easy use by beneficiaries who file their own claims. The form can be obtained from any Social Security office or Medicare carrier. *Frequency:* Reporting—On occasion; *Affected Public:* State, Local, or Tribal Government, Business or other-for-profit, Not-for-profit institutions; *Number of Respondents:* 1,048,243; *Total Annual Responses:* 991,160,925; *Total Annual Hours:* 23,815,541. (For policy questions regarding this collection contact Brian Reitz at 410–786–5001. 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.

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 10, 2011.*

OMB, Office of Information and Regulatory Affairs.

Attention: CMS Desk Officer.

Fax Number: (202) 395–6974.

E-mail:

OIRA_submission@omb.eop.gov.

Dated: December 6, 2010.

Michelle Shortt,

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

[FR Doc. 2010–31075 Filed 12–9–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–21 and CMS–21B, CMS–37, CMS–64, CMS–10120, CMS–10224, CMS–10098, CMS–10292 and CMS–10220]

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:* Extension without change of a currently approved collection; *Title of Information Collection:* CMS–21 (Quarterly Children's Health Insurance Program (CHIP) Statement of Expenditures for the Title XXI Program) and CMS–21B (State Children's Health Insurance Program Budget Report for the Title XXI Program State Plan Expenditures); *Use:* Forms CMS–21 and –21B provide CMS with the information necessary to issue quarterly grant awards, monitor current year expenditure levels, determine the allowability of State claims for reimbursement, develop CHIP financial management information, provide for State reporting of waiver expenditures, and ensure that the Federally established allotment is not exceeded. Further, these forms are necessary in the redistribution and reallocation of unspent funds over the Federally mandated timeframes; *Form Numbers:* CMS–21 and CMS–21B (OMB#: 0938–0731); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 448; *Total Annual Hours:* 7,840. (For policy questions regarding this collection contact Jonas Eberly at 410–786–6232. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicaid Program Budget Report; *Use:* Form CMS–37 is prepared and submitted to the Centers for Medicare & Medicaid Services (CMS) by State Medicaid agencies. Form CMS–37 is the primary document used by CMS in developing the national Medicaid budget estimates that are submitted to the Office of Management and Budget and the Congress; *Form Number:* CMS–37 (OMB#: 0938–0101); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 7,616. (For policy questions regarding this collection contact Jonas Eberly at 410–786–6232. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program; *Use:* Form CMS–64 has been used since January 1980 by the Medicaid State Agencies to report their actual program benefit costs and administrative expenses to CMS. CMS uses this information to compute the Federal financial participation (FFP) for the State's Medicaid Program costs. Certain schedules of the CMS–64 form are used by States to report budget, expenditure and related statistical information required for implementation of the Medicaid portion of the State Children's Health Insurance Programs; *Form Number:* CMS–64 (OMB#: 0938–0067); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 16,464. (For policy questions regarding this collection contact Jonas Eberly at 410–786–6232. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* 1932 State Plan Amendment Template; *Use:* Section 1932(a)(1)(A) of the Social Security Act (the Act) grants states the authority to enroll Medicaid beneficiaries on a mandatory basis into managed care entities, managed care organizations (MCOs) and primary care case managers (PCCMs). Under this authority, a state can amend its Medicaid state plan to require certain categories of Medicaid beneficiaries to enroll in managed care entities without being out of compliance. This template may be used by states to easily modify their state plans if they choose to implement the provisions of section 1932(a)(1)(A).

The State Medicaid Agencies will complete the template. CMS will review the information to determine if the state has met all the requirements of section 1932(a)(1)(A) and 42 CFR 438.50. If the requirements are met, CMS will approve the amendment to the state's title XIX plan giving the state the authority to enroll Medicaid beneficiaries on a mandatory basis into managed care entities MCOs and PCCMs. For a state to receive Medicaid funding, there must be an approved title XIX state plan; *Form Number:* CMS–10120 (OMB#:

0938–0933); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 10; *Total Annual Hours:* 100. (For policy questions regarding this collection contact Camille Dobson at 410–786–7065. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Healthcare Common Procedure Coding System (HCPCS); *Use:* In October 2003, the Secretary of Health and Human Services delegated the Center for Medicare and Medicaid Services (CMS) authority to maintain and distribute HCPCS Level II Codes. As a result, the National Panel was delineated and CMS continued with the decision-making process under its current structure, the CMS HCPCS Workgroup (herein referred to as "the Workgroup". CMS' HCPCS Workgroup is an internal workgroup comprised of representatives of the major components of CMS, and private insurers, as well as other consultants from pertinent Federal agencies. Currently the application intake is paper-based. However, the process has grown and the HCPCS staff is exploring electronic processes for the collection and storage of applications. We have received feedback on the nature of the application; and have streamlined the form into a user-friendly application. The content of the material is the same, but the questions have been refined in accordance with comments received from industry members; and the level of necessity of the information required to render quality coding decision as determined by the CMS workgroup. The information on the form is used to update the HCPCS code set. All information is received and distributed to CMS' HCPCS workgroup and is reviewed and discussed at workgroup meetings. In turn, CMS' HCPCS workgroup reaches a decision as to whether a change should be made to codes in the HCPCS code set. The respondent who submits the application form can be anyone who has an interest in obtaining a code or modifying an existing code. However, respondents are usually manufacturers of products, or consultants on behalf of the manufacturer. *Form Number:* CMS–10224 (OMB#: 0938–1042; *Frequency:* Occasionally; *Affected Public:* Private Sector, Business and other for-profit and not-for-profit institutions; *Number of Respondents:* 300; *Total Annual Responses:* 300; *Total Annual Hours:* 3300. (For policy questions regarding this collection contact Felicia Eggleston at 410–786–9287 or Lori Anderson at 410–786–6190. For all other issues call 410–786–1326.)

6. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Beneficiary Satisfaction Survey; *Use:* The Beneficiary Satisfaction survey is performed to insure that the CMS 1–800–MEDICARE Helpline contractor is delivering satisfactory service to the Medicare beneficiaries. It gathers data on several Helpline operations such as print fulfillment and websites tool hosted on *http://www.medicare.gov.* Respondents to the survey are Medicare beneficiaries that have contacted 1–800–MEDICARE for information on benefits and services. CMS is seeking approval for additional questions to be added to the original collection entitled 800-Medicare Beneficiary Satisfaction survey. The original set of questions was used when placing outbound calls to callers regarding the service they received when they called the 800 Medicare Helpline with a Medicare question. The new expanded collection will include multiple survey methods to measure customer satisfaction not only with the Beneficiary Contact Center's (BCC's) handling of issues via telephone, but also the service provided to beneficiaries when they write a letter regarding their Medicare issue or use the e-mail and/or web chat services provided by the BCC. The use of Customer Satisfaction Surveys is critical to the CMS mission to provide service to beneficiaries that is convenient, accessible, accurate, courteous, professional and responsive to the needs of diverse groups. *Form Number:* CMS–10098 (OMB#: 0938–0919); *Frequency:* Weekly, Monthly, and Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 36,144; *Total Annual Responses:* 36,144; *Total Annual Hours:* 6033. (For policy questions regarding this collection contact Mark Broccolino at 410–786–6128. For all other issues call 410–786–1326.)

7. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Medicaid Health Information Technology Plan, Planning-Advance Planning Document and Update, Implementation Advance Planning Document and Update, and Annual Implementation of Advance Planning Document to Implement Section 4201 of the American Reinvestment and Recovery Act of 2009; *Use:* Section 4201 of Recovery Act establishes 100 percent Federal Financial Participation (FFP) as reimbursement to States for making incentive payments to providers for meaningful use of certified electronic health record technology and 90 percent FFP for administering these payments. Additionally, States are required to conduct oversight of this program and ensure no duplicate payments; thus, CMS is requiring States to submit information to CMS for prior approval before drawing down funding. These documents, if States choose to implement these flexibilities, will require a collection of information to effectuate these changes.

The State Medicaid agencies will complete the templates. CMS will review the information to determine if the State has met all of the requirements of the Recovery Act provisions the States choose to implement. If the requirements are met, CMS will approve the amendments giving the State the authority to implement their Health Information Technology (HIT) strategy and implementation plans. For a State to receive Medicaid Title XIX funding, there must be an approved State Medicaid HIT Plan, Planning Advance Planning Document and Implementation Advance Planning Document; *Form Number:* CMS–10292 (OMB#: 0938–1088); *Frequency:* Yearly, Once, Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 56. (For policy questions regarding this collection contact Sherry Armstead at 410–786–4342. For all other issues call 410–786–1326.)

8. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Provider Enrollment, Chain and Ownership System (PECOS) Security Consent Form; *Use:* The primary function of the Medicare enrollment application is to obtain information about the provider or supplier and whether the provider or supplier meets Federal and/or State qualifications to participate in the Medicare program. In addition, the Medicare enrollment application gathers information regarding the provider or supplier's practice location, the identity of the owners of the enrolling organization, and information necessary to establish the correct claims payment. In establishing a Web based application process, we allow providers and suppliers the ability to enroll in the Medicare program via the Internet. For these applicants, no security consent form is needed to enroll or make a change in their Medicare enrollment information. These applicants receive complete access to their own

enrollments through Internet-based Provider Enrollment, Chain and Ownership System (PECOS).

In order to allow a provider or supplier to delegate the Medicare credentialing process to another individual or organization, it is necessary to establish a Security Consent Form for those providers and suppliers who choose to have another individual or organization access their enrollment information and complete enrollments on their behalf. These users could consist of administrative staff, independent contractors, or credentialing departments and are represented as Employer Organizations. Employer Organizations and its members must request access to enrollment data through a Security Consent Form. The security consent form replicates business service agreements between Medicare applicants and organizations providing enrollment services.

We are proposing two different versions of the Security Consent Form. The form, once signed, mailed and approved, grants an employer organization or its members access to all current and future enrollment data for the Medicare provider. *Form Number:* CMS–10220 (OMB#: 0938–1035); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 197,500; *Total Annual Responses:* 197,500; *Total Annual Hours:* 49,375. (For policy questions regarding this collection contact Alisha Banks at 410–786–0671. 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 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 and recommendations must be submitted in one of the following ways by February 8, 2011:

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: December 6, 2010.

Michelle Shortt,

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

[FR Doc. 2010–31071 Filed 12–9–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–E–0510]

Determination of Regulatory Review Period for Purposes of Patent Extension; COARTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for COARTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product COARTEM (artemether/lumefantrine). COARTEM is indicated for treatment of acute, uncomplicated malaria infections due to *Plasmodium falciparum* in patients of 5 kilograms bodyweight and above. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for COARTEM (U.S. Patent No. 5,677,331) from Novartis AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 17, 2010, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of COARTEM represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for COARTEM is 285 days. Of this time, zero days occurred during the testing phase of the regulatory review period, while 285 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C act) (21 U.S.C. 355(i)) became effective:* not applicable. FDA has verified the