

**SUPPLEMENTARY INFORMATION:****I. Background**

House Appropriations Committee Report 108–636 includes a provision for the Health and Human Services Assistant Secretary for Planning and Evaluation (HHS/ASPE) and the Office of Management and Budget (OMB) to establish an interagency committee, to be coordinated by HHS. The committee's role is to examine major Federal regulations governing the health care industry and to make suggestions regarding how health care regulation could be coordinated and simplified to reduce costs and burdens and improve translation of biomedical research into medical practice, while continuing to protect patients. The interagency committee will examine the economic impact of the major Federal regulations governing the health care industry, and will explore both immediate steps and longer-term proposals for reducing regulatory burden, while maintaining the highest quality health care and other patient protections.

In accord with the House Appropriations Committee's intent, ASPE and OMB have undertaken several complementary activities. The HHS/OMB interagency committee is conducting a comprehensive review of Federal health care regulations, guidance, and paperwork requirements in order to identify areas for reform. In order to facilitate the work of this committee, ASPE and OMB are soliciting public nominations of regulatory reforms in several ways. First, we published a notice in the **Federal Register** on October 4, 2005, soliciting public nominations of reforms. Second, we are holding a series of Town Hall meetings in several cities across the country to provide an opportunity for input from health care administrators, institutional providers, physicians, practitioners, patients, and others about the impact of regulations, and to identify other potential areas for reform.

The purpose of this **Federal Register** notice is to give potential participants in these Town Hall meetings more information regarding how their participation and the information they provide can facilitate the consideration of their suggestions for regulatory reform. In particular, participants in the Town Hall meetings and individuals who submit written comments are requested to provide, to the extent feasible, an estimate of the economic impact of health care regulations, guidance documents, or paperwork requirements, and also to describe the methods used to calculate the economic

impact of the regulations. The findings from the Town Hall meetings, other reform nominations and comments from the public, and the subsequent work of the HHS/OMB committee will be synthesized and included in a report to Congress.

**II. Registration**

Registration Procedures: Registration can be completed online at <http://aspe.hhs.gov/arrb/index.shtml>. To register by telephone, contact Bridgette Saunders of Social and Scientific Systems at (301) 628–3158. (Social and Scientific Systems is the Contractor to HHS/ASPE to provide logistical support for the Town Hall meetings.) The following information must be provided when registering: Name, organization name and address, and consent to publish contact information on a participants list and other reports to document the Town Hall Meeting. A Social & Scientific Systems, Inc. staff member will confirm your registration by mail, e-mail, or fax.

**III. Presentations and Comment Format****A. "5-Minute" Public Comment Presentations**

Meeting attendees can sign up at the meeting, on a first-come, first-served basis, to make 5-minute presentations. We ask that commenters focus on the economic impacts of health care regulations, and quantify these impacts to the extent possible. Depending on the number of persons who sign up to make public comments, we will decide whether additional time will be allotted. In order to offer the same opportunity to all attendees, there is no pre-registration for 5-minute speakers. Attendees can sign up only on the day of the meeting to make a 5-minute presentation. They must provide their name, title, and organization name on the sign-up sheet, and identify the general area of health care regulation that they will address.

**B. Written Comments From Meeting Attendees**

Written comments are welcome from the public regardless of attendance at a Town Hall Meeting or whether they make an oral presentation at a Town Hall Meeting. Written comments can be submitted either at the meeting, or before or after the meeting via e-mail to the mailboxes specified on the project Web site: <http://aspe.hhs.gov/arrb/index.shtml> or via regular mail to Marty McGeein, Office of the Assistant Secretary for Planning and Evaluation, 200 Independence Avenue, SW., Washington, DC 20201. Please note that electronic submissions are preferred due

to delays in receiving U.S. Postal Mail. We are able to consider only those comments received in writing and/or via e-mail by 5 p.m. EST on February 9, 2006.

**IV. Special Accommodations**

Individuals attending a meeting who are hearing- or visually-impaired and have special requirements, or a condition that requires special assistance or accommodations, must provide this information when registering for the meeting and accommodations will be made.

Dated: November 29, 2005.

**Donald Young,**

*Acting Assistant Secretary for Planning and Evaluation (ASPE), HHS.*

**John D. Graham,**

*Administrator, Office of Information and Regulatory Affairs (OIRA), OMB.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services**

[Document Identifier: CMS–10001, CMS–10009, CMS–10167, and CMS–10062]

**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:* HIPAA Nondiscrimination Provisions (Regulation HCFA 2022–IFC); *Form*

*Number:* CMS-10001 (OMB#: 0938-827); *Use:* The provisions of Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are designed to make it easier for people to access health care coverage; to reduce the limitations that can be put on the coverage; and to make it more difficult for issuers to terminate the coverage. Title I provisions are divided into group and individual market protections. The group provisions apply to employment-related group health plans and to the issuers who sell insurance in connection with group health plans. Section 2702 of the Public Health Service Act (PHS Act) (the HIPAA nondiscrimination provisions) establish rules generally prohibiting group health plans and group health insurance issuers from discriminating against individual participants or beneficiaries based on any health factor of such participants or beneficiaries.; *Frequency:* Third party disclosure, Reporting—Annually; *Affected Public:* Business or other-for-profit, Individuals or Households, Not-for-profit institutions, Federal government, and State, Local, or Tribal Government; *Number of Respondents:* 18; *Total Annual Responses:* 18; *Total Annual Hours:* 194.

*2. Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* HIPAA Nondiscrimination Provisions (Regulation HCFA 2078-P); *Form Number:* CMS-10009 (OMB#: 0938-819); *Use:* The provisions of Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are designed to make it easier for people to access health care coverage, to reduce the limitations that can be put on the coverage, and to make it more difficult for issuers to terminate the coverage. Title I provisions are divided into group and individual market protections. The group provisions apply to employment-related group health plans and to the issuers who sell insurance in connection with group health plans. Section 2702 of the Public Health Service Act (PHS Act—the HIPAA nondiscrimination provisions) establish rules generally prohibiting group health plans and group health insurance issuers from discriminating against individual participants or beneficiaries based on any health factor of such participants or beneficiaries.; *Frequency:* Third party disclosure, Reporting—Annually; *Affected Public:* Business or other-for-profit, Individuals or Households, Not-for-profit institutions, Federal government, and

State, Local, or Tribal Government; *Number of Respondents:* 2600; *Total Annual Responses:* 2600; *Total Annual Hours:* 100.

*3. Type of Information Collection Request:* New collection; *Title of Information Collection:* Competitive Acquisition Program (CAP) for Medicare Part B Drugs: CAP Physician Election Agreement; *Form Number:* CMS-10167 (OMB#: 0938-NEW); *Use:* Beginning in 2006, physicians will have a choice between acquiring and billing for Part B covered drugs under the Average Sales Price (ASP) drug payment methodology or electing to receive these drugs from vendors/suppliers selected for the CAP through a competitive bidding process. The provisions for this new payment system are described in the proposed rule entitled, “Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B,” that published March 4, 2005 (70 FR 10746), the interim final rule entitled, “Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B,” that published July 6, 2005 (70 FR 39022), and the final rule entitled, “Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006,” that published on November 21, 2005. Competitive bidding is seen as a means of using the dynamics of the marketplace to provide incentives for suppliers to provide reasonably priced products and services of high quality in an efficient manner. The CAP’s objectives include the following: 1) to provide an alternative method for physicians to obtain Part B drugs to administer to Medicare beneficiaries; and 2) to reduce drug acquisition and billing burdens for physicians; *Frequency:* Reporting—Annually; *Affected Public:* Business or other-for-profit; *Number of Respondents:* 10,000; *Total Annual Responses:* 10,000; *Total Annual Hours:* 20,000.

*4. Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments Supporting Regulations 42 CFR Part 422 Subparts F and G and 42 CFR Part 423 Subparts F and G; *Form Number:* CMS-10062 (OMB#: 0938-0878); *Use:* Under the Medicare Prescription Drug Benefit, Improvement and Modernization Act of 2003 (MMA), the Congress restructured the M+C program into the Medicare Advantage (MA) program, Part C, and added an outpatient prescription drug benefit, Part D. In accordance with mandates in these laws, the Secretary of

the Department of Health and Human Services must implement health status risk adjustment, a payment methodology for Parts C and D that takes into account the health status of plan enrollees. CMS collects inpatient and outpatient data. Part C data is collected using the CMS-HCC (hierarchical condition category) model. Part D data will be collected using the CMS Rx-HCC model. The Rx-HCC model is different from the CMS-HCC model primarily in that it predicts plan liability for drug costs instead of medical/surgical costs for service under Parts A and B. CMS will use the data to make risk adjusted payment under Parts C and D. MA plans, Medicare Advantage Prescription Drug (MA-PD) plans, and stand-alone Prescription Drug Plans (PDP’s) will use the data to develop their Parts C and D bids.; *Frequency:* Reporting—Quarterly; *Affected Public:* Business or other-for-profit and Not-for-profit institutions; *Number of Respondents:* 505; *Total Annual Responses:* 14,091,370; *Total Annual Hours:* 8,351.

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/regulations/prar/>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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 at the address below, no later than 5 p.m. on January 31, 2006.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attention: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: November 17, 2005.

**Michelle Shortt,**

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

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