Authority: Section 1923(a)(2), (f), and (h) of the Social Security Act (42 U.S.C. 1396r–4(a)(2), (f), and (h), and Pub. L. 105–33).

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

Dated: May 6, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: May 20, 2005.

Michael O. Leavitt,

Secretary.

[FR Doc. 05–16997 Filed 8–25–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1309–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), in accordance with section 1138(a)(2) of the Social Security Act. This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 25, 2005.

ADDRESSES: In commenting, please refer to file code CMS–1309–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

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–1309–NC, P.O. Box 8015, Baltimore, MD 21244–8015.

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–1309–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 one of the following addresses. 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. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(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.)

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: *Submitting Comments:* We welcome comments from the public on all issues set forth in this notice with comment period to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1309–NC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

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. CMS posts all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will 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

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

Organ Procurement Organizations (OPOs) are not-for-profit organizations that recover human organs from potential donors in hospitals and distribute them to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover organs in CMS-defined exclusive geographic service areas, 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 486.307. 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, according to section 1138(a) 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) 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) 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 (MSAs); 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 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 42 CFR 486.316(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 42 CFR 486.316(e), Rockford Health System of Rockford, Illinois has requested a waiver in order to enter into an agreement with an alternative, out-of-area OPO. Rockford Health System is requesting a waiver to work with: University of Wisconsin OPO, University of Wisconsin Hospital and Clinic, 600 Highland Avenue, Madison, Wisconsin 53792. Rockford Health System's designated OPO is: Gift of Hope Organ and Tissue Donor Network, 660 North Industrial Drive, Elmhurst, Il 60126–1520. Rockford Health System must continue to work with its designated OPO until the completion of our review.

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: August 9, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–16796 Filed 8–25–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4106–PN]

Medicare Program; Changes in Medicare Advantage Deeming Authority

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

ACTION: Proposed notice.

SUMMARY: This proposed notice announces that on September 26, 2005, we will begin to accept revisions from private accrediting organizations (AOs) who seek to modify their deeming authority.

EFFECTIVE DATE: This proposed notice is effective on September 26, 2005.

FOR FURTHER INFORMATION CONTACT: Shaheen Halim, 410–786–0641.

SUPPLEMENTARY INFORMATION:

I. Background

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted on August 5, 1987, added section 1852(e)(4) to the Social Security Act (the Act), which gives us the authority to determine that a Medicare Advantage (MA) organization is deemed to be in compliance with certain Medicare requirements if the MA organization has been accredited (and is periodically reaccredited) by an accrediting organization that we have determined applies and enforces requirements at least as stringent as those the MA organization would be deemed to meet. Section 518 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), enacted on November 29, 1999, amended section 1852(e)(4) of the Act to expand the scope of deeming from two to six areas. Accrediting organizations may seek authority for any of the categories. The BBRA specified that we cannot require an accrediting entity to be able to certify plans for all the deeming categories. It also required us to determine, within 210 days from the day the application is determined to be complete, the eligibility of the accrediting organizations to be granted deeming authority. Conditions and procedures for granting deeming authority to accrediting organizations are outlined in § 422.157 and § 422.158 of title 42 of the Code of Federal Regulations.

Since the start of the Medicare Deeming program, we have approved three organizations to be AOs. These consist of the National Committee for Quality Assurance, the Joint Commission on the Accreditation of Healthcare Organizations, and Accreditation Association for Ambulatory Health Care (AAAHC).

Section 722 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) revised section 1852(e)(4) of the Act. When we published the final rule of the Medicare Advantage program on January 28, 2005 (70 FR 4588), we made further changes to several sections of the rules that apply to the AOs. These changes consisted of the addition of the Chronic Care Improvement Program requirements (§ 422.152), and the deletion of some requirements in the areas of access and quality improvement projects. (§ 422.112 and § 422.152). Furthermore, it added prescription drug program requirements to the deemable areas. These areas include:

- Access to covered drugs, as provided under § 423.120 and § 423.124.
- Drug utilization management programs, quality assurance measures and systems, and Medication Therapy Management Programs as provided under § 423.153.
- Privacy, confidentiality, and accuracy of enrollee records, as provided under § 423.136.
- A program to protect against fraud, waste and abuse, as described in § 423.504(b)(4)(vi)(H).

II. Provisions of the Proposed Notice

This proposed notice announces that 30 days after publication, we will begin to accept applications from national private AOs who seek to modify their deeming authority. The application will consist of a letter stating how the applicant will modify their