

We are requesting emergency clearance of a pilot study designed to elicit information from discharged patients concerning their hospital/acute care experience. Given the current momentum, enthusiasm and support expressed by hospitals and the hospital associations for public reporting of hospital quality information, it is important to provide the tools needed for reliable and valid data collection as soon as possible. CMS would like to take advantage of the opportunity of testing the H-CAHPS instrument in the Hospital State Pilots that has just started. It is important to provide hospitals a standard tool and data collection methodology by July/August 2003 to support this joint initiative. We are interested in receiving comments on the pilot during the course of the pilot, as well as during the comment period mentioned below. However, those received after the close of the comment period will not be included in the materials that OMB reviews in determining whether to approve the collection.

CMS is requesting OMB review and approval of this collection by February 21, 2003, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by February 20, 2003. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New collection; *Title of Information Collection:* Pilot Test of Hospital CAHPS Survey; *Form No.:* CMS-10083 (OMB #0938-XXXX); *Use:* CMS has requested a hospital survey as a way of providing comparison information for consumers who need to select a hospital and as a way of encouraging accountability of hospitals for the care they provide. With a standardized instrument consumers will be able to make "apples to apples" comparisons among hospitals, allow hospitals and hospital chains to self compare, and provide state oversight officials with useful data. A standardized instrument, developed under the CAHPS umbrella, will produce a reliable and valid instrument that any organization can use at no cost to obtain patient data about hospital experiences. This tool will be adopted by the National Hospital Voluntary Initiative; *Frequency:* Once; *Affected Public:* Individuals or households;

Number of Respondents: 16,500; *Total Annual Responses:* 16,500; *Total Annual Hours:* 5,500.

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

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://cms.hhs.gov/regulations/prd/default.asp> or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, in order to be considered in the OMB approval process, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, by February 20, 2003.

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attn: Reports Clearance Officer, Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850. Fax Number: (410) 786-3064. Attn: Julie Brown; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395-6974 or (202) 395-5167, Attn: Brenda Aguilar, CMS Desk Officer.

Dated: January 30, 2003.

John P. Burke, III,

CMS Reports Clearance Officer, CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-0109]

Medical Devices: Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test Systems; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA." This guidance document was developed as a special control guidance to support the reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance entitled "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Freddie M. Poole, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2096.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document was developed as a special control guidance to support the reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility device from class III to class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify