

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

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:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Uniform Institutional Provider Bill and Supporting Regulations in 42 CFR 424.5; *Use:* Section 42 CFR 424.5(a)(5) requires providers of services to submit a claim for payment prior to any Medicare reimbursement. Charges billed are coded by revenue codes. The bill specifies diagnoses according to the International Classification of Diseases, Tenth Edition (ICD-10) code. Inpatient procedures are identified by ICD-10 codes, and outpatient procedures are described using the CMS Common Procedure Coding System (HCPCS). These are standard systems of identification for all major health insurance claims payers. Submission of information on the UB-04 CMS-1450 permits Medicare Part A MACs to receive consistent data for proper payment. Medicare receives over 99.97 percent of the claims submitted by institutional providers electronically. CMS only accepts electronic claims in the Accredited Standards Committee (ASC) Health Insurance Portability and Accountability Act (HIPAA) 837 format for institutional providers unless the provider meets CMS requirements to submit paper claims. With the uniform

bill, we have been able to achieve a more uniform and a more automated bill processing system for Medicare institutional and providers. The UB-04 CMS-1450 is managed by the National Uniform Billing Committee (NUBC), sponsored by the American Hospital Association. Most payers are represented on this body, and the UB-04 is widely used in the industry. Medicare Part A MACs use the information on the UB-04 CMS-1450 to determine whether to make Medicare payment for the services provided, the payment amount, and whether or not to apply deductibles to the claim. The same method is also used by other payers. CMS is also a secondary user of data. CMS uses the information to develop a database, which is used to update, and revise established payment schedules and other payment rates for covered services. CMS also uses the information to conduct studies and reports. *Form Number:* CMS-1045 (OMB control number: 0938-0997); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 53,111; *Total Annual Responses:* 204,138,881; *Total Annual Hours:* 1,797,958. (For policy questions regarding this collection contact Mohammad B Ullah at 410-786-4143.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act; *Use:* Sections 2723 and 2761 of the Public Health Service Act (PHS Act) direct the Centers for Medicare and Medicaid Services (CMS) to enforce a provision (or provisions) of title XXVII of the PHS Act (including the implementing regulations in parts 144, 146, 147, and 148 of title 45 of the Code of Federal Regulations) with respect to health insurance issuers when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the group and individual market reforms with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions. Section 2723 of the PHS Act directs CMS to enforce an applicable provision (or applicable provisions) of title XXVII of the PHS Act (including the implementing regulations in parts 146 and 147 of title 45 of the Code of Federal Regulations) with respect to group health plans that are non-Federal governmental plans. This

collection of information includes requirements that are necessary for CMS to conduct compliance review activities. *Form Number:* CMS-10430 (OMB control number: 0938-0702); *Frequency:* Annually; *Affected Public:* State Governments, Private Sector, State or local governments; *Number of Responses:* 780; *Total Annual Responses:* 42,716; *Total Annual Hours:* 1,721. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650.)

Dated: July 16, 2019.

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

Centers for Medicare & Medicaid Services

[Document Identifier CMS-576A]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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 September 17, 2019.

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, 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.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

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-576A Organ Procurement Organization’s (OPOs) Health Insurance Benefits Agreement and Supporting Regulations

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:* Revision of a currently approved collection; *Title of Information Collection:* Organ Procurement Organization’s (OPOs) Health Insurance Benefits Agreement and Supporting Regulations; *Use:* The Medicare and Medicaid Programs final conditions for coverage for Organ Procurement Organizations (OPOs) require OPOs to sign agreements with the Center for Medicare and Medicaid Services (CMS) in order to be reimbursed and perform their services. The information provided on this form serves as a basis for continuing the agreements with CMS and the OPOs for participation in the Medicare and Medicaid programs for reimbursement of service. *Form Number:* CMS-576A (OMB Control Number: 0938-0512); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 58; *Total Annual Responses:* 58; *Total Annual Hours:* 29. (For policy questions regarding this collection contact Melissa Rice at 410-786-3270.)

Dated: July 16, 2019.

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-2018-N-3163]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Physician Interpretation of Information About Prescription Drugs in Scientific Publications Versus Promotional Pieces

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is

announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 19, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title “Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces

OMB Control Number 0910-New

I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The FD&C Act prohibits the dissemination of false or misleading information about medications in consumer-directed and professional prescription drug promotion. As part of its Federal mandate, FDA regulates whether advertising of prescription drug products is truthful, balanced, and accurately communicated (see 21 U.S.C. 352(n)). FDA’s regulatory policies are aligned with the principles of free speech and due process in the U.S. Constitution. To inform current and future policies, and to seek to enhance