

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 any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) 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 *February 10, 2014*:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or Email: OIRA_submission@omb.eop.gov.

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' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
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: Reports Clearance Office at (410) 786-1326.

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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Healthcare Fraud Prevention Partnership (HFPP): Data Sharing and Information Exchange; *Use:* Section 1128C(a)(2) of the Social Security Act (42 U.S.C. 1320a-7c(a)(2)) authorizes the Secretary and the Attorney General to consult with, and arrange for the sharing of data with representatives of health plans to establish a Fraud and Abuse Control Program as specified in Section 1128(C)(a)(1) of the Social Security Act. This is known as the Healthcare Fraud Prevention Partnership (HFPP). It was officially established by a Charter in fall 2012 and signed by HHS Secretary Sibelius and US Attorney General Holder. The HFPP is a joint initiative established by the Department of Health and Human Services (HHS) and Department of Justice (DOJ) to detect and prevent the prevalence of healthcare fraud through data and information-sharing and applying analytic capabilities by the public and private sectors. The HFPP collaboration provides a unique opportunity to transition from traditional "pay and chase" approaches for fraud detection and recovery towards a data-driven model for identifying and predicting aberrant activity. A central goal of the HFPP is to identify the optimal way to coordinate nationwide sharing of health care claims information, including aggregating claims and payment information from large public healthcare programs and private insurance payers. In addition to sharing data and information, the HFPP is focused on advancing analytics, training, outreach, education to support anti-fraud efforts and achieving its objectives, primarily through goal-oriented, well-designed fraud studies. *Form Number:* CMS-10501 (OCN: 0938-New); *Frequency:*

Occasionally; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 75; *Total Annual Responses:* 75; *Total Annual Hours:* 180,000. (For policy questions regarding this collection contact Johnalyn Lyles at 410-786-8410.)

Dated: January 6, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014-00188 Filed 1-9-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-102 and 105, and CMS-10209]

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 any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by March 11, 2014.

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). 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' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

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: Reports Clearance Office at (410) 786-1326.

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-102 and 105 Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations

CMS-10209 Medicare Advantage Chronic Care Improvement Program (CCIP) and Quality Improvement (QI) Project Reporting Tools

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 Collections

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations; *Use:* We will use the collected information to determine the amount of Federal reimbursement for surveys conducted. Use of the information includes program evaluation, audit, budget formulation and budget approval. Form CMS-102 is a multi-purpose form designed to capture and record all budget and expenditure data. Form CMS-105 captures the annual projected CLIA workload that the State survey agency will accomplish. Our regional offices also use the information to approve the annual projected CLIA workload. The information is required as part of the section 1864 agreement with the state. *Form Numbers:* CMS-102 and CMS-105 (OCN: 0938-0599); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 4,500. (For policy questions regarding this collection contact Angela Stancel at 410-786-4876.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Advantage Chronic Care Improvement Program (CCIP) and Quality Improvement (QI) Project Reporting Tools; *Use:* Medicare Advantage Organizations (MAOs) are required to have an ongoing quality improvement (QI) program that meets our requirements and includes at least one chronic care improvement program (CCIP) and one QI Project. Every MAO must have a QI program that monitors and identifies areas where implementing appropriate interventions would improve patient outcomes and patient safety. Information collected using the CCIP and QIP reporting tools is an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure high quality value-based health care for Medicare beneficiaries. *Form Number:* CMS-10209 (OCN: 0938-1023);

Frequency: Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 1,904; *Total Annual Responses:* 1,904; *Total Annual Hours:* 28,560. (For policy questions regarding this collection contact Ellen Dieujuste at 410-786-2191).

Dated: January 6, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1630]

Draft Guidance for Industry on Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease.” This draft guidance provides a statement of qualification for the Exacerbations of Chronic Pulmonary Disease Tool (EXACT) patient-reported outcome instrument and summarizes the concept of interest and context of use (COU) for which the tool is qualified through the Center for Drug Evaluation and Research's (CDER's) drug development tool (DDT) qualification program. Qualification of the EXACT represents a conclusion that, within the stated COU, the instrument can be relied on to have a specific interpretation and application in drug development and regulatory review. This draft guidance is an attachment to the guidance for industry entitled “Qualification Process for Drug Development Tools.”

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency