

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10117, 10118, 10119, 10135, 10136, 10214, and CMS-10216]

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

**AGENCY:** Centers for Medicare & Medicaid Services, Department of Health and Human Services.

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:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Advantage Applications: Medicare Advantage (MA) Application Coordinated Care Plans (CMS-10117), Medicare Advantage (MA) Application Private Fee-For-Service Plans (CMS-10118); Medicare Advantage (MA) Application Regional PPO Plans (CMS-10119); Medicare Advantage (MA) Application Service Area Expansion (SAE) for Coordinated Care Plans: Private Fee For Service Plans (CMS-10135); Medical Savings Account Plans (CMS-10136), and Employer Group Waiver Plans (CMS-10214); *Form Number:* CMS-10117, 10118, 10119, 10135, 10136 and 10214 (OMB#: 0938-0935); *Use:* An entity seeking a contract as an MA organization must be able to provide Medicare's basic benefits plus meet the organizational requirements set out under the regulations at 42 CFR Part 422. An applicant must demonstrate that it can meet the benefit and other requirements within the specific geographic area it is requesting. The

application forms are designed to give CMS the information needed to determine a health plan's compliance with the regulations at 42 CFR Part 422. The MA application forms will be used by CMS to determine whether an entity is eligible to enter into a contract to provide services to Medicare beneficiaries; *Frequency:* Reporting—Once; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 220; *Total Annual Responses:* 220; *Total Annual Hours:* 5580.

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Alternative Benefits State Plan Amendment Health Opportunity Accounts (HOA) Demonstration Program; *Use:* The DRA provides States with numerous flexibilities in operating their State Medicaid programs. For example, Section 6082 of the DRA allows up to 10 States to operate Medicaid demonstrations to test alternative systems for delivering their Medicaid benefits. Under these demonstrations, States would have the flexibility to deliver their Medicaid benefits to volunteer beneficiaries through a program that is comprised of an HOA and a High Deductible Health Plan (HDHP). Under the DRA, States can submit a State Plan Pre-print to CMS to effectuate this change to their Medicaid programs. CMS will provide a State Medicaid Director letter providing guidance on this provision and the implementation of the DRA and the associated State Plan Amendment template for use by States to modify their Medicaid State Plans if they choose to implement this flexibility; *Form Number:* CMS-10216 (OMB#: 0938-1007); *Frequency:* Reporting: One-time; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 10; *Total Annual Hours:* 10.

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](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch,

Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: June 8, 2007.

**Michelle Shortt,**

*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 Identifier: CMS-R-216, CMS-R-262, CMS-10173, and CMS-R-308]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Department of Health and Human Services.

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 of a currently approved collection; *Title of Information Collection:* Issuance of Advisory Opinions Concerning Physicians' Referrals; *Use:* Section 1877(g)(6) of the Social Security Act (the Act), requires that the Department of Health and Human Services issue advisory opinions concerning whether the referral of a Medicare patient by a physician for certain designated health services (other than clinical laboratory services) is prohibited under the physician referral provisions of the Social Security Act. Section 1877(g)(6) of the Act requires that the Department of Health and Human Services accept

requests for advisory opinions made after November 3, 1997 and before August 21, 2000. Section 543 of the Benefits Improvement and Protection Act of 2001, Public Law 106-554, extended indefinitely the period during which the Department of Health and Human Services accepts requests for these advisory opinions. The collection of information contained in 42 CFR 411.372 and 411.373 is necessary to comply with this statutory mandate, and allow CMS to consider requests for advisory opinions and provide accurate and useful opinions. *Form Number:* CMS-R-216 (OMB#: 0938-0714); *Frequency:* Once; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 50 *Total Annual Responses:* 50; *Total Annual Hours:* 1,000.

2. *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:* CMS requires that MA and PDP organizations submit a completed formulary and PBP 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. To see the comprehensive list of changes from CY2007 to CY2008, please refer to the document entitled "Appendix B—PBP-Formulary CY2008 List of Changes." *Form Number:* CMS-R-262 (OMB#: 0938-0763); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 450 *Total Annual Responses:* 4725; *Total Annual Hours:* 10,800.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Individuals Authorized Access to the CMS Computer Services (IACS); *Form Number:* CMS-10173 (OMB#: 0938-0989) *Use:* The Centers for Medicare and Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval of the Individuals Authorized to Customer Service Application for Access to CMS Computer Systems. The IACS system provides a centralized user provisioning and administration service that supports the creation, deletion, and lifecycle management of enterprise identities. This service creates accounts, supports Role Based Access Control (RBAC), the form flow approval process and

enterprise identity audit and recertification, and provides business application integration points. An application integration point allows business application owners to use the form flow process of the user provisioning service to approve or deny requests for access to business applications. The primary purpose of this system is to implement a unified framework for managing user information and access rights, for those individuals who apply for and are granted access across multiple CMS systems and business contexts. Information in this system will also be used to: (1) Support regulatory and policy functions performed within the Agency or by a contractor or consultant; (2) support constituent requests made to a Congressional representative; and (3) to support litigation involving the Agency related to this system. Although the Privacy Act requires only that the "routine use" portion of the system be published for comment, CMS invites comments on all portions of this notice. *Frequency:* As required; *Affected Public:* Individuals or households; Business or other for-profit and not-for-profit; State, Local or Tribal governments; *Number of Respondents:* 60,000,000 *Total Annual Responses:* 15,000,000; *Total Annual Hours:* 15,000,000.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Children's Health Insurance Program and Supporting Regulations in 42 CFR 431.636, 457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, and 457.1180; *Form Number:* CMS-R-308 (OMB#: 0938-0841) *Use:* States are required to submit title XXI plans and amendments for approval by the Secretary pursuant to section 2102 of the Social Security Act in order to receive funds for initiating and expanding health insurance coverage for uninsured children. States are also required to submit State expenditure and statistical reports, annual reports and State evaluations to the Secretary as outlined in title XXI of the Social Security Act. *Frequency:* Yearly and quarterly; *Affected Public:* State, Local or Tribal governments; *Number of Respondents:* 56; *Total Annual Responses:* 1,454,601; *Total Annual Hours:* 864,933.

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/>

*Paperwork Reduction Act of 1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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 at the address below, no later than 5 p.m. on August 14, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L Harkless, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: June 7, 2007.

**Michelle Shortt,**

*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. 2007N-0220]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Cover Sheet, FDA Form 3546

**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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the hourly burden necessary to complete FDA Form 3546, "Animal Drug User Fee Cover Sheet."

**DATES:** Submit written or electronic comments on the collection of information by August 14, 2007.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets