years preceding this notice. Section 306(c)(2)(A)(ii) of the act requires that Mr. Uddin's debarment be permanent.

III. Proposed Action and Notice of Opportunity for a Hearing

Based on the findings discussed previously in this document, FDA proposes to issue an order under section 306(a)(2) of the act permanently debarring Mr. Uddin from providing services in any capacity to a person that has an approved or pending drug product application.

In accordance with section 306 of the act and part 12 (21 CFR part 12), Mr. Uddin is hereby given an opportunity for a hearing to show why he should not be debarred. If Mr. Uddin decides to seek a hearing, he must file on or before February 11, 1999, a written notice of appearance and request for a hearing. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in part 12 and section 306(i) of the act.

Mr. Uddin's failure to file a timely written notice of appearance and request for a hearing constitutes an election by him not to use the opportunity for a hearing concerning his debarment, and a waiver of any contentions concerning this action. If Mr. Uddin does not request a hearing in the manner prescribed by the regulations, the agency will not hold a hearing and will issue the debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the information and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact which precludes the order of debarment, the Commissioner of Food and Drugs will enter summary judgment against Mr. Uddin, making findings and conclusions and denying a hearing.

The facts underlying Mr. Uddin's conviction are not at issue in this proceeding. The only material issue is whether Mr. Uddin was convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction mandates his debarment.

A request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 94N–0424 and sent to the Dockets Management Branch (address above). All submissions pursuant to this notice of opportunity for a hearing are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.99).

Dated: December 23, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–562 Filed 1–11–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–0319, 0381, 1856/1893, and 1880/1882]

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.

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: State Medicaid Eligibility Quality Control (MEQC) Sample Section Lists and Supporting Regulations in 42 CFR 431.800–431.865; Form No.: HCFA–0319 (OMB# 0938–0147); Use: At the beginning of each month, State agencies are required to submit sample selection lists which identify all of the cases selected for review in the States' samples. These reviews are conducted to determine whether the sampled cases meet applicable State Title XIX eligibility requirements. The sample selection lists contain identifying information on Medicaid beneficiaries such as: State agency review number; beneficiary's name and address; the name of the county where beneficiary resides; and the Medicaid case number. The reviews are also used to assess beneficiary liability, if any, and to determine the amounts paid to provide Medicaid services for these cases.; Frequency: Monthly; Affected Public: State, Local or Tribal Government; Number of Respondents: 55; Total Annual Responses: 660; Total Annual Hours: 5,280.

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Identification of Extension Units of Outpatient Physical Therapy (OPT) and Outpatient Speech Pathology (OSP) Providers and Supporting Regulations in 42 CFR 485.701–785.729; Form No.: HCFA–381 (OMB# 0938–0273); Use: Medicare requires OPT/OSP providers to be surveyed to determine compliance with Federal requirements. When an OPT/OSP provider furnishes services to locations other than their already certified premises (extension locations), those premises are considered to be part of the OPT/OSP provider and are subject to the same Medicare regulations as the primary location. This form is used by the State survey agencies and by the HCFA regional offices to identify and monitor extension locations to ensure their compliance with Federal requirements. The HCFA–381 form requests information such as: facility name, provider number, where services are rendered, and the number of OPT/OSP services rendered.; Frequency: Annually; Affected Public: Business or other for-profit; Number of Respondents: 2,300; Total Annual Responses: 2,300; Total Annual Hours: 575.

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Request for Certification in the Medicare and/ or Medicaid Program to Provide Outpatient Physical Therapy (OPT) and/or Speech Pathology Services, Outpatient Physical Therapy Speech Pathology Survey Report and Supporting Regulations in 42 CFR 485.701–485.729; Form No.: HCFA–1856/1893 (OMB# 0938–0065); Use: The request for certification form is

used by State agency surveyors to determine if minimum Medicare eligibility requirements are being met by OPT providers. The survey report form records whether providers or suppliers are complying with HCFA health and safety requirements. The basic identifying information from this form is coded into the Online Survey Certification and Reporting System and serves as the information base for the creation of a record for future Federal certification and for monitoring activity.; Frequency: On occasion; Affected Public: Business or other for-profit; Number of Respondents: 1,700; Total Annual Responses: 1,700; Total Annual Hours: 446.

4. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Request for Certification as Supplier of Portable X-ray Services under the Medicare/Medicaid Program for Portable X-ray Survey Report and Supporting Regulations in 42 CFR 405.1411–405.1416 and 486.100–486.110; Form No.: HCFA–1880/1882 (OMB# 0938–0027); Use: The Medicare program requires portable X-ray suppliers to be surveyed for health and safety standards. The HCFA–1880 is used by the surveyor to determine if a portable X-ray applicant meets the eligibility requirements. It also promotes data reduction or introduction, and retrieval from the Online Survey Certification and Reporting (OSCAR) System by the HCFA Regional Offices. The HCFA–1882 is the survey form that records survey results. The form is primarily a coding work sheet designed to facilitate data reduction and retrieval into the OSCAR system at the HCFA Regional Offices. Frequency: On occasion; Affected Public: Business or other for profit; Number of Respondents: 520; Total Annual Responses: 520; Total Annual Hours: 137.

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: Louis Blank, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 4, 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. 99–669 Filed 1–11–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1062–NC]

RIN 0938–AJ32

Medicare and Medicaid Programs; Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Area Assignments

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

ACTION: Notice with comment period.

SUMMARY: This notice announces additional applications that we have received from hospitals requesting waivers from entering into agreements with their designated organ procurement organizations (OPOs). Section 1138(a)(2) of the Social Security Act allows the Secretary of the Department of Health and Human Services to grant waivers to hospitals that want to enter into an agreement with a specific OPO that is not the designated OPO for the hospital's service area. This notice also requests comments from OPOs and the general public for our consideration in determining whether these waivers should be granted.

DATES: Comments will be considered if we receive them at the appropriate address no later than 5 p.m. on March 15, 1999.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1062–NC, P.O. Box 26676, Baltimore, MD 21244–0517.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments may also be submitted electronically to the following e-mail address: HCFA1062NC@hcfa.gov. E-mail comments must include the full name, postal address, and affiliation (if applicable) of the sender and must be submitted to the referenced address to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1062–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 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, Monday through Friday from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Mark A. Horney, (410) 786–4554.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1138(a)(1)(A)(iii) of the Social Security Act (the Act) provides that a participating hospital must notify its designated organ procurement organization (OPO) of potential organ donors. The designated OPO, as defined under section 1138(a)(3)(B) of the Act, is determined by the service area in which the hospital is located. Under section 1138(a)(1)(C) of the Act, the hospital must have an agreement to identify potential organ donors only to that designated OPO.

Section 1138(a)(2) of the Act provides that a participating hospital may obtain a waiver of these requirements from the Secretary of the Department of Health and Human Services (the Secretary). A waiver allows the hospital to have an agreement with an OPO other than its designated OPO if conditions specified in section 1138(a)(2)(A) of the Act are met.

Section 1138(a)(2)(A) states that in granting a waiver, the Secretary must determine that such a waiver—

- Is expected to increase organ donation; and
- Will ensure equitable treatment of patients referred for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver.

In making a waiver determination, section 1138(a)(2)(B) of the Act provides