

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

Research's Approved Cellular and Gene Therapy Products website at <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-1812]

Agency Information Collection Activities; Proposed Collection; Comment Request; Q-Submission and Early Payor Feedback Request Programs and Medical Device Development Tools

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by March 20, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0756. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Q-Submission and Early Payor Feedback Request Programs and Medical Device Development Tools

OMB Control Number 0910-0756—Revision

The guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" (May 2025) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>) provides an overview of the mechanisms available to submitters through which they can request feedback from or a meeting with FDA regarding certain potential or planned medical device submissions reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding certain types of Q-Submissions, such as Pre-Submissions, Submission Issue Requests, Study Risk Determinations, Informational Meetings, and other Q-Submission Types and other uses of the Q-Submission Program.

Recent updates in May 2025 to the Q-Submission guidance moved the instructions for information collection related to requests for feedback regarding development of a Medical Device Development Tool (MDDT), which were previously tracked as Informational Meeting Q-Submissions. We are revising this information collection to add the FDA guidance entitled "Qualification of Medical Device Development Tools: Guidance for Industry, Tool Developers, and Food and Drug Administration Staff" (July 2023) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-medical-device-development-tools>), which includes instructions for submitting requests for feedback regarding MDDTs. The submission instructions are otherwise unchanged, but the MDDT guidance is now the collection instrument associated with the existing MDDT burden.

Early Payor Feedback Program

Prior to submitting a Pre-Submission, medical device sponsors may request

that one or more payor organizations join a Pre-Submission meeting. Payors include public payors such as Centers for Medicare & Medicaid Services, private health plans, health technology assessment groups, and others who provide input into coverage, procurement, and reimbursement decisions. To facilitate such opportunities to obtain payor input, FDA provides information about our Early Payor Feedback Program (EPFP) and a list of current payor participants on our website (available at <https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force#2>). For payors to decide which devices to provide feedback on, we have developed a voluntary form for manufacturers to provide basic information regarding their device. This form is shared with the payors from whom the manufacturer is requesting feedback.

eSTAR for Q-Submissions

Under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k-1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (Pub. L. 115-52), and consistent with the Medical Device User Fee Amendments 2017 (MDUFA IV) Commitment Letter and the FDA guidance document entitled "Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act" (July 2020) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab>), FDA has developed an "electronic Submission Template and Resource" (eSTAR) for Q-submissions to facilitate the preparation of submissions in electronic format (available at <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>). The use of eSTAR for Q-Submissions is currently voluntary.

In the **Federal Register** of July 14, 2025 (90 FR 31225), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows: