pending IND's and NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

FDA regrets that it was unable to publish this notice 15 days prior to the May 6 and 7, 1997, Arthritis Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Arthritis Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: April 15, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–10251 Filed 4–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BPD–894–NC]

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

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

ACTION: Notice with comment period.

SUMMARY: This notice announces eight additional applications that HCFA has received from hospitals requesting waivers from dealing with their designated organ procurement organizations (OPOs) in accordance

with section 1138(a)(2) of the Act. It supplements notices published in the **Federal Register** on January 19, 1996, May 17, 1996, and November 8, 1996, that announced hospital waiver requests received by HCFA. This notice requests comments from OPOs and the general public for our consideration in determining whether these waivers should be granted.

DATES: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on June 20, 1997.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, department of Health and Human Services, Attention: BPD–894-NC, P.O. Box 7517, Baltimore, MD 21244–0517.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201,
or
Room C5–09–26, 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 BPD–894–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 309–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

On January 19, 1996, May 17, 1996, and November 8, 1996, we published notices in the **Federal Register** (61 FR 1389, 61 FR 24941, and 61 FR 57876) that announced applications which HCFA had received from hospitals requesting a waiver from dealing with their designated organ procurement organizations (OPOs) in accordance with section 1138(a)(2) of the Social Security Act (the Act).

This notice supplements these three notices. Section 1138(a)(1)(A)(iii) of the Social Security Act (the Act) provides that a hospital or rural primary care hospital that participates in the Medicare or Medicaid programs must establish written protocols for the identification of potential organ donors.

Section 155 of the Social Security Act Amendments of 1994 (SSA '94) (Pub. L. 103–432) amended section 1138 of the Act to require that effective January 1, 1996, a hospital must notify the organ procurement organization (OPO) designated for the service area in which it is located of potential organ donors (sections 1138 (a)(1)(A)(iii) and (a)(3)(B) of the Act). The hospital must also have an agreement to do so only with that designated OPO (sections 1138 (a)(1)(C) and (a)(3)(A)).

The statute also provides that the hospital may obtain a waiver of these requirements from the Secretary. A waiver would allow the hospital to have an agreement with an ''out-of-area'' OPO (section 1138(a)(2)) if it meets conditions specified in the statute (section 1138(a)(2)(A) (i) and (ii)).

The law further states that in granting a waiver, the Secretary must determine that such a waiver: (1) Would be expected to increase donation; and (2) will assure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the out-of-area OPO (section 1138(a)(2)(A)). In making a waiver determination, 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 definition of metropolitan statistical areas (MSAs); and (4) the length and continuity of a hospital's relationship with the out-of-area OPO (section 1138(a)(2)(B)). Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver applications within 30 days of receiving the application and offer interested parties an opportunity to comment in writing within 60 days of the published notice.

Regulations at 42 CFR 486.318(d) provide that if HCFA changes 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 will use to evaluate the waiver in these cases are the same as that described above under section 1138(a)(2)(A) of the Act and incorporated in the regulations at § 486.318(e). The regulations further specify that a hospital may continue to operate under its existing agreement with an out-of-area OPO while HCFA is processing the waiver request.

HCFA recently redesignated all OPO service areas as a result of the 2-year recertification process required under the statute and regulations at § 486.304(e)(2).

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 law (section 1138(a)(2)(D)).

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

III. Additional Hospital Waiver Requests

As allowed under § 483.316(d), the following seven hospitals have requested waivers to have an agreement with an alternative, out-of-area OPO, as a result of changes in their designated OPOs due to the recent redesignation of OPO service areas. The listing includes the name of the facility, the city and State location of the facility, the requested OPO, and the currently designated area OPO. These hospitals have submitted timely waiver requests and may work on an interim basis with the requested out-of-area OPO, pending receipt of public comments and our final determination.

Name of facility	City	State	Requested OPO	Designated OPO
Wing Memorial Hospital	Palmer	MA	MAOB	CTHH

Name of facility	City	State	Requested OPO	Designated OPO
Noble Memorial Hospital	Westfield	MA	MAOB	CTHH
Holyoke Hospital	Holyoke	MA	MAOB	CTHH
Crestline Memorial Hosptial	Crestline	OH	OHLC	OHLP
River Valley Health System	Ironton	OH	KYDA	OHLP
Samaritan Health System	Lake Havasu	AZ	AZOB	NVLV
Kingman Regional Medical Center	Kingman	AZ	AZOB	NVLV

In addition, the following hospital has requested a waiver that is unrelated to changes made as a result of recent redesignations of OPO service areas. This hospital's request was made on a prospective basis. Therefore, our determination on this request will be made only upon receipt of public comments and completion of our review. Any approval of this request will be prospective.

Name of facility	City	State	Requested OPO	Designated OPO
Hutcheson Medical Center	Fort Oglethorpe	GA	GALL	TNDS

IV. Keys to the OPO Codes

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

AZOB
DONOR NETWORK OF ARIZONA, 3877 North Seventh Street, Phoenix, AZ 85014

CTHH NORTHEAST OPO AND TISSUE BANK, Hartford Hospital, 80 Seymour Street, Hartford, CT 06102–5037

GALL LIFELINK OF GEORGIA, 3715 Northside Parkway, 100 Northcreek, Suite 300, Atlanta, GA 30327

KYDA
KENTUCKY ORGAN DONOR AFFILIATES, 105 East Broadway, Louisville, KY 40202

MAOB
NEW ENGLAND ORGAN BANK, One Gateway Center, Newton, MA 02158

NVLV
NEVADA DONOR NEWTWORK, 4580 Southeastern Avenue, Suite 33, Las Vegas, NV 89119

OHLC
LIFE CONNECTION OF OHIO, 1545 Holland Road, Suite C, Maumee, OH 43537

OHLP
LIFELINE OF OHIO, 770 Kinnear Road, Suite 200, Columbus, OH 43212

TNDS
TENNESSEE DONOR SERVICES, 1714 Hayes Street, Nashville, TN 37203

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 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 to be collected.

The information collection requirement and the burden associated with requiring a Medicare or Medicaid participating hospital to have an agreement with the OPO designated for its area or to submit a waiver request to HCFA for approval to have an agreement with a designed OPO other than the OPO designated for its service area currently are approved under OMB approval number 0938–0688 (HCFA-R-13), with an expiration date of November 30, 1997.

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; and Program No. 93.774, and No. 93.778, Medical Assistance Program)

Dated: March 21, 1997.

Barbara Wynn,

Acting Director, Bureau of Policy Development, Health Care Financing Administration.

[FR Doc. 97–10144 Filed 4–18–97; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[BPO–141–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—Third Quarter 1996

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

ACTION: Notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published during July, August, and September of 1996 that relate to the Medicare and Medicaid programs. It also identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that may be potentially covered under Medicare.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this time frame.

FOR FURTHER INFORMATION CONTACT:

Bridget Wilhite, (410) 786–5248 (For Medicare instruction information).

Pat Prete, (410) 786–3246 (For Medicaid instruction information).

Sharon Hippler, (410) 786–4633 (For Food and Drug Administration-approved investigational device exemption information).

Cathy Johnson, (410) 786–5241 (For all other information).