''manufacturing and mixing.'' This draft guidance provides our rationale for this interpretation.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance is issued as a Level 1 guidance consistent with GGP's. If finalized, this document will represent current FDA thinking on on-farm feed manufacturing and mixing operations and their responsibilities under § 589.2000. The guidance will not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

II. Comments

Interested persons should submit written comments on or before November 23, 1998, to the Dockets Management Branch (address above) regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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Persons with access to the Internet may obtain the draft guidance using the World Wide Web (WWW). For WWW access, connect to CVM at ''http://www.fda.gov/cvm''.

Dated: September 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–25357 Filed 9–22–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1047–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 two additional applications that HCFA has 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. It supplements notices published in the **Federal Register** on January 19, 1996, May 17, 1996, November 8, 1996, April 21, 1997, and September 17, 1997, that announced hospital waiver requests received by us. This notice requests comments from OPOs and the general public for our consideration in determining whether these waivers should be granted.

COMMENT DATE: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 23, 1998.

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–1047–NC, P.O. Box 7517, Baltimore, MD 21244–0517.

If you prefer, you may deliver your written comments (1 original and 3 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.

Comments may also be submitted electronically to the following e-mail address: HCFA1047NC@hcfa.gov. E-mail comments must include the full name, postal address, and affiliation (if applicable) of the sender and must be submitted to the referenced address to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1047–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, November 8, 1996, and April 21, 1997, and September 17, 1997, we published notices in the **Federal Register** (61 FR 1389, 61 FR 24941, 61 FR 57876, 62 FR 19326, and 62 FR 48872) that announced applications that HCFA had 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 (the Act). This notice supplements these five notices. Section 1138(a)(1)(A)(iii) of 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 conditions specified in section 1138(a)(2)(A) of the Act are met.

Section 1138(a)(2)(A) further states that in granting a waiver, the Secretary must determine that such a 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 definition of metropolitan statistical areas (MSAs); and (4) the length and continuity of a hospital's relationship with the OPO other than the 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 section 1138(a)(2)(A) of the Act and have been incorporated into the regulations at § 486.316(e). 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. The exception under § 486.316(g) does not apply to these two hospitals, so 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
Jennie Stuart Medical Center	Hopkinsville	KY	KYDA	TNDS
Medical University of S.C.	Charleston	SC	GALL	SCOP

IV. Keys to the OPO Codes

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

KYDA KENTUCKY ORGAN DONOR AFFILIATES, 106 East Broadway, Louisville, KY 40202

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

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

SCOP SOUTH CAROLINA ORGAN PROCUREMENT AGENCY, 1064 Gardner Road, Suite 105, Charleston, SC 29407.

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, including automated collection techniques.

Therefore, we are soliciting public comment on the following issue for the information collection requirements described below.

Section 486.316 Designation of one OPO for each service area:

In summary, § 486.316 states the requirements for a Medicare or Medicaid participating hospital to request a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. However, 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, 1999.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Groups, Division of HCFA Enterprise Standards, Attention: Louis Blank, HCFA–1047–NC, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Allison Eydt, HCFA Desk Officer, Room 10235, New Executive Office Building, Washington, DC 20503.

Authority: Sec. 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 8, 1998.

Robert A. Berenson,

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

[FR Doc. 98–25403 Filed 9–22–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4364–FA–03]

Housing Opportunities for Persons with AIDS Program, Announcement of Funding Award, Fiscal Year 1998

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: In accordance with section 102(a)(4)(C) of the Department of