information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by April 25, 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.

3. *By Facsimile or E-mail to OMB.* OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: March 18, 2011.

**Martique Jones,**

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

[FR Doc. 2011–7106 Filed 3–24–11; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[Document Identifier CMS–370, CMS–377, CMS–378; CMS–10145, CMS–10362, CMS–10384, CMS–10342 and CMS–10338]**

### 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 & 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:* Revision of a currently approved collection; *Titles of Information Collection:* (CMS–370) Health Insurance Benefits Agreement, (CMS–377) ASC Request for Certification or Update of Certification Information in the Medicare Program, and (CMS–378) Ambulatory Surgical Center (ASC) Survey Report Form; *Use:* CMS–370 has not been revised and will continue to be used to establish eligibility for payment under Title XVIII of the Social Security Act (the "Act"). As revised, CMS–377 will be used to collect facility-specific characteristics that facilitate CMS' oversight of ASCs. The data also enables CMS to respond to inquiries from the Congress, GAO, and the OIG concerning the characteristics of Medicare-participating ASCs. The data base that supports survey and certification activities will be revised to reflect changes in the data fields on this revised form, such as the data on the types of surgical procedures performed in the ASC. CMS–378 will be discontinued since it duplicates information collected by other means; *Form Numbers:* CMS–370, –377 and –378 (OCN: 0938–0266); *Frequency:* Occasionally (initially an then every three years); *Affected Public:* Private Sector: Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 7,213; *Total Annual Responses:* 1,795; *Total Annual Hours:* 648. (For policy questions regarding this collection contact Gail Vong at 410–786–0787. 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:* Medicare Part B Drug and Biological Competitive Acquisition Program (CAP) and Supporting Regulations in 42 CFR Sections 414.906, 414.908, 414.910, 414.914, 414.916, and 414.917; *Use:* Section 303(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides an alternative payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. In particular, Section 303(d) of the MMA amends Title XVIII of the Social Security Act by adding a new section 1847B, which establishes a competitive acquisition program for the acquisition of and payment for Part B covered drugs and biologicals furnished on or after January 1, 2006. Since its inception, additional legislation has augmented the CAP. Section 108 of the Medicare Improvements and Extension Act under Division B, Title I of the Tax Relief Health Care Act of 2006 (MIEA–TRHCA) amended Section 1847b(a)(3) of the Social Security Act and requires that CAP implement a post payment review process. This procedure is done to assure that payment is made for a drug or biological under this section only if the drug or biological has been administered to a beneficiary. *Form Number:* CMS–10145 (OCN: 0938–0945); *Frequency:* Weekly, quarterly and occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 3000; *Total Annual Responses:* 156,020; *Total Annual Hours:* 31,208.

3. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Autism Spectrum Disorders (ASD): State of the States Services and Supports for People with ASD; *Use:* The information that is collected in the interviews will be used to communicate additional information about services available to people with ASD and the public policy issues that affect people with ASD to key stakeholder audiences. The format of the report will include data tables from various state programs and narrative about the data being presented based on the interviews with state agency staff. We propose interviewing multiple staff in each state because several state agencies have an impact on services and supports for people with ASD; *Form Number:* CMS–10362 (OCN: 0938–New); *Frequency:* Once; *Affected Public:* State, local, or Tribal Governments; *Number of Respondents:* 459; *Total Annual Responses:* 459; *Total Annual Hours:* 803. (For policy questions regarding this collection contact Ellen Blackwell at 410–786–4498. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Health Insurance Assistance Database; *Use:* In October 2010, the Office of Consumer Support began to take and respond to direct consumer inquiries related to the Affordable Care Act. As of February 15th 2011, CCIIO has received 906 consumer inquiries. Consumer inquiries continue to come in to CCIIO at a rate of 30 to 35 inquiries per week. Starting in January 2011, the HHS Hotline will begin to refer ACA calls to CCIIO. To date, the HHS Hotline receives, on average, 400 calls per month pertaining to ACA.

Accordingly, a system to collect, track and store consumer information is urgently needed in order to accomplish

successful case management to ensure that the information, coverage, and health care needs of consumers are addressed fairly and in a timely fashion. Further, the Team will provide detailed reports on these consumer inquiries with a focus on Affordable Care Act and PHS Act compliance issues. These reports will assist the Office of Oversight in identifying areas where compliance concerns may arise. Reports will be stripped of any information in identifiable form (IIF) and personal health information when written and prepared. Authority for maintenance, collection and disclosures of this information is given under sections 2719, 2723, and 2761 of the Public Health Service Act (PHS Act) and section 1321(c) of the Affordable Care Act.

Analysis of this data reporting will help identity patterns of practice in the insurance marketplaces and uncover suspected patterns of noncompliance. HHS may share program data reports with the Departments of Labor and Treasury, and State regulators. Program data also can offer CCIIO one indication of the effectiveness of State enforcement, affording opportunities to provide technical assistance and support to State insurance regulators and, in extreme cases, inform the need to trigger federal enforcement. *Form Number:* CMS–10384 (OCN: 0938–New); *Frequency:* Occasionally; *Affected Public:* Individuals or households; *Number of Respondents:* 1200; *Number of Responses:* 1,860; *Total Annual Hours:* 195 (For policy questions regarding this collection, contact Paul Tibbits (301) 492–4229. For all other issues call (410) 786–1326.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Annual Limits Waiver Online Application Form; *Use:* Under section 2711(a)(2) of the Public Health Service Act, as amended by the Affordable Care Act section 1302(b), The Secretary of Health and Human Services is required to impose restrictions on the dollar value of essential benefits provided by new or existing group health plans or individual policies in the market between September 23, 2010 and January 1, 2014. The interim final regulations published June 28, 2010 (45 CFR § 147.126) give the Secretary the authority to waive these restricted annual limits if compliance would result in a significant increase in premium or significant decrease in access to benefits for those already covered. CMS is in the process of evaluating applications for waivers of annual limits and seeks to publish an updated Microsoft Excel spreadsheet to standardize and simplify the data collection process. Applicants must fill out (1) spreadsheet per application. The spreadsheet is a mandatory component of each waiver application necessary to fulfill the statutory requirements under section 2711(a)(2) of the Public Health Service Act. The information collected includes applicant contact information; information about the annual limit(s) on the overall plan or policy and on essential health benefits (as defined by the Affordable Care Act section 1302(b)); information about plan design such as copayment, coinsurance, and deductibles; financial projections by enrollee tier; and a description of how a significant decrease in access to benefits would result from compliance with section 2711(a)(2) of the Affordable Care Act. This information is required to accurately and objectively assess whether compliance with the restricted annual limits would result in the aforementioned significant increase in premium or significant decrease in access to benefits, on which the grant of a waiver is conditioned in the interim final regulations. The updated spreadsheet contains a more detailed description of what values should be entered into each cell. This description should save applicants time when completing the spreadsheet initially, and it should lessen the need for applicants to go back and correct mistakes after submission. *Form Number:* CMS–10342 (OCN: 0938–1105); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 4,872; *Number of Responses:* 4,608,372; *Total Annual Hours:* 178,183. (For policy questions regarding this collection, contact Erika Kottenmeier at (301) 492–4170. For all other issues call (410) 786–1326.)

6. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers; *Use:* The Patient Protection and Affordable Care Act, Public Law 111–148, (the Affordable Care Act) was enacted by President Obama on March 23, 2010. As part of the Act, Congress added PHS Act section 2719, which provides rules relating to internal claims and appeals and external review processes. These interim final regulations (IFR) set forth rules implementing PHS Act section 2719 for internal claims and appeals and external review processes. With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 and paragraph (b)(2)(i) of the interim final regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503–1 (the DOL claims procedure regulation) and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulations. Paragraph (b)(3)(i) requires issuers offering coverage in the individual health insurance market to also comply with the DOL claims procedure regulation as updated by the Secretary of HHS in paragraph (b)(3)(ii) of the interim final regulations for their internal claims and appeals processes.

The DOL claims procedure regulation requires plans to provide every claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions. In addition, paragraph (b)(3)(ii)(C) of the interim final regulations adds an additional requirement that non-grandfathered ERISA-covered group health plans provide to the claimant, free of charge, any new or additional evidence considered relied upon, or generated by the plan or issuer in connection with the claim.

Also PHS Act section 2719 and these interim final regulations provide that group health plans and issuers offering group health insurance coverage must comply either with a State external review process or a Federal review process. The regulations provide a basis for determining when plans and issuers must comply with an applicable State external review process and when they must comply with the Federal external review process. *Form Number:* CMS–10338 (OCN: 0938–1099); *Frequency:* Occasionally; *Affected Public:* State, Local, Tribal Governments; *Number of Respondents:* 36,344; *Number of Responses:* 2,762,824; *Total Annual Hours:* 211,216,845. (For policy questions regarding this collection,

contact Tara Oakman at (301) 492–4253. 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 at 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 May 24, 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: March 18, 2011.

**Martique Jones,**

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

[FR Doc. 2011–7104 Filed 3–24–11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

**[Document Identifier CMS–10328 and CMS–10319]**

### Agency Information Collection Activities: Submission for OMB Review; 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 & 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:* Revision of currently approved collection; *Title of Information Collection:* Medicare Self-Referral Disclosure Protocol; *Use:* Section 6409 of the ACA requires the Secretary to establish and post information on the CMS' public Internet Web site concerning a self-referral disclosure protocol (SRDP) that sets forth a process for providers of services and suppliers to self-disclose actual or potential violations of section 1877 of the Act. In addition, section 6409(b) of the ACA gives the Secretary authority to reduce the amounts due and owing for the violations. This information collection request is necessary in order to inform the public of the process and the types of information needed to participate in the SRDP.

The SRDP is a voluntary self-disclosure instrument that will allow providers of services and suppliers to disclose actual or potential violations of section 1877 of the Act. CMS will analyze the disclosed conduct to determine compliance with section 1877 of the Act and the application of the exceptions to the physician self-referral prohibition. In addition, the authority granted to the Secretary under section 6409(b) of the ACA, and subsequently delegated to CMS, may be used to reduce the amount due and owing for violations. *Form Number:* CMS–10328 (OMB#: 0938–1106; *Frequency:* Once; *Affected Public:* Private Sector, Business and other for-profit and not-for-profit institutions; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 1,175. (For policy questions regarding this collection contact Ronke Fabayo at 410–786–4460. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Pre-Existing Condition Insurance Plan Program Solicitation and Contractor's Proposal Package; *Use:* The Department of Health and Human Services (HHS) is requesting a renewal of this package by the Office of Management and Budget (OMB); specifically, HHS is now seeking a three-year approval for this collection. On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111–148. Section 1101 of the law establishes a "temporary high risk health insurance pool program" (which has been named the Pre-Existing Condition Insurance Plan, or PCIP) to provide health insurance coverage to currently uninsured individuals with pre-existing conditions. The law authorizes HHS to carry out the program directly or through contracts with states or private, non-profit entities.

This package renewal is requested as a result of a possible transition in administration of the program from a federally-run to a State administered program. A State who originally decided to have HHS administer the program in their State may in the future notify HHS of their desire to administer the Pre-Existing Condition Plan (PCIP) program. PCIP is also referred to as the temporary qualified high risk insurance pool program, as it is called in the Affordable Care Act, but we have adopted the term PCIP to better describe the program and avoid confusion with the existing state high risk pool programs. *Form Number:* CMS–10319 (OMB#: 0938–1085); *Frequency:* Occasionally; *Affected Public:* State governments; *Number of Respondents:* 2; Total *Annual Responses:* 2; *Total Annual Hours:* 2,992. (For policy questions regarding this collection contact Laura Dash at 301–492–4296. 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 *April 25, 2011.* OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*