

regarding the burden estimate 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.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by November 20, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-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. 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:* Reinstatement without change

to a previously approved information collection; *Title of Information Collection:* National Provider Identifier (NPI) Application and Update Form and Supporting Regs in 45 CFR 142.408, 45 CFR 162.408, 45 CFR 162.406; *Use:* The adoption by the Secretary of HHS of the standard unique health identifier for health care providers is a requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The unique identifier is to be used on standard transactions and may be used for other lawful purposes in the health care system. The CMS Final Rule published on January 23, 2004, adopts the National Provider Identifier (NPI) as the standard unique health identifier for health care providers. Health care providers that are covered entities under HIPAA must apply for and use NPIs in standard transactions. Other health care providers are eligible for NPIs but are not required by regulation to apply for them or use them. Health care providers began applying for NPIs on May 23, 2005.

The National Provider Identifier Application and Update Form is used by health care providers to apply for NPIs and furnish updates to the information they supplied on their initial applications. The form is also used to deactivate their NPIs if necessary. The original application form was approved in February 2005 and has been in use since May 23, 2005. The form is available on paper or can be completed via a web-based process. Health care providers can mail a paper application, complete the application via the web-based process via the National Plan and Provider Enumeration System (NPPES), or have a trusted organization submit the application on their behalf via the Electronic File Interchange (EFI) process. The Enumerator uses the NPPES to process the application and generate the NPI. NPPES is the Medicare contractor tasked with issuing NPIs, and maintaining and storing NPI data. *Form Number:* CMS-10114 (OMB control number: 0938-0931); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits, Not for-profits and Federal Government; *Number of Respondents:* 1,275,912; *Number of Responses:* 1,275,912; *Total Annual Hours:* 298,777. (For policy questions regarding this collection contact Da'Vona Boyd at 410-786-7483).

2. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Medicare Drug Coverage and Your Rights; *Use:* Section 423.562(a)(3) and an associated regulatory provision at

§ 423.128(b)(7)(iii) require that Part D plan sponsors' network pharmacies provide Part D enrollees with a printed copy of our standardized pharmacy notice "Medicare Drug Coverage and Your Rights" (hereafter, "notice") if an enrollee's prescription cannot be filled.

The purpose of this notice is to provide enrollees with information about how to contact their Part D plans to request a coverage determination, including a request for an exception to the Part D plan's formulary. The notice reminds enrollees about certain rights and protections related to their Medicare prescription drug benefits, including the right to receive a written explanation from the drug plan about why a prescription drug is not covered. Through delivery of this standardized notice, a Part D plan sponsor's network pharmacies are in the best position to inform enrollees at point of sale about how to contact their Part D plan if the prescription cannot be filled. *Form Number:* CMS-10147 (OMB control number: 0938-0975); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not for-profits; *Number of Respondents:* 72,900; *Number of Responses:* 55,215,940; *Total Annual Hours:* 919,898. (For policy questions regarding this collection contact Sabrina Edmonston at 410-786-3209 or Sabrina.edmonston@cms.hhs.gov).

William N. Parham, III,

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

[FR Doc. 2024-24264 Filed 10-18-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Federal Tax Refund Offset, Administrative Offset, and Passport Denial

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

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Services (OCSS), Administration for Children and Families (ACF), is requesting the federal Office of Management and Budget (OMB) to approve the Federal Tax Refund Offset, Administrative Offset, and Passport Denial with minor edits to change

“Office of Child Support Enforcement (OCSE)” to “Office of Child Support Services (OCSS)” and minor formatting enhancements. The current OMB approval expires on June 30, 2025.

DATES: *Comments* due December 20, 2024. 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.

ADDRESSES: 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: The Federal Tax Refund Offset and Administrative Offset programs collect past-due child and spousal support by intercepting certain federal payments, including federal tax refunds, of parents who have been ordered to pay support and are delinquent. The Federal Offset Program is a cooperative effort among the Department of the Treasury’s Bureau of the Fiscal Service, OCSS, and state child

support agencies (CSAs). The Passport Denial Program reports noncustodial parents who owe child and spousal support above a specified threshold to the Department of State, which will then deny passports to these individuals. State CSAs routinely submit the names, Social Security numbers, and the amount(s) of past-due child and spousal support of noncustodial parents who are delinquent in making payments to OCSS.

Respondents: Child Support Agencies.

ANNUAL BURDEN ESTIMATES

Information collection instrument	Number of respondents	Annual number of responses per respondent	Average annual burden hours per response	Annual burden hours
Input Record Specifications	54	52	.3	842.4
Output Record Specifications	54	52	.46	1,291.68
Payment File (Charts 4–5)	54	52	.14	393.12
Annual Certification Letter	54	1	.4	21.6
Child Support Portal Processing Screens	173	281	.01	486.13

Estimated Total Annual Burden Hours: 3,034.93.

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. 652(b); 42 U.S.C. 664; 26 U.S.C. 6402(c); 31 CFR 285.3; 45 CFR 302.60; 45 CFR 303.72; 31 U.S.C. 3701 *et seq.*; 31 U.S.C. 3716(h); 31 CFR 285.1; 42 U.S.C. 652(k); 42 U.S.C. 654(31); 22 CFR 51.60; 42 U.S.C. 654(31); 42 U.S.C. 664; 31 CFR 285.1; and 31 CFR 285.3.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–24228 Filed 10–18–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–E–3056]

Determination of Regulatory Review Period for Purposes of Patent Extension; Pascal Precision Transcatheter Valve Repair System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by December 20, 2024. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence

during the regulatory review period by April 21, 2025. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 20, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that