

information collection for the proper performance of the Agency's function; (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.

1. *Type of Information Collection Request:* New collection (request for a new OMB control number). *Title of Information Collection:* Medicaid and CHIP Program (MACPro). *Use:* Medicaid, authorized by Title XIX of the Social Security Act and, CHIP, reauthorized by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), play an important role in financing health care for approximately 48 million people throughout the country. By 2014, it is expected that an additional 16 million people will become eligible for Medicaid and CHIP as a result of the Affordable Care Act (Pub. L. 111-148). In order to implement the statute, CMS must provide a mechanism to ensure timely approval of Medicaid and CHIP state plans, waivers and demonstrations, and provide a repository for all Medicaid and CHIP program data that supplies data to populate Healthcare.gov and other required reports. Additionally, 42 CFR 430.12 sets forth the authority for the submittal and collection of state plans and plan amendment information. Pursuant to this requirement, CMS has created the MACPro system.

Generally, MACPro will be used by both state and CMS officials to: Improve the state application and federal review processes, improve federal program management of Medicaid programs and CHIP, and standardize Medicaid program data. More specifically, it will be used by state agencies to (among other things): (1) Submit and amend Medicaid state plans, CHIP state plans, and Information System Advanced Planning Documents, and (2) submit applications and amendments for state waivers, demonstration, and benchmark and grant programs. It will be used by CMS to (among other things): (1) Provide for the review and disposition of applications, and (2) monitor and track application activity.

A paper-based version of the MACPro instrument would be sizable and time consuming for interested parties to follow as a paper-based instrument. In our effort to provide the public with the most efficient means to make sense of the MACPro system, we held four webinars in lieu of including a paper-

based version of MACPro. Those webinars were associated with our 60-day **Federal Register** notice (June 8, 2012; 77 FR 34046). The following changes have been made subsequent to the publication of that notice:

- MACPro will be used to create the data feed for updating Healthcare.gov based on changes from state plan and CHIP eligibility. This effort is in support of the Federally-facilitated Exchange (FFE) to conduct assessments of eligibility for state Medicaid and CHIP.

- Section 1115 Waiver Demonstration and Medicaid Eligibility authorities will no longer be part of the phase 1 release. They will be included in the subsequent releases of the system.

Consequently, this first phase will only include CHIP Eligibility and Alternative Benchmark Plans (ABP) portions/modules.

The webinar associated with this 30-day **Federal Register** notice will be made available for public review/comment at any time/date in this notice's public comment period. The webinar can be accessed on the Internet at: <http://www.medicaid.gov/State-Resource-Center/Medicaid-and-CHIP-Program-Portal/Medicaid-and-CHIP-Program-Portal.htm>. A login and password is not necessary. *Form Number:* CMS-10434 (OCN: 0938-New). *Frequency:* Annual and once. *Affected Public:* State, Local, or Tribal Governments. *Number of Respondents:* 56. *Total Annual Responses:* 411. *Total Annual Hours:* 10,490. (For policy questions regarding this collection contact Darlene Anderson at 410-786-9828. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on January 22, 2013.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number:* (202) 395-6974, *Email:* OIRA_submission@omb.eop.gov.

Dated: December 17, 2012.

Martique Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-906 and CMS-855B]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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 function; (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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The Fiscal Soundness Reporting Requirements; *Use:* The Centers for Medicare and Medicaid Services (CMS) is assigned responsibility for overseeing the ongoing financial performance for all Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) sponsors and Program of All-Inclusive Care for the Elderly (PACE) organizations. Specifically, CMS needs the requested collection of information to establish that contracting entities within those programs maintain fiscally sound organizations. The revised fiscal soundness reporting form combines MAO, PDP, 1876 Cost Plans, Demonstration Plans and PACE organizations. Entities contracting in

these programs currently submit all documentation being requested. Specifically, all contracting organizations must submit annual independently audited financial statements one time per year. The MAOs with a net loss, a negative net worth or both must file three quarterly statements. Currently there are approximately 44 MAOs filing quarterly financial statements. The PDPs must also file three unaudited quarterly financial statements. The PACE organizations are required to file 3 quarterly financial statements for the first three years in the program. Additionally, PACE organizations with a net loss, a negative net worth or both must file statements as well.

The information collection request is being revised to include one additional data element for PACE organizations only, Total Subordinated Liabilities. The addition of the new data element will actually reduce the time to analyze the financial standing of PACE organizations because we will no longer have to contact the PACE organizations to establish whether or not the organization's total liabilities calculation includes subordinated debt. *Form Number:* CMS-906 (OCN: 0938-0469); *Frequency:* Annually, Quarterly; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 648; *Total Annual Responses:* 1,281; *Total Annual Hours:* 428. (For policy questions regarding this collection contact Joe Esposito at 410-786-1129. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: New collection; **Title of Information Collection:** Medicare Enrollment Application for Clinics/ Group Practice and Certain Other Suppliers; **Use:** The primary function of the CMS-855B enrollment application for Clinics, Group Practices and Certain Other Suppliers is to gather information from the organization that tells us what it is, whether it meets certain qualifications to be a health care supplier, where it renders services and information necessary to establish the correct claims payment. The goal of evaluating and revising the CMS-855B enrollment application is to simplify and clarify the information collection without jeopardizing our need to collect specific information. The majority of the revisions are very minor in nature such as spelling and formatting corrections, removal of duplicate fields and instruction clarification for the organization/group. The Sections and Sub-Sections within the form are also being re-numbered and re-sequenced to create a more logical flow of the data

collection. In addition, CMS is adding a data collection for an address to mail the periodic request for the revalidation of enrollment information (only if it differs from other addresses currently collected). Other than the revalidation mailing address described above, new data being collected in this revision package is a checkbox indicating whether or not an organization is wholly owned or operated by a hospital, the inclusion of a new supplier type (Centralized Flu Biller) and information on, if applicable, where the supplier stores its patient records electronically. While the CMS-855B is not a new form, this is considered a new information collection request because we are submitting it to OMB for approval under its own OMB control number. *Form Number:* CMS-855B (OCN: 0938-New); *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 31,000; *Total Annual Responses:* 31,000; *Total Annual Hours:* 103,000 (For policy questions regarding this collection contact Kim McPhillips at 410-786-5374. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on January 22, 2013.

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number:* (202) 395-6974, *Email:* OIRA_submission@omb.eop.gov.

Dated: December 17, 2012.

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-2012-N-1181]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medicated Feed Mill License Application; Extension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the medicated feed mill licensing system.

DATES: Submit written or electronic comments on the collection of information by February 19, 2013.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PIFO-410B, Rockville, MD 20850, 301-796-3794.

SUPPLEMENTARY INFORMATION: 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. "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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information,