8, 2001, and any data and information justifying a hearing must be submitted by April 9, 2001. Other interested persons may submit written comments on the proposed license revocation to the Dockets Management Branch by April 9, 2001. 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. If the Commissioner determines upon review of any objections or requests for a hearing that a hearing is not justified, in whole or in part, or if a request for a hearing is not made within the required time with the required format or required analyses, the Commissioner will deny the hearing request, with an explanation for 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 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 the 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: January 24, 2001.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 01–3094 Filed 2–5–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Notice of Hearing: Reconsideration of Disapproval of Missouri State Plan Amendment (SPA) 99–29

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on March 8, 2001, at 10:00 a.m., Plaza Room 664, Richard Bolling Federal Building, 601 E. Twelfth Street, Kansas City, Missouri 64106, to reconsider our decision to disapprove Missouri SPA 99–29.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by February 21, 2001.

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, HCFA, C1–09–13, 7500 Security Boulevard, Baltimore, MD 21244, Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider HCFA's decision to disapprove Missouri's SPA 99–29. Missouri submitted SPA 99–29 on December 29, 1999, which proposed to pay for school-based assessment services described in an individualized education plan pursuant to the Individuals with Disabilities Education Act (IDEA) using a bundled rate methodology. One rate would be paid for a variable package of assessment services, regardless of the number of assessment services provided to a particular child. As explained below, HCFA disapproved Missouri SPA 99–29 after consulting with the Secretary on October 31, 2000.

Section 1116 of the Social Security Act (the Act) and 42 CFR part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. HCFA is required to publish a copy of the notice to a State Medicaid agency that informs said agency of the time and place of the hearing and the issues to be considered. If the agency is subsequently notified of additional issues that will be considered at the hearing, that notice will also be published.

In accordance with the requirements contained at 42 CFR 430.76(b)(2), any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice. Any interested person or organization that wants to participate as amicus curiae must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The first issue is whether payment for Medicaid services using a bundled rate methodology, under which payment is made at a single rate for one or more in a group of different services furnished to an eligible individual over a fixed period of time, meets the conditions set forth in section 1902(a)(30) of the Act. Section 1902(a)(30)(A) provides that Medicaid State plans must provide for such methods and procedures relating to the payment for care and services available under the plan as may be necessary to ensure that payments are consistent with efficiency, economy, and quality of care. The amendment proposed to pay for school-based assessment services furnished pursuant to the IDEA using a bundled rate methodology. Under the proposed payment methodology, one rate would be paid for a variable package of assessment services, regardless of the number of assessment services provided to a particular child. As explained below, HCFA was unable to approve Missouri SPA 99–29 because the proposed payment methodology was not in compliance with section 1902(a)(30)(A) of the statute, and could not generate sufficient documentation to establish such compliance.

On May 21, 1999, HCFA issued a letter to all State Medicaid directors indicating that it would no longer approve State plan amendments proposing reimbursement for school-based health services using a bundled rate. That letter described a bundled rate as a single rate for one or more in a group of different services furnished to an eligible individual during a fixed period of time. In the May 21 letter, HCFA explained that such rates do not ensure accurate and reasonable payments consistent with efficiency, economy, and quality of care. Specifically, HCFA stated that the bundled rate is inconsistent with economy since the rate is not designed to accurately reflect true costs or reasonable fee-for-service rates. The bundled rate is also inconsistent with efficiency since it requires substantially more Federal oversight resources to establish the accuracy and reasonableness of State expenditures. In sum, HCFA concluded that, with a bundled rate, there is no reliable basis for determining that the payments

would be accurate, reasonable, and consistent with statutory requirements.

The second issue is whether the proposed amendment provided sufficient information on the payment methodology or rate structure to demonstrate that the requirements of 42 CFR part 447, subpart F (Payment Methods for Other Institutional and Noninstitutional Services) were met. HCFA concluded that the proposed amendment did not meet the requirements because it (including all associated communications with the State) did not fully explain how payments would be calculated and how rates would be determined. Therefore, based on the above, and after consultation with the Secretary as required under 42 CFR 430.15(c)(2), HCFA disapproved Missouri SPA 99–29.

The notice to Missouri announcing an administrative hearing to reconsider disapproval of its SPA reads as follows:

Mr. Steven E. Renne, Acting Director, Missouri Department of Social Services, P.O. Box 1527, Broadway State Office Building, Jefferson City, MO 65102–1527

Dear Mr. Renne:

I am responding to your request received January 3, 2001, for reconsideration of the October 31, 2000, decision by the Health Care Financing Administration (HCFA) to disapprove Missouri State Plan Amendment (SPA) 99–29. I set forth below a statement of the issues and scheduled a hearing on your request.

The first issue is whether payment for Medicaid services using a bundled rate methodology, under which payment is made at a single rate for one or more in a group of different services furnished to an eligible individual over a fixed period of time, meets the conditions set forth in section 1902(a)(30) of the Social Security Act (Act). Section 1902(a)(30)(A) provides that Medicaid State plans must provide for such methods and procedures relating to the payment for care and services available under the plan as may be necessary to ensure that payments are consistent with efficiency, economy, and quality of care. The amendment proposed to pay for school-based assessment services furnished to special education children pursuant to the Individuals with Disabilities Education Act using a bundled rate methodology. Under the proposed payment methodology, one rate would be paid for a variable package of assessment services, regardless of the number of assessment services provided to a particular child. As explained below, HCFA was unable to approve Missouri SPA 99–29 because the proposed payment methodology was not in compliance with section 1902(a)(30)(A) of the statute, and sufficient documentation was not provided to establish such compliance.

On May 21, 1999, HCFA issued a letter to all State Medicaid directors indicating that it would no longer approve State plan amendments proposing reimbursement for school-based health services using a bundled rate. That letter described a bundled rate as a single rate for one or more in a group of different services furnished to an eligible individual during a fixed period of time. In the May 21 letter, HCFA explained that such rates do not ensure accurate and reasonable payments consistent with efficiency, economy, and quality of care. Specifically, HCFA stated that the bundled rate is inconsistent with economy since the rate is not designed to accurately reflect true costs or reasonable fee-for-service rates. The bundled rate is also inconsistent with efficiency since it requires substantially more Federal oversight resources to establish the accuracy and reasonableness of State expenditures. In sum, HCFA concluded that, with a bundled rate, there is no reliable basis for determining that the payments would be accurate, reasonable, and consistent with statutory requirements.

The second issue is whether the proposed amendment provided sufficient information on the payment methodology or rate structure to demonstrate that the requirements of 42 CFR part 447, subpart F (Payment Methods for Other Institutional and Noninstitutional Services) were met. HCFA concluded that the proposed amendment did not meet these requirements because it (including all associated communications with the State) did not fully explain how payments would be calculated and how rates would be determined.

A hearing on your request for reconsideration has been scheduled for 10:00 A.M. on March 8, 2001, Plaza Room 664, Richard Bolling Federal Building, 601 E. Twelfth Street, Kansas City, Missouri 64106. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR, part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication, which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the scheduled hearing date and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786–2055.

Sincerely,
Michael McMullan,
Acting Deputy Administrator.

Section 1116 of the Social Security Act (42 U.S.C., section 1316); 42 CFR, section 430.18).

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: January 31, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

[FR Doc. 01–3058 Filed 2–5–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Application for the Pharmacology Research Associate Program

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of General Medical Sciences (NIGMS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Application for the Pharmacology Research Associate Program. *Type of Information Collection Request:* Extension of a currently approved collection, OMB No. 0925–0378, expiration date July 31, 2001. *Form Numbers:* NIH 2721–1, NIH 2721–2. *Need and Use of Information Collection:* The Pharmacology Research Associate (PRAT) Program will use the applicant and referee information to award opportunities for training and experience in laboratory or clinical investigation to individuals with a Ph.D. degree in pharmacology or a related science, M.D., or other professional degree through appointments as PRAT Fellows at the National Institutes of Health or the Food and Drug Administration. The goal of the program is to develop leaders in pharmacological research for key positions in academic, industrial, and Federal research laboratories. *Frequency of Response:* Once a year. *Affected Public:* Individuals or households; Businesses or other for-profit. *Type of Respondents:* Applicants and Referees.

The annual reporting burden is as follows: