

both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 22, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Form # HCFA-R-0269]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHHS), is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of 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.

We are, however, requesting an emergency review of the information collections referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320 and is essential to the mission of the Agency. The Agency cannot reasonably comply with the normal clearance procedures because of a statutory deadline imposed by section 4319 of the Balanced Budget Act of 1997. Without this information, HCFA would not be able to properly

implement all of the requirements set forth in the statute prior to the statute's sunset provision. Specifically, the statute mandates evaluations of competitive bidding projects, along with evaluation reporting requirements. The statutory requirement includes an evaluation of competitive bidding impacts on access to care, quality of care, and diversity of product selection. The first evaluation project will measure these characteristics before competitive bidding as well as after the competitively bid fees become effective. The baseline and follow-up measurements will be compared. To ensure valid comparisons, marketplace changes that may be attributable to competitive bidding should not affect the baseline measurements. Therefore, the baseline measurements must be completed before the competitive bidding contracts are established in the Spring of 1999. If HCFA were to follow the normal clearance procedures, resulting in a delay in the baseline measurements, it would have difficulty determining whether competitive bidding causes reductions in access, quality, or product selection.

HCFA is requesting OMB review and approval of this collection by January 11, 1999, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below by January 8, 1999.

During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection

Request: New collection.

Title of Information Collection: Evaluation of Competitive Bidding Demonstration for Durable Medical Equipment (DME) and Prosthetics, Orthotics, and Supplies (POS)—Data Collection Plan for Baseline Beneficiary Surveys, Oxygen Consumer Survey, Medical Equipment and Supplies Consumer Survey and Supporting Statute Section 4319 of the Balanced Budget Act of 1997.

Form No.: HCFA-R-0269.

Use: Section 4319 of the Balanced Budget Act (BBA) mandates HCFA to implement demonstration projects under which competitive acquisition areas are established for contract award purposes for the furnishing of Part B items and services, except for physician's services. The first of these demonstration projects implements competitive bidding of categories of

durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Under the law, suppliers can receive payments from Medicare for items and services covered by the demonstration only if their bids are competitive in terms of quality and price. Each demonstration project may be conducted in up to three metropolitan areas for a three year period. Authority for the demonstration expires on December 31, 2002. The schedule for the demonstration anticipates about a six month period required between mailing the bidding forms to potential bidders and the start of payments for DMEPOS under the demonstration. HCFA intends to operate the demonstration in two rounds, the first of two years, and the second of one year. HCFA has announced that it intends to operate its first demonstration in Polk County, Florida, which is the Lakeland-Winter Haven Metropolitan Area.

This evaluation is necessary to determine whether access to care, quality of care, and diversity of product selection are affected by the competitive bidding demonstration. Although secondary data will be used wherever possible in the evaluation, primary data from beneficiaries themselves is required in order to gain an understanding of changes in their level of satisfaction and in the quality and selection of the medical equipment.

The purpose of the data collection plan is to describe the baseline data collection procedures and the plan for analyzing the data to be collected.

The baseline beneficiary surveys will take place February to May 1999, prior to the competitive bidding demonstration. We will sample beneficiaries from enrollment files provided by the durable medical equipment regional carrier (DMERC). The sample will be stratified into two groups: beneficiaries who use oxygen and beneficiaries who are non-oxygen users, i.e., users of the other four product categories covered by the demonstration (hospital beds, enteral nutrition, urological supplies, and surgical dressings) but not oxygen. To draw a comparison, we will sample in both the demonstration site (Polk County, Florida) and a comparison site (Brevard County, Florida) that matches Polk County on characteristics such as number of Medicare beneficiaries and DME/POS utilization.

Information collected in the beneficiary survey will be used by the University of Wisconsin-Madison (UW-M), Research Triangle Institute (RTI), and Northwestern University (NU) to evaluate the Competitive Bidding Demonstration for DME and POS.

Results of the evaluation will be presented to HCFA and to Congress, who will use the results to determine whether the demonstration should be extended to other sites.

The research questions to be addressed by the surveys focus on access, quality, and product selection. Our collection process will include fielding a survey for oxygen users and a survey for non-oxygen users before the demonstration begins and again once the new demonstration prices have been put into effect. The same data collection process will be followed in the comparison site (Brevard County). In the analysis of the data, we will also control for socioeconomic factors. This will allow us to separate the effects of the demonstration from beneficiary- or site-specific effects.

In the survey, we will also ask beneficiaries about the types of equipment that they use. This will allow us to determine if certain users are affected while others are not. For example, we will be able to evaluate whether oxygen users experience a greater increase or decrease in access and quality than beneficiaries who receive enteral nutrition.

The information that this survey will provide about access, quality, and product selection will be very important to the future of competitive bidding within the Medicare program. This is the first Medicare demonstration that allows competitive bidding for services and equipment provided to beneficiaries. A negative impact on access, quality, or product selection would have significant implications for the future of competitive bidding within the Medicare program.

Frequency: Two times for each affected beneficiary.

Affected Public: Individuals or Households.

Number of Respondents: 2,560.

Total Annual Responses: 2,560.

Total Annual Hours: 724.4.

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, and HCFA form number(s) referenced above, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be

mailed and/or faxed to the designee referenced below, by January 8, 1999:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room: N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850, Fax Number: (410) 786-0262, Attn: John Burke; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395-6974 or (202) 395-5167, Attn: Allison Herron Eydt, HCFA Desk Officer.

Dated: December 21, 1998.

John P. Burke III,

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

[FR Doc. 98-34398 Filed 12-28-98; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importation of Controlled Substances; Notice of Application

Pursuant to Section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(I)), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under Section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with Section 1301.34 of Title 21, Code of Federal Regulations (CFR), notice is hereby given that on November 16, 1998, B.I. Chemical, Inc., 2820 N. Normandy Drive, Petersburg, Virginia 23805, made application to the Drug Enforcement Administration to be registered as an importer of phenylacetone (8501), a basic class of controlled substance listed in Schedule II.

The firm plans to import the phenylacetone for the bulk manufacture of amphetamine.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in

accordance with 21 CFR 1301.43 is such form as prescribed by 21 CFR 1316.47.

Any such comments, objections or requests for a hearing may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than (30 days from publication).

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745-46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: December 17, 1998.

John H. King,

Deputy Assistance Administrator, Office of Diversion Control, Drug Enforcement Administration.

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DEPARTMENT OF LABOR

Bureau of International Labor Affairs; U.S. National Administrative Office National Advisory Committee for the North American Agreement on Labor Cooperation; Notice of Open Meeting

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of Open Meeting January 28, 1999.

SUMMARY: Pursuant to the Federal Advisory Committee Act (Pub. L. 94-463), the U.S. National Administrative Office (NAO) gives notice of a meeting of the National Advisory Committee for the North American Agreement on Labor Cooperation (NAALC), which was established by the Secretary of Labor.

The Committee was established to provide advice to the U.S. Department of Labor on matters pertaining to the implementation and further elaboration of the NAALC, the labor side accord to the North American Free Trade Agreement (NAFTA). The Committee is authorized under Article 17 of the NAALC.

The Committee consists of 12 independent representatives drawn