industry entitled ''IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations to industry on formal meetings between sponsors of investigational new drug applications (IND's) and the Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) on chemistry, manufacturing, and controls (CMC) information.

DATES: Submit written comments on the draft guidance by May 4, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1488, FAX: 888–CBERFAX or 301–827–3844. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Stephen K. Moore, Center for Drug Evaluation and Research (HFD–501), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6430; or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Bldg. N29B, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information.'' This draft guidance covers three kinds of meetings held between sponsors and the agency: (1) Pre-IND, (2) end-of-phase 2, and (3) pre-new drug application or pre-biologics license application. These meetings address questions and scientific issues that arise during the course of clinical investigations, aid in the resolution of problems, and facilitate evaluation of the drug. The meetings often coincide with critical points in the drug development and/or regulatory process. This draft guidance is intended to assist in making these meetings on CMC information more efficient and effective by providing information on the: (1) Purpose, (2) meeting request (3) information package, (4) format, and (5) focus of the meeting.

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on ''IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information.'' 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, regulations, or both.

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

Dated: January 24, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–2436 Filed 2–3–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Loan Information System Records for the DHHS and DHUD Hospital Mortgage Insurance, Guarantee, and Direct Loan Programs (OMB 0915–0174)—Extension

The Division of Facilities Loans within the Health Resources and Services Administration monitors outstanding direct and guaranteed loans made under Section 621 of Title VI and Section 1601 of Title XVI of the Public Health Service Act, as well as loans insured under the Section 242 Hospital Mortgage Insurance Program of the National Housing Act. These programs were designed to aid construction and modernization of health care facilities by increasing the access of facilities to capital through the assumption of the mortgage credit risk by the Federal Government.

Operating statistics and financial information are collected annually from hospitals with mortgages that are insured under these programs. The information is used to monitor the financial stability of the hospitals to protect the Federal investment in these facilities. The form used for the data collection is the Hospital Facility Data Abstract. No changes in the form are proposed.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total hour burden
Hospital Facility Data Abstract	150	1	1	150

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 28, 2000.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–2433 Filed 2–3–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds for Grants for the Community Access Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of $25 million to assist communities and their safety net providers in developing integrated health care delivery systems that serve the uninsured and underinsured with greater efficiency and improved quality of care. The $25 million in available funding has been appropriated under the FY 2000 HHS Appropriations Act.

In FY 2000, HRSA will provide funding for approximately 20 communities to further their development of integrated delivery systems for the uninsured and underinsured. Grants will vary in size, based on the scope of the project and the size of the service area.

During the first year of funding for this program, HRSA will support infrastructure development in communities that have already begun to reorganize and integrate their health care delivery systems. FY 2000 funding is not intended to support those communities that have not yet begun the planning and development of necessary organizational structure.

Up to 100 communities may ultimately be funded as part of this national program targeted by the Administration to spend $1 billion over five years. FY 2000 funded communities may be eligible for available FY 2001 funding (assuming continued appropriations) to support further infrastructure development and filling service gaps. In addition, using the experiences of the FY 2000 funded communities as potential models for adaptation, FY 2001 funding is anticipated for support of new communities for planning and system development. Thus, communities that have not yet begun the planning and development of necessary organizational structure should have an opportunity to apply in FY 2001.

Over the years that the program is funded, funds are anticipated to be available to fill service gaps within coordinated systems of care.

This program shares some of the same goals of the W.K. Kellogg Foundation's Community Voices Program and the Robert Wood Johnson Foundation's Communities in Charge Program. Thus, CAP will take into account the experiences of these foundations as well as other programs that promote the integration of services to the uninsured and underinsured.

DATES: The timeline for application submission, review, and award are as follows:

February 10, 2000: Application kits and additional guidance will be available through the HRSA Grants Application Center (GAC).

March 7–16, 2000: There will be a series of six pre-application workshops conducted across the country: Boston, MA—March 7, 2000; Atlanta, GA—March 8, 2000; Chicago, IL—March 9, 2000; Dallas, TX—March 14, 2000; Los Angeles, CA—March 15, 2000; Seattle, WA March 16, 2000.

June 1, 2000: Applications due.

July 3–17, 2000: Applications reviewed.

August 2000: Site visits to selected applicants.

September 2000: Grant awards announced.

ADDRESSES: To receive a complete application kit (*i.e.,* application instructions, necessary forms, and application review criteria), contact the HRSA GAC at: HRSA GAC, 1815 N. Fort Meyer Drive, Suite 300, Arlington, VA 22209, Phone: 1–877-HRSA–123, Fax: 1–877-HRSA–345, E-Mail: *hrsagac@hrsa.gov*

FOR FURTHER INFORMATION CONTACT: For further information, contact the Community Access Program Office: Community Access Program Office, Health Resources and Services Administration, Parklawn Building, Suite 9A–30, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 443–0536, Fax: (301) 443–0248.

SUPPLEMENTARY INFORMATION: In 1998, 44.5 million people in the United States did not have health insurance. Of these, 24.6 million were employed—18.7 million worked full time and 5.9 million worked part time.

The uninsured and underinsured often have complex medical needs, remain outside organized systems of care, and have insufficient resources to obtain care. They may defer care or not receive needed services, and they are about half as likely to receive a routine check-up as insured adults. The uninsured and underinsured also rely heavily on expensive emergency rooms, and because they lack a routine source of care, they often do not receive needed follow-up services.

Many of the uninsured and underinsured rely on the nation's institutions, systems, and individual health professionals that provide a significant volume of health care services without regard for ability to pay. In many communities, these providers are struggling to care for the increasing numbers of uninsured and underinsured individuals. They face many challenges such as an uneven distribution of the burden of uncompensated care, the fragmentation of services for the uninsured, insufficient numbers of certain types of providers, reduced Medicaid revenues, and a growing need for mental health and substance abuse services.

While integration among these providers is critical to serve the uninsured and underinsured with greater efficiency and to improve quality of care, many of these providers are so pressured by basic caregiving tasks, that they need assistance to coordinate their efforts with other providers and to develop integrated community-based systems of care.

The Community Access Program

Program Purpose

The purpose of this program is to assist communities and consortia of