

**FOR FURTHER INFORMATION CONTACT:**

William Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* QHP Issuers Data Collection for Notices for Plan or Display Errors Special Enrollment Periods; *Use:* The Patient Protection and Affordable Care Act (Pub. L. 111-148) and Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), collectively referred to as the PPACA, established new competitive private health insurance markets called Marketplaces, or Exchanges, which gave millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)—private health and dental insurance plans that have been certified as meeting certain standards.

In the final rule, the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 (CMS-9937-F), we finalized 45 CFR 156.1256, which requires QHP issuers, in the case of a material plan or benefit display error included in 45 CFR 155.420(d)(12), to notify their enrollees of the error and the enrollees' eligibility for a special enrollment period (SEP) within 30 calendar days after the issuer is informed by an Federally-facilitated Exchange (FFE) that the error is corrected, if directed to do so by the FFE. This requirement provides notification to QHP enrollees of errors that may have impacted their QHP selection and enrollment and any associated monthly or annual costs, as

well as the availability of an SEP under § 155.420(d)(12) for the enrollee to select a different QHP, if desired. This ICR serves as the formal request for an extension without change of a currently approved clearance. *Form Number:* CMS-10595 (OMB control number 0938-1301); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions) *Number of Respondents:* 394; *Number of Responses:* 394; *Total Annual Hours:* 153. (For questions regarding this collection, contact Emily Martin at 301-492-4423).

**William N. Parham, III.**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2026-03118 Filed 2-17-26; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1861-NC]

#### Medicare and Medicaid Programs; Announcement of Application From a Hospital Requesting Waiver for Organ Procurement Service Area (Alleghany County Memorial Hospital, Inc.)

**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 April 20, 2026.

**ADDRESSES:** In commenting, refer to file code CMS-1861-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-1861-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-1861-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:

Alleghany County Memorial Hospital, Inc. doing business as Alleghany Memorial Hospital, Sparta, 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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2026–N–0958]

### Issuance of Priority Review Voucher; Rare Pediatric Disease Product; ZEVASKYN (Prademagene Zamikeracel)

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that ZEVASKYN (prademagene zamikeracel), approved on April 28, 2025, manufactured by Abeona Therapeutics, Inc., meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that ZEVASKYN (prademagene zamikeracel), manufactured by Abeona Therapeutics, Inc., meets the criteria for a priority review voucher. ZEVASKYN (prademagene zamikeracel) is indicated for the treatment of wounds in adult and pediatric patients with recessive dystrophic epidermolysis bullosa.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs>. For further information about ZEVASKYN (prademagene zamikeracel), go to the Center for Biologics Evaluation and