

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:* Medicare Consumer Assessment of Health Plan Survey-Fee for Service (CAHPS-FFS); *Form No.:* CMS-10000 (OMB# 0938-0796); *Use:* Under the Balanced Budget Act of 1997, CMS is required to provide general and plan comparative information to beneficiaries that will help them make more informed plan choices. A CAHPS fee-for-service survey is needed to provide information comparable to those data collected from the CAHPS managed care survey; *Frequency:* Annually; *Affected Public:* Individuals or Households; *Number of Respondents:* 142,920; *Total Annual Responses:* 142,920; *Total Annual Hours:* 47,640.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* UPIN (Unique Physician Identification Number) Participating Physicians Directory; *Form No.:* CMS-10091 (OMB# 0938-0905); *Use:* In November of 2000, CMS launched the Participating Physicians Directory on <http://www.medicare.gov>. This particular directory was created to provide beneficiaries with the names, addresses, and specialties of Medicare participating physicians who have agreed to accept assignment on all Medicare claims and covered services. CMS is adding information from already existing sources; in addition, CMS wants to collect a new data element "Accepting New Patients Indicator" which is essential to a beneficiary's search for a physician; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 10,980; *Total Annual Responses:* 10,980; *Total Annual Hours:* 915.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Health Insurance Assistance Program (SHIP) Client Contact Form, Public and Media Activity Form, and Resource Report; *Form No.:* CMS-10028A, B, C (OMB#

0938-0850); *Use:* The State Health Insurance Assistance Program (SHIP) Client Contract form will be completed by SHIP counselors at each counseling event in order to collect SHIP performance data. This data will then be accumulated and analyzed to measure SHIP performance; *Frequency:* Semi-annually and annually; *Affected Public:* State, Local, or Tribal Government, Not-for-profit institutions, and Federal Government; *Number of Respondents:* 12,000; *Total Annual Responses:* 1,000,000; *Total Annual Hours:* 116,747.

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://cms.hhs.gov/regulations/pr/default.asp>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 18, 2003.

Melissa Musotto,

Acting, Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-R-39, CMS-R-243, CMS-R-131, and CMS-10103]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and 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 and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), 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 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:* Home Health Medicare Conditions of Participation (CoP) Information Collection Requirements and Supporting Regulations in 42 CFR 484.10, 484.12, 484.14, 484.16, 484.18, 484.36, 484.48, and 484.52; *Form No.:* CMS-R-39 (OMB# 0938-0365); *Use:* 42 CFR 484 outlines Home Health Agency Medicare CoP to ensure HHAs meet the Federal patient health and safety regulations; *Frequency:* Annually; *Affected Public:* Business or other for-profit, not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents:* 7,122; *Total Annual Responses:* 7,122; *Total Annual Hours:* 854,891.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Agreement Application, Health Care Prepayment Plan and Supporting Regulations in 42 CFR 417.800-417.840.; *Form No.:* CMS-R-243 (OMB# 0938-0768); *Use:* An organization must meet certain requirements to be a Health Care Prepayment Plan that is eligible for a Medicare Section 1833 agreement. The application is the collection form to obtain the information from an organization that would allow CMS staff to determine compliance with the regulations.; *Frequency:* One-time Submission; *Affected Public:* Business or other for-profit, not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 15; *Total Annual Responses:* 15; *Total Annual Hours:* 1,125.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Advanced Beneficiary Notice and Supporting Regulations in 42 CFR 411.404, 411.406, and 411.408.; *Form No.:* CMS-R-131 (OMB# 0938-0566); *Use:* Physicians, practitioners, suppliers, and providers

furnishing Part A or Part B items or services may bill a patient for items of services denied by Medicare as not reasonable and necessary, under Medicare program standards (Section 1862(a)(1) of title XVIII of the Social Security Act (the Act), or under one of several other statutory bases (Section 1862(a)(9), Section 1814(a)(2)(C), Section 1835(a)(2)(A), Section 1861(dd)(3)(A), Section 1834(j)(1), Section 1834(a)(15), and Section 1834(a)(17)(B) of the Act), if they informed the patient, prior to furnishing the items or services and the patient, after being so informed, agreed to pay for the items or services.; *Frequency*: As-needed; *Affected Public*: Business or other for-profit, not-for-profit institutions, and Individuals or households; *Number of Respondents*: 1,084,932; *Total Annual Responses*: 21,171,480; *Total Annual Hours*: 1,764,290.

4. *Type of Information Request*: New Collection; *Title of Information Collection*: Evaluation of PACE as a Permanent Program and a For-Profit Demonstration; *Form No.*: CMS-10103 (OMB# 0938-NEW); *Use*: The Balanced Budget Act of 1997 (BBA) established PACE as a permanent Medicare program and a state option under Medicaid. It also mandated a for-profit demonstration and a study of the "quality and cost" of the permanent program "under the Medicare and Medicaid programs." All PACE Demonstration sites must convert to permanent program sites in 2003. This evaluation will build on the efforts made in the first PACE evaluation (final reports in 2000). Data will be gathered to assess changes in access to care, patient satisfaction, mortality, organizational/operational changes, patient characteristics, outcomes, quality, etc. that have resulted from the BBA legislation. Patient surveys, site surveys, and claims and utilization data gathered at 12 sites will help answer these study questions. Mathematica Policy Research, Inc. is awarded a contract (No. 500-00-0033) to perform this evaluation. A final report is expected in the summer of 2006.; *Frequency*: Other: One-time; *Affected Public*: Individuals or Households, Not-for-profit institutions; *Number of Respondents*: 2,996; *Total Annual Responses*: 2,996; *Total Annual Hours*: 1,723.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at <http://cms.hhs.gov/regulations/pract/default.asp>, or e-mail your request, including your address,

phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room C5-14-03, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 18, 2003.

Melissa Musotto,

Acting, Paperwork Reduction Act Team Leader, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities (PCPID): Notice of Meeting

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID), HHS.

ACTION: Notice of meeting.

DATES: Thursday, January 29, 2004, from 8:30 a.m. to 5 p.m. and Friday, January 30, 2004, from 8:30 a.m. to 12 p.m. The full Committee meeting of the President's Committee for People with Intellectual Disabilities will be open to the public.

ADDRESSES: The meeting will be held at the Aerospace Center Building, Aerospace Auditorium, 6th Floor East, 370 L'Enfant Promenade, SW., Washington, DC 20447. Individuals with disabilities who need special accommodations in order to attend and participate in the meeting (*i.e.*, interpreting services, assistive listening devices, materials in alternative format) should notify Executive Director, Salley Atwater, at 202-619-0634 no later than January 16, 2004. Effort will be made to meet special requests received after that date, but availability of special needs accommodations to respond to these requests cannot be guaranteed. All meeting sites are barrier free.

Agenda: The Committee plans to discuss critical issues relating to

individuals with intellectual disabilities concerning education and transition, family services and support, public awareness, employment, and assistive technology and information.

FOR FURTHER INFORMATION CONTACT:

Sally Atwater, Executive Director, President's Committee for People with Intellectual Disabilities, Aerospace Center Building, Suite 701, 370 L'Enfant Promenade, SW., Washington, DC 20447, Telephone—(202) 619-0634, Fax—(202) 205-9519, E-mail—satwater@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: The PCPID acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs, services, and supports for persons with intellectual disabilities. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with intellectual disabilities and their families.

Dated: December 16, 2003.

Sally Atwater,

Executive Director, President's Committee for People with Intellectual Disabilities.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0549]

Draft Guidance for Industry: Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing, Revision; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing." This draft guidance provides recommendations for sponsors of abbreviated new drug applications (ANDAs) on the design of bioequivalence studies for generic clozapine products. This draft guidance is being issued because an earlier guidance on this topic published in November 1996 needed to be revised to