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).

[FR Doc. 2025–20058 Filed 11–17–25; 8:45 am]

BILLING CODE 4120–03–P

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

for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993–0002, 301–796–8112, *Ethan.Gabbour@fda.hhs.gov;* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911, or the Office of Strategic Partnerships and Technology Innovation, Center for Devices and Radiological Health, *cdrh-pro@fda.hhs.gov,* 800–638–2041 or 301–796–7100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a 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 PFDD guidance documents that describe how stakeholders (patients, researchers, medical product developers, and others) can collect and submit patient experience data and other relevant information from patients and caregivers to be used for medical product development and regulatory decision-making. For purposes of this guidance a ''medical product'' refers to a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) intended for human use, a device (as defined in such section 201) intended for human use, or a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262)).

The series of guidance documents is intended to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can more consistently inform medical product development and regulatory decision-making. Guidance 3 discusses approaches to selecting, modifying, developing, and evaluating clinical outcome assessments to measure outcomes of importance to patients in clinical trials.

This guidance finalizes the draft guidance entitled ''Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments'' issued on June 30, 2022 (87 FR 39101). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to final guidance included the following: clarification of the relationships between relevant terminology, reformulation of the conceptual framework into a description of the COA-based endpoint approach, addition of clarifying language on the importance of qualitative data and patient input, updates to the evidence-based rationale, updated references that reflect the state of science, and moving content that was more relevant to COA-based endpoints to PFDD Guidance 4: ''Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making.'' In addition, editorial changes were made to improve flow and clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C 3501–3521). This guidance refers to collections of information from ''individuals under treatment or clinical examination in connection with research,'' which are not subject to review by the Office of Management and Budget (OMB) under 5 CFR 1320.3(h)(5). Respondents submit to FDA collections of information to support the medical product's effectiveness and to support claims in approved medical labeling.

The collections of information for 21 CFR part 812 for investigational device exemptions have been approved under OMB control number 0910–0078 and the collections of information in 21 CFR part 814 subpart H for humanitarian use devices have been approved under OMB control number 0910–0332. The collections of information in 21 CFR part 814, subparts A through E for premarket approval applications have been approved under OMB control number 0910–0231. The collections of information in 21 CFR part 807, subpart E for premarket notifications have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR 860, subpart D for De Novo classifications have been approved under OMB control number 0910–0844. The collections of information described in FDA's guidance entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' have been approved under OMB control number 0910–0756. The collections of information in 21 CFR part 822 for postmarket surveillance have been approved under OMB control number 0910–0449.

The collections of information in 21 CFR parts 314.50, 314.26, and 601.2 are submitted to FDA to support the medical product's effectiveness and to support claims in approved medical product labeling. The collections of information have been approved under OMB control numbers 0910–0001 and 0910–0338. The collections of

information in 21 CFR 312.23 regarding investigational new drug applications, including clinical trial design and study protocols, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 regarding institutional review boards and the protection of human subjects have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 11 regarding electronic records and signatures have been approved under OMB control number 0910–0303. The collections of information described in FDA's guidance entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (*https://www.fda.gov/media/109951/download*) have been approved under OMB control number 0910–0429.

III. Additional Information

Section 3002 of Title III, Subtitle A, of the 21st Century Cures Act (Pub. L. 114–255) directs FDA to develop patient-focused drug development guidance to address a number of areas, including under section 3002(c)(2): Methodological approaches that may be used to develop and identify what is important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease.

In addition, FDA committed to meet certain performance goals under the sixth authorization of the Prescription Drug User Fee Act. These goal commitments were developed in consultation with patient and consumer advocates, healthcare professionals, and other public stakeholders, as part of negotiations with regulated industry. Section I.J.1 of the commitment letter ''Enhancing the Incorporation of the Patient's Voice in Drug Development and Decision-Making'' (*https://www.fda.gov/media/99140/download*) outlines work, including the development of a series of guidance documents and associated public workshops to facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development, and, as appropriate, regulatory decision-making.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov*.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20153 Filed 11–17–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Supplemental Funding; Rural Residency Planning and Development Technical Assistance

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of supplemental funding.

SUMMARY: HRSA provided supplemental funds to the Rural Residency Planning and Development (RRPD–TA) recipient under HRSA–25–008 to provide additional technical assistance on rural residency program development and support the improvement of health care in rural areas.

FOR FURTHER INFORMATION CONTACT: Jason Steele, RRPD Program Coordinator, Federal Office of Rural Health Policy, HRSA, at *ruralresidency@hrsa.gov* and 301–443–2203.

SUPPLEMENTARY INFORMATION:

Recipient of the Award: The University of North Carolina at Chapel Hill.

Amount of Non-Competitive Award: One award for $600,000.

Project Period: September 30, 2025, to September 29, 2030.

Assistance Listing Number: 93.155.

Award Instrument: Cooperative Agreement Supplement.

Authority: Section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)).

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	City, state	Supplemental award amount
UK6RH32513	University of North Carolina at Chapel Hill	Chapel Hill, NC	$600,000

Justification: This funding provides a one-time supplement to the University of North Carolina at Chapel Hill through the RRPD–TA Cooperative Agreement. This supplement will allow the University of North Carolina at Chapel Hill to build on past and ongoing projects supported by HRSA to support health care in rural areas by providing additional technical assistance to developing and recently established rural residency programs. The University of North Carolina at Chapel Hill is the recipient of the only award under the RRPD–TA program and has established relationships with rural stakeholders and has longstanding experience developing resources to support development of rural residency programs. The supplement to the RRPD–TA Cooperative Agreement will allow the University of North Carolina at Chapel Hill to provide additional technical assistance tools and resources to create and sustain new rural residency programs that will expand the rural physician workforce.

Thomas J. Engels,

Administrator.

[FR Doc. 2025–20094 Filed 11–17–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the NIH Sleep Disorders Research Advisory Board (SDRAB).

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the