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

Dated: September 27, 2011.

Martique Jones,

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

[FR Doc. 2011–25271 Filed 9–29–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10241, CMS–10412, CMS–R–263, CMS–R–262, CMS–10142 and CMS–855(O)]

Agency Information Collection Activities: Proposed Collection; 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) 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 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Survey of Retail Prices: Payment and Utilization Rates, and Performance Rankings; *Use:* CMS will develop a National Average Drug Acquisition Cost (NADAC) for States to consider when developing reimbursement methodology. The NADAC is a new pricing benchmark that will be based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. It is intended to provide States with a more accurate reference price to base reimbursement for prescription drugs and will be based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey will be conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date. A NADAC Survey Request for Information has been developed to send to random pharmacies for voluntary completion. CMS proposes to add the survey to an existing collection, ''Annual State Report and Annual State Performance Rankings.'' The requirements and burden associated with the annual report/rankings are unaffected by this proposed action; *Form Number:* CMS–10241 (OCN: 0938–1041); *Frequency:* Biennially, Once; *Affected Public:* Private Sector; Business or other for-profits; *Number of Respondents:* 30,000; *Total Annual Responses:* 30,000; *Total Annual Hours:* 15,000. (For policy questions regarding this collection contact Lisa Ferrandi at 410–786–5445. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Section 1115 Demonstration: Long Term Services and Supports and Other Service Models for Individuals with Disabilities and Chronic Conditions; *Use:* Section 1115 of the Social Security Act provides the Secretary of Health and Human Services broad authority to authorize experimental, pilot, or demonstration projects likely to assist in promoting the objectives of the Medicaid statute. Flexibility under Section 1115 is sufficiently broad to allow states to test substantially new ideas of policy merit. States seeking interventions for individuals needing LTSS to lower costs, improve care and improve health can utilize the 1115 demonstration to test and deliver innovative services and approaches to better and more efficiently meet the needs of this population. Section 1115 demonstrations provide a vehicle for innovations in both care delivery and payment methodologies. Demonstrations must be ''budget neutral'' over the life of the project, meaning they cannot be expected to cost the Federal government more than it would cost without the waiver. State Medicaid agencies are responsible for developing section 1115 demonstration applications and submitting them to CMS; *Form Number:* CMS–10412 (OCN: 0938–New); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 2,240. (For policy questions regarding this collection contact Adrienne Delozer at 410–786–0278. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Site Investigation for Durable Medical Equipment (DME) Suppliers; *Use:* CMS is mandated to identify and implement measures to prevent fraud and abuse in the Medicare program. To meet this challenge, CMS has moved forward to improve the quality of the process for enrolling suppliers into the Medicare program by establishing a uniform application for enumerating suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Implementation of enhanced procedures for verifying the enrollment information has also improved the enrollment process. As part of this process, verification of compliance with supplier standards is necessary. The site investigation form has been used in the past to aid the Medicare contractor (the National Supplier Clearinghouse and/or its subcontractors) in verifying compliance with the required supplier standards found in 42 CFR 424.57(c). The primary function of the site investigation form is to provide a standardized, uniform tool to gather information from a DMEPOS supplier that tells us whether it meets certain qualifications to be a DMEPOS supplier (as found in 42 CFR 424.57(c)) and where it practices or renders its services.

This site investigation form collects the same information as its predecessor, with the exception of one new yes/no question under the ''Records and Telephone'' section (question 11(a)) used to verify if the DMEPOS supplier maintains physician ordering/referring records for the supplies and/or services it renders to Medicare beneficiaries (if applicable). This information is required by Section 1833(q) of the Social Security Act which states that all physicians and non-physician practitioners that meet the definitions at section 1861(r) and 1842(b)(18)(C) be uniquely identified for all claims for services that are ordered or referred. Other information collected on this site investigation remains unchanged, but has been reformatted for greater functionality. *Form Number:* CMS–R–263 (OCN: 0938–0749); *Frequency:* Once; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 30,000; *Total Annual Responses:* 30,000; *Total Annual Hours:* 15,000. (For policy questions regarding this collection contact Kimberly McPhillips at 410–

786–5374. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the Plan Benefit Package (PBP) software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. Additionally, CMS uses the PBP and formulary data to review and approve the plan benefit packages proposed by each MA and PDP organization.

CMS requires that MA and PDP organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval.

