/cms.hhs.gov/regulations/pra/default.asp, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hefa.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 CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Dawn Willinghan, Room CS–14–03, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 21, 2003.

Dawn Willinghan,

Acting, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–22077 Filed 8–28