

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 N. Parham at (410) 786–4669.
SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

Under the 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 requires federal agencies to publish a 60-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.

Information Collections

1. *Type of Information Collection Request:* Revision with change of currently approved collection; *Title of Information Collection:* Medicare Transaction Facilitator under Sections 11001 and 11002 of the Inflation Reduction Act (IRA); *Use:* The MTF consists of two key functionalities: (1) the MTF DM and (2) the MTF PM. Participation in the MTF PM is voluntary for Primary Manufacturers and no information will be collected by the MTF PM; the MTF PM is structured exclusively as a pass through mechanism to assist affected parties in the transfer of Primary Manufacturer funds. In accordance with sections 1193(a)(5) and 1196 of the Act, for the purposes of administering and monitoring compliance with the Negotiation Program, Primary Manufacturer participation in the MTF

DM is mandatory. Because the Primary Manufacturer's participation in the MTF DM is mandatory and Primary Manufacturers with an active Medicare Drug Price Negotiation Program Agreement (“Agreement”) are already engaged in the Negotiation Program, CMS will leverage existing information to establish Primary Manufacturer access to the MTF DM platform. The MTF DM will establish accounts for each Primary Manufacturer that is participating in the Negotiation Program and will provide information to each participating Primary Manufacturer to facilitate access to the MTF DM platform.

Under the authority of sections 1193 and 1196 of the Act, CMS is authorized to collect data and information required for negotiation, as well as any information necessary for administration and oversight of the program. The information collected by CMS will be used to operate the MTF which is a key facet in administering the Negotiation Program and facilitating MFP effectuation; MTF will also play a key role in CMS' oversight efforts as a central repository for monitoring access to the MFP and processing complaints and disputes. The MTF is an IT platform that enables the transmission of certain claims data and payment data, between the MTF DM, MTF PM, Primary Manufacturers, Part B providers, and dispensing entities to facilitate MFP effectuation for Medicare beneficiaries via dispensing entities and/or Part B providers. *Form Number:* CMS–10912 (OMB control number: 0938–1483); *Frequency:* Yearly; *Affected Public:* Private sector, Business or other for-profits; *Number of Respondents:* 73,925; *Total Annual Responses:* 73,925; *Total Annual Hours:* 274,980. (For policy questions regarding this collection contact Brennan Folsom at 667–414–0014 or Brennan.folsom@cms.hhs.gov.)

2. *Type of Information Collection Request:* Revision with change of currently approved collection; *Title of Information Collection:* Collection of Prescription Drug Event Data from Contracted Part D Providers for Payment; *Use:* CMS fundamental goal is to have the least burdensome data submission requirements necessary to acquire the data needed for accurate Medicare Part D payment and appropriate program oversight. CMS believes that claims data provide the most reliable approach to ensuring that payment calculations are accurate. Without claims-level data, we cannot verify the accuracy of payments related to reinsurance, risk corridors, low-income subsidies, CGDP reconciliation,

MDP reconciliation, IRASA, and Selected Drug Subsidy.

This claims-level information is reported by Part D sponsors to CMS on the PDE record. CMS limits there data collection to only those critical data elements necessary for accurate payment-related calculations, along with other elements required for validation of the PDE record, quality monitoring, and program integrity and oversight.

The information users will be pharmacy benefit managers (PBMs), third party administrators and pharmacies, PDPs, MA–PDs, Fallbacks, and other plans that offer coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The statutorily required data is used primarily for payment and is used for claim validation as well as for other legislated functions such as quality monitoring, program integrity and oversight. In addition, the PDE data are used to support operations and program development *Form Number:* CMS–10174 (OMB control number: 0938–0982); *Frequency:* Yearly; *Affected Public:* Private sector, Federal Government profits; *Number of Respondents:* 994; *Total Annual Responses:* 1,627,799,680; *Total Annual Hours:* 11,208. (For policy questions regarding this collection contact Shelly Winston at (443) 934–3621.)

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026–15048 Filed 7–23–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0171]

Proposed Information Collection Activity; Voluntary Acknowledgment of Paternity and Required Data Elements for Paternity Establishment Affidavits

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is requesting a 3-year extension of the Voluntary Acknowledgment of Paternity and

Required Data Elements for Paternity Establishment Affidavits. No changes are proposed to the data elements, but burden has been adjusted to reflect improved automation for processes.

DATES: Comments due September 22, 2026.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:
Description: Section 466(a)(5)(C) of the Social Security Act requires states to enact laws ensuring a simple civil process for voluntarily acknowledging paternity via an affidavit. The development and use of an affidavit for the voluntary acknowledgment of

paternity would include the minimum requirements of the affidavit specified by the Secretary under section 452(a)(7) of the Social Security Act and give full faith and credit to such an affidavit signed in any other state according to its procedures. The state must provide that, before a mother and putative father can sign a voluntary acknowledgment of paternity, the mother and putative father must be given notice, orally, or through the use of video equipment, and in writing, of the alternatives to, the legal consequences of, and the rights (including any rights, if one parent is a minor, due to minority status) and responsibilities of acknowledging paternity. The affidavits will be used by hospitals, birth record agencies, and other entities participating in the voluntary paternity establishment program to collect information from the parents of nonmarital children.

Respondents: The parents of nonmarital children, state and tribal agencies operating child support

programs under Title IV–D of the Social Security Act, hospitals, birth record agencies, and other entities participating in the voluntary paternity establishment program.

Annual Burden Estimates: Annual burden estimates have been updated to remove ordering brochures from the annual burden hours calculation, as ordering brochures is not required under federal guidelines. With advancements in automation and digital service delivery, most partners now rely on electronic devices located in hospitals and other automated public facing platforms to deliver education on paternity establishment and highlight the benefits of signing the paternity establishment affidavit. This results in a 40 percent overall decrease in estimated annual burden compared to the most recently approved annual burden estimates (2024). The number of responses and estimated time per response for the remaining instruments have not changed.

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Training	135,155	1	1	135,155
Paternity Acknowledgment Process	1,372,816	1	0.17	233,379
Data Elements	54	1	1	54
Estimated Total Annual Burden Hours:				368,588

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 666(a)(5)(C) and 652(a)(7).

Mary C. Jones,
ACF/OPRE Certifying Officer.
[FR Doc. 2026–15044 Filed 7–23–26; 8:45 am]
BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7231]

Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments—Biologics License Application (BLA) 125827, From Replimune, Inc. for Vusolimogene Oderparepvec

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee (the Committee). This meeting was announced in the **Federal Register** on June 30, 2026. The amendment is being made to reflect a change in the **DATES**, **ADDRESSES**, and **SUPPLEMENTARY INFORMATION:** *Procedure* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Cicely Reese; Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993–0002, 301–796–9025, email: CBERCTGTAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 30, 2026, meeting notice and citation, 91 FR 42203, FDA announced that a meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee would be held on July 30, 2026. On page 42203, in the second column, the **DATES** portion of the document is changed to read as follows:

The meeting will be held on July 30, 2026, from 9:30 a.m. to 4:30 p.m. Eastern Time. Online public viewing will be available at the following link on the day of the meeting at: <https://youtube.com/live/7x4xuKJti1o?feature=share>.