DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1812–NC]

Medicare and Medicaid Programs; Announcement of an Application From a Hospital Requesting Waiver for Organ Procurement Service Area

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces a hospital's request for a waiver from entering into an agreement with its designated organ procurement organization (OPO).

This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

DATE: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 19, 2008.

ADDRESSES: In commenting, please refer to file code CMS–1812-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the filecode to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1812–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1812–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses.

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Mark A. Horney, (410) 786–4554.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of transplantable organs to transplant centers throughout the country. OPOs are certified by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive designated service areas (DSAs), according to section 371(b)(1)(F) of the Public Health Service Act (42 U.S.C. 273(b)(1)(F)) and our regulations at 42 CFR 486.303 through 486.308. Once an OPO has been designated for a DSA, hospitals and critical access hospitals (CAHs) in that DSA that participate in Medicare and Medicaid are required to work with that OPO in procuring organs for transplant, according to section 1138(a)(1)(C) of the Social Security Act (the Act), and our regulations at § 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital or CAH must notify the designated OPO (for the DSA in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every participating hospital must have an agreement to identify potential donors only with its designated OPO.

However, section 1138(a)(2)(A) of the Act provides that a hospital or CAH may obtain from the Secretary a waiver of the above requirements under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one designated by CMS for the DSA in which the hospital or CAH is located, if the hospital meets certain 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 the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act 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 due to the changes made in definitions for metropolitan statistical areas; 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 received from a hospital within 30 days of receiving the application, and before making a final determination on the waiver

applicability offer interested parties an opportunity to comment in writing during the 60-day period beginning on the date the notice is published in the **Federal Register**.

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 § 486.308(e) and (f).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) detailing the waiver process and discussing the information that hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the request 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 request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Request

As permitted by § 486.308(e), McCullough-Hyde Memorial Hospital of Oxford, Ohio has requested a waiver in order to enter into an agreement with a designated OPO other than the OPO designated for the DSA in which the hospital is located. McCullough-Hyde Memorial Hospital is requesting a waiver to work with: LifeConnection of Ohio, 40 Wyoming Street, Dayton, OH 45409.

McCullough-Hyde Memorial Hospital's Designated OPO is: LifeCenter Organ Donor Network, 2925 Vernon Place, Suite 300, Cincinnati, OH 45219.

(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: June 9, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–13821 Filed 6–19–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Public Comment on Tribal Consultation Sessions To Be Held on July 21, July 23, and July 31, 2008

AGENCY: Office of Head Start (OHS), Administration for Children and Families, HHS.

ACTION: Notice of Public Comment on Tribal Consultation Sessions to be held on July 21, July 23, and July 31, 2008.

SUMMARY: Pursuant to the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, notice is hereby given of three one-day Tribal Consultation Sessions to be held between the Department of Health and Human Services, Administration for Children and Families, Office of Head Start leadership and the leadership of Tribal governments operating Head Start (including Early Head Start) programs. The purpose of these Consultation Sessions is to discuss ways to better meet the needs of Indian, including Alaska Native, children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations [42.U.S.C. 9835, Section 640(l)(4)].

Dates & Locations:

July 21, 2008—Kansas City, Missouri.

July 23, 2008—Denver, Colorado.

July 31, 2008—Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Renée Perthuis, Acting Regional Program Manager, American Indian/Alaska Native Program Branch, Office of Head Start, e-mail *reneeaian@acf.hhs.gov* or (202) 260–1721. Register to attend one of these sessions online at *http://www.hsnrc.org.*

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services would like to invite leaders of Tribal governments operating Head Start (including Early Head Start) programs to participate in a formal Consultation Session with OHS leadership. The Consultation Sessions will take place as follows:

July 21, 2008—Kansas City, Missouri.

July 23, 2008—Denver, Colorado.

July 31, 2008—Seattle, Washington.

Limited resources (fiscal, staff, and time constraints) preclude holding a Consultation Session in each ACF Region. These three Regions (VII, VIII, and X) have been selected in an attempt to accommodate the majority of Tribes operating Head Start and Early Head Start programs.

The purpose of the Consultation Sessions is to solicit input on ways to better meet the needs of Indian, including Alaska Native, children and their families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. Specific topics will include policy, research, Head Start/Early Head Start conversion, program quality, and monitoring.

Tribal leaders and designated representatives interested in submitting written testimony or topics for the Consultation Session agenda should contact Renée Perthuis at *reneeaian@acf.hhs.gov.* Tribal leaders submitting testimony or topics should provide a brief description of the subject matter along with contact information for the proposed presenter.

The Consultation Sessions will be conducted with elected or appointed leaders of Tribal governments and their designated representatives [42.U.S.C. 9835, Section 640(l)(4)(A)]. Representatives from Tribal organizations and Native non-profit organizations are welcome to attend as observers. Those wishing to participate in the discussions must have a copy of a written resolution, voted on and approved by the Tribal government, which authorizes them to serve as a representative of the Tribe. This should be submitted not less than three days in advance of the Consultation Session to Renée Perthuis at 202–260–9336 (fax).

A detailed report of each Consultation Session will be prepared and made available within 90 days of each consultation to all Tribal governments receiving funds for Head Start (including Early Head Start) programs.

Dated: June 16, 2008.

Patricia Brown,

Acting Director, Office of Head Start.

[FR Doc. E8–14015 Filed 6–19–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1986–F–0277] (formerly Docket No. 1986F–0364)

Danisco USA, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a