CMS determines risk scores for MA enrollees for a year and uses the appropriate enrollee risk score to adjust the monthly payment amount.

CMS used RAPS data, in combination with encounter data and Fee-For-Service (FFS) data, to develop the diagnosis-based portion of the risk scores for risk adjusted payment to MA organizations, PACE organizations, and MMPs. *Form Number:* CMS–10662 (OMB control number: 0938–0878); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 189; *Total Annual Responses:* 29,729,927; *Total Annual Hours:* 990,007. (For policy questions regarding this collection contact Sage Pasquale at 410–786–0091)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* State Exchange Improper Payment Measurement (SEIPM); *Use:* The Payment Integrity Information Act of 2019 (PIIA) requires Federal agencies to annually identify, review, measure, and report on the programs they administer that have been determined to be susceptible to significant improper payments. In 2016, HHS determined that payments of APTC are susceptible to significant improper payments and, as a result, are subject to the requirements of PIIA. In accordance with 45 CFR part 155, FFEs, SBE–FPs, and state Exchanges that operate their own eligibility and enrollment systems, determine the amount of APTC to be paid to qualified applicants. Starting in the FY22 Agency Financial Report (AFR), HHS began annually reporting improper payments of APTC administered through FFEs and SBE–FPs as part of the Exchange Improper Payment Measurement (EIPM) program. In 2024, HHS required State Exchanges to participate in the Improper Payment Pre-Testing and Assessment (IPPTA) to prepare State Exchanges for the future implementation of the SEIPM program.

HHS proposes to require state Exchanges to submit to HHS, a sample of tax household information from Qualified Health Plans (QHPs) that have associated APTC payments, for the purpose of being reviewed for improper payments. HHS proposes that the sample size would be of a sufficient quantity to produce a statistically valid estimate of improper payments and in accordance with requirements established by the Office of Management and Budget (OMB). HHS proposes that the measurement of all state Exchanges would occur on an annual basis unless otherwise determined by HHS. The calculated estimate of improper payments would be reported annually in the HHS Agency Financial Report (AFR) as an aggregate rate across all state Exchanges. At HHS' discretion, contractors would be used to support these activities. The burden associated with completion and return of the proposed required information will be the time it will take each state Exchange to meet with HHS to review the information. We estimate that the burden associated with this data collection and transfer will be no more than 8 hours for each sample collected. *Form Number:* CMS–10942 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 800. (For policy questions regarding this collection contact Halina DeSantis at *halina.desantis@cms.hhs.gov*.)

William N. Parham, III,

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

[FR Doc. 2025–22478 Filed 12–10–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10065/10066, CMS–10637 and CMS–10338]

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 required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments 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 January 12, 2026.

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:* Extension of a currently approved collection; *Title of Information Collection:* Hospital Notices: IM/DND; *Use:* This information collection applies to beneficiaries in Original Medicare and enrollees in Medicare health plans. The purpose of

the IM is to inform beneficiaries and enrollees of their rights as hospital inpatients and how to request a discharge appeal by a Quality Improvement Organization (QIO) and how to file a request. Consistent with 42 CFR 405.1205 for Original Medicare and 422.620 for Medicare health plans, hospitals must provide the initial IM within 2 calendar days of admission. A follow-up copy of the signed IM is given no more than 2 calendar days before discharge. The follow-up copy is not required if the first IM is provided within 2 calendar days of discharge. *Form Number:* CMS–10065/10066 (OMB control number: 0938–1019); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for profits, Not for profit institutions; *Number of Respondents:* 25,397,156; *Total Annual Responses:* 25,397,156; *Total Annual Hours:* 4,313,823. (For policy questions regarding this collection contact: Katherine Hosna at 410–786–4993 or *KatherineHosna@cms.hhs.gov*).

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Marketplace Operations*; Use:* On June 19, 2013, HHS published the proposed rule CMS–9957–P: Program Integrity: Exchanges, SHOP, Premium Stabilization Programs, and Market Standards (78 FR 37302) (Program Integrity Proposed Rule). Among other things, the Program Integrity Proposed Rule sets forth financial integrity provisions and protections against fraud and abuse. On January 30, 2013, CMS published Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges under the Affordable Care Act (CMS–2334–P) (E&E II Proposed Rule). On August 30, 2013, HHS published the final rule CMS–9957–F: Program Integrity: Exchanges, SHOP, Eligibility Appeals (Program Integrity Final Rule), finalizing a number of the provisions from the Program Integrity and E&E II Proposed Rules. The third-party disclosure requirements and data collections in the Program Integrity Final Rule support the oversight of qualified health plan (QHP) issuers in Federally-facilitated Exchanges (FFEs) and other provisions. *Form Number:* CMS–10637 (OMB control number 0938–1353); *Frequency:* Annually; *Affected Public:* State, Local or Tribal Governments; Private Sector—Business or other for-profits and Not-for-profits Institutions; *Number of Respondents:* 503; *Number of Responses:* 503; *Total Annual Hours:* 2,325,320. (For questions regarding this collection, contact Nikolas Berkobien at 667–290–9903).

3. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers; *Use:* PHS Act section 2719 and paragraph (b)(2)(i) of the Appeals regulation provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503–1 of the Department of Labor (DOL) claims procedure regulation, and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulation. Paragraph (b)(3)(i) requires issuers offering coverage in the individual health insurance market to also comply with the DOL claims procedure regulation as updated by the Secretary of Health and Human Services (HHS) in paragraph (b)(3)(ii) of the Appeals regulation for their internal claims and appeals processes.

The information collection requirements included in the DOL claims procedure regulation and the Appeals regulation ensure that claimants receive clear and adequate information regarding the plan's claims procedures and the plan's handling of specific benefit claims. This transparency enables claimants to understand plan procedures and decisions, allowing them to effectively request benefits and appeal denied claims when necessary. The information collected in connection with the HHS-administered federal external review process is collected by HHS and is used to provide claimants with an independent external review, ensuring a fair and impartial assessment of denied health benefit claims. *Form Number:* CMS–10338 (OMB control number: 0938–1099); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 91,355; *Total Annual Responses:* 375,202; *Total Annual Hours:* 861,785. (For policy questions regarding this collection contact Daniel Kidane at *Daniel.Kidane@cms.hhs.gov*.)

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–6743]

Food and Drug Administration Expert Panel on Testosterone Replacement Therapy for Men; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a request for information from interested parties and the public to share their perspectives with FDA on testosterone replacement therapy for men. The Agency intends to use the information submitted to help inform considerations related to testosterone therapy for men.

DATES: Either electronic or written comments on the notice must be submitted by February 9, 2026.

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 February 9, 2026. 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 identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a