CMS is requesting to continue its use of the PBP software and formulary submission for the collection of benefits and related information for CY 2013 through CY 2015. CMS estimates that 571 MA organizations and 64 PDP organizations will be required to submit the plan benefit package information in CY 2013. Based on operational changes and policy clarifications to the Medicare program and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission. *Form Number:* CMS–R–262 (OCN: 0938–0763); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 635; *Total Annual Responses:* 6,015; *Total Annual Hours:* 53,291. (For policy questions regarding this collection contact Kristy Holtje at 410–786–2209. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and implementing regulations at 42 CFR, Medicare Advantage organizations (MAO) and Prescription Drug Plans (PDP) are required to submit an actuarial pricing ''bid'' for each plan offered to Medicare beneficiaries for approval by the Centers for Medicare & Medicaid Services (CMS).

MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid. The information provided in the BPT is the basis for the plan's enrollee premiums and CMS payments for each contract year. The tool collects data such as medical expense development (from claims data and/or manual rating), administrative expenses, profit levels, and projected plan enrollment information. By statute, completed BPTs are due to CMS by the first Monday of June each year.

CMS reviews and analyzes the information provided on the Bid Pricing Tool. Ultimately, CMS decides whether to approve the plan pricing (i.e., payment and premium) proposed by each organization. CMS is requesting to continue its use of the BPT for the collection of information for CY2013 through CY2015. *Form Number:* CMS–10142 (OCN: 0938–0944); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 530; *Total Annual Responses:* 4,770; *Total Annual Hours:* 143,100. (For policy questions regarding this collection contact Diane Spitalnic at 410–786–5745. For all other issues call 410–786–1326.)

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Registration Application; *Use:* The CMS 855O allows a physician to receive a Medicare identification number (without being approved for billing privileges) for the sole purpose of ordering and referring Medicare beneficiaries to Medicare approved providers and suppliers. This new Medicare registration application form allows physicians who do not provide services to Medicare beneficiaries to be given a Medicare identification number without having to supply all the data required for the submission of Medicare claims. It also allows the Medicare program to identify ordering and referring physicians without having to validate the amount of data necessary to determine claims payment eligibility (such as banking information), while continuing to identify the physician's credentials as valid for ordering and referring purposes. Since the physicians and non-physician practitioners submitting this application are not enrolling in Medicare to submit claims but are only registering with Medicare as eligible to order and refer, CMS believes changing the title from Medicare Enrollment Application to Medicare Registration Application better captures the actual purpose of this form.

Where appropriate, CMS has changed all references to enrollment or enrolling to registration and registering and Medicare billing number to National Provider Identifier. CMS also added a check box to allow physicians and non-physician practitioners to withdraw from the ordering and referring registry. A section to collect information on professional certifications was added for those practitioners who are not professionally licensed. Editorial and formatting corrections were made in response to prior comments received during the approval of the current version of this application. Other minor editorial and formatting corrections were made to better clarify the purpose of this application. *Form Number:* CMS–855(O) (OCN: 0938–1135); *Frequency:* Occasionally; *Affected Public:* Individuals; *Number of Respondents:* 48,500; *Total Annual Responses:* 48,500; *Total Annual Hours:* 24,125. (For policy questions regarding this collection contact Kimberly 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 E-mail 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.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments must be received by November 29, 2011, and submitted in one of the following ways:

1. *Electronically.* You may submit 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) 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.

Dated: *September 27, 2011.*

Martique Jones,

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

[FR Doc. 2011–25274 Filed 9–29–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Refugee Data Submission System for Allocation of Formula Funds.

OMB No.: 0970–0043.

Description: The Refugee Data Submission System for Allocation of Formula Funds is designed to satisfy the statutory requirements of the Immigration and Naturalization Act (INA). Section 412(a)(3)of the Act requires that the Director of the Office of Refugee Resettlement (ORR) make a periodic assessment of the needs of refugees for assistance and services and the resources available to meet those needs. This assessment includes compiling and maintaining data on secondary migration of refugees within the United States after arrival. Further, INA 412(c)(1)(B)states that formula funds shall be allocated based on the total number of refugees in each State, taking into account secondary migration.

In order to meet these statutory requirements, ORR requires each State to submit disaggregated individual records containing certain data elements for eligible populations. ORR uses the information collected through the Web site to determine secondary migration for the purposes of formula funds allocation to States.

The submission of individual records via the Refugee Data Submission System for Allocation of Formula Funds is a reliable and secure process for collecting data for the purposes of tracking secondary migration and allocating formula funds. Data submitted by the States via the Web site are also compiled and analyzed for inclusion in ORR's Annual Report to Congress.

Respondents: States, Wilson/Fish Alternative Projects, and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Refugee Data Submission for Formula Funds Allocations	50	1	20	1,000

Estimated Total Annual Burden Hours: 1,000.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–25210 Filed 9–29–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0691]

Draft Guidance on Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Media Fills for Validation of Aseptic Preparations for Positron Emission Tomography (PET) Drugs.'' This draft guidance is intended to help manufacturers of PET drugs meet the requirements for the Agency's current good manufacturing practice regulations for PET drugs.

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