Biological Veterinary Medicinal Products'' (VICH GL17) has been adapted for veterinary use by the VICH from a guidance regarding pharmaceuticals for human use, which was adopted by the ICH and published in the **Federal Register** of July 10, 1996 (61 FR 36466).

In the **Federal Register** of October 12, 1999 (64 FR 55294), FDA published the VICH draft guidance, giving interested persons until November 12, 1999, to submit comments. FDA shared the comments it received with the appropriate VICH Expert Working Group and after considering the comments, the work group submitted the final guidance to the VICH Steering Committee. No changes were made in response to the comments. At a meeting held on June 14 through 16, 2000, the VICH Steering Committee endorsed the final guidance for industry, VICH GL17.

Biotechnological/biological products have distinguishing characteristics to which consideration should be given in any well-defined testing program designed to confirm their stability during the intended storage period. For such products, in which the active components are typically proteins and/or polypeptides, maintenance of molecular conformation and biological activity is dependent on noncovalent as well as covalent forces. The products are particularly sensitive to environmental factors such as temperature changes, oxidation, light, ionic content, and shear. In order to ensure maintenance of biological activity and to avoid degradation, stringent conditions for their storage are usually necessary. The evaluation of stability may require complex analytical methodologies. With these concerns in mind, applicants should develop proper supporting stability data for new products of this type.

This final guidance document is intended to provide guidance to applicants regarding the type of stability studies that should be conducted and the stability data that should be provided in support of NADA's for veterinary biotechnological/biological products that are regulated by FDA. It is intended to supplement the tripartite VICH GL3 guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products'' (a copy of this final guidance document may be obtained on the Internet from the CVM home page at www.fda.gov/cvm).

This Level 1 final guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115; 65 FR 56468, September 19, 2000). 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.

Information collected is covered under OMB control number 0910–0117.

III. Electronic Access

Copies of the final guidance document entitled ''Stability Testing of New Biotechnological/Biological Veterinary Medicinal Products'' (VICH GL17) may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this final guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend this final guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this final guidance document at any time. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the final 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.

Dated: April 6, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–9259 Filed 4–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3068–N]

Medicare Program; Educational Symposium To Discuss the Use of Evidence-Based Medicine in the Medicare Coverage Decision Process—May 3, 2001

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This document announces an educational symposium open to all interested parties at which presenters will describe evidence-based medicine and its role in the decision making process for Medicare coverage issues. This meeting represents one aspect of the evolving process for making the Medicare coverage process more open and comprehensible to the public.

DATES: *The Meeting:* The meeting will be held on May 3, 2001, from 8 a.m. until 12 noon, E.D.T.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the **FOR FURTHER INFORMATION CONTACT** person by April 20, 2001.

ADDRESSES: The meeting will be held at the HCFA headquarters MultiPurpose Room, 7500 Security Boulevard, Baltimore, Maryland 21244. Seating in the MultiPurpose Room is limited to 150 persons, and is available on a first come, first served basis.

FOR FURTHER INFORMATION CONTACT: Janet Anderson at 410–786–2700, email *JAnderson@hcfa.gov*, or Janet Anderson, Coverage and Analysis Group, 7500 Security Blvd, mailstop S3–02–01, Baltimore, MD 21244.

SUPPLEMENTARY INFORMATION:

I. Background

On April 27, 1999, we published a general notice in the **Federal Register** (64 FR 22619) that announced the process we use to make national coverage decisions under the Medicare program. In the notice, we explained that these coverage decisions are prospective, population-based policies that apply to a clinical subset or class of Medicare beneficiaries. We described the clinical circumstances and setting under which an item or service is available (or not available). We included information and approaches we are considering for making coverage decisions. One approach is the use of the principles of evidence-based medicine in evaluating the effectiveness of health services. We also clarified that the notice was not intended to address individual medical necessity determinations and claims adjudication by our contractors and other adjudicators, nor was it intended to address changes in current Medicare payment policies.

On August 13, 1999, we published a notice in the **Federal Register** (64 FR 44231) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical issues. The MCAC is charged with providing recommendations on a variety

of topics relating to the effectiveness of health services. The MCAC uses guidelines for evaluating evidence through applying criteria that employs the principles of evidence-based medicine.

Since the publication of these **Federal Register** notices we have employed the principles of evidence-based medicine in the coverage process, both in the creation of decision memorandum and in involvement with the MCAC.

II. Format of Meeting

We will begin the meeting with a brief overview of the purpose of the meeting. Following this introduction, there will be an informative presentation highlighting the principles of evidence-based medicine. This discussion will then be followed by presentations given by experts who have experience with the use of evidence-based medicine in the coverage decision process. Public comments and questions to the panel will follow these last presentations.

III. Registration

Since seating is limited to 150 persons, and is available on a first come, first served basis, prior registration with the contact person is not necessary.

Authority: 5 U.S.C. App. 2, section 10(a)(1) and (a)(2).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 6, 2001.

Jeffrey L. Kang, M.D.,

Director, Office of Clinical Standards and Quality, Health Care Financing Administration.

[FR Doc. 01–9257 Filed 4–12–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Special Projects of National Significance Targeted HIV Outreach and Intervention Model Development; Evaluation and Program Support Center

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 fiscal year (FY) 2001 funds to be awarded under the Special Projects of National Significance (SPNS) program for discretionary grants, under a new competition that supports the development and evaluation of models of targeted HIV outreach and intervention for under-served HIV-positive populations not in care. The purpose of this new grant initiative is to support multi-year projects that will refine and evaluate programs that identify individuals who are HIV-positive and not in health care and engage them in comprehensive and continual health care, and develop an evaluation and program support center to provide advice and technical assistance to the funded multi-year projects regarding program refinement and evaluation. Special emphasis is placed on reaching individuals from communities of color and under-served populations.

The SPNS program is authorized by section 2691 of the Public Health Service Act. Grants may be awarded directly to public and non-profit private entities, including community-based organizations. The program has $3.5 million dollars available for this initiative. HRSA expects to make approximately 15 awards for demonstration projects and one award for the Evaluation and Program Support Center. The budget and project periods for approved and funded projects will begin on or about September 30, 2001. Funds for Category I awards must be requested for the initial two years. Funds for Category II must be requested for all five years.

Funds will be awarded in two categories. In the first category (Category I), HRSA expects to award approximately fifteen (15) grants for the development and evaluation of models of targeted HIV outreach and intervention for under-served HIV-positive populations not in care. It is anticipated that in the first two years (Phase 1), each Category I site will be awarded $200,000 per year. For those study sites approved for continuation in years three through five (Phase 2), up to $400,000 per year will be available. All Category I grantees will be eligible to submit a competitive grant application during the second year for continuation funding for years three through five (Phase 2).

In the second category (Category II), HRSA expects to award one award up to $500,000 per year for a five-year project period to support an Evaluation and Program Support Center. This Center will work with grantees to develop an overall multi-site evaluation of the grant initiative and provide technical support to grantees on program development and evaluation issues.

Eligible applicants under Categories I and II may include, but are not limited to, State, local, or tribal public health, mental health, housing, or substance abuse departments; public or non-profit hospitals and medical facilities; community-based service organizations (e.g., AIDS service organizations, community and migrant health centers funded by HRSA's Bureau of Primary Health Care, other primary health care clinics, family planning centers, AIDS anti-discrimination and advocacy organizations, homeless assistance providers, hemophilia centers, community health or mental health centers, substance abuse treatment centers, urban and tribal Indian health centers or facilities, migrant health centers, etc.), institutions of higher education, and national service provider and/or policy development associations and organizations.

Outreach projects proposed in Category I should seek to improve participation by HIV infected persons in HIV counseling and testing, diagnosis, prophylaxis, and treatment of manifestations and complications of HIV infection and AIDS, including: (a) Antiretroviral therapy, and (b) prophylactic therapy for opportunistic infections, including tuberculosis. Models of care should target under served populations and determine: the spectrum of HIV disease among treated and untreated HIV-infected persons (upon entry into care), the progression of HIV disease, adherence to antiretroviral treatment and PCP prophylaxis, and the impact of the model of care upon these parameters longitudinally. Models should include links to HIV counseling and testing services.

During Phase 1 of the program (project years 1–2), Category I grantees are expected to continue to provide their existing outreach services while engaging in planning activities for the implementation and evaluation of an intervention during Phase 2 (project years 3–5) which may be: (1) A refinement and/or expansion of the intervention being implemented during Phase 1; or (2) a new intervention which was not being implemented during Phase 1. Phase 2 continuation awards will be made based on review by an external objective review committee which will use review criteria that is expected to consist of the Category I grantees' implementation of Phase 1 activities, success in implementing local and cross-site evaluation activities during Phase 1, and their ability to incorporate local and cross-site evaluation activities into the proposed Phase 2 scope of work.