DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10511, CMS–10788, CMS–10052, CMS–460 and CMS–10105]

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 August 15, 2022.

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, you may make your request using one of following:

1. Access CMS' website address at website address at: *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 without change; *Title of Information Collection:* Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage; *Use:* Section 1862(m) of the Social Security Act (and regulations at 42 CFR Subpart B (sections 405.201–405.215) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. Medicare does not cover the Category A device itself because Category A (Experimental) devices do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary. Medicare may cover Category B (Non-experimental) devices, and associated routine costs of care, if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met. Under the current centralized review process, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are met, as described in our regulations, CMS (or its designated entity) must review documents submitted by interested parties or study sponsors. Such information submitted will be a FDA IDE approval letter, IDE study protocol, IRB approval letter, National Clinical Trials (NCT) number, and Supporting materials as needed. *Form Number:* CMS–10511 (OMB control number: 0938–1250); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 116; *Total Annual Responses:* 116; *Total Annual Hours:* 232. (For policy questions regarding this collection contact Xiufen Sui at 410–786–3136.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Prescription Drug and Health Care Spending; *Use:* On December 27, 2020, the Consolidated Appropriations Act, 2021 (CAA) was signed into law. Section 204 of Title II of Division BB of the CAA added parallel provisions at section 9825 of the Internal Revenue Code (the Code), section 725 of the Employee Retirement Income Security Act (ERISA), and section 2799A–10 of the Public Health Service Act (PHS Act) that require group health plans and health insurance issuers offering group or individual health insurance coverage to annually report to the Department of the Treasury, the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, ''the Departments'') certain information about prescription drug and health care spending, premiums, and enrollment under the plan or coverage. This information will support the development of public reports that will be published by the Departments on prescription drug reimbursements for plans and coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under the plans or coverage. The 2021 interim final rules, ''Prescription Drug and Health Care Spending'' issued by the Departments and the Office of Personnel Management (OPM) implement the provisions of section 9825 of the Code, section 725 of ERISA, and section 2799A–10 of the PHS Act, as enacted by section 204 of Title II of Division BB of the CAA. OPM joined the Departments in issuing the 2021 interim final rules, requiring Federal Employees Health Benefits (FEHB) carriers to report information about prescription drug and health care spending, premiums, and plan enrollment in the same manner as a group health plan or health insurance

issuer offering group or individual health insurance coverage. *Form Number:* CMS–10788 (OMB control number: 0938–1405); *Frequency:* Annual; *Affected Public:* Private Sector; *Number of Respondents:* 356; *Total Annual Responses:* 356; *Total Annual Hours:* 1,684,080. (For policy questions regarding this collection, contact Christina Whitefield at 301–492–4172.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Recognition of Pass-Through Payment for Additional (New) Categories of Devices under the Outpatient Prospective Payment System and Supporting Regulations; *Use:* The transitional pass-through provision provides a way for ensuring appropriate payment for new technologies whose use and costs are not adequately represented in the base year claims data on which the outpatient PPS is constructed as required by law. Categories of medical devices will receive transitional pass-through payments for 2 to 3 years from the date payments are initiated for the category. However, the underlying provision is permanent and provides an on-going mechanism for reflecting timely introduction of new items into the payment structure.

Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient PPS. After we receive all requested information, we evaluate the information to determine if the creation of an additional category of medical devices for transitional pass-through payments is justified. We may request additional information related to the proposed new device category, as needed. We advise the applicant of our decision, and update the outpatient PPS during its next scheduled quarterly payment update cycle to reflect any newly approved device categories. We list below the information that we require from all applicants. The following information is required to process requests for additional categories of medical devices for transitional pass-through payments. *Form Number:* CMS–10052 (OMB control number: 0938–0857); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 10; *Number of Responses:* 10; *Total Annual Hours:* 160. (For questions regarding this collection contact Kimberly A. Campbell at 410–786–2289.)

4. *Type of Information Collection Request:* Revision of a currently approved collection: *Title of Information Collection:* Medicare Participating Physician or Supplier Agreement; *Use:* Form CMS–460 is the agreement a physician, supplier, or their authorized official signs to become a participating provider in Medicare Part B. By signing the agreement to participate in Medicare, the physician, supplier, or their authorized official agrees to accept the Medicare-determined payment for Medicare covered services as payment in full and to charge the Medicare Part B beneficiary no more than the applicable deductible or coinsurance for the covered services. For purposes of this explanation, the term ''supplier'' means certain other persons or entities, other than physicians, that may bill Medicare for Part B services (*e.g.,* suppliers of diagnostic tests, suppliers of radiology services, durable medical suppliers (DME) suppliers, nurse practitioners, clinical social workers, physician assistants). Institutions that render Part B services in their outpatient department are not considered ''suppliers'' for purposes of this agreement. *Form Number:* CMS–460 (OMB control number: 0938–0373); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 36,000; *Number of Responses:* 36,000; *Total Annual Hours:* 9,000. (For questions regarding this collection contact Mark G. Baldwin at 410–786–8139.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* National Implementation of the In-Center Hemodialysis CAHPS Survey; *Use:* The national implementation of the ICH CAHPS Survey is designed to allow third-party, CMS-approved survey vendors to administer the ICH CAHPS Survey using mail-only, telephone-only, or mixed (mail with telephone follow-up) modes of survey administration. Experience from previous CAHPS surveys shows that mail, telephone, and mail with telephone follow-up data collection modes work well for respondents, vendors, and health care providers. Any additional forms of information technology, such as web surveys, is under investigation as a potential survey option in this population.

Data collected in the national implementation of the ICH CAHPS Survey are used for the following purposes:

- To provide a source of information from which selected measures can be publicly reported to beneficiaries as a decision aid for dialysis facility selection.
- To aid facilities with their internal quality improvement efforts and external benchmarking with other facilities.
- To provide CMS with information for monitoring and public reporting purposes.
- To support the ESRD Quality Improvement Program.

Form Number: CMS–10105 (OMB control number: 0938–0926); *Frequency:* Semi Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 103,500; *Total Annual Responses:* 621,000; *Total Annual Hours:* 55,890. (For policy questions regarding this collection contact Israel H. Cross at 410–786–0619.)

Dated: July 12, 2022.

William N. Parham, III,

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

[FR Doc. 2022–15175 Filed 7–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1615]

Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products—Content and Format; Guidance for Industry; 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 entitled ''Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This guidance provides recommendations for developing the content and format of an Instructions for Use (IFU) document for human prescription drug and biological products, as well as drug-led or biologic-led combination products submitted under a new drug application (NDA) or a biologics license application (BLA). The IFU is written for patients (or their caregivers) who use drug products that have complicated or detailed patient-use instructions. The recommendations in this guidance are intended to help ensure that patients receive clear and concise information that is easily understood for the safe and