

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Member of Research Community	325	1	20/60	108

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2010-6903 Filed 3-26-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10108, CMS-367, CMS-10302, CMS-10179, CMS-R-234 and CMS-2540]

Agency Information Collection Activities: Proposed Collection; 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) 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:* Medicaid Managed Care Regulations for 42 CFR 438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102, 438.114, 438.202, 438.204, 438.206, 438.207, 438.240, 438.242, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.604, 437.710, 438.722, 438.724, and 438.810; *Use:* These information collection requirements implement regulations that allow States greater flexibility to implement mandatory

managed care program, implement new beneficiary protections, and eliminate certain requirements viewed by State agencies as impediments to the growth of managed care programs. Information collected includes information about managed care programs, grievances and appeals, enrollment broker contracts, and managed care organizational capacity to provide health care services. *Form Number:* CMS-10108 (OMB#: 0938-0920); *Frequency:* Reporting: Occasionally; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 39,114,558; *Total Annual Responses:* 4,640,344; *Total Annual Hours:* 3,930,093.5. (For policy questions regarding this collection contact Angela Garner at 410-786-7062. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Program Monthly and Quarterly Drug Reporting Format; *Use:* Section 1927 of the Social Security Act requires drug manufacturers to enter into and have in effect a rebate agreement with the federal government for States to receive funding for drugs dispensed to Medicaid beneficiaries. The Deficit Reduction Act (DRA) of 2005 modified section 1927 to require additional reporting requirements beyond the quarterly data currently collected. CMS Form 367 identifies the data fields that manufacturers must submit to CMS on both a monthly and quarterly basis. *Form Number:* CMS-367 (OMB#: 0938-0578); *Frequency:* Monthly and Quarterly; *Affected Public:* Private Sector; Business or other for-profits; *Number of Respondents:* 580; *Total Annual Responses:* 9,280; *Total Annual Hours:* 137,344. (For policy questions regarding this collection contact Samone Angel at 410-786-1123. For all other issues call 410-786-1326.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen *Use:* Congress enacted the Medicare

Improvement of Patients and Providers Act (MIPPA). Section 182(b) of MIPPA amended section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: 'On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.' We believe that the implementation of this statutory provision that compendia have a "publicly transparent process for evaluating therapies and for identifying potential conflicts of interests" is best accomplished by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. *Form Number:* CMS-10302 (OMB #: 0938-1078); *Frequency:* Reporting, Recordkeeping and Third-party disclosure; *Affected Public:* Business and other for-profits and Not-for-profit institutions; *Number of Respondents:* 845; *Total Annual Responses:* 900; *Total Annual Hours:* 5,135. (For policy questions regarding this collection contact Brijet Burton at 410-786-7364. For all other issues call 410-786-1326.)

4. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Requests by Hospitals for an Alternative Cost-to-Charge Ratio. *Use:* Section 1886(d)(5)(A) of the Act provides for additional Medicare payments to Inpatient Prospective Payment System (IPPS) hospitals for cases that incur

extraordinarily high costs. To qualify for outlier payments, a case must have costs above a predetermined threshold amount (a dollar amount by which the estimated cost of a case must exceed the Medicare payment). Hospital-specific cost-to-charge ratios are applied to the covered charges for a case to determine the estimated cost of the case. In general, additional outlier payments for eligible cases are made based on a marginal cost factor of 80 percent, i.e. a fixed percentage of the costs. Therefore, if the estimated cost of the case exceeds the Medicare payment for that discharge plus the outlier threshold, generally Medicare will pay the hospital 80 percent of the excess amount. The outlier threshold is updated annually at the beginning of the Federal Fiscal Year. *Form Number:* CMS-10179 (OMB #: 0938-1020); *Frequency:* Occasionally; *Affected Public:* Private Sector and Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 18; *Total Annual Responses:* 18 *Total Annual Hours:* 144. (For policy questions regarding this collection contact Michael Treitel at 410-786-4525. For all other issues call 410-786-1326.)

5. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Subpart D—Private Contracts and Supporting Regulations contained in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455. *Use:* Section 4507 of Balancing Budget Act (BBA) 1997 amended section 1802 of the Social Security Act to permit certain physicians and practitioners to opt-out of Medicare and to provide through private contracts services that would otherwise be covered by Medicare. Under such contracts the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. Subpart D and the Supporting Regulations contained in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, and 405.455, counters the effect of certain provisions of Medicare law that, absent section 4507 of BBA 1997, preclude physicians and practitioners from contracting privately with Medicare beneficiaries to pay without regard to Medicare limits. *Form Number:* CMS-R-234 (OMB#: 0938-0730); *Frequency:* Biennially; *Affected Public:* Private Sector and Business or other for-profits; *Number of Respondents:* 26,820; *Total Annual Responses:* 26,820; *Total Annual Hours:* 7,197. (For policy questions regarding this collection contact Fred Grabau at

410-786-0206. For all other issues call 410-786-1326.)

6. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report. *Use:* Providers of services participating in the Medicare program are required under sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act (42 USC 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. *Form Number:* CMS-2540 (OMB#: 0938-0463); *Frequency:* Yearly; *Affected Public:* Private Sector; *Number of Respondents:* 15,071; *Total Annual Responses:* 15,071; *Total Annual Hours:* 2,953,916 (For policy questions regarding this collection contact Edwin Gill Sr. at 410-786-4525. 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 *May 28, 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: March 19, 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-10292, CMS-718-721 and CMS-685]

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:* New Collection; *Title of Information Collection:* State Medicaid HIT Plan and Templates for Implementation of Section 4201 of ARRA; *Form Number:* CMS-10292 (OMB#: 0938-NEW); *Use:* This information is being requested in order that States can submit documentation to CMS for review and approval in order that States can implement the Medicaid program and draw down Federal financial participation. The American Reinvestment and Recovery Act of 2009 (ARRA) provides States with the flexibility to request funds to develop a health information technology vision and road to get to the ultimate goal of meaningful use of certified electronic health records technology. We will be sending State Medicaid Directors letters and templates for the State Medicaid Hit Plan (SMHP), the Planning Advance Planning Document (PAPD) and the Implementation Advance Planning Document (IAPD) to States in an effort to request these changes if they so choose to make the process as simple as possible. *Frequency:* Yearly, once and/or occasionally; *Affected Public:* State, Tribal and Local governments; *Number*