would apply to a limited class of research activities involving human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have a legally authorized person to represent them. The preamble to part 50 stated that the agency intends to monitor and evaluate the implementation of these regulations on an ongoing basis. Since the effective date of these emergency research regulations (November 1, 1996), FDA has reviewed the efforts of sponsors, Institutional Review Boards, and clinical investigators to interpret and comply with these regulations and has determined that guidance is needed.

The draft guidance document, available for public comment, addresses issues pertinent to the implementation of FDA's emergency research regulations. The draft guidance document provides guidance on the development and conduct of community consultation and public disclosure activities; the establishment of informed consent procedures to be used when feasible; the need for the concurrence of a licensed physician; use of data monitoring committees; use of independent IRB's; documentation of efforts to contact a subject's legally authorized representative or family member regarding the subject's participation in the study; and other aspects of the emergency research regulations.

This draft Level 1 guidance document is being issued consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on ways to effectively implement its emergency research regulations in order to protect the rights and welfare of human subjects participating in that research. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information contained in the guidance document may be applicable to all situations.

II. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the Internet at http://www.fda.gov/ora/compliance ref/bimo/default.html.

Dated: March 21, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–7778 Filed 3–29–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–295]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), 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 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.

Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Medicare CAHPS Disenrollment Survey;

Form No.: HCFA–R–295 (OMB 0938–0779);

Use: This survey is used to collect information from Medicare beneficiaries who have disenrolled from their health plans during the past year. The purpose of this information is to obtain their ratings of their former plans and the reasons why they left. The survey results will be reported to all beneficiaries in print and on the Internet for the purpose of informed choices. Secondary uses of survey results include quality improvement and contract oversight;

Frequency: Quarterly, Annually;

Affected Public: Individuals or Households;

Number of Respondents: 112,800;

Total Annual Responses: 90,240;

Total Annual Hours: 39,744.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 20, 2000.

John P. Burke III

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

[FR Doc. 00–7905 Filed 3–29–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Withdrawal

AGENCY: Health Resources and Services Administration.

ACTION: Notice; withdrawal.

SUMMARY: In the **Federal Register** notice of Wednesday, August 18, 1999, in FR Doc. 99–21257, on page 45025, the grant category beginning in the third column under the heading ''State and Local Data Utilization and Enhancement (DUE) Cooperative Agreements, CFDA# 93.110U,'' is withdrawn from competition because of insufficient funds to support the full scope of