need to reprint the stamp with a new numerical denomination. When the First-Class Mail single-piece rate is increased to 33 cents on January 10, 1999, the postage value of Semi-postal stamps purchased before such change is effected will remain the same. Stamps purchased after a change in the First-Class Mail single-piece rate is effected will have a postage value equivalent to that rate at the time of purchase. Thus, Semi-postal stamps purchased before the First-Class Mail single-piece rate is changed on January 10, 1999, will have a postage value of \$0.32; Semi-postal stamps purchased after the rate change is implemented will have a postage value of \$0.33.

In lieu of a numerical denomination, the stamp will bear the words "First-Class." This measure is intended to inform mailers that the stamp's postage value is equal to the First-Class Mail single-piece letter rate in effect at the time of purchase. In addition, the Domestic Mail Manual distinguishes the price of the stamp from its postage value and establishes that the postage value of the stamp is determined by the First-Class Mail first-ounce single-piece letter rate in effect at the time of purchase.

Conforming limitations on refunds and valuation for purposes of exchange or conversion are also included in the final rule. A conforming amendment is also made to DMM R000.4.0.

Although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding rulemaking by 39 U.S.C. 410(a), the Postal Service is seeking comments on the following revisions of the Domestic Mail Manual (DMM), incorporated by reference in the Code of Federal Regulations. See 39 CFR part 111.

List of Subjects in 39 CFR Part 111

Postal Service.  
Accordingly, 39 CFR 111 is amended as follows:

PART 111—[AMENDED]

1. The authority citation for 39 CFR part 111 is amended to read as follows:  
**Authority:** 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 414, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.  
2. Revise the following sections of the Domestic Mail Manual as set forth below:

P Postage and Payment Methods  
\* \* \* \* \*

P014 Refunds and Exchanges

1.0 STAMP EXCHANGES

1.1 USPS Fault

[Amend to read:]  
The post office may correct mistakes in selling damaged, defective, or otherwise unserviceable stamps by exchanging stamps at full postage value.

1.2 Damaged in Customer's Possession

[Amend the last sentence to read as follows:]  
\* \* \* Each such transaction is limited to \$100 worth of postage from each customer.  
\* \* \* \* \*

1.5 Purchase Error

[Amend the first sentence to read as follows:]  
If a customer bought the wrong denomination stamps (or the wrong kind, size, or denomination envelope), they may be exchanged at full postage value. \* \* \*  
\* \* \* \* \*

2.0 POSTAGE AND FEES REFUNDS  
\* \* \* \* \*

[Add new 2.10 to read as follows:]

2.10 Breast Cancer Research Semi-postal Stamps

Customers may exchange or convert Breast Cancer Research Semi-postal Stamps for their postage value, i.e., the price of the stamps less the contribution amount, to the extent exchange or conversion of postage stamps is permitted under P014. The postage exchanged or converted is equivalent to the First-Class Mail single-piece rate in effect at the time of purchase (currently \$0.32), as supported by the mailer's receipt. The contribution amount is not included in the exchange or conversion value. If the mailer cannot produce a receipt, the exchange or conversion value of each Breast Cancer Research Semi-postal Stamp cannot exceed \$0.32 per stamp, regardless of whether the First-Class Mail single-piece rate in effect at the time of purchase is \$0.33 or higher.  
\* \* \* \* \*

P020 Postage Stamps and Stationery

P022 Adhesive Stamps

1.0 PURCHASE AND USE

\* \* \* \* \*  
[Create 1.6 to read as follows:]

1.6 Breast Cancer Research Semi-postal Stamps

Breast Cancer Research Semi-postal Stamps are subject to special limitations and conditions:  
a. Breast Cancer Research Semi-postal Stamps provide a means for customers to make contributions toward breast cancer research. Breast Cancer Research Semi-postal Stamps are offered for sale for a limited time as provided under 39 U.S.C. 414.

b. The price of the Breast Cancer Research Semi-postal Stamp is 40 cents. The postage value of the Breast Cancer Research Semi-postal Stamp is the First-Class Mail Nonautomation Single-Piece first-ounce letter rate in R100.1.2 that is in effect at the time of purchase. The difference between the purchase price and the First-Class Mail Nonautomation Single-Piece first-ounce letter rate in effect at the time of purchase constitutes a contribution to breast cancer research, and cannot be used to pay postage. Additional postage must be affixed to pieces weighing in excess of one ounce, pieces subject to the nonstandard surcharge, or pieces for which special services have been elected. The postage value of Breast Cancer Research Semi-postal Stamps is fixed according to the First-Class Mail Nonautomation Single-Piece first-ounce letter rate in effect at the time of purchase; the postage value of Breast Cancer Research Semi-postal Stamps purchased before any subsequent change in the First-Class Mail Nonautomation Single-Piece first-ounce letter rate is unaffected by any subsequent change in that rate.

c. Contributions to breast cancer research made through purchase of Breast Cancer Research stamps are not refundable. The postage value of Breast Cancer Research stamps for purposes of exchange or conversion under P014 is determined by the First-Class Mail Nonautomation Single-Piece rate in effect at the time of purchase, or as otherwise provided in P014.2.10.

\* \* \* \* \*

R Rates and Fees

R000 Stamps and Stationery  
\* \* \* \* \*

[Amend the table in R000.4.0 to include the following line item:]

Purpose	Form	Denomination
* Breast Cancer Research.	* Panels of up to 20 .....	* Purchase Price of \$0.40; Postage Value Equivalent to First-Class Mail Nonautomation Single-Piece Rate (currently \$0.32); remainder is contribution to fund Breast Cancer Research.

\* \* \* \* \*

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

**Stanley F. Mires,**

*Chief Counsel, Legislative.*

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

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## 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 Act<sup>1</sup>; 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.<sup>2</sup> 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.

<sup>2</sup> 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.

<sup>1</sup> 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.