DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Time and Date: June 16, 2010: 9 a.m.–5 p.m. and June 17, 2010: 9 a.m.–11:30 a.m.

Place: Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA 22202.

Status: Open.

Purpose: At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. On the morning of the first day the Committee will hear updates from the Department, the Center for Medicare and Medicaid Services, ONC, and the plans for the NCVHS 60th Anniversary Symposium. In the afternoon there will be Subcommittee breakout sessions.

On the morning of the second day the Committee will be briefed on the Community Data Initiative. There will also be a discussion of Committee plans for September 2010 and future meetings. Upon the adjournment of the full meeting, the Committee will convene at the National Academy of Science Keck Center for the NCVHS 60th Anniversary Symposium.

The times shown above are for the full Committee meeting. Subcommittee breakout sessions are scheduled for late in the afternoon of the first day. Agendas for these breakout sessions will be posted on the NCVHS Web site (URL below) when available.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: May 28, 2010.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2010–13496 Filed 6–3–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10308]

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:* New collection; *Title of Information Collection:* Part C and D Complaints Resolution Performance Measures: *Use:* Part C Sponsors provide medical coverage through at-risk arrangements with CMS. Part C Sponsors include: Local Coordinated Care Plans which include health maintenance organizations (HMOs), preferred provider organizations (PPOs), and provider sponsored organizations (PSO) plans; Private fee-for-service plans (PFFS); Special needs plans (SNPs); Medical savings account (MSAs); and Regional PPOs. Part D Sponsors provide prescription drug benefit coverage through private at-risk prescription drug plans that offer drug-only coverage Prescription Drug Plans, or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans).

Due to Executive Order 13410, "Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs," performance measurement ratings for Medicare Parts C & D can be found on Medicare Options Compare and the Medicare Prescription Drug Plan Finder (MPDPF), providing rating information for beneficiary use with plans being assigned a performance-based star rating. These ratings are provided to help beneficiaries make informed choices among the many plan alternatives available to them under Medicare Parts C and D.

The purpose of the project is to develop and support implementation of a performance measure for the Medicare Advantage (Part C) and Prescription Drug (Part D) programs that represents plan resolution of beneficiary complaints from the beneficiary perspective. The project includes development of methodologies for: (1) Identifying a statistically valid sample of beneficiary complaints needed to analyze the complaint's closure; (2) contacting, interviewing, and summarizing beneficiary experience; and, (3) summarizing/analyzing the resultant data to assess accuracy of the resolution of beneficiary complaints from the perspective of the beneficiaries via objective exploration of the beneficiary's complaint resolution experience. For a summary of changes, refer to the Part C and D Complaints Resolution Performance Measures Summary of Revisions document. *Form Number:* CMS–10308 (OMB#: 0938–New); *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 5,300; *Total Annual Responses:* 5,300; *Total Annual Hours:* 884. (For policy questions regarding this collection contact Rachel Schreiber at 410–786–8657. 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 July 6, 2010.

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

Dated: *May 28, 2010.*

Martique Jones,

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

[FR Doc. 2010–13302 Filed 6–3–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10203]

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:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Health Outcomes Survey (HOS); *Use:* CMS has a responsibility to its Medicare beneficiaries to require that care provided by managed care organizations under contract to CMS is of high quality. One way of ensuring high quality care in Medicare Managed Care Organizations (MCOs), or more commonly referred to as Medicare Advantage Organizations (MAOs), is through the development of standardized, uniform performance measures to enable CMS to gather the data needed to evaluate the care provided to Medicare beneficiaries.

The goal of the Medicare HOS program is to gather valid, reliable, clinically meaningful health status data in Medicare managed care for use in quality improvement activities, plan accountability, public reporting, and improving health. All managed care plans with Medicare Advantage (MA) contracts must participate. CMS, in collaboration with the National Committee for Quality Assurance (NCQA), launched the Medicare HOS as part of the Effectiveness of Care component of the former Health Plan Employer Data and Information Set, now known as the Healthcare Effectiveness Data and Information Set (HEDIS®).

The HOS measure was developed under the guidance of a Technical Expert Panel comprised of individuals with specific expertise in the health care industry and outcomes measurement. The measure includes the most recent advances in summarizing physical and mental health outcomes results and appropriate risk adjustment techinques. In addition to health outcomes measures, the HOS is used to collect the Management of Urinary Incontinence in Older Adults, Physical Activity in Older Adults, Fall Risk Management, and Osteoporosis Testing in Older Women HEDIS® measures. The collection of Medicare HOS is necessary to hold Medicare managed care contractors accountable for the quality of care they are delivering. This reporting requirement allows CMS to obtain the information necessary for proper oversight of the Medicar Advantage program. *Form Number:* CMS–10203 (OMB#: 0938–0701; *Frequency:* Yearly; *Affected Public:* Individuals and households; *Number of Respondents:* 1,099,560 *Total Annual Responses:* 1,099,560; *Total Annual Hours:* 366,520 (For policy questions regarding this collection contact Chris Haffer at 410–786–8764. 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 *August 3, 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.

Date: *May 28, 2010.*

Martique Jones,

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

[FR Doc. 2010–13303 Filed 6–3–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0278]

Determination That Cysteine Hydrochloride Injection, USP, 7.25%, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that Cysteine Hydrochloride Injection, USP, 7.25% (Cysteine HCl), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Cysteine HCl if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6358, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved.