

they are consistent with regulations that are currently in effect. *Form Number:* CMS–10653 (OMB control number: 0938–1344); *Frequency:* Occasionally; *Affected Public:* Private Sector; *Number of Respondents:* 60; *Total Annual Responses:* 595,312; *Total Annual Hours:* 72. (For policy questions regarding this collection contact Russell Tipps at 301–869–3502).

**William N. Parham, III,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10266]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA) federal agencies are also required to publish notice in the **Federal Register** concerning each proposed collection of information before the agency's request is submitted to OMB for approval.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by March 23, 2026.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 60-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**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.

Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

#### Information Collection

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Conditions of Participation for Transplant Programs; *Use:* The purpose of this package is to request approval from the Office of Management and Budget (OMB) to reinstate, with change, the information collection request for OMB Control No. 0938–1069, which expired on November 30, 2022. The information collection request described herein is associated with the Conditions of Participation (CoPs) for Transplant Programs, specified at Title 42 Code for Regulations (CFR) Sections §§ 482.68 to 482.104.

A certified Transplant Program is an approved Medicare provider type that is located within an approved Medicare Hospital provider type. Approved Medicare dialysis facilities also work in conjunction with Transplant Programs, as they support patients before and possibly after kidney transplants. Transplant Programs may receive payment for heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplants if, and only if, they are in compliance with the Conditions of Participation (CoPs) specified in 42 CFR 482.68 to 482.104.

The previous iteration was approved on November 29, 2019, with an estimated annual burden of 2,593 hours and an annual cost of \$181,130. For this re-instatement, the total annual hourly

burden is revised to 3,340, with an annual burden cost of \$352,462. The 29% increase in burden hours (from 2,593 to 3,340) is primarily due to the addition of one missing IC, (IC–3), minor corrections to burden estimates, and updating labor wage data to more recently available data. *Form Number:* CMS–10266 (OMB control number: 0938–1069); *Frequency:* Yearly; *Affected Public:* Private sector Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 476; *Total Annual Responses:* 476; *Total Annual Hours:* 3,340. (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

**William N. Parham, III,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2025–N–7129]

#### Issuance of Priority Review Voucher; Rare Pediatric Disease Product; KYGEVVI (Doxecitine and Doxribtimine)

**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 KYGEVVI (doxecitine and doxribtimine), approved November 3, 2025, manufactured by UCB, Inc., meets the criteria for a priority review voucher.

#### FOR FURTHER INFORMATION CONTACT:

Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2771.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product