

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. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to [Sherette.funncoleman@hhs.gov](mailto:Sherette.funncoleman@hhs.gov), or call the Reports Clearance Office on (202) 690-6162. Written comments and

recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60-days.

*Proposed Project:* Girls at Greater Risk for Juvenile Delinquency and HIV Prevention Program—OMB No. 0990-NEW—Office on Women’s Health (OWH).

*Abstract:* The Office on Women’s Health (OWH) is seeking a new clearance to conduct a three year data collection associated with the evaluation of the “Girls at Greater Risk for Juvenile Delinquency and HIV Prevention Program”. The evaluation is

designed to determine best practices and gender-responsive strategies for at-risk girls and adolescents between the ages of nine and 17 years. Data will be collected from program participants, parents of program participants, program staff (i.e. program directors and program staff), program partners and community residents and will be submitted to OWH on a quarterly basis. Primarily private non-profit organizations and girls and adolescents participating in the program and their parents will be affected by this data collection.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms (If necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Prevention Education Questionnaire	Program participant .....	750	2	2	3,000
Focus group .....	Program participant .....	120	1	90/60	180
Focus group .....	Parent of Program participant .....	120	1	90/60	180
Interview .....	Program Director .....	10	2	90/60	30
	Program Staff .....	10	150	30/60	750
Interview .....	Program Staff .....	10	2	45/60	15
Interview .....	Program Partner .....	60	1	45/60	45
Focus group .....	Program Partner .....	120	1	90/60	180
Community Event Survey .....	Community Resident .....	250	1	5/60	21
Total .....	.....	.....	.....	.....	4,401

**Seleda Perryman,**  
*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-0990-New]

**Agency Information Collection Request; 60-Day Public Comment Request**

**AGENCY:** Office of the Secretary.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed information collection request 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.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to [Sherette.funncoleman@hhs.gov](mailto:Sherette.funncoleman@hhs.gov), or call the Reports Clearance Office on (202) 690-5683. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 60 days.

*Proposed Project:* Evaluation of Office for Human Research Protections Outreach Pamphlet on Public

Participation in Research—Office for Human Research.

*Abstract:* This evaluation project addresses the Office for Human Research Protection’s need for the evaluation of an informational outreach pamphlet, “Becoming a Research Participant: It’s Your Decision,” to educate the general public about factors to consider in their choice to participate or not participate in research. The evaluation is particularly important for the development and efficient distribution of future educational material. Participants in this survey will be members of the research community, broadly defined, including members of the human research protections community, who received the pamphlet for distribution by their organizations. The survey will collect a small amount of descriptive information regarding the research setting, how the institution utilized the pamphlet, the impact of the pamphlet’s appearance and content, and to a brief degree, if and how the pamphlet had an effect on research participation.

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.*

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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