

application. To meet this requirement, the agency is providing notice that Deprenyl Animal Health, Inc., 10955 Lowell, suite 710, Overland Park, KS 66210, has filed application number 8008 requesting approval for export of the animal drug ANIPRYL® (l-selegiline hydrochloride, l-deprenyl hydrochloride) tablets to Canada. The drug is administered orally for the treatment of uncomplicated canine pituitary dependent hyperadrenocorticism. The tablets are not indicated for treatment of other forms of Cushing's syndrome. The application was received and filed in the Center for Veterinary Medicine on January 4, 1996, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by February 5, 1996, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.44).

Dated: January 18, 1996.

Robert C. Livingston,
*Director, Office of New Animal Drug
Evaluation, Center of Veterinary Medicine.*
[FR Doc. 96-1321 Filed 1-25-96; 8:45 am]
BILLING CODE 4160-01-F

Health Care Financing Administration [ORD-078-N]

Medicare Program; Announcement of Funding Availability for a Cooperative Agreement for an End-Stage Renal Disease (ESRD) Managed Care Demonstration

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

ACTION: Notice.

SUMMARY: This notice is to inform
interested parties of an opportunity to

apply for funds for a cooperative
agreement from HCFA's Office of
Research and Demonstrations for the
"End-Stage Renal Disease (ESRD)
Managed Care Demonstration."

FOR FURTHER INFORMATION, CONTACT:
Bonnie Edington (410) 786-6617.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2355 of the Deficit Reduction Act of 1984 (Pub. L. 98-369) required the Secretary to grant demonstration waivers for social health maintenance organization (SHMO) projects that provide for the integration of health and social services at a fixed annual prepaid capitation rate.

Section 4207(b)(4)(B) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) amended section 2355 of Pub. L. 98-369 to include a requirement that the Secretary conduct up to four additional SHMO projects to demonstrate the effectiveness and feasibility of innovative approaches to refining current targeting and financing methodologies and benefit design for SHMOs.

Section 13567(b) of the Omnibus Budget Reconciliation Act (OBRA) of 1993 (Pub. L. 103-66) further amended section 2355 of Pub. L. 98-369, requiring the Secretary to include the integration of acute and chronic care management for patients with end-stage renal disease through expanded community care case management services in at least one of the four additional SHMO projects.

II. Provisions of this Notice

This notice is to inform interested parties of the opportunity to apply for funds for a cooperative agreement to operate an "End-Stage Renal Disease (ESRD) Managed Care Demonstration," involving the treatment of Medicare-eligible ESRD patients in a managed care setting as required by OBRA 1993. Interested parties are required to submit an official application for consideration for grant funding and commencement of site development activities. Subject to funds availability, a one-time award of approximately \$175,000 is expected to be given to each selected awardee. HCFA expects to award one or more demonstrations through the application process.

Any organizational entity may apply. However, the applicant must be capable of assuring that the service delivery system under the demonstration will integrate acute and chronic care services, through expanded community care case management services, for ESRD patients. In addition, the

applicant must meet all applicable State requirements for bearing financial risk.

Awardees are expected to have a 9 to 12-month development period subsequent to award and prior to service delivery. In the three-year service delivery phase of the demonstration, awardees will be paid on a capitation basis in which the capitation amount will be adjusted to reflect treatment status (that is, maintenance dialysis, transplant, or functioning graft).

Potential applicants who wish to request the full solicitation and application packet should call Ms. Edington at the above telephone number, send an E-mail message to BEDINGTON@HCFA.GOV, or write to the following address: Bonnie Edington, Health Care Financing Administration, Office of Research and Demonstrations, Mail Stop C3-24-07, 7500 Security Boulevard, Baltimore, MD 21244-1850. These packets will be mailed to all requestors within approximately 10 days from the date of this notice. Completed applications, including full proposals, will be due approximately 70 days following the date of this notice. The exact due date for applications will be specified in the application packet. Awards are expected to be made in 1996.

Authority: Section 402 of the Social Security Amendments of 1967, as amended (42 U.S.C. 1395b-1); section 222(a) of the Social Security Amendments of 1972, as amended (42 U.S.C. 1395-1(note)); section 2355 of the Deficit Reduction Act of 1984, as amended; section 4207(b)(4)(B) of the Omnibus Budget Reconciliation Act of 1990; section 13567(b) of the Omnibus Budget Reconciliation Act of 1993.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.779 Health Financing Research, Demonstrations and Experiments)

Dated: October 3, 1995.

Bruce C. Vladeck,
*Administrator, Health Care Financing
Administration.*

[FR Doc. 96-1261 Filed 1-25-96; 8:45 am]

BILLING CODE 4120-01-P

[BPO-134-NC]

Medicare Program; Revised Criteria and Standards for Evaluating Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Regional Carriers' Performance Beginning February 1, 1996

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

ACTION: Notice with comment period.

SUMMARY: This notice revises the criteria and standards we use to evaluate the performance of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies regional carriers in administering the Medicare program under their contracts with us.

These revisions are necessary to make the performance standards consistent with HCFA's current expectations and to improve service to Medicare beneficiaries.

DATES: *Effective Date:* This notice is effective on February 1, 1996.

Comment Date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 26, 1996.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPO-134-NC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPO-134-NC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

FOR FURTHER INFORMATION CONTACT: Sue Lathroum, (410) 786-7409 or Rich Morrison, (410) 786-7142.

SUPPLEMENTARY INFORMATION:**I. Background**

Section 1842(a) of the Social Security Act (the Act) authorizes contracts with carriers for the payment of Part B claims for Medicare-covered services and items. Section 1842(b) of the Act requires us to publish in the Federal Register criteria and standards for the effective and efficient performance of contract obligations before implementing them. On June 18, 1992, we published in the Federal Register (57 FR 27302) the criteria and standards

to be used for evaluating the performance of regional carriers for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under their contracts with us. The criteria and standards measure the effectiveness and efficiency of the DMEPOS regional carriers in carrying out the requirements of their contracts. The initial evaluation period for the DMEPOS regional carriers was from October 1, 1993 through September 30, 1994. We announced that we will consider the results of these evaluations in entering into, renewing/extending, or terminating contracts or contract amendments with the DMEPOS regional carriers. We also announced that we may revise the criteria and standards if changes are needed because of administrative mandate, congressional action, or performance expectations.

The criteria and standards were included in the current contracts with the DMEPOS regional carriers, which were effective beginning January 1, 1993, with option periods extending to September 30, 1996. The criteria and standards are subject to possible revision if the contracts or contract amendments are renegotiated, new contracts are awarded, or different carrier contracts are amended to provide for the performance of the DMEPOS functions. In accordance with section 1842(b) of the Act, we must publish in the Federal Register any revisions to these criteria and standards before their implementation.

The criteria and standards published in the June 1992 final rule (57 FR 27302) are structured into six criteria to evaluate the overall performance of the DMEPOS regional carriers. They include: (1) Quality; (2) efficiency; (3) service; (4) fraud and abuse; (5) National Supplier Clearinghouse; and (6) Statistical Analysis DMEPOS regional carrier. The six criteria contain a total of 12 standards. There are two for quality, four for efficiency, three for service, one for fraud and abuse, one for the National Supplier Clearinghouse, and one for the Statistical Analysis DMEPOS regional carrier.

II. Provisions of this Notice**A. Changes to the June 1992 Criteria and Standards**

We used the June 1992 criteria and standards to evaluate the performance of the DMEPOS regional carriers for the period October 1, 1993 through September 30, 1994. We have determined through our experience that revisions to the "Efficiency" and "Service" criteria are necessary to reflect current needs. We also believe

that some minor clarifications to the "Quality" and "National Supplier Clearinghouse" criteria are appropriate. Therefore, as described below, we will revise the criteria and standards we use to evaluate the performance of our DMEPOS regional carriers. The revised criteria and standards will be effective February 1, 1996. These criteria will replace those listed in the June 1992 final rule (57 FR 27302).

Efficiency Criterion

We will retain Standard 1 under the "Efficiency" criterion. We will no longer use Standards 2 through 4. Standard 2 for Electronic Media Claims (EMC) is no longer included since DMEPOS regional carriers are no longer assigned specific EMC goals previously measured under this standard. Now that specific goals are no longer being assigned, more focus can be placed on standardization of file formats. Standards 3 and 4 relating to expenditures and costs under these contracts no longer apply because contracts are awarded or contract amendments are entered into on the basis of proposed costs related to the entire DMEPOS regional carrier workload. Consequently, under the "Efficiency" criterion, beginning February 1, 1996, the DMEPOS regional carrier is required to: (1) Process 95.0 percent of clean claims within mandated timeframes, and (2) process 97.0 percent of all claims within 60 days.

Service Criterion

We will retain Standard 1 under the Service criterion. Under Standard 2, we will retain the requirement for DMEPOS regional carriers to ensure that 95 percent of written inquiries are responded to timely and accurately. We will revise the standard to require DMEPOS regional carriers to respond to 97.5 percent of telephone inquiries timely and accurately to increase our ongoing efforts to improve services to Medicare beneficiaries.

We will revise Standard 3 regarding responses to beneficiaries and supplier education and training needs. When this standard was established, it was necessary for carriers to publish, as well as update, a supplier manual that explains the program requirements. Now that carriers have a supplier manual in place, they only need to *update* the manual. Therefore, we will remove the requirement for publishing the manual and retain only the requirement to update the supplier manual.

Quality Criterion

In Standard 2, concerning measures to improve program effectiveness, we will clarify that the DMEPOS regional carrier is not limited to performing only the listed activities.

National Supplier Clearinghouse Criterion

We will also clarify under the National Supplier Clearinghouse criterion that the National Supplier Clearinghouse DMEPOS regional carrier function is assigned to one of the DMEPOS regional carriers.

B. Complete List of Revised Criteria and Standards

The complete list of the criteria and standards for evaluating the performance of DMEPOS regional carriers beginning February 1, 1996 follows:

We will use six criteria to evaluate the overall performance of DMEPOS regional carriers. They are: (1) Quality; (2) efficiency; (3) service; (4) fraud and abuse; (5) National Supplier Clearinghouse; and (6) Statistical Analysis DMEPOS regional carrier.

The six criteria contain a total of 9 standards. There are two for quality, one for efficiency, three for service, one for fraud and abuse, one for the National Supplier Clearinghouse, and one for the Statistical Analysis DMEPOS regional carrier.

1. Quality Criterion

A DMEPOS regional carrier must pay claims accurately and in accordance with program instructions. The DMEPOS regional carrier is required to:

Standard 1. Process claims at an accuracy rate of 98.5 percent.

Claims are processed accurately with respect to coverage determinations, secondary payer consideration, supplier enrollment, and the correct payment amount.

Standard 2. Implement measures to improve program effectiveness.

The DMEPOS regional carriers must undertake actions to promote effective program administration with respect to DMEPOS claims. These activities include, but are not limited to the following: overpayment recovery and offsetting of claim payment; assuring the proper submission of certificates of medical necessity; review of the implementation of fee schedules and reasonable charge updates; medical review activities; and implementation of coverage policy.

2. Efficiency Criterion

Standard 1. The DMEPOS regional carrier is required to process 95.0

percent of clean claims within mandated timeframes and 97.0 percent of all claims within 60 days.

3. Service Criterion

Beneficiaries and suppliers are served by prompt and accurate administration of the program in accordance with all applicable laws, regulations, and general instructions. The DMEPOS regional carrier is required to:

Standard 1. Ensure that 95.0 percent of reviews and hearings are accurate and timely.

We evaluate the reviews and hearings to determine that decisions are accurate and communicated to the appropriate party within 45 days for reviews and 120 days for hearings.

Standard 2. Ensure that 97.5 percent of telephone inquiries and 95 percent of written inquiries are responded to accurately and timely.

The DMEPOS regional carriers must answer calls within 120 seconds, callers do not get a busy signal more than 20 percent of the time, and responses are accurate. Written responses must be accurate and prepared within 30 calendar days of date of receipt.

Standard 3. Respond to beneficiary and supplier education and training needs.

The DMEPOS regional carriers must undertake actions that serve the beneficiary and supplier communities by explaining program requirements through up-to-date information, periodic educational training and bulletins, updating the supplier manual, meeting with trade associations, and coordinating with local contractors on DMEPOS issues.

4. Fraud and Abuse Criterion

Standard 1. The DMEPOS regional carrier is required to conduct an effective program integrity program.

We evaluate the DMEPOS regional carriers on a number of activities including: effectiveness in identifying and developing cases of fraud and abuse, bringing the cases to conclusion and collecting inappropriate payments, promoting beneficiary education in referring questionable suppliers or practices, and searching out supplier practices that are inappropriate.

5. National Supplier Clearinghouse Criterion

(The National Supplier Clearinghouse DMEPOS regional carrier function is assigned to one of the DMEPOS regional carriers. It performs the functions measured under this criterion.)

Standard 1. The National Supplier Clearinghouse DMEPOS regional carrier is required to properly administer the National Supplier Clearinghouse.

We review the National Supplier Clearinghouse activities to ensure the National Supplier Clearinghouse DMEPOS regional carrier meets various requirements such as: processing new and renewal applications for billing numbers, maintaining supplier files, matching Office of the Inspector General sanctioned suppliers, and enforcing supplier standards. In addition, we evaluate the National Supplier Clearinghouse DMEPOS regional carrier's performance in conducting statistical analysis of data to identify potential areas of overutilization, overpayments, fraudulent or abusive claims practices, and other areas of concern we identify.

6. Statistical Analysis DMEPOS Regional Carrier Criterion

(The Statistical Analysis DMEPOS regional carrier function is assigned to one of the DMEPOS regional carriers. It performs the functions measured under this criterion.)

Standard 1. The Statistical Analysis DMEPOS regional carrier is required to properly administer the Statistical Analysis DMEPOS regional carrier program.

We review the activities of the Statistical Analysis DMEPOS regional carrier to ensure it meets various requirements such as: Analyzing national reports to identify trends, aberrancies, and utilization patterns; generating reports according to our specifications; serving as the HCFA Common Procedure Coding System definition resource center; and developing national parental and enteral nutrition pricing and national floors and ceiling for DME prices.

III. Response To Comments

Because of the large number of items of correspondence we normally receive on Federal Register documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Prior Notice and 30-Day Delay in the Effective Date

We are publishing this notice as a final notice without prior publication of a proposed notice for public comment. For the reasons discussed below, we believe that publishing a proposed notice is unnecessary.

This notice only makes minor revisions to the criteria for evaluating

DMEPOS regional carriers' performance and has no major impact on public interest. Therefore, we believe that publication of a proposal is unnecessary, and we find good cause to waive the procedure.

We also normally provide a delay of 30 days in the effective date. However, if adherence to this procedure would be impractical, unnecessary, or contrary to public interest, we may waive the delay in the effective date. As a practical matter, if we allowed a 30-day delay in the effective date of this notice, those DMEPOS regional carriers would not be in compliance with the performance standards for fiscal year 1996. This would be contrary to public interest. Therefore, we find good cause to waive the usual 30-day delay in the effective date.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Section 1842(b) of the Social Security Act (42 U.S.C. 1395u).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 14, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Note: This document was received at the Office of the Federal Register on January 22, 1996.

[FR Doc. 96-1262 Filed 1-25-96; 8:45 am]

BILLING CODE 4120-01-P

Health Resources and Services Administration

Program Announcement for Grants for Family Medicine Training for Fiscal Year 1996

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year (FY) 1996 Grants for Family Medicine Training funded under the authority of section 747 (a) and (b), title VII of the Public Health Service Act (the Act), as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102-408, dated October 13, 1992. These grant programs include:

Grants for Predoctoral Training in

Family Medicine

Grants for Establishment of Departments of Family Medicine

This program announcement is subject to reauthorization of the

legislative authority and to the appropriation of funds. Applicants are advised that this program announcement is a contingency action being taken to assure that should authority and funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for even distribution of funds throughout the fiscal years. At this time, given a continuing resolution and the absence of FY 1996 appropriations for title VII programs, the amount of available funding for these specific grant programs cannot be estimated.

Grants for Predoctoral Training in Family Medicine

Purpose: Section 747(a) of the Public Health Service Act authorizes the award of grants to assist in meeting the cost of planning, developing and operating or participating in approved predoctoral training programs in the field of family medicine. Grants may include support for the program only or support for both the program and the trainees.

Eligibility: Eligible applicants are accredited public or nonprofit private schools of medicine or osteopathic medicine.

Grants for Establishment of Departments of Family Medicine

Purpose: Section 747(b) of the PHS Act authorizes support to meet the costs of projects to establish, maintain, or improve family medicine academic administrative units (which may be departments, divisions, or other units) to provide clinical instruction in family medicine. Funds awarded will be used to: (1) plan and develop model educational predoctoral, faculty development and graduate medical education programs in family medicine which will meet the requirements of section 747(a), by the end of the project period of section 747(b) support; and (2) support academic and clinical activities relevant to the field of family medicine.

The program may also assist schools to strengthen the administrative base and structure that is responsible for the planning, direction, organization, coordination, and evaluation of all undergraduate and graduate family medicine activities. Funds are to complement rather than duplicate programmatic activities for actual operation of family medicine training programs under section 747(a).

Eligibility: To be eligible to receive support for this grant program, the applicant must be a public, or nonprofit private, accredited school of medicine or osteopathic medicine.

National Health Objectives for the Year 2000

The Public Health Service urges applicants to submit work plans that address specific objectives of Healthy People 2000. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; Stock No. 017-001-00474-0) or *Healthy People 2000* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone 202-783-3238).

Education and Service Linkage

As part of its long-range planning, HRSA will be targeting its efforts to strengthening linkages between U.S. Public Health Service education programs and programs which provide comprehensive primary care services to the underserved.

Smoke-Free Workplace

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Review Criteria

The following review criteria were established in 42 CFR part 57, subparts Q and R, and following public comment at 60 FR 2976, dated January 12, 1995.

1. The administrative and management ability of the applicant to carry out the proposed project in a cost-effective manner.

2. The potential of the project to continue on a self-sustaining basis after the period of grant support.

3. The degree to which the proposed project adequately provides for the project requirements.

4. Potential effectiveness of the proposed project in carrying out the training purposes of section 747 of the PHS Act.

Weighted indicators were also established for these review criteria following public comment at 60 FR 2976, dated January 12, 1995.

Other Considerations

In addition, funding factors may be applied in determining funding of approved applications. A funding preference is defined as the funding of a specific category or group of approved applicants ahead of other categories or