Products'' published in the **Federal Register** of July 24, 1997 (62 FR 39904).

On December 2, 1997 (62 FR 56193, October 29, 1997), CBER held a public workshop entitled ''Workshop on the Biologics License Application (BLA) for Blood Products, and Reporting Changes to an Approved Application.'' The workshop was intended for firms that manufacture licensed human blood products, including products for transfusion and source materials for further manufacture. The workshop discussion focused on the application procedures, forms, and documentation needed for the BLA and how changes to an approved application are to be reported to FDA.

In response to comments received from industry requesting guidance specifically for blood and blood components, CBER has developed the draft guidance document for the manufacturers of licensed Whole blood and blood components intended for transfusion and for further manufacture into both injectable and noninjectable products. The draft guidance document, when finalized, will replace the recommendations in the ''Guidance for Industry: Changes to an Approved Application: Biological Products'' for Whole Blood, blood components, Source Plasma, and Source Leukocytes. The ''Guidance for Industry: Changes to an Approved Application: Biological Products'' remains applicable for all other biological products.

This draft guidance document represents the agency's current thinking on changes to an approved application for all licensed human blood and blood components intended for transfusion or for further manufacture. 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 requirement of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft guidance document is being distributed for comment purposes only, and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments at any time, however, comments should be submitted by April 3, 2000, to ensure adequate consideration in preparation of the final document. 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 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 at http://www.fda.gov/cber/guidelines.htm.

Dated: December 22, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–34039 Filed 12–30–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0296]

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. The proposed collections consist of uniform mandatory notices to be given to Medicare home health beneficiaries by home health agencies (HHAs) when the HHA believes that services may not or may no longer be covered. Interested persons are invited to send comments regarding burden or any other aspect of these collections of information requirements. All comments will be considered together, including those comments submitted with respect to the Emergency **Federal Register** notice published on September 22, 1999, with regard to balancing the burden on providers with the provision of sufficient information to beneficiaries. We are particularly interested in receiving input regarding the form of the notices and the order in which the information is presented. We also invite comments on how best to fully inform beneficiaries with regard to services not covered by Medicare. Comments may also be sent regarding 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.

Additionally, we acknowledge that comments regarding these notices were made by beneficiary advocates in the context of the ongoing litigation in *Healey* v. *Shalala,* Civil Action No.3:98CV00418 (DJS) (D.Conn.). These comments related to: (1) the extent and type of notice that is required in cases in which the physician concurs in the reduction, termination, or denial of services; (2) the incorporation of a statement regarding a requirement that a beneficiary agree to share her medical records with the RHHI in the event that she requests the submission of a demand bill; and (3) general concerns about design and readability. The comments will be considered along with all other comments received in response to this request. However, we consider it most efficient and effective to publish these notices for comment in their present form and to consider all comments in a single comprehensive proceeding.

We also received comments from the National Association of Home Care (''NAHC'') , representing members of the provider community, regarding these notices. These comments related to the time required for implementation and general readability concerns. Among other things, NAHC also stated its belief that the notices misstate, in the boxes regarding the beneficiaries' choices, the standard under which coverage is determined. Similarly, these concerns will be considered with all other comments received in response to this request.

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

Title of Information Collection: Home Health Advance Beneficiary Notices (HHABNs) and Supporting Regulations in 42 CFR Section 411.404-.406, 484.10, and 484.12(a);

Form No.: HCFA–R–0296 (OMB# 0938–0781);

Use: Beneficiaries must receive timely, accurate, complete, and useful notices which will enable them to make informed consumer decisions, with a proper understanding of their rights to a Medicare initial determination, their appeal rights in the case of payment

denial, and how these rights are waived if they refuse to allow their medical information to be sent to Medicare. It is essential that such notice be timely, readable and comprehensible, provide clear directions, and provide accurate and complete information about the services affected and the reason that Medicare denial of payment for those services is expected by the HHA. For these reasons, uniform mandatory notices (the HHABNs) with very specific content and graphic design have been prepared (they are attached as Exhibits 1–3 hereto), which are to be used by all HHAs furnishing services to Medicare beneficiaries.

When an HHA expects payment for the home health services to be denied by Medicare, a beneficiary must be advised before home health care is initiated or continued, that in the HHA's opinion, payment probably will be required from him or her personally. The attached HHABNs are designed to ensure that HHAs inform beneficiaries in writing, in a timely fashion, about changes to their home health care, the fact that they may have to pay for care themselves if Medicare does not pay, the process they must follow in order to obtain an initial determination by Medicare and, if payment is denied, to file an appeal, and the fact that they waive those rights if they refuse to allow their medical information to be sent to Medicare. The HHABNs are to be issued by the HHA each time, and as soon as, the HHA makes the assessment that it believes Medicare payment will not be made. The HHABNs are to be provided by HHAs in any case where a reduction or termination of services is to occur, or where services are to be denied before being initiated, except in any case in which a physician concurs in the reduction, termination, or denial of services. Failure to do so would be a violation of the HHA Conditions of Participation in the Medicare Program, which are currently approved PRA requirements approved under OMB number 0938–0365, and may result in the HHA being held liable under the Limitation on Liability (LOL) provision.

Home Health Advance Beneficiary Notices (HHABNs) HHABNs, Exhibits 1–3 serve as notice to the beneficiary that the HHA believes that home health services are not, or will no longer be, covered in different situations. HHABN–T, Termination, is used when all home health services will be terminated. HHABN–I, Initiation, is used when the HHA expects that Medicare will not pay, even before services have been initiated. HHABN–R, Reduction, is used when ongoing home health services will be reduced (e.g., reduced in number, frequency, or for a particular subset of services, or otherwise).

Frequency: On occasion.

Affected Public: Individuals or Households, Business or other for-profit, Not-for-profit institutions.

Number of Respondents: 540,000.

Total Annual Responses: 1,080,000.

Total Annual Hours: 180,000.

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: Health Care Financing Administration, 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: December 22, 1999.

John P. Burke III,

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

[FR Doc. 99–33945 Filed 12–30–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Competitive Comprehensive Grants Preview (1999 FY) Availability

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice; correction.

SUMMARY: In the **Federal Register** issue of Thursday, August 18, 1999, make the following correction:

Correction

In the **Federal Register** issue of Wednesday, August 18, 1999, in FR Doc. 99–21257, on page 45025, the cooperative agreement category in the second column under the heading ''Health Care Information and Information for Families of Children with Special Health Care Needs (CFDA# 93.110S)'' is withdrawn from competition due to Agency delay in implementing the prerequisite pilot phase of the Initiative.

Dated: December 23, 1999.

Claude Earl Fox,

Administrator.

[FR Doc. 99–34041 Filed 12–30–99; 8:45 am]

BILLING CODE 4160–15–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. AA1921–124 and 731–TA–546–547 (Reviews)]

Certain Steel Wire Rope From Japan, Korea, and Mexico

Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission determines,[2] pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)) (the Act), that revocation of the antidumping duty finding and orders on certain steel wire rope from Japan, Korea, and Mexico would not be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on January 4, 1999 (64 FR 367) and determined on April 8, 1999 that it would conduct full reviews (64 FR 19198, April 19, 1999). Notice of the scheduling of the Commission's reviews and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on June 30, 1999 (64 FR 35181). The hearing was held in Washington, DC, on October 14, 1999, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on December 20, 1999. The views of the Commission are contained in USITC Publication 3259 (December 1999), entitled Certain

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Chairman Lynn M. Bragg dissenting on Japan, and Commissioner Stephen Koplan dissenting on Japan and Mexico.