

that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: December 17, 2009.

**Charlene Frizzera,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: January 22, 2010.

**Kathleen Sebelius,**

*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1343-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:** A hospital has requested a waiver of statutory requirements that would otherwise require the hospital to enter into an agreement with its designated Organ Procurement Organization (OPO). The request was made in accordance with section 1138(a)(2) of the Social Security Act (the Act). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

**DATES:** *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 22, 2010.

**ADDRESSES:** In commenting, please refer to file code CMS-1343-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 this regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1343-NC, P.O. Box 8010, Baltimore, MD 21244-1850.

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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1343-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 before the close of the comment period to either of the following addresses: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey 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. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 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 information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**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. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR 482.45.

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) 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 may obtain a waiver of the above requirements from the Secretary under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one initially designated by CMS, 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 to offer interested parties an opportunity to comment in writing during the 60-day period beginning on the publication date 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 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 Health Resources and Services Administration'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 Requests

As permitted by § 486.308(e), the following hospital has requested a waiver in order to enter into an agreement with an OPO other than the OPO designated for the service area in which the hospital is located:

Jennie Stuart Medical Center (Medicare provider number 18-0051) of Hopkinsville, Kentucky, is requesting a waiver to work with: Kentucky Organ Donor Affiliates, 106 E. Broadway, Louisville, Kentucky 40202.

The Hospital's Designated OPO is: Tennessee Donor Services, 7015 Middlebrook Pike, Knoxville, Tennessee 37909.

(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: April 15, 2010.

**Charlene Frizzera,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee:

Time and Date: 3 p.m.–5 p.m., May 10, 2010.

*Teleconference:* Audio Conference Call via FTS Conferencing. The USA toll free dial in number is 1-866-659-0537 with a pass code of 9933701.

*Status:* Open to the public, but without a public comment period.

*Background:* The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of

probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2011.

*Purpose:* The Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

*Matters to be Discussed:* The agenda for the Subcommittee meeting includes: selection of individual radiation dose reconstruction cases to be considered for review by the Advisory Board.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

*Contact Person for More Information:* Theodore Katz, Executive Secretary, NIOSH, CDC, 1600 Clifton Road, Mailstop E-20, Atlanta GA 30333, Telephone (513) 533-6800, Toll Free 1 (800)CDC-INFO, E-mail [ocas@cdc.gov](mailto:ocas@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of