

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Care Financing Administration
[BPD-898-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 six 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, November 8, 1996, and April 21, 1997, 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. This notice also makes a technical correction to two of the listings in the April 21, 1997 notice.

DATES: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on November 17, 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-898-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-898-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. Honey, (410) 786-4554.

SUPPLEMENTARY INFORMATION:**I. Background**

On January 19, 1996, May 17, 1996, November 8, 1996, and April 21, 1997, we published notices in the **Federal Register** (61 FR 1389, 61 FR 24941, 61 FR 57876, and 62 FR 19326) 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 four notices. Section 1138(a)(1)(A)(iii) of 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 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 486.316(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 § 486.316(e). Section 486.316(g) further specifies that a hospital may continue to operate under its existing agreement with an out-of-area OPO while HCFA is processing the waiver request.

Earlier this year HCFA 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 § 486.316(e), the following six 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 redesignation of OPO service areas earlier this year. 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 with the requested OPO

rather than the designated OPO pending our review.

Name of facility	City	State	Requested OPO	Designated OPO
Alamance Regional Medical Center	Burlington	NC	NCNC	NCBG
Bullhead Community Hospital	Bullhead City	AZ	AZOB	NVLV
Cooley Dickinson Hospital Inc	Northampton	MA	MAOB	CTHH
Ohio Valley Medical Center	Wheeling	WV	PATF	OHLP
Reynolds Memorial Hospital	Glen Dale	WV	PATF	OHLP
Wheeling Hospital	Wheeling	WV	PATF	OHLP

IV. Technical Correction

In the April 21, 1997, notice with comment period at 62 FR 19328, in the first chart, the listings of the OPO codes of the requested and designated OPOs for Crestline Memorial Hospital and River Valley Health System were inadvertently reversed. The corrected entries for these hospitals read as follows:

Name of facility	City	State	Requested OPO	Designated OPO
River Valley Health System	Ironton	OH	OHLP	KYDA
Crestline Memorial Hospital	Crestline	OH	OHLP	OHLC

V. 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
KYDA—KENTUCKY ORGAN DONOR
AFFILIATES, 105 East Broadway,
Louisville, KY 40202
MAOB—NEW ENGLAND ORGAN
BANK, INC., One Gateway Center,
Newton, MA 02158
NCBG—CAROLINA LIFE CARE, North
Carolina Baptist Hospitals, Medical
Center Boulevard, Winston-Salem, NC
27157
NCNC—CAROLINA ORGAN
PROCUREMENT, 702 Johns Hopkins
Drive, Greenville, NC 27834
NVLV—NEVADA DONOR NETWORK,
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
PATF—CENTER FOR ORGAN
RECOVERY AND EDUCATION, 204
Sigma Drive, RIDC Park, Pittsburgh,
PA 15238.

VI. 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 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 an 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; Program No. 93.774 Medicare—Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: September 2, 1997.

Bruce M. Fried,

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

[FR Doc. 97–24644 Filed 9–16–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: December 1996

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of December 1996, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an