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 with change of a previously approved collection; *Title of Information* Collection: Medicare and Medicaid Programs: Conditions of Participation for Hospices; *Use:* Under the Medicare program, eligible beneficiaries may receive covered services in a hospice, provided that certain requirements are met by the hospice. Hospice care means a comprehensive set of services identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

The information collection requirements (ICRs) described herein are needed to implement the Medicare Conditions of Participation (CoPs) for Medicare-participating hospices. The CoPs help assure an adequate level of patient health and safety in participating hospices and help ensure that Medicare hospice eligibility requirements are being met. CMS originally published the Hospice Conditions of Participation on June 5, 2008 (hereinafter ''2008 Final Rule''). The regulations containing the information collection requirements are located at 42 CFR part 418 of the Code of Federal Regulations, Subparts B, C and D.

This is a reinstatement of the information collection request that expired on March 31, 2024. The previous iteration of this OMB Control Number: 0938–1067 (approved March 23, 2021) had an annual burden of 3,639,215 hours and annual costs of $273,001,454. For this requested reinstatement, with changes, the total annual burden hours for industry is 4,032,329 hours and the annual burden costs are $350,449,922. The 10.8% increase in hours is primarily due to the increase in the number of hospices since the last iteration.

Since the last reinstatement was approved in March 2021, CMS revised one of the hospice CoPs at 42 CFR 418.76 in the proposed rule, *Medicare Program: FY 2022 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice and Home Health Quality Reporting Program Requirements* published on April 14, 2021 (86 FR 19700). As CMS addressed in the final rule (CMS–1754–F) published on August 4, 2021 (86 FR 42528), the comments received supported the proposed revisions and did not require any changes to the original burden estimates in this PRA package. This reinstatement incorporates the policy changes made to Section 418.76 through this rule and updates the associated burden estimates based on the original assumptions.

In November 2021, CMS required hospices to develop policies and procedures as a CoP to ensure all staff were fully vaccinated and the burden requirements were detailed in OMB Control Number: 0938–0266. However, CMS removed this requirement and related burden for hospices (and other facilities) in June 2023. *Form Number:* CMS–10277 (OMB control number: 0938–1067); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 7,356; *Total Annual Responses:* 9,209,893; *Total Annual Hours:* 4,032,329. (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Blueprint for Approval of State-based Exchange; *Use:* The Patient Protection and Affordable Care Act (ACA) and its implementing regulations provide states with flexibility in the design and operation of Exchanges to ensure states are implementing Exchanges that best meet the needs of their consumers. States can choose to establish and operate a State-based Exchange (SBE) or a State-based Exchange on the Federal Platform (SBE–FP). To ensure a state can operate a successful and compliant SBE or SBE–FP, it is critical that states provide CMS with a complete and thorough Exchange Blueprint Application, Declaration of Intent Letter, and attest to demonstrate operational readiness. The information collected from states will be used by CMS, IRS, SSA and reviewed by other Federal agencies to determine if a state can implement a complete and fully operational Exchange. *Form Number:* CMS–10416 (OMB control number: 0938–1172); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal governments; *Number of Respondents:* 2; *Total Annual Responses:* 21; *Total Annual Hours:* 106. (For policy questions regarding this collection contact Tiffany Y. Animashaun at *Tiffany.Animashaun@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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BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2396]

Chemistry, Manufacturing, and Controls Development and Readiness Pilot Program; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing year four of the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP). This program facilitates the expedited CMC development of products under an investigational new drug application (IND) based on the anticipated clinical benefit of earlier

patient access to the products. FDA has implemented this pilot program to assist with CMC readiness for products regulated by both the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) that have accelerated clinical development timelines. To accelerate CMC development and facilitate CMC readiness, the pilot features increased communication between FDA and sponsors and explores the use of science- and risk-based regulatory approaches, as applicable. This notice outlines the eligibility criteria and process for submitting a request to participate in the pilot.

DATES: Starting October 1, 2025, FDA will accept requests to participate in year four of the CDRP program. See the ''Participation'' section of this document for eligibility criteria, instructions on how to submit a request to participate, and selection criteria and process.

FOR FURTHER INFORMATION CONTACT: Tanya Clayton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4506, Silver Spring, MD 20993–0002, 301–796–0871; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

For general questions about the CDRP Program for CBER: industry.biologics@fda.hhs.gov.

For general questions about the CDRP Program for CDER: cder-opq-opro-crad-inquiries@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Development programs for CBER- and CDER-regulated drugs and biologics intended to diagnose, treat, or prevent a serious disease or condition where there is an unmet medical need may have accelerated clinical development timelines. Yet, marketing applications for products in expedited development programs still need to meet FDA's approval standards, including manufacturing facility compliance with current good manufacturing practice (CGMP). Products with accelerated clinical development activities may face challenges in expediting CMC development activities to align with the accelerated clinical timelines. Successfully expediting CMC readiness may require additional interactions with FDA during product development and, if applicable, warrant the use of science- and risk-based regulatory approaches to streamline CMC development activities so that clinical benefits of earlier patient access to these products can be realized.

As described in the FDA Prescription Drug User Fee Act (PDUFA) VII Commitment Letter for fiscal years (FYs) 2023 Through 2027 (Ref. 1), FDA implemented the CDRP program to facilitate CMC readiness for selected CBER- and CDER-regulated products with accelerated clinical development timelines in FY 2023. To accelerate CMC development and facilitate CMC readiness, the pilot features increased communication between FDA and sponsors and explores the use of science- and risk-based regulatory approaches, such as those described in the FDA guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (May 2014) (Ref. 2), as applicable.

FDA (CBER and CDER) is continuing to administer the CDRP to facilitate the CMC development of selected products under INDs which have expedited clinical development timeframes, based on the anticipated clinical benefits of earlier patient access to the products. For sponsors participating in the pilot, FDA will provide product-specific CMC advice during product development, including two additional CMC-focused Type B meetings, as well as additional CMC-focused discussions. To support these interactions, once a sponsor is admitted to the pilot, FDA will expand the IND quality assessment team so as to ensure it has representation from the full complement of relevant disciplines. The increased communication between FDA review staff and sponsors is intended to ensure a mutual understanding of approaches to completing CMC activities, including what information should be provided at the appropriate timepoint (*i.e.,* at the time of new drug application (NDA) or biologics license application (BLA) submission, prior to the end of the review cycle, or post-approval) to ensure CMC readiness for a marketing application.

II. Participation

FDA will accept requests to participate in the CDRP program continuously throughout the fiscal year. FDA will select no more than nine proposals per fiscal year, with approximately two-thirds being CBER-regulated products and one-third CDER-regulated products. FDA will renew the CDRP program each fiscal year and announce the opening of the pilot program in the **Federal Register** for the remainder of this PDUFA VII period (until the end of FY 2027). However, once enrolled in the pilot a participating firm will continue to be enrolled in the program until their marketing application is filed. Sponsors who are interested in participating in the pilot program should submit a request to participate in the pilot as an amendment to their IND. The cover letter should state ''Request to Participate in the CMC Development and Readiness Pilot.''

To promote innovation and understanding in this area, FDA will hold a public workshop on September 10, 2025 and issue a strategy document focused on CMC aspects of expedited development incorporating lessons from the CDRP. At the workshop, sponsors may be asked to present lessons learned from the pilot. FDA may also present summary lessons and case studies. Generally, FDA does not anticipate that the case studies will need to include information, such as the sponsor's name, that can identify a unique product or product-specific manufacturing process information. Case studies will focus on FDA-sponsor interactions and problem solving, and address scientific and technical issues only in general terms. However, as described in the FDA PDUFA VII Commitment Letter for FYs 2023 Through 2027, to be eligible for the pilot, the sponsor must reach agreement with FDA on the information that could be publicly disclosed. FDA will notify a sponsor in advance when it plans to include some aspect of their experience in the program in a public discussion (*e.g.,* a slide presentation, a white paper).

A. Eligibility Criteria

The following eligibility criteria apply for consideration for participation in the pilot program:

1. Joint CBER and CDER Eligibility Criteria

- An active commercial IND (see the definition of commercial IND at *https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/research-investigational-new-drug-applications-what-you-need-know*).
- IND has been submitted in, or converted to, Electronic Common Technical Document (eCTD) format, unless the IND is of a type granted a waiver from eCTD format as per FDA's guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (September 2024) (Ref. 3).
- INDs for combination products (21 CFR 3.2(e)) are eligible; products that require significant cross-Center interactions (*e.g.,* complex combination

products) may be less likely to be selected for the pilot.

- In general, there should be enough time remaining before submission of the marketing application to allow the pilot to have an impact on CMC readiness.
- CMC-related information is provided to demonstrate a commitment to pursue a CMC development plan that aligns with the expedited clinical development program (see ''CMC Development Plan'' in section II.B of this document for details).

Due to the differences in product complexity between CBER- and CDER-regulated products, the following eligibility and selection criteria differ between the Centers.

2. CBER-Specific Eligibility Criteria

- IND is an existing, CBER-regulated IND intended for submission as an application for licensure of a biological product under section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)) for cellular therapies, gene therapies, and other products regulated by the Office of Therapeutic Products/CBER or vaccines regulated by the Office of Vaccines Research and Review/CBER.
- IND has a Breakthrough Therapy (BT) or Regenerative Medicine Advance Therapy (RMAT) designation.

3. CDER-Specific Eligibility Criteria

- IND is an existing, CDER-regulated IND for a product intended for submission as an application for: (1) approval of a new drug submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), or (2) licensure of a biological product under section 351(a) of the PHS Act.
- IND has an expedited clinical timeframe warranted based on anticipated clinical benefits of earlier patient access. This would include INDs with BT or Fast Track designations as well as other INDs that meet this criterion, with eligibility to be determined by FDA.

B. What To Submit in a Request To Participate in the Pilot

To participate in the CDRP, sponsors should submit a written request as an amendment to the IND. In addition to providing a point of contact and noting any expedited program designations the IND has received to date, the request should include the following information.

CMC Development Plan

To focus pilot resources where they will be most useful and have an impact on the timeliness with which CMC readiness is achieved, prospective applicants to the pilot program should include in their Request to Participate a brief description of their CMC development plan, with a prospective timeline for CMC development that would align with when the clinical development program is expected to be complete:

- The plan should list the remaining CMC tasks and activities anticipated to be necessary, with estimated timeframes. This part of the plan should cover the following CMC-related areas:
  - Currently available product characterization and preliminary identification of critical quality attributes.
  - Summary of the current drug substance and drug product manufacturing process and control strategy (including assays, noting any that are still under development).
  - A brief description of the proposed commercial scale manufacturing and control strategy, including any necessary microbial control strategy—focusing on important differences from clinical scale.
  - Identification of potential commercial manufacturing facilities, including any contract facilities, or, at least, the type (in house, contract manufacturing organization) of facilities anticipated.
  - Plans for ensuring product availability at approval.
  - Drug substance and drug product stability assessment plan.
  - Strategy for process validation (see FDA's guidance for industry entitled ''Process Validation: General Principles and Practices'' (Ref. 4)).
- Given the expedited clinical timeframe, mapping out a plan for manufacturing readiness within the same overall timespan may reveal potential challenges in accomplishing CMC readiness. The plan should highlight any anticipated CMC challenges—whether related to the bullets above or otherwise. This will facilitate FDA engagement and collaboration. Participants in the pilot should plan to discuss these challenges with FDA during the pilot. For CDER-regulated products, see MAPP 5015.13, ''Quality Assessment for Products in Expedited Programs'' (Ref. 5).
- The CMC Development Plan should include proposed timing (*i.e.,* month and year) for the first CMC-specific Type B meeting afforded by the pilot.

C. Selection Criteria and Process

FDA intends to select CBER and CDER INDs based on the criteria outlined below. Requests will be acknowledged and reviewed when received. FDA intends to issue a Proceed to Disclosure Agreement letter, if selected into the pilot, or deny letter within 90 days of receipt.

In selecting INDs for the pilot program, FDA intends to consider factors such as: (1) anticipated clinical benefits of facilitating earlier patient access to the product, (2) novelty of the product, (3) complexity of the product or its manufacturing process, including technology, and (4) anticipated CMC challenges. Overall, FDA intends to seek balance and diversity in product types and therapeutic indications to obtain a variety of relevant experience and learnings from the pilot.

D. FDA-Sponsor Interactions During the Pilot

During this CDRP program, sponsors will have the ability to discuss their product development strategies and goals with FDA review staff during the two dedicated Type B meetings, as well as in additional CMC-focused discussions. Besides additional interactions and collaboration with FDA, for those INDs in the pilot, FDA will assemble a team to support the CMC development and readiness of the IND, *e.g.,* participating in the meetings and other discussions under the pilot.

In preparation for a meeting, sponsors should submit written questions along with a background information package clearly marked as a ''PDUFA VII CDRP meeting'' as part of the cover letter to enable FDA review staff to address the questions. The briefing package should be submitted to the corresponding IND. Meetings associated with the pilot should be requested by sponsors. For additional information on meetings and other communications between the sponsors and FDA, see the FDA draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (September 2023) (Ref. 6), CDER MAPP 6025.6: ''Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics'' (Rev. 1) (February 2024) (Ref. 7), CBER ''SOPP 8101.1: Regulatory Meetings With Sponsors and Applicants for Drugs and Biological Products'' (March 2023) (Ref. 8), and CBER ''SOPP 8212: Breakthrough Therapy Products—Designation and Management'' (August 2023) (Ref. 9).

III. Paperwork Reduction Act of 1995

Collections of information from fewer than 10 respondents within any 12-month period are not subject to the Paperwork Reduction Act of 1995 (PRA) (5 CFR 1320.3(c)(4)). To the extent this information collection involves 10 or

more respondents within any 12-month period, the collections of information are subject to the PRA. These collections of information are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3521). The collections of information for NDAs, formal meetings with sponsors and applicants for PDUFA products, and the PDUFA VII Commitment Letter have been approved under OMB control number 0910–0001. The collections of information for INDs have been approved under OMB control number 0910–0014. The collections of information for BLAs have been approved under OMB control number 0910–0338. The collections of information pertaining to CGMP requirements have been approved under OMB control number 0910–0139. The collections of information pertaining to expedited programs for serious conditions for drugs and biologics and breakthrough therapy-designation for drugs and biologics have been approved under OMB control number 0910–0765.

IV. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027'' at *https://www.fda.gov/media/151712/download.*
2. FDA guidance for industry ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (May 2014): *https://www.fda.gov/media/86377/download.*
3. FDA guidance for industry ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (Rev. 8) (September 2024): *https://www.fda.gov/media/135373/download.*
4. FDA guidance for industry ''Process Validation: General Principles and Practices'' (Rev. 1) (January 2011): *https://www.fda.gov/files/drugs/published/Process-Validation—General-Principles-and-Practices.pdf.*
5. CDER MAPP 5015.13: ''Quality Assessment for Products in Expedited Programs'' (December 2022): *https://www.fda.gov/media/162786/download?attachment.*
6. FDA draft guidance for industry ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (Rev. 1) (September 2023): *https://www.fda.gov/media/172311/download.*
7. CDER MAPP 6025.6: ''Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics'' (Rev. 1) (February 2024): *https://www.fda.gov/media/89155/download.*
8. CBER ''SOPP 8101.1: Regulatory Meetings With Sponsors and Applicants for Drugs and Biological Products'' (July 2024): *https://www.fda.gov/media/84040/download.*
9. CBER ''SOPP 8212: Breakthrough Therapy Products—Designation and Management'' (August 2023): *https://www.fda.gov/media/98351/download.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16513 Filed 8–27–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2368]

Patient-Focused Drug Development: Workshop #2 To Discuss Methodologic and Other Challenges Related to Patient Experience Data; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Patient-Focused Drug Development: Workshop #2 to Discuss Methodologic and Other Challenges Related to Patient Experience Data.'' The purpose of the public workshop is to discuss methodological challenges related to patient experience data, and other areas of greatest interest or concern to public stakeholders.

DATES: The public workshop will be held virtually on September 18, 2025, from 12:30 p.m. to 5 p.m. Eastern Time, and September 19, 2025, from 12:30 p.m. to 4 p.m. Eastern Time. Either electronic or written comments on this public workshop must be submitted by November 18, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held virtually using the Zoom platform. The link for the public workshop will be sent to registrants upon registration.

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 November 18, 2025. 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 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–2025–N–2368 for ''Patient-Focused Drug Development: Workshop #2 to Discuss Methodologic and Other Challenges Related to Patient Experience Data.'' Received comments, those filed in a timely manner(see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the