

clearance submission.. A three-year Extension for the Generic Clearance is

requested. CDC requests OMB approval for an estimated 59,465 annualized

burden hours. There is no cost to respondents other than their time

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Individuals or households	Developmental Projects & Focus Group documents.	35,000	1	1.5	52,500
Volunteers	Developmental Projects & Focus Group documents.	300	1	1.5	450
Individuals or households, Volunteers, NHANES Participants.	24-hour developmental projects	200	1	25	5,000
NHANES Participants	Developmental Projects	1,000	1	1.5	1,500
Subject Matter Experts	Focus Group/Developmental Project Documents.	15	1	1	15
Total	59,465

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1862-NC]

Medicare and Medicaid Programs; Announcement of Applications From 12 Hospitals Requesting Waivers for Organ Procurement Service Area

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

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of applications from 12 hospitals that have requested a waiver of statutory requirements that would otherwise require the hospitals to enter into an agreement with their 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 waivers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by May 8, 2026.

ADDRESSES: In commenting, refer to file code CMS-1862-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-1862-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-1862-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](https://www.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. This notice applies to 12 separate requests by 12 hospitals to each enter into an agreement with an OPO other than the OPO designated for the service area in which each hospital is located. Commenters must clearly identify the specific hospital to which each comment applies. Commenters can identify specific hospitals using the information found in Table 1. If a

comment does not identify a specific hospital or hospitals, we will assume the comment applies to all 12 hospitals.

As part of the process of determining whether to grant a hospital's waiver request, we will review the applicable 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 hospitals or others. We will then make a final determination on each waiver request and notify the hospitals and the designated and requested OPOs.

III. Hospital Waiver Requests

As permitted by § 486.308(e), each of the hospitals identified in Table 1 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:

TABLE 1—HOSPITALS REQUESTING WAIVERS TO ENTER INTO AN AGREEMENT WITH AN OPO OTHER THAN THEIR DESIGNATED OPO

Name of hospital	City	State	Designated OPO	Requested OPO
Prisma Health-Upstate d/b/a Prisma Health Baptist Easley Hospital O/P Therapy Services.	Easley	SC	SCOP	NCCM
Prisma Health-Midlands d/b/a Prisma Health Baptist Hospital	Columbia	SC	SCOP	NCCM
Prisma Health-Midlands d/b/a Prisma Health Baptist Parkridge	Columbia	SC	SCOP	NCCM
Prisma Health-Upstate d/b/a Prisma Health Pediatrics Verdae	Greenville	SC	SCOP	NCCM
Prisma Health-Upstate d/b/a Prisma Health Greer Memorial Hospital.	Greer	SC	SCOP	NCCM
Prisma Health-Upstate d/b/a Prisma Health Hillcrest Hospital	Simpsonville	SC	SCOP	NCCM
Prisma Health-Upstate d/b/a Prisma Health Laurens County Hospital.	Clinton	SC	SCOP	NCCM
Prisma Health-Upstate d/b/a Prisma Health North Greenville LTACH	Travelers Rest	SC	SCOP	NCCM
Prisma Health-Upstate d/b/a Prisma Health Oconee Memorial Hospital.	Seneca	SC	SCOP	NCCM
Prisma Health-Upstate d/b/a Prisma Health Patewood Hospital	Greenville	SC	SCOP	NCCM
Prisma Health-Midlands d/b/a Prisma Health Richland Hospital	Columbia	SC	SCOP	NCCM
Prisma Health Tuomey d/b/a Prisma Health Tuomey Hospital	Sumter	SC	SCOP	NCCM

IV. Keys to the OPO Codes

The keys to the acronyms used in the listings to identify OPOs and their addresses are as follows:

SCOP We are Sharing Hope SC, 2215 Henry Tecklenburg Drive, Charleston, SC 29414

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

V. 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.*).

VI. 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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