

neither an environmental assessment nor an environmental impact statement is required.

Dated: September 14, 2000.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1145-NC]

Medicare and Medicaid Programs; Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces two additional applications that we have received from hospitals requesting waivers from entering into agreements with their designated organ procurement organizations (OPOs) in accordance with section 1138(a)(2) of the Social Security Act. This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant these waivers.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 27, 2000.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1145-NC, P.O. Box 8016, Baltimore, MD 21244-8016.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1145-NC. Comments received

timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

FOR FURTHER INFORMATION CONTACT:

Mark A. Horney, (410) 786-4554.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1138(a)(1)(A)(iii) of the Social Security Act (the Act) provides that a hospital must notify the designated OPO (for the service area in which it is located), as defined under section 1138(a)(3)(B) of the Act, of potential organ donors. Under section 1138(a)(1)(C) of the Act, the hospital must have an agreement to identify potential donors only with that designated OPO.

Section 1138(a)(2) of the Act provides that the hospital may obtain a waiver from the Secretary of these requirements. A waiver allows the hospital to have an agreement with an OPO, other than the designated OPO, if the hospital meets conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to evaluate a hospital's waiver.

Section 1138(a)(2)(A) further states that in granting a waiver, the Secretary must determine that the waiver—(1) Is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO service area due to the changes made in definitions for metropolitan statistical areas (MSAs); and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application within 30 days of receiving the application and offer interested parties an opportunity to

comment in writing within 60 days of the published notice.

The regulations at 42 CFR 486.316(d) provide that if we change the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver within 30 days of notice of the change in designation. The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under sections 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at §§ 486.316(e) and (f). Section 486.316(g) further specifies that a hospital may continue to operate under its existing agreement with a now out-of-area OPO while we are processing the waiver request submitted in accordance with § 486.316(d).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A-95-11) that has been supplied to each hospital. This Program Memorandum detailed the waiver process and discussed the information that hospitals must provide in requesting a waiver. We indicated that upon receipt of the waiver requests, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

We will review the requests and comments received. During the review process, we may consult on an as-needed basis with the Public Health Service's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver requests and notify the affected hospitals and OPOs.

III. Additional Hospital Waiver Requests

As allowed under § 486.316(e), each of the following two hospitals has requested a waiver to have an agreement with an alternative, out-of-area OPO. The listing includes the name of the facility, the city and State of the facility, the requested OPO, and the currently designated area OPO. This request is not a result of a governmental change; therefore, the exception under § 486.316(g) does not apply to these two hospitals. Moreover, these hospitals may not work with the requested OPOs rather than the designated OPOs until the completion of our review.

Name of facility	City	State	Requested OPO	Designated OPO
Copley Hospital	Morrisville	VI	NYAP	MAOB
Mercy Memorial Hospital	Urbana	OH	OHLC	OHLP

IV. Keys to the OPO Codes

The keys to the acronyms used in the listings to identify OPOs and their addresses are as follows:

MAOB	New England Organ Bank, One Gateway Center, Newton, MA 02158.
NYAP	Center for Donation and Transplant, 218 Great Oaks Blvd, Albany, NY 12203.
OHLC	Life Connection of Ohio, 1545 Holland Road, Suite C, Maumee, OH 43537- 1694.
OHLP	Lifeline of Ohio, 770 Kinnear Road, Suite 200, Columbus, OH 43212.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, through the use of automated collection techniques or other forms of information technology.

Section 486.316 states the requirements for a Medicare or Medicaid participating hospital to request a waiver permitting the hospital to have an agreement with an OPO other than the OPO designated for the service area in which the hospital is located. The burden associated with these requirements are currently approved under OMB 0938-0688, HCFA-R-13, Conditions of Coverage for Organ Procurement Organizations, with an expiration date of November 30, 2001.

Authority: Section 1138 of the Social Security Act (42 U.S.C. 1320b-8).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774 Medicare—Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: August 31, 2000.

Robert A. Berenson,

Director, Center for Health Plans and Providers, Health Care Financing Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

White House Initiative on Asian Americans and Pacific Islanders, President's Advisory Commission; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to conduct a public meeting by teleconference during the month October 2000.

Name: President's Advisory Commission on Asian Americans and Pacific Islanders (AAPIs).

Date and Time: October 11, 2000; 5 p.m. – 7 p.m. EST.

The President's Advisory Commission on AAPIs will conduct a public meeting by teleconference on October 11, from 5 p.m. to 7 p.m. EST inclusive. The meeting is open to the public; however, teleconference lines are limited. Please call Mr. Tyson Nakashima, (301) 443-2492, if you are interested in participating in the call and to obtain the dial-in number. Agenda items will include, but will not be limited to: Approval of September Commission meeting minutes; reports from subcommittees; administrative tasks; and deadlines.

The purpose of the Commission is to advise the President on the issues facing Asian Americans and Pacific Islanders (AAPIs). Requests to address the Commission should be made in writing and should include the name, address, telephone number and business or professional affiliation of the interested party. Individuals or groups addressing similar issues are encouraged to combine comments and present through a single representative. The allocation of time for remarks may be adjusted to accommodate the level of expressed interest. Written requests should be faxed to (301) 443-0259. Anyone who has interest in joining any

portion of the meeting or who requires additional information about the Commission should contact: Mr. Tyson Nakashima, Office of the White House Initiative on AAPIs, Parklawn Building, Room 10-42, 5600 Fishers Lane, Rockville, MD, 20857, Telephone (301) 443-2492. Anyone who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mr. Nakashima no later than October 4, 2000.

Dated: September 21, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00-24845 Filed 9-26-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Shared Pathology Informatics Network.

Date: October 30-31, 2000.

Time: 7 pm to 5 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Kenneth L. Bielat, Scientific Review Administrator, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8043, Bethesda, MD 20892, (301) 496-7576.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and