

Dated: May 28, 2010.

Martique Jones,

Director, Regulations Development Division-B, 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-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 techniques. 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 Medicare 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.

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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.