



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1858-NC]

Medicare and Medicaid Programs; Announcement of Application from a Hospital Requesting Waiver for Organ Procurement Service Area (WRMC Hospital Operating Corporation)

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

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from a hospital that 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). 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, by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: In commenting, refer to file code CMS-1858-NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://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-1858-NC,

P.O. Box 8010

Baltimore, MD 21244-8010.

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-1858-NC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Lindsay Pulliam, (410) 786-8674.

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 website as soon as possible after they have been received: <https://www.regulations.gov> . Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post

acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of 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, under 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 establish protocols which require the hospital to 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 hospital must have an agreement only with its designated OPO to identify potential donors.

Section 1138(a)(2)(A) of the Act provides that a hospital may submit a request to the Secretary of the Department of Health and Human Services (the Secretary) for a waiver of the above requirements. If the requested waiver meets certain conditions specified in section 1138(a)(2)(A) of the Act, the Secretary shall grant the waiver and allow the hospital to have an agreement with an OPO other than the one designated by CMS. The Secretary may consider factors described in section 1138(a)(2)(B) of the Act when determining whether to grant the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that the Secretary shall grant a waiver if he determines 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 factors that include but are not limited to: (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. The regulations identifying the relevant considerations are codified in 42 CFR 486.308(e) and (f).

II. Solicitation of Public Comments

Section 1138(a)(2)(D) of the Act states the Secretary shall publish a public notice of any waiver application received from a hospital within 30 days of receiving such application and offer interested parties the opportunity to submit written comments to the Secretary during the 60-day period beginning on the date such notice is published.

As part of the process of determining whether to grant a waiver, we will review the comments received. During the review process, we may consult with relevant parties, including but not limited to, 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 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), the following hospital has requested a waiver to enter into an agreement with an OPO other than the OPO designated for the service area in which the hospital is located:

WRMC Hospital Operating Corporation doing business as Wilkes Regional Medical Center, North Wilkesboro, NC, is requesting a waiver to work with:

LifeShare Carolinas (NCCM)
3621 Randolph Road, Suite 100
Charlotte, North Carolina 28211

The Hospital's Designated OPO is:

HonorBridge (NCNC)
1430 WestBrook Plaza Drive
Winston-Salem, North Carolina 27103

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

We will consider all comments we receive by the date and time specified in the **DATES** section of this document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,
Federal Register Liaison,
Centers for Medicare & Medicaid Services.

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