Dated: August 10, 2007.

Maryam Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–16119 Filed 8–15–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–07–0679]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

Comments are invited 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) ways to enhance 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. Written comments should be received within 60 days of this notice.

Proposed Project

Implementation of an Automated Management Information System (MIS) for the Division for Heart Disease and Stroke Prevention—REVSION—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 1993, the U.S. Congress authorized the Centers for Disease Control and Prevention (CDC) to establish the WISEWOMAN demonstration program to extend the services provided within the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) framework. A subset of the women (those who are 40–64 years of age) who participate in NBCCEDP may also participate in WISEWOMAN. Addressing risk factors such as elevated cholesterol, high blood pressure, obesity, sedentary lifestyle, poor diet, diabetes, and smoking can help reduce a woman's risk of cardiovascular disease-related illness and death.

The Division for Heart Disease and Stroke Division Management Information System will collect in electronic format: (a) Data needed to measure progress by State Heart Disease and Stroke Prevention and WISEWOMAN Programs toward, or achievement of, program performance measures. The respondent population will consist of State Health Department Heart Disease and Stroke Prevention Program Managers and WISEWOMEN Program Managers.

There are no costs to respondents except their time to participate in the survey. Thirty-four respondents from HDSP program and 15 respondents from the WISEWOMAN program will provide input into the proposed system. Respondents reside in each of 39 States, two Tribal organizations, and the District of Columbia.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State Health Officials	49	2	6	588

Dated: August 10, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–16120 Filed 8–15–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–308, CMS–116, CMS–1561/1561A, CMS–417, CMS–10227, CMS–437, CMS–724, CMS–10116, CMS–10142, and CMS–10225]

Agency Information Collection Activities: Submission for OMB Review; 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), 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 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.

2. *Type of Information Collection Request:* Revision of a currently approved collection. In this revision, a number of changes were made to the form and accompanying instructions to facilitate the completion and data entry of the form. Specifically, the enumeration of individuals involved in laboratory testing was eliminated, and the reporting of hours of laboratory operations was streamlined. Some fields were expanded to reflect changes in laboratory demographics (added prison and assisted living facility to location of laboratory testing) and to collect complete information on the number of tests performed in laboratories. There are no program changes; *Title of Information Collection:* Clinical Laboratory Improvement Amendments Application Form and Supporting Regulations at 42 CFR 493.1–.2001; *Form Number:* CMS–116 (OMB#: 0938–0581); *Use:* The application must be completed by entities performing laboratory testing specimens for diagnostic or treatment purposes. This information is vital to the certification process. *Frequency:* Reporting—Biennially; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 187,000; *Total Annual Responses:* 17,960; *Total Annual Hours:* 22,450.

3. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Health Insurance Benefit Agreement and Supporting Regulations at 42 CFR 489; *Form Numbers:* CMS–1561 and 1561A (OMB#: 0938–0832); *Use:* Applicants to the Medicare program are required to agree to provide services in accordance with Federal requirements. The CMS–1561 and 1561A are essential for CMS to ensure that applicants are in compliance with the requirements. Applicants will be required to sign the completed form and provide operational information to CMS to assure that they continue to meet the requirements after approval; *Frequency:* Reporting—Other: All new applicants must complete; *Affected Public:* State, Local or Tribal Governments, Business or Other for-profits and Not-for-profit institutions; *Number of Respondents:* 3,300; *Total Annual Responses:* 3,300; *Total Annual Hours:* 275.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospice Request for Certification in the Medicare Program; *Form Number:* CMS–417 (OMB#: 0938–0313); *Use:* The Hospice Request for Certification Form is the identification and screening form used to initiate the certification process and to determine if the provider has sufficient personnel to participate in the Medicare program; *Frequency:* Reporting—Yearly; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 2,286; *Total Annual Responses:* 2,286; Total Annual Hours: 572.

5. *Type of Information Collection Request:* Existing collection in use without an OMB Control Number; *Title of Information Collection:* PACE State Plan Amendment Pre-print; *Form Number:* CMS–10227 (OMB#: 0938–NEW); *Use:* The Balanced Budget Act of 1997 created section 1934 of the Social Security Act that established the Program for the All-Inclusive Care for the Elderly (PACE). The legislation established the PACE program as a Medicaid State plan option serving the frail and elderly in the home and community. In accordance with the rule published in the November 24, 1999 **Federal Register** (64 FR 66271), if a State elects to offer PACE as an optional Medicaid benefit, it must complete a State Plan Amendment described as Enclosures #3, 4, 5, 6 and 7. In State Medicaid Director letters dated March 23, 1998 and November 9, 2000, CMS advised States that it had provided a suggested pre-print and supplemental pages for a State to express its intention to elect PACE as an option to its State plans. As pre-print packet Enclosures #3–7 were suggested and not required, CMS did not believe at the time that a suggested form required clearance from OMB. The PACE regulation 42 CFR Part 460 was first published in the **Federal Register** as an interim final rule on November 24, 1999. The final PACE rule was published on December 8, 2006. CMS is seeking OMB approval to use Enclosures #3, 4, 5, 6 and 7. The information is used by CMS to affirm that the State elects to offer PACE an optional State plan service and the specifications of eligibility, payment and enrollment for the program. *Frequency:* Reporting—Once; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56 possible responses but we have only received 20 thus far; *Total Annual Hours:* 1,120.

6. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Psychiatric Unit Criteria Worksheet and Supporting Regulations at 42 CFR 412.25 and 412.27. *Form Number:* CMS–437 (OMB# 0938–0358); *Use:* The psychiatric unit criteria worksheets are necessary to verify that these units comply and remain in compliance with the exclusion criteria for the Medicare prospective payment system. *Frequency:* Reporting—Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local and Tribal Government; *Number of Respondents:* 1,333; *Total Annual Responses:* 1,333; *Total Annual Hours:* 333.

7. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Psychiatric Hospital Survey Data and Supporting Regulations at 42 CFR 482.60, 482.61, and 482.62; *Form Number:* CMS–724 (OMB#: 0938–0378); *Use:* The Medicare/Medicaid Psychiatric Hospital Survey is used to collect data that is not collected elsewhere and assists CMS in program planning and evaluation of survey needs. In addition, the survey assists CMS in maintaining an accurate data base on providers participating in the Medicare psychiatric hospital program; *Frequency:* Reporting—Yearly; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 420; *Total Annual Responses:* 200; *Total Annual Hours:* 100.

8. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Program; Conditions of Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles (CMS–3017–F); *Form Numbers:* CMS–10116 (OMB#: 0938–0971); *Use:* The CMS is seeking the reapproval of the collection requirements associated with the final rule, CMS–3017–F (71 FR 17021), which was published on April 5, 2006, and

became effective on June 5, 2006. Specifically, we are seeking OMB approval for the following terms of clearance identified in the Notice of Action dated October 16, 2006, of which OMB has requested CMS to monitor the paperwork burden required of providers and suppliers to determine if the paperwork requirements impose any unnecessary burden on the industry and/or need to be revised in order to improve the utility of the information.

After analyzing the documentation requirements burden, CMS does not believe that the documentation requirements impose any additional unnecessary burden on the durable medical equipment (DME) Industry. We believe that most physicians are already conducting a face-to-face examination before prescribing a wheelchair. Given that physicians and treating practitioners can now prescribe power-operated vehicles (POVs), thereby removing the requirement that a specialist can order a POV, CMS believes that the increased burden of 48,600 hours for physicians and treating practitioners is based on the Congressional decision to allow a broader range of physicians and treating practitioners to prescribe POVs. This increased burden is offset by the new payments implemented in connection with the Final Rule, which is demonstrated by the shift in prescriptions from one class of equipment, power wheelchairs, to another class of equipment, POVs.

In addition, CMS believes that with the recent coverage decision on Mobility Assistive Equipment, the implementing details in the Final Rule (e.g., improved documentation for suppliers; physician and treating practitioner payments; improved classification of mobility equipment; the elimination of the certificate of medical necessity (CMN)), and the provider outreach and education provided by CMS, the DME program safeguard contractors (PSCs) and DME Medicare administrative contractors (MACs), the needs of mobility-impaired beneficiaries and the needs of suppliers have been better met. *Frequency:* Recordkeeping—On occasion; *Affected Public:* Business or for-profits, Not-for-profit institutions, and State, Local or Tribal governments; *Number of Respondents:* 38,000; *Total Annual Responses:* 243,000; *Total Annual Hours:* 48,600.

9. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDPs); *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization (MMA), Medicare Advantage organizations (MAO) and Prescription Drug Plans (PDP) are required to submit an actuarial pricing ''bid'' for each plan offered to Medicare beneficiaries. CMS requires that MAOs and PDPs complete the BPT as part of the annual bidding process. During this process, organizations prepare their proposed actuarial bid pricing for the upcoming contract year and submit them to CMS for review and approval. The purpose of the BPT is to collect the actuarial pricing information for each plan. The BPT calculates the plan's bid, enrollee premiums, and payment rates. *Form Number:* CMS–10142 (OMB#: 0938–0944); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 550 *Total Annual Responses:* 6,050; *Total Annual Hours:* 42,350.

10. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Disclosures to Patients by Certain Hospitals and Critical Access Hospitals; Form Numbers: CMS–10225 (OMB#: 0938–New); *Use:* There is no Medicare prohibition against physician investment in a hospital or critical access hospital (CAH). Likewise, there is no Medicare requirement that a hospital or CAH have a physician on-site at all times, although there is a requirement that they be able to provide basic elements of emergency care to their patients. Medicare quality and safety standards are designed to provide a national framework that is sufficiently flexible to apply simultaneously to hospitals of varying sizes, offering varying ranges of services in differing settings across the Nation. At the same time, however, patients might consider an ownership interest by their referring physician and/or the presence of a physician on-site to be important factors in their decisions about where to seek hospital care. A well-educated consumer is essential to improving the quality and efficiency of the healthcare system. Accordingly, patients should be made aware of the physician ownership of a hospital, whether or not a physician is present in the hospital at all times, and the hospital's plans to address patients' emergency medical conditions when a physician is not present. The intent of the proposed disclosures are increase the transparency of the hospital's ownership and operations to patients as they make decisions about receiving care at the hospital.

Based on public comments received during the 60-day comment period for the **Federal Register** notice (72 FR 21024) for this information collection request, we revised our burden estimates to include the burden associated with the physician-ownership disclosure and recordkeeping requirement for outpatient visits. In addition, we revised the burden associated with the disclosure requirement for critical access hospitals that may not have a physician on-site at all times to account for outpatient visits as well. *Frequency:* Reporting—On occasion; *Affected Public:* Business or for-profits, Not-for-profit institutions; *Number of Respondents:* 2,679; *Total Annual Responses:* 52,984,510; *Total Annual Hours:* 839,599.

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.

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: August 9, 2007.

Michelle Shortt,

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

[FR Doc. E7–16160 Filed 8–15–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0306]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles

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