

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
	Social and community service managers .....	300	1	12/60	60
TOTAL .....	.....	.....	.....	.....	1,882

**Leroy A. Richardson,**  
*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2013-16106 Filed 7-3-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10316]

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

**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 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 August 5, 2013.

**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) 395-6974 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:* Revision of a currently approved collection; *Title of Information Collection:* Implementation of the Medicare Prescription Drug Plan

(PDP) and Medicare Advantage (MA) Plan Disenrollment Reasons Survey; *Use:* This data collection complements the satisfaction data collected through the Medicare Consumer Assessment of Healthcare Providers and Systems survey by providing dissatisfaction data in the form of reasons for disenrollment from a Prescription Drug Plan. The data collected in this survey can be used to improve the operation of Medicare Advantage (MA) (both MA and MA-PD) contracts and standalone prescription drug plans (PDPs) through the identification of beneficiary disenrollment reasons. Plans can use the information to guide quality improvement efforts. The data can also be used by beneficiaries who need to choose among the different MA and PDP options. To the extent that these data identify areas for improvement at the contract level they can be used for contract oversight. *Form Number:* CMS-10316 (OCN: 0938-1113); *Frequency:* Yearly; *Affected Public:* Individuals or households; *Number of Respondents:* 88,492; *Total Annual Responses:* 88,492; *Total Annual Hours:* 22,887. (For policy questions regarding this collection contact Sai Ma at 410-786-1479.)

Dated: June 28, 2013.

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

[FR Doc. 2013-16084 Filed 7-3-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifiers: CMS-10171, CMS-10207, CMS-10476 and CMS-855(C)]

**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 (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 September 3, 2013.

**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](mailto: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-10171 Coordination of Benefits Between Part D Plans and Other Prescription Coverage Providers.

CMS-10207 Physician Self-Referral Exceptions for Electronic Prescribing and Electronic Health Records.

CMS-10476 Medical Loss Ratio (MLR) Report for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP).

CMS-855(C) Medicare Enrollment Application for Registration of Eligible Entities That Provide Health Insurance Coverage Complementary to Medicare Part B

Under the Paperwork Reduction Act (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:* Revision of a currently approved collection; *Title of Information Collection:* Coordination of Benefits Between Part D Plans and Other Prescription Coverage Providers; *Use:* We will use the information along with Part D plans, other health insurers or payers, and pharmacies to coordinate prescription drug benefits provided to the Medicare beneficiary. *Form Number:* CMS-10171 (OCN: 0938-0978); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:*

57,116; *Total Annual Responses:* 2,402,582; *Total Annual Hours:* 5,205,128. (For policy questions regarding this collection contact Heather Rudo at 410-786-7627.)

2. *Type of Information Collection*

*Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Physician Self-Referral Exceptions for Electronic Prescribing and Electronic Health Records; *Use:* The collected information would be used for enforcement purposes. Specifically, if we were investigating the financial relationships between donors and physicians to determine whether the provisions in the exceptions at 42 CFR 411.357(v) and (w) were met, first, we would review the written agreements that indicate what items and services each entity intended to provide. *Form Number:* CMS-10207 (OCN: 0938-1009); *Frequency:* Monthly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 9,409; *Total Annual Responses:* 17,744; *Total Annual Hours:* 1,896. (For policy questions regarding this collection contact Michael Zleit at 410-786-2050.)

3. *Type of Information Collection*

*Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medical Loss Ratio (MLR) Report for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* We will use the data collection of annual reports provided by plan sponsors for each contract to ensure that beneficiaries are receiving value for their premium dollar by calculating each contract's medical loss ratio (MLR) and any remittances due for the respective MLR reporting year. The recordkeeping requirements will be used to determine plan sponsors' compliance with the MLR requirements, including compliance with how plan sponsors' experience is to be reported, and how their MLR and any remittances are calculated. *Form Number:* CMS-10476 (OCN: 0938-New); *Frequency:* Yearly; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 616; *Total Annual Responses:* 616; *Total Annual Hours:* 28,980. (For policy questions regarding this collection contact Ilna Chaudhuri at 410-786-8628.)

4. *Type of Information Collection*

*Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Enrollment Application for Registration of Eligible Entities That Provide Health Insurance Coverage Complementary to Medicare Part B; *Use:* The primary

function of a Medicare enrollment application is to gather information from a provider, supplier or other entity that tells us who it is, whether it meets certain qualifications to be a health care provider, supplier or entity, where it practices or renders its services, the identity of the owners of the enrolling entity, and information necessary to establish correct claims payments. We are adding a new CMS-855 Medicare Registration Application, the CMS-855C: Medicare Enrollment Application for Registration of Eligible Entities That Provide Health Insurance Coverage Complementary to Medicare Part B. This Medicare registration application is to be completed by all entities that provide a complimentary health benefit plan and intend to bill Medicare as an indirect payment procedure (IPP) biller and the entity or health plan meets all Medicare requirements to submit claims for indirect payments. The entity must furnish the name of at least one authorized official, preferably the administrator of the health plan, who must sign this registration application attesting that the registering entity meets the requirements to register as an indirect payment procedure biller and will also abide by the requirements stated in the Certification & Attestation Statement in Section 10 of the application.

The CMS-855C will be submitted at the time the applicant first requests a Medicare identification number for the sole purpose of submitting claims under the "Indirect Payment Procedure (IPP)" for reimbursement, and when necessary to report any changes to information previously submitted. The application will be used by Medicare contractors to collect data to ensure the applicant has the necessary credentials to submit Medicare claims for reimbursement, including information that allows Medicare contractors to ensure that the entity and its owners and administrators are not sanctioned from the Medicare program, or debarred, suspended or excluded from any other Federal agency or program. *Form Number:* CMS-855(C) (OCN: 0938-New); *Frequency:* Occasionally; *Affected Public:* Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 440; *Total Annual Responses:* 440; *Total Annual Hours:* 500. (For policy questions regarding this collection contact Kim McPhillips at 410-786-5374.)

Dated: June 28, 2013.

**Martique Jones,**

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

[FR Doc. 2013-16085 Filed 7-3-13; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-P-0303]

#### **Determination That METADATE ER (Methylphenidate Hydrochloride) Extended-Release Tablet, 10 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that METADATE ER (methylphenidate hydrochloride (HCl)) extended-release tablet, 10 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for methylphenidate HCl extended-release tablet, 10 mg, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:**

Reena Raman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6238, Silver Spring, MD 20993-0002, 301-796-7577.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to

publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, is the subject of ANDA 40-306, held by UCB, Inc., and initially approved on October 20, 1999. METADATE ER is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: Moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity.

In a letter dated November 4, 2011, UCB, Inc., notified FDA that METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, had been discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Tedor Pharma Inc. submitted a citizen petition dated March 6, 2013 (Docket No. FDA-2013-P-0303), under 21 CFR 10.30, requesting that the Agency determine whether METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that METADATE ER (methylphenidate HCl) extended-release tablet, 10 mg, was withdrawn for