available to the public to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop microbial safety policies protective of the public health. This document discussed several risk management approaches to the regulatory management of antimicrobial drug resistance associated with food-producing animal use of antimicrobials. These strategies covered both preapproval and postapproval approaches and included: (1) Revision of the preapproval safety assessment for antimicrobial resistance for new animal drug applications to assess all uses for microbial safety, (2) categorization of antimicrobials based upon the importance of the drug for human medicine and upon which pre- and postapproval requirements would be based, (3) postapproval monitoring of the development of antimicrobial drug resistance and, (4) elaboration of resistance and monitoring thresholds.

The Framework Document discussed the concept of two thresholds, the resistance threshold and the monitoring threshold, that would be established prior to the approval of an antimicrobial new animal drug for use in food-producing animals to ensure that food products derived from treated animals are safe for consumers. The resistance threshold would be established in humans to represent the upper limit of resistant bacteria that can be transferred from animals to consumers. The Framework Document discussed the possibility of establishing resistance thresholds based on human data, animal data, or both.

Monitoring thresholds would also be established to guide the postapproval monitoring of resistance development in animals. According to the Framework Document, a monitoring threshold would need to be determined for each antimicrobial prior to approval, and the threshold may vary depending on the human or animal pathogen of concern. Monitoring thresholds would be established in animals so that they would serve as an early warning system, signaling when loss of susceptibility or resistance prevalence is approaching the resistance threshold.

If a monitoring threshold were reached, the drug sponsor would implement mitigation actions to address the loss of susceptibility or increasing resistance trend. If mitigation were not successful, and resistance continued to increase and reach the resistance threshold, withdrawal of the approval of the drug for the use(s) of concern would be warranted.

II. Submission of Comments

Interested persons may submit written comments regarding this meeting until December 11, 2000. Written comments should be submitted to the Dockets Management Branch (address above), or by fax to 301–827–6870. Comments should be identified with the docket number found in the brackets in the heading of this document.

III. Related Information

Transcripts of the three previous CVM public meetings on antimicrobial resistance, related public comments, the ''Draft Risk Assessment on the Human Health Impact of Fluoroquinolone Resistant Campylobacter Associated with the Consumption of Chicken (Revised as of February 9, 2000),'' and ''A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for use in Food-Producing Animals'' can be found on the Internet at http://www.fda.gov/cvm/fda/mappgs/antitoc.html.

Dated: July 20, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19048 Filed 7–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0495]

Prescription Drug User Fee Act (PDUFA) II Five-Year Plan—FY 2000 Update; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an internal planning document entitled ''PDUFA II Five-Year Plan: FY 2000 Update.'' The updated plan to achieve PDUFA II goals for the drug review process takes into account changes in revenue projections and workload based on actual revenue and application receipts in fiscal year (FY) 1998 and FY 1999 and updated projections for FY 2000 through FY 2002.

DATES: Submit written comments on the plan at any time. Comments will be considered as the agency makes annual adjustments to the plan in the second quarter of each FY.

ADDRESSES: Copies of this document are available on the Internet at www.fda.gov/oc/pdufa2/5yrplan.html. For those without Internet access, single copies of this plan may be obtained from the Office of Management and Systems (HF–20), Attention: Frank P. Claunts (HF–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please send a self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the plan to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Frank P. Claunts, Office of Management Systems (HF–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of an internal planning document entitled ''PDUFA II Five-Year Plan—FY 2000 Update.'' PDUFA was amended and extended through the year 2002 by the Food and Drug Administration Modernization Act of 1997. The amended and extended PDUFA is referred to as PDUFA II. PDUFA II authorizes appropriations and fees that will provide FDA with resources to sustain the drug review staff developed through FY 1997 and to achieve the even more stringent new goals.

The FY 2000 updated plan begins with a statement of purpose, provides background information on PDUFA and a summary of the new goals, and updates the 10 major assumptions on which the plan is based. This is the second update of the plan since it was initially published in July 1998. The updated plan summarizes individual plans of agency components with major PDUFA responsibilities, and it also provides a consolidated agency summary. The updated plan to achieve PDUFA II goals for the drug review process takes into account changes in revenue projections and workload based on actual revenue and application receipts in FY 1998 and FY 1999 and updated projections for FY 2000 through FY 2002. Attachments include: The **Federal Register** notice of December 28, 1999 (64 FR 72669) establishing prescription drug user fee rates for FY 2000, updated 5-year estimates of PDUFA fees and revenues, and the revised PDUFA II Information Management Five-Year Plan.

We are making this plan available to all who have an interest. We welcome comments and will consider them in the future as annual adjustments are made to the plan.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the plan. 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 guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 21, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19046 Filed 7–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1115–N]

RIN 0938–AI26

Medicare Program; Solicitation for Proposals for the Medicare Coordinated Care Demonstration

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

ACTION: Notice.

SUMMARY: This notice informs interested parties of an opportunity to apply for a cooperative agreement for the Medicare Coordinated Care Demonstration. This demonstration uses existing models of coordinated care interventions to improve the quality of services furnished to specific beneficiaries and manage expenditures under Parts A and B of the Medicare program. We are interested in testing models aimed at beneficiaries who have one or more chronic conditions that represent high costs to the Medicare program.

Section 4016 of the Balanced Budget Act of 1997 requires a review of best practices and that the Medicare Coordinated Care Demonstration design be based on the findings of this assessment. We intend to select at least eight proposed projects for this demonstration through this competitive application process.

Eligible Organizations

Potentially qualified applicants are existing providers of coordinated care services applicable to the Medicare population. See section II.C.1. of this notice for additional details.

FOR FURTHER INFORMATION CONTACT: For information concerning this demonstration, contact Catherine Jansto, HCFA Project Officer, at (410) 786–7762, or cjansto@hcfa.gov.

For information regarding cooperative agreement procedures, fiscal matters, or guidance in completing the application forms, contact Nettie Faulkner, Grants Management Specialist, at (410) 786–6639, or nfaulkner@hcfa.gov.

General information regarding this project is available on HCFA's website (www.hcfa.gov/ord/coorcare.htm).

DATES: Applications will be considered ''on time'' if we receive them on or before October 11, 2000.

ADDRESSES: Mail applications to: Department of Health and Human Services, Health Care Financing Administration, Office of Internal Customer Support, Acquisition and Grants Group, Attn: Ms. Nettie Faulkner, Grants Management Specialist, Mail Stop: C2–21–15, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Applications must be typed for clarity and should not exceed 40 double-spaced pages, exclusive of the executive summary, resumes, forms, and documentation supporting the cost proposal. Please refer to the file code HCFA–1115–N on the application.

Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission. Applications postmarked after the closing date, or postmarked on or before the closing date but not received in time for panel review, will be considered late applications.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Requirements

Section 4016 of the Balanced Budget Act of 1997 (Pub. L. 105–33) requires the Secretary of Health and Human Services (the Secretary) to evaluate best practices in the private sector for methods of coordinated care. The statute also directs the Secretary to design a demonstration project for the original Medicare fee-for-service population based on this evaluation. The purpose of the demonstration is to evaluate models of coordinated care that improve the quality of services provided to specific beneficiaries with a chronic illness and manage expenditures under Parts A and B of the Medicare program so that, under the demonstration, Medicare expenditures do not exceed what they would have been in the absence of the demonstration.

Section 4016(b)(3) authorizes the continuation of demonstration projects that are cost-effective. That is, the evaluation of the demonstration projects conducted by HCFA establishes that these projects reduce Medicare expenditures or do not increase Medicare expenditures while increasing the quality of services furnished and beneficiary and provider satisfaction. This section also authorizes us to expand the number of demonstration sites if the models tested are shown to be cost-effective. In addition, we may issue regulations to implement, on a permanent basis, the components of the demonstration projects that are proven to be cost-effective for the Medicare program.

In July 1998, we competitively awarded a task order for conducting a review of best practices in coordinating care and for providing a recommendation of demonstration design options to Mathematica Policy Research, Inc. (MPR). We have evaluated the findings from the review of best practices and selected the following demonstration design.

B. Problem

Historically, a small proportion of Medicare beneficiaries has accounted for a major proportion of Medicare expenditures. For example, in 1996, 12.1 percent of all Medicare enrollees accounted for 75.5 percent ($126.1 billion) of all Medicare fee-for-service program payments. Many of these high-cost beneficiaries are chronically ill with certain common diagnoses, and most of the Medicare expenditures for their care are for repeated hospitalizations. During the next 30 years, as the population ages, the number of these individuals is expected to grow dramatically.

Health care for individuals with chronic illness is often fragmented and poorly coordinated across multiple health care providers and multiple sites of care. Oftentimes, evidence-based practice guidelines are not followed, nor are patients taught how best to care for themselves. These shortcomings are particularly true for patients served under reimbursement systems in which providers lack incentives for controlling the frequency, mix, and intensity of services, and have limited accountability for the outcomes of care.

A number of health care organizations, including health maintenance organizations, private insurers, commercial firms, and academic medical centers, have developed programs to support adherence (by both provider and patient) to evidence-based medical practices, to better coordinate care across providers and between face-to-face encounters with chronically ill patients, and to reduce costs. At best, the literature on the effectiveness of