

II. Registration, Security, Building, and Parking Guidelines

For security purposes, members of the public who wish to attend the meeting must pre-register on-line at <http://www.findyouthinfo.gov> no later than October 12, 2010. Should problems arise with Web registration, call the help desk at 1-877-231-7843 or send a request to register for the meeting to FindYouthInfo@air.org. To register, complete the online registration form, which will ask for your name, title, organization or other affiliation, full address and phone, fax, and e-mail information or e-mail this information to FindYouthInfo@air.org. Additional identification documents may be required. The meetings are held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. Space is limited. In order to gain access to the building and grounds, participants must bring government-issued photo identification as well as their pre-registration confirmation.

Authority: Division F, Pub. L. 111-8; E.O. 13459, 73 FR 8003, February 12, 2008.

Dated: September 30, 2010.

Sherry Glied,

Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-244 and CMS-R-249]

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

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506I(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:** Medicare and Medicaid Programs: Programs of All-Inclusive Care for the Elderly (PACE); **Use:** PACE organizations must demonstrate their ability to provide quality community-based care for the frail elderly who meet their State's nursing home eligibility standards using capitated payments from Medicare and the state. The model of care includes as core services the provision of adult day health care and multidisciplinary team case management, through which access to and allocation of all health services is controlled. Physician, therapeutic, ancillary, and social support services are provided in the participant's residence or on-site at the adult day health center. PACE programs must provide all Medicare and Medicaid covered services including hospital, nursing home, home health, and other specialized services. Financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments. The information collection requirements are necessary to ensure that only appropriate organizations are selected to become PACE organizations and that CMS has the information necessary to monitor the care provided to the frail, vulnerable population served. **Form Number:** CMS-R-244 (OMB#: 0938-0790); **Frequency:** Once and Occasionally; **Affected Public:** State, Local, or Tribal Governments and Not-for-profit institutions; **Number of Respondents:** 99; **Total Annual Responses:** 99; **Total Annual Hours:** 81,911.5. (For policy questions regarding this collection contact Daniella Stanley at 410-786-3723. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Hospice Cost and Data Report and supporting regulations 42 CFR 413.20 and 42 CFR 413.24; **Use:** In accordance with sections 1815(a), 1833(e), and 1861(v)(A)(ii) of the Social Security Act, providers of service in the Medicare program are required to submit annual information to achieve reimbursement for health care services rendered to Medicare beneficiaries. In addition, 42 CFR

413.20(b) sets forth that cost reports will be required from providers on an annual basis. Such cost reports are required to be filed with the provider's fiscal intermediary (FI) or Medicare Administrative Contractor (MAC) no later than the last day of the fifth month following the close of the period covered by the report. **Form Number:** CMS-R-249 (OMB#: 0938-0758); **Frequency:** Yearly; **Affected Public:** Business or other for-profits and Not-for-profit institutions; **Number of Respondents:** 2,303; **Total Annual Responses:** 2,303; **Total Annual Hours:** 405,328. (For policy questions regarding this collection contact Gail Duncan at 410-786-7278. 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 *November 8, 2010*.

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 30, 2010.

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-18F5, CMS-R-262, CMS-10142 and CMS-R-26]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid 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:** Application for Hospital Insurance; **Use:** Individuals who are not entitled to or eligible for railroad retirement board (RRB) or Social Security Administration benefits must file an application for Part A. This group includes individuals who defer filing an application for monthly benefits, individuals who are transitionally insured, government employees who pay only the Hospital Insurance portion of the Federal Insurance Contributions Act tax and individuals eligible for Premium Part A for the Working Disabled. The Application for Hospital Insurance CMS-18F5 was designed to capture all the information needed to make a determination of an individual's entitlement to Part A and Supplementary Medical Insurance (Part B). **Form Number:** CMS-18F5 (OMB#: 0938-0251); **Frequency:** Once; **Affected Public:** Individuals or households; **Number of Respondents:** 50,000; **Total Annual Responses:** 50,000; **Total Annual Hours:** 12,495. (For policy questions regarding this collection contact Naomi Rappaport at 410-786-2175. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Revision of a currently approved collection; **Title of Information Collection:** CY 2012 Plan Benefit Package (PBP) Software and Formulary Submission; **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. Refer to the supporting document "Appendix B" for a list of changes. **Form Number:** CMS-R-262 (OMB#: 0938-0763); **Frequency:** Yearly; **Affected Public:** Business or other for-profits and not-for-profit institutions; **Number of Respondents:** 655; **Total Annual Responses:** 6,878; **Total Annual Hours:** 18,020. (For policy questions regarding this collection contact Kristy Holtje at 410-786-2209. For all other issues call 410-786-1326.)

3. Type of Information Collection Request: Revision of a currently approved collection; **Title of Information Collection:** CY 2012 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 are required to submit an actuarial pricing "bid" for each plan offered to Medicare beneficiaries for approval by 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. **Form Number:** CMS-10142 (OMB#: 0938-0944); **Frequency:** Yearly; **Affected Public:** Business or

other for-profits and not-for-profit institutions; **Number of Respondents:** 550; **Total Annual Responses:** 4,950; **Total Annual Hours:** 34,650. (For policy questions regarding this collection contact Diane Spitalnic at 410-786-5745. For all other issues call 410-786-1326.)

4. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Clinical Laboratory Improvement Amendment (CLIA) of 1988 and Supporting Regulations in 42 CFR 493.1-2001; **Use:** The information collection requirements in 42 CFR 493 outline the requirements necessary to determine an entity's compliance with CLIA. CLIA requires laboratories that perform testing on human beings to meet performance requirements (quality standards) in order to be certified by the Department of Health and Human Services (DHHS). DHHS conducts inspections to determine a laboratory's compliance with CLIA requirements. CLIA implements the certificate, laboratory standards and inspection requirements. **Form Number:** CMS-R-26 (OMB#: 0938-0612); **Frequency:** Occasionally; **Affected Public:** Federal Government; State, Local, or Tribal Governments; Private Sector; Business or other for-profits and Not-for-profit institutions; **Number of Respondents:** 168,688; **Total Annual Responses:** 756,240; **Total Annual Hours:** 11,363,280. (For policy questions regarding this collection contact Raelene Perfetto at 410-786-6876. 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 *December 7, 2010*:

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 30, 2010.

Michelle Shortt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information

are 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.

Proposed Project: 2011-2014 National Survey on Drug Use and Health: Methodological Field Tests (OMB No. 0930-0290-Revision)

The National Survey on Drug Use and Health (NSDUH) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

In March 2008, SAMHSA received a three-year renewal of its generic clearance for methodological field tests. This will be a request for another renewal of the generic approval to continue methodological tests over the next three years, with conditions similar to the previous clearance. These methodological tests will continue to be designed to examine the feasibility, quality, and efficiency of new

procedures or revisions to existing survey protocol. Specifically, the tests will measure the reliability and validity of certain questionnaire sections and items through multiple measurements on a set of respondents; assess new methods for gaining cooperation and participation of respondents with the goal of increasing response and decreasing potential bias in the survey estimates; and assess the impact of new sampling techniques and technologies on respondent behavior and reporting. Research will involve focus groups, cognitive laboratory testing, field tests, and customer surveys.

The next wave of methodological tests will continue to examine ways to increase data quality, lower operating costs, and gain a better understanding of sources and effects of nonsampling error on the NSDUH estimates. Particular attention will be given to minimizing the impact of design changes so that survey data continue to remain comparable over time. If these tests provide successful results, current procedures or data collection instruments may be revised.

The number of respondents to be included in each field test will vary, depending on the nature of the subject being tested and the target population. However, the total estimated response burden is 8,251 hours. The exact number of subjects and burden hours for each test are unknown at this time, but will be clearly outlined in each individual submission. The table below, however, describes the anticipated burden for each of the major testing activities for which generic approval is being tested.

ESTIMATED BURDEN FOR NSDUH METHODOLOGICAL FIELD TESTS

Activity	Number of respondents	Responses per respondent	Total number of responses	Average burden per response (hrs.)	Total burden (hrs.)
a. Focus Groups	270	1	270	2.0	540
b. Cognitive laboratory testing	200	1	200	1.0	200
c. Field Tests	6,600	1	6,600	1.0	6,600
d. Customer Satisfaction Surveys	300	1	300	0.25	75
Household screening for c	8,910	1	8,910	0.083	740
Screening Verification for c	445	1	445	0.067	30
Interview Verification for c	990	1	990	0.067	66
Total	17,715	17,715	8,251
Annual Average (Total divided by 3 years)	5,905	5,905	2,750