

cooperative agreements are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. If the proposed project involves research on human subjects, the applicants must comply with Department of Health and Human Services regulations (45 CFR part 46) regarding the protection of human subjects. The applicants must ensure that the project will be subject to initial and continuing review by the appropriate institutional review committees. Overall, by providing additional scientific information for the risk assessment process, data generated from this research will support other researchers who are conducting human health assessments involving these two substances.

The mechanisms for implementing SSARP are discussed next. The status of SSARP in addressing priority data needs of the first 60 priority hazardous substances through these mechanisms was described in a **Federal Register** Notice on December 13, 2005 (70 FR 73749).

A. TSCA/FIFRA

In developing and implementing SSARP, ATSDR and EPA established procedures to identify priority data needs of common interest to multiple federal programs. Where practicable, these data needs will be addressed through a program of toxicologic testing under TSCA or FIFRA. This part of the research will be conducted according to established TSCA/FIFRA procedures and guidelines.

B. Private-Sector Voluntarism

As part of SSARP, on February 7, 1992, ATSDR announced a set of proposed procedures for conducting voluntary research (57 FR 4758). Revisions based on public comments were published on November 16, 1992 (57 FR 54160). ATSDR strongly encourages private-sector organizations to propose research to address priority data needs at any time until ATSDR announces that research has already been initiated for a specific priority data need. Private-sector organizations may volunteer to conduct research to address specific priority data needs identified in this notice by submitting a letter of intent.

The letter of intent should be a brief statement (1–2 pages) that identifies the priority data need(s) to be filled and the methods to be used. TASARC will review these proposals and recommend to ATSDR the voluntary research projects that should be pursued—and how they should be conducted—with the volunteer organizations. ATSDR will

enter into only those voluntary research projects that lead to high-quality, peer-reviewed scientific work. Additional details regarding the process for voluntary research are in the **Federal Register** Notices cited in this section.

C. CERCLA

Those priority data needs that are not addressed by TSCA/FIFRA or initial voluntarism will be considered for funding by ATSDR through its CERCLA budget. Much of this research program is envisioned to be unique to CERCLA—for example, research on substances not regulated by other programs or research needs specific to public health assessments. A current example of the direct use of CERCLA funds is a cooperative agreement with the Association of Minority Health Professions Schools (AMHPS) that supports the AMHPS Environmental Health, Health Services, and Toxicology Research programs.

Mechanisms to address these priority data needs may include a second call for voluntarism. Again, scientific peer review of study protocols and results would occur for all research conducted under this auspice.

ATSDR encourages private-sector organizations and other governmental programs to use ATSDR's priority data needs to plan their research activities.

Dated: January 6, 2009.

Ken Rose,

Director, Office of Policy, Planning, and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–262, CMS–10142 and CMS–R–137]

Agency Information Collection Activities: Submission for OMB Review; 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), 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 a currently approved collection; *Title of Information Collection:* CY 2010 Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP) *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 formulary file, Plan Benefit Package (PBP) software, and supporting documentation as necessary. MA and PDP organizations will generate a formulary to illustrate their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. Additionally, the PBP software will be used to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. CMS uses the formulary and PBP 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 formulary and PBP 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. Based on operational changes and policy clarifications to the Medicare program and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission. *Form Number:* CMS–R–262 (OMB# 0938–0763); *Frequency:* Yearly; *Affected Public:* Business or other for-profits b. Not-for-profit institutions; *Number of Respondents:* 475; *Total Annual Responses:* 4987.5; *Total Annual Hours:* 12112.5.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of*

Information Collection: CY 2010 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 (PDP) 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 b. Not-for-profit institutions; *Number of Respondents:* 550; *Total Annual Responses:* 6050; *Total Annual Hours:* 42,350.

3. Type of Information Collection
Request: Extension of a currently approved collection; *Title of Information Collection:* Internal Revenue Service (IRS)/Social Security Administration (SSA)/Centers for Medicare and Medicaid Services (CMS) Data Match and Supporting Regulations in 42 CFR 411.20-491.206 *Use:* Medicare Secondary Payer (MSP) is essentially the same concept known in the private insurance industry as coordination of benefits; it refers to those situations where Medicare assumes a secondary payer role to certain types of private insurance for covered services provided to a Medicare beneficiary.

Congress sought to reduce the losses to the Medicare program by requiring in 42 U.S.C. 1395y(b)(5) that the Internal Revenue Service (IRS), the Social Security Administration (SSA), and CMS perform an annual data match (the IRS/SSA/CMS Data Match, or "Data Match" for short). CMS uses the information obtained through Data Match to contact employers concerning possible application of the MSP provisions by requesting information about specifically identified employees

(either a Medicare beneficiary or the working spouse of a Medicare beneficiary). This statutory data match and employer information collection activity enhances CMS's ability to identify both past and present MSP situations. *Form Number:* CMS-R-137 (OMB# 0938-0763); *Frequency:* Annually; *Affected Public:* Business or other for-profit, not-for-profit institutions, farms, State, Local or Tribal Governments; *Number of Respondents:* 326,597; *Total Annual Responses:* 326,597; *Total Annual Hours:* 1,900,795.

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 February 9, 2009: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: December 28, 2008.

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-10062, CMS-10275, and CMS-10137]

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:* Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments: *Use:* CMS requires hospital inpatient, hospital outpatient and physician diagnostic data from Medicare Advantage (MA) organizations to continue making payment under the risk adjustment methodology as required by the Social Security Act, as amended by the Balanced Budget Act; the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act; and the Medicare Prescription Drug Benefit, Improvement and Modernization Act. CMS will use the data to make risk adjusted payment under Parts C. MA and MA-PD plans will use the data to develop their Parts C bids. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the CMS-Hierarchical Condition Category (HCC) and RxHCC models' output and the risk scores and reimbursements for each beneficiary that is enrolled in their plan. *Form Number:* CMS-10062 (OMB# 0938-0878); *Frequency:* Quarterly; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 852; *Total Annual Responses:* 22,097,070; *Total Annual Hours:* 10,826.1.

2. Type of Information Collection
Request: New collection; *Title of Information Collection:* CAHPS Home Health Care Survey: *Use:* As part of the Department of Health and Human Services (DHHS) Transparency Initiative on Quality Reporting, CMS plans to implement a process to measure and publicly report home health care patient experiences through the CAHPS (Consumer Assessment of Healthcare