

in December 2020, the MRC Master Plan Final EIS issued in April 2023, and the comments of Federal and State agencies, stakeholder organizations, members of the public and elected officials and other information in the Administrative Record.

Implementation of Alternative B will be distributed between the MOD 1 and MOD 2 buildings and the Beltsville Research Facility (BRF) site. Alternative B has been broken out into three phases which include:

- Phase 1—construction of an approximate 18,000-square-foot annex to the MOD 2 building. The population at the MRC West Parcel will remain at 300. The annex building will accommodate both staff from the BRF and the renovation occurring within MOD 2.

- Phase 2—construction of two laboratory buildings that will accommodate 168 scientists and support staff in approximately 168,000 gross square feet (gsf) of lab space and 6,300 gsf of special use space. Phase 2 includes the removal of the surface parking lot adjacent to MOD 1 and the construction of a parking garage with 235 spaces. An approximate 10,000 gsf maintenance/storage building adjacent to the new parking garage will also be built. Phase 2 will include maintaining the metal warehouse building and fitness center at the BRF, creating a temporary surface lot on the BRF site, and constructing a new entrance to Odell Road for truck screening. A visitor parking lot will be constructed and the Muirkirk Road entrance will be rebuilt with a shared drop-off.

- Phase 3—construction of two office buildings that will accommodate a population of 1,332 and shared use space to support the campus. The two new office buildings will be constructed on the site of the BRF. The total gross area is approximately 166,500 gsf of office space and 24,5000 gsf of special use space. This phase will also include a four-level parking garage for 665 spaces. Additionally, during Phase 3, temporary parking and all remaining existing buildings at the BRF site will be removed.

An elevated boardwalk will be constructed within the natural landscape that will connect the laboratory buildings with the office buildings. A skybridge between the laboratory and office buildings will encourage collaboration. Alternative B will also include space for shared amenities including a conference center, cafeteria, and fitness center.

Alternative B is necessary to continue to guide future long-term development of the MRC. Alternative B highlights

views, improves connectivity and walkability, and conserves the natural landscape. Alternative B is in line with the Master Plan as both aim to:

- maintain a 100-foot landscape buffer along the perimeter of the campus,
- set the buildings back at least 75 feet from the interior roadways,
- respect the woodlands as much as possible and make them accessible for employees,
- create new view corridors into the woodlands at the heart of the campus,
- avoid development and human interference in the pasture areas as these are being used by FDA for research and the preservation of open space,
- connect the existing and Phase 2 buildings through a continuous service corridor,
- allow people to move between new buildings through a physical connection that protects them from the elements, and
- conserve the stream valleys and natural drainage patterns

Location of Record of Decision

The ROD can be found on GSA's project website at www.gsa.gov/ncrnepa.

Mydelle Wright,

Director, Office of Planning and Design Quality, Public Buildings Service, National Capital Region, General Services Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10861 and CMS–10137]

Agency Information Collection Activities: Proposed Collection; 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by August 25, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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 N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10861—Health Insurance

Common Claims Form

CMS–10137—Solicitation for

Applications for Medicare

prescription Drug Plan 2025 Contracts

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Health Outcomes Survey Field Test; *Use:* CMS is required to collect and report quality and performance of Medicare health plans under provisions of the Social Security Act. Specifically, section 1851(d) of the Act (Providing Information to Promote Informed Choice) requires CMS to collect data for MA plan comparison, including data on enrollee satisfaction and health outcomes, and report this information and other plan quality and performance indicators to Medicare beneficiaries prior to the annual enrollment period. The HOS meets the requirement for collecting and publicly reporting quality and other performance indicators, as HOS survey measures are incorporated into the Medicare Part C Star Ratings that are published each fall for consumers on the Medicare website.

This request is to conduct a field test with the goal of evaluating the measurement properties of new survey items, and the effects of new content and a web-based mode on response patterns and measure scores as compared to existing HOS survey items and protocols. Within each of the proposed field test protocol arms, there will be two versions of the questionnaire (see Attachments A and B) that will be identical except for slight differences in selected items where empirical data are needed to ascertain which of the two versions produces the best results (see Attachment C). The two versions of the questionnaire will test alternatives for selected new survey content that will potentially enhance and refine existing measures, allow

CMS to develop new and methodologically simpler cross-sectional and longitudinal measures, expand on CMS’s measurement of physical functioning and mental health, and add to CMS’s efforts to measure and address health equity.

The data collected in this field test will be used by CMS to inform decisions on possible changes to HOS content and survey administration procedures. The items in the questionnaire reflect current health priorities and would provide CMS with data to study new longitudinal PROMs, cross-sectional measures, and enhancements to existing HOS measures for MA plans to use as a focus of their quality improvement efforts. Potential new measures derived from new HOS items will go through the Measures Under Consideration (MUC) process and rule-making before they are added to Star Ratings. *Form Number:* CMS–10861 (OMB Control Number: 0938–New); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 136; *Number of Responses:* 6,800; *Total Annual Hours:* 1,700. (For policy questions regarding this collection contact Kimberly DeMichele at 410–786–4286.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Solicitation for Applications for Medicare prescription Drug Plan 2025 Contracts; *Use:* Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application.

Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) in Subpart 3. The application requirements are codified in subpart K of 42 CFR 423 entitled “Application Procedures and Contracts with PDP Sponsors.”

The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, Program of All-Inclusive Care for the Elderly (PACE), and EGWP applicants. The collected

information will be used by CMS to: (1) ensure that applicants meet CMS requirements for offering Part D plans (including network adequacy, contracting requirements, and compliance program requirements, as described in the application), (2) support the determination of contract awards. *Form Number:* CMS–10137 (OMB Control Number: 0938–0936); *Frequency:* Yearly; *Affected Public:* Private sector, business or other for-profit and not-for-profit institutions; *Number of Respondents:* 795; *Number of Responses:* 433; *Total Annual Hours:* 1,839. (For policy questions regarding this collection contact April Forsythe at 410–786–8493.)

Dated: June 21, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2034]

Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding When Conventional Platelets Are Not Available or Their Use Is Not Practical; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of an immediate in effect guidance entitled “Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical.” FDA is issuing this guidance to provide a notice of exceptions and alternatives to certain requirements in the biologics regulations regarding blood and blood components. This notice is being issued to respond to a public health need and address the urgent and immediate need for platelets for the treatment of active bleeding when conventional platelets are not available, or their use is not practical. In addition, the guidance document provides recommendations to blood establishments for the manufacture and labeling of cold-stored platelets (CSP).