approved collection; *Title of Information Collection:* Medicare Authorization to Disclose Personal Health Information; *Use:* The Medicare Authorization to Disclose Personal Health Information will be used by Medicare beneficiaries to authorize Medicare to disclose their protected health information to a third party. Medicare beneficiaries can submit the Medicare Authorization to Disclose Personal Health Information electronically at *Medicare.gov*. Beneficiaries may also submit the Medicare Authorization to Disclose Personal Health Information by mailing a complete and valid authorization form to Medicare. Beneficiaries can submit the Medicare Authorization to Disclose Personal Health Information verbally over the phone by calling 1–800–Medicare. *Form Number:* CMS–10106 (OMB Control number: 0938–0930); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 1,000,000; *Total Annual Responses:* 1,000,000; *Total Annual Hours:* 250,000. (For policy questions regarding this collection contact Samuel Jenkins at 410–786–3261.)

William N. Parham, III,

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

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BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Matching Program

AGENCY: Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Notice of a new matching program.

SUMMARY: In accordance with subsection (e)(12) of the Privacy Act of 1974, as amended, the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is providing notice of the re-establishment of a matching program between CMS and State-Based Administering Entities (AEs), titled ''Determining Eligibility for Enrollment in Applicable State Health Subsidy Programs Under the Patient Protection and Affordable Care Act.''

DATES: The deadline for comments on this notice is December 18, 2025. The re-established matching program will commence not sooner than 30 days after publication of this notice, provided no comments are received that warrant a change to this notice. The matching program will be conducted for an initial term of 18 months (from approximately October 2025 to March 2027) and, within three months of expiration, may be renewed for up to one additional year if the parties make no changes to the matching program and certify that the program has been conducted in compliance with the matching agreement.

ADDRESSES: Interested parties may submit written comments on this notice to the CMS Privacy Act Officer by mail at: Division of Security, Privacy Policy & Governance, Information Security & Privacy Group, Office of Information Technology, Centers for Medicare & Medicaid Services, Location: N1–14–56, 7500 Security Blvd., Baltimore, MD 21244–1850, or by email at *Barbara.Demopulos@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: If you have questions about the matching program, you may contact: Robert Yates, Deputy Director, Division of State and Grant Operations, State Marketplace and Insurance Programs Group, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, 7500 Security Blvd., Baltimore, MD 21224, or by email to *Robert.Yates@cms.hhs.gov,* or Jenny Chen, Director, Division of State Technical Assistance, State Marketplace and Insurance Programs Group, Center for Consumer Information and Insurance Oversight, Centers for Medicare & Medicaid Services, 7501 Wisconsin Ave., Bethesda, MD 20814, or by email to *Jenny.Chen@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Privacy Act of 1974, as amended (5 U.S.C. 552a) provides certain protections for individuals applying for and receiving federal benefits under federal benefit programs. The law governs the use of computer matching by federal agencies when records in a system of records (meaning, federal agency records about individuals retrieved by name or other personal identifier) are matched with records of other federal or non-federal agencies. The Privacy Act requires agencies involved in a matching program to:

1. Enter into a written agreement, which must be prepared in accordance with the Privacy Act, approved by the Data Integrity Board of each source and recipient federal agency, provided to Congress and the Office of Management and Budget (OMB), and made available to the public, as required by 5 U.S.C. 552a(o), (u)(3)(A), and (u)(4).

2. Notify the individuals whose information will be used in the matching program that the information they provide is subject to verification through matching, as required by 5 U.S.C. 552a(o)(1)(D).

3. Verify match findings before suspending, terminating, reducing, or making a final denial of an individual's benefits or payments or taking other adverse action against the individual, as required by 5 U.S.C. 552a(p).

4. Report the matching program to Congress and the Office of Management and Budget (OMB), in advance and annually, as required by 5 U.S.C. 552a(o)(2)(A)(i), (r), and (u)(3)(D).

5. Publish advance notice of the matching program in the **Federal Register** as required by 5 U.S.C. 552a(e)(12).

This matching program meets these requirements.

Barbara Demopulos,

Privacy Act Officer, Division of Security, Privacy Policy and Governance, Office of Information Technology, Centers for Medicare & Medicaid Services.

PARTICIPATING AGENCIES:

The agencies participating in the matching program are the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), and State-Based Administering Entities (AEs). Currently, each of the 50 states, the District of Columbia, and Puerto Rico has one or more AE(s) participating in this matching program. Other U.S. territories may eventually participate. Each party (CMS and each participating AE) is a source agency, and each AE is a recipient agency, in this matching program, as explained in the Purpose(s) section below.

AEs administer insurance affordability programs, and include Medicaid/Children's Health Insurance Program (CHIP) agencies, state-based exchanges (SBEs), and basic health programs (BHPs). In states that operate a SBE, the AE would include the Medicaid/CHIP agency. Additionally, there are two states—Minnesota and New York—where the AE operates as both a SBE and BHP. In states that have elected to utilize the federally-facilitated exchange (FFE), the AE would include only the Medicaid/CHIP agency.

AUTHORITY FOR CONDUCTING THE MATCHING PROGRAM:

The principal authority for conducting the matching program is 42 U.S.C. 18001, *et seq.*

PURPOSE(S):

The matching program will enable CMS to provide information (including information CMS receives from other federal agencies under related matching agreements) to AEs, to assist AEs in verifying applicant information as required by the Patient Protection and Affordable Care Act of 2010 (PPACA) to determine applicants' eligibility for enrollment in applicable state health subsidy programs, including exemption from the requirement to maintain minimum essential coverage (MEC) or from the individual responsibility payment. In addition, to avoid dual enrollment, information will be shared between CMS and AEs, and among AEs, for the purpose of verifying whether applicants and enrollees are currently eligible for or enrolled in a Medicaid/CHIP program. All information will be shared through a data services hub (Hub) established by CMS to support the federally-facilitated health insurance exchange (which CMS operates) and state-based exchanges.

CATEGORIES OF INDIVIDUALS:

The individuals whose information will be used in the matching program are consumers who apply for eligibility to enroll in applicable state health insurance subsidy programs through an exchange established under the PPACA and other relevant individuals (such as, applicants' household members).

CATEGORIES OF RECORDS:

The categories of records that will be used in the matching program are identifying records; minimum essential coverage period records; return information (household income and family size information); citizenship status records; birth and death information; disability coverage and income information; and imprisonment status records.

The data elements CMS will receive from AEs may include: Social Security Number (if applicable), Last Name, First Name, and Date of Birth.

The data elements the AEs will receive from CMS may include: Validation of SSN; Verification of citizenship or immigration status; Incarceration status; Eligibility and/or enrollment in certain types of MEC; Income, based on Federal Tax Information (FTI), Title II benefits, and current income sources; Quarters of Coverage; and Death Indicator.

SYSTEM(S) OF RECORDS:

The records that CMS will disclose to AEs will be disclosed from the following system of records, as authorized by routine uses 2 and 3 published in the System of Records Notice (SORN) cited below:

CMS Health Insurance Exchanges System (HIX), CMS System No. 09–70–0560, last published in full at 78 FR 63211 (Oct. 23, 2013), as amended at 83 FR 6591 (Feb. 14, 2018).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1385]

Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments; Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry, FDA staff, and other stakeholders entitled ''Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments.'' This guidance (Guidance 3) is the third in a series of four methodological patient-focused drug development (PFDD) guidance documents that describe how stakeholders (patients, researchers, medical product developers, and others) can submit patient experience and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making. This guidance finalizes the draft guidance of the same title issued on June 30, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on November 18, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–1385 for ''Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments; Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available