

Questioning Regarding Possible Exposure to Malaria" dated May 2000 to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance document entitled "Guidance for Industry: Recommendations for Donor Questioning Regarding Possible Exposure to Malaria" dated May 2000. The draft guidance document recommends questions to be asked of donors to determine possible exposure to malaria. The draft guidance document also provides recommendations for deferral of donors for malarial risk. The recommendations apply only to donations containing intact Red Blood Cells or platelets. Donations used for preparing plasma or plasma derivatives devoid of intact Red Blood Cells or platelets are excluded. The draft guidance document currently being announced, when finalized, will replace the recommendations in the guidance entitled "Recommendations for Deferral of Donors for Malaria Risk" dated July 26, 1994.

The draft guidance document represents the agency's current thinking on malarial risks for prospective donors. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. As with other guidance documents, FDA does not

intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

##### **II. Comments**

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by September 6, 2000. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

##### **III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: May 18, 2000.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00-14371 Filed 6-7-00; 8:45 am]

**BILLING CODE 4160-01-F**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Health Care Financing Administration**

**[Document Identifier: HCFA-10003]**

##### **Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions;

(2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* New Collection.

*Title of Information Collection:* Medicare + Choice Beneficiary Appeal Notices, "Notices of Denial of Medical Services," "Notice of Denial of Request for Payment" and Supporting Regulations in 42 CFR 422.568.

*Form No.:* HCFA-10003 (OMB# 0938-NEW).

*Use:* This collection includes two Medicare + Choice appeal notices, Denial of Service and Denial of Payment. Pursuant to the Social Security Act Section 1852(g)(1)(B), M+C organizations are required to issue notices to Medicare managed care beneficiaries when a request for either medical service or payment is denied. Additionally, the notices inform beneficiaries of their right to file an appeal.

All M+C organizations will be required to use these forms. Neither the Health Care Financing Administration (HCFA) nor the M+C organizations will use such notices to collect and analyze data on M+C beneficiary appeals. They are for information purposes only.

*Frequency:* On occasion.

*Affected Public:* Business or other for-profit and Individuals or Households.

*Number of Respondents:* 29,892.

*Total Annual Responses:* 29,892.

*Total Annual Hours:* 2,994.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 30, 2000.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 00-14451 Filed 6-07-00; 8:45 am]

**BILLING CODE 4120-03-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-2384]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection;

*Title of Information Collection:* Third Party Premium Billing Request and Supporting Regulations in 42 CFR 408.6;

*Form No.:* HCFA-2384 (OMB 0938-0041);

*Use:* The Third Party Premium Billing Request is used as an authorization form to designate that a family member or other interested party receive the Medicare premium bill and pay it on behalf of a Medicare beneficiary.

*Frequency:* On occasion;

*Affected Public:* Individuals or Households;

*Number of Respondents:* 15,000;

*Total Annual Responses:* 15,000;

*Total Annual Hours:* 6,250.

To obtain copies of the supporting statement and any related forms for the

proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 30, 2000.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 00-14452 Filed 6-7-00; 8:45 am]

**BILLING CODE 4120-03-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-216]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection;

*Title of Information Collection:* Organ Procurement Organization/Histocompatibility Laboratory Statement of Reimbursable Costs, Manual Instructions and Supporting Regulations Contained in 42 CFR 413.20 and 413.24;

*Form No.:* HCFA-216 (OMB No. 0938-0102);

*Use:* This form is required by statute for participation in the Medicare program. The information is used to determine reasonable costs incurred to furnish treatment to End Stage Renal Disease (ESRD) patients by Organ Procurement Organizations and Histocompatibility Laboratories.

*Frequency:* Annually;

*Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government;

*Number of Respondents:* 108;

*Total Annual Responses:* 108;

*Hours:* 4,860.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willingham, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 30, 2000.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 00-14453 Filed 6-7-00; 8:45 am]

**BILLING CODE 4120-03-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain