opportunity for a hearing on a proposal to revoke the establishment license (U.S. License No. 1116) and product licenses issued to Bestblood, Ltd., doing business as Optimum Healthcare, Inc., for the manufacture of Whole Blood, Red Blood Cells, Red Blood Cells Frozen, Whole Blood CPD, Red Blood Cells Deglycerolized, and Whole Blood CPDA–1. The proposed revocation is based on the inability of authorized FDA employees to conduct an inspection of this facility, which is no longer in operation.

DATES: The firm may submit written requests for a hearing by May 17, 1999, and any data and information justifying a hearing by June 14, 1999. Other interested persons may submit written comments on the proposed revocation by June 14, 1999.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is initiating proceedings to revoke the establishment license (U.S. License No. 1116) and product licenses issued to Bestblood, Ltd., doing business as Optimum Healthcare, Inc., 239 Randall St., San Francisco, CA 94131, for the manufacture of Whole Blood, Red Blood Cells, Red Blood Cells Frozen, Whole Blood CPD, Red Blood Cells Deglycerolized, and Whole Blood CPDA–1. Proceedings to revoke the licenses are being initiated because an attempted inspection of the facility by FDA, as required under § 600.21 (21 CFR 600.21), revealed that the firm was no longer in operation.

In a certified, return-receipt letter dated June 16, 1997, FDA notified the Responsible Head of the firm that its attempt to conduct an inspection at Bestblood, Ltd., 239 Randall St., San Francisco, CA 94131, was unsuccessful because the facility was apparently no longer in operation, and requested that the firm notify FDA in writing of the firm's status. This letter was sent to 239 Randall St., San Francisco, CA 94131, and to P.O. Box 843, Cupertino, CA 95054–0843, and each was returned to the agency as undeliverable.

In a certified, return-receipt letter sent to Bestblood, Ltd., dated March 4, 1998, at both addresses mentioned previously and returned as undeliverable, FDA indicated that an attempt to conduct an inspection at the facility was unsuccessful. The letter advised the Responsible Head that, under 21 CFR 601.5(b)(1) and (b)(2), when FDA finds that authorized employees have been unable to gain access to an establishment for the purpose of carrying out an inspection required under § 600.21, or the manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection cannot be made, proceedings for license revocation may be instituted. In the same letter, FDA indicated that a meaningful inspection could not be made at the establishment and issued the firm notice of FDA's intent to revoke U.S. License No. 1116 and announced its intent to offer an opportunity for a hearing.

Because FDA has made reasonable efforts to notify the firm of the proposed revocation and no response was received from the firm, FDA is proceeding under 21 CFR 12.21(b) and publishing this notice of opportunity for a hearing on a proposal to revoke the licenses of the previously mentioned establishment.

FDA has placed copies of the documents relevant to the proposed revocation on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. These documents include: (1) Summary of Findings, May 28, 1997 (Endorsement Form FDA 481), and (2) FDA letters to the Responsible Head dated June 16, 1997, and March 4, 1998. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Bestblood, Ltd., may submit a written request for a hearing to the Dockets Management Branch by May 17, 1999, and any data and information justifying a hearing must be submitted by June 14, 1999. Other interested persons may submit written comments on the proposed license revocation to the Dockets Management Branch by June 14, 1999. The failure of the licensee to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation.

FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data to justify a hearing on proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must set forth a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, or if a request for a hearing is not made within the required time with the required format or required analyses, the Commissioner of Food and Drugs will deny the hearing request, making findings and conclusions that justify the denial.

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Such submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: April 5, 1999.

Mark Elengold,

Deputy Director, Operations, Center for Biologics Evaluation and Research.

[FR Doc. 99–9457 Filed 4–14–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–279]

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.

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.

Type of Information Collection Request: New Collection;

Title of Information Collection: Study to Develop a Classification System for Patients in Inpatient Rehabilitation Hospitals and Exempt Rehabilitation Units;

Form No.: HCFA–R–279 (OMB# 0938–NEW);

Use: To conduct a study using patient and facility characteristics and resource utilization as determined by staff time measurement to develop a classification and payment system for Medicare beneficiaries. This information will be used to develop a classification system for Medicare patients using rehabilitation services in inpatient rehabilitation hospitals and exempt rehabilitation units. This classification system will be referred to as Rehabilitation Resources Groups, Version 2000 (R2G2).

The purpose of this study is to develop, assess, and test this classification system through a representative sample of inpatient rehabilitation hospitals and exempt units (note that throughout this request, we will refer to rehabilitation facilities; these include both freestanding rehabilitation hospitals and exempt rehabilitation units). The principal goal is to determine the extent to which measurable patient characteristics permit classifying patients into identifiable groups that accurately predict the use of resources in these facilities.

Patient characteristics will be collected using the Minimum Data Set for Post Acute Care (MDS–PAC) (previously approved; OMB No. 0938–0720). This instrument collects demographic and clinical information that will be used to develop the classification system. We are requesting utilization of this instrument, as revised and tested to include specific variables designed to collect information on patients using rehabilitation services. Secondary analysis of existing data has provided information used to develop the sampling plan. Medicare administrative files (including the cost reports, OSCAR files, and the Standard Analytic National Claims History 100 percent file) were used to develop the sampling frame for this study.

We will be using a staff time measurement study to collect information within the sampled rehabilitation facilities to assess the resources utilized by Medicare beneficiaries. While the staff time measurement has been used in other studies to develop both resource utilization and payment methodologies (i.e., staff time measurement was used to develop the prospective payment system for skilled nursing homes), this is the first time that direct, on-site information will be collected regarding resource utilization in rehabilitation facilities.

The methodology is similar to the Resource Utilization Groups (RUG) methodology used by the Health Care Financing Administration (HCFA) to identify patient characteristics related to variance in patients' needs for resources in skilled nursing facilities (SNFs) and to develop the SNF prospective payment system (PPS).

HCFA is requesting clearance of the study, including the sample, sample selection methodology, and data collection plans, including staff time measurement and use of the revised MDS–PAC. This study will enable HCFA to develop, test, and assess a classification system for inpatient rehabilitation hospitals and exempt rehabilitation units:

Frequency: On occasion;

Affected Public: Business or other for-profit, and Not-for-profit institutions;

Number of Respondents: 4,000;

Total Annual Responses: 4,000;

Total Annual Hours: 6,800.

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: HCFA, 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: April 8, 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. 99–9423 Filed 4–14–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodation, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: May 6–7, 1999.

Closed: May 6, 1999, 10:30 a.m. to recess.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Open: May 7, 1999, 8:00 a.m. to adjournment.

Agenda: Presentation of NIMH Director's Report and discussion of NIMH program and policy issues.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31C, Conference Room 6, Bethesda, MD 20892.

Contact Person: Jane A. Steinberg, PhD, Executive Secretary, Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–3367.