

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

Section 401(a) of the Children's Health Insurance Program Reauthorization Act of 2009 (Pub. L. 111-3) (CHIPRA), added section 1139A to the Social Security Act (the Act). Section 1139A(a)(6), as added by section (401)(a), requires the Secretary to report to the Congress by January 1, 2011, and every 3 years thereafter, on the status of the following factors that influence the quality of care given to children under the Medicaid and Children's Health Insurance Program.

- The duration and stability of health insurance coverage for children under titles XIX and XXI of the Social Security Act.

- The quality of care provided under titles XIX and XXI for:

- + Preventive health care services.
- + Health care for acute conditions.
- + Chronic health care.
- + Health services to ameliorate the effects of physical and mental conditions and to aid in the growth and development of infants, young children, school-age children, and adolescents with special health care needs.

- The quality of children's health care under titles XIX and XXI, across the various domains of quality, including:

- + Clinical quality.
- + Health care safety.
- + Family experience with health care.
- + Health care in the most integrated setting.
- + Elimination of racial, ethnic, and socio-economic disparities in health and health care.

- The status of voluntary reporting by States under titles XIX and XXI, utilizing the initial core quality measurement set. Based on the assessment of these factors affecting the quality of care given to children under titles XIX and XXI, the Secretary is also required to make any recommendations for legislative changes that are needed to improve the quality of care provided to children under titles XIX and XXI, including recommendations for quality reporting by the States.

### II. Solicitation of Comments

We request public comments for consideration in the formulation of legislative changes to be recommended by the Secretary, including requirements for the process and

content of quality reporting by the States. We request that these suggestions address the dimensions of quality and the subject areas listed above.

### III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

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

Dated: July 19, 2010.

**Marilyn Tavenner**,

*Principal Deputy Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2010-18140 Filed 7-29-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1579-NC]

#### Medicare and Medicaid Programs; Announcement of an Application From a Hospital Seeking To Enter Into an Agreement With a Different Organ Procurement Organization

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

**ACTION:** Notice with comment period.

**SUMMARY:** A hospital that had previously been granted a waiver under section 1138(a)(2) of the Social Security Act (the Act), has requested to enter into an agreement with a different Organ Procurement Organization (OPO). This notice requests comments from hospitals, OPOs, and the general public for our consideration in determining whether we should grant the request. We are particularly interested in information and material that will help determine whether the change is likely to increase organ donation and will ensure equitable treatment for patients in both affected OPO service areas.

**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 September 28, 2010.

**ADDRESSES:** In commenting, please refer to file code CMS-1579-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 "Submit a comment" instructions.

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-1579-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-1579-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 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 § 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 comment period beginning on the publication date of the notice in the **Federal Register**.

On June 11, 2010, we published a **Federal Register** notice (75 FR 33313) that established a public process for hospitals that had previously been granted a waiver under section 1138(a)(2) of the Act. Under the notice, a hospital may request approval to work with a different OPO.

### II. Procedures for Requesting a Change in OPOs

For hospitals that had previously been granted a waiver request under section 1138(a)(2) of the Act but are now seeking to enter into an agreement with a different OPO, the hospital may file a request, by letter, to CMS containing the information set forth in the June 11, 2010 notice (75 FR 33313). Upon receipt of a request, we publish a **Federal Register** notice to solicit public comments, modeled after the procedures set forth in section 1138(a)(2)(D) of the Act.

Under these procedures, 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 request to change the OPO and notify the hospital and the OPOs involved.

### III. Hospital Requests To Change OPOs

As permitted by the June 11, 2010 notice (75 FR 33313), the following hospital has requested to work with an OPO other than the OPO it had been designated to work through based on a previous waiver request:

OSF St. Anthony Medical Center of Rockford, Illinois, Provider Number 14-0233, is requesting to work with: Gift of Hope Organ & Tissue Donor Network, 425 Spring Lake Drive, Itasca, IL 60143.

OSF St. Anthony Medical Center has an existing waiver to work with: UW Health Organ Procurement Organization, 450 Science Drive, Suite 220, Madison, WI 53711.

(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: July 21, 2010.

#### Marilyn Tavenner

*Principal Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0260]

#### Report: A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration: The Reportable Food Registry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a report entitled "A New Approach to Targeting Inspection Resources and Identifying Patterns of Adulteration: The Reportable Food Registry." The report presents FDA's experience with the Reportable Food Registry (RFR or the Registry) from the opening of the Reportable Food electronic portal on September 8, 2009, until March 31, 2010.

**ADDRESSES:** Submit written requests for single copies of the report to the Office of Food Defense, Communication and Emergency Response (HFS-005), Center for Food Safety and Applied Nutrition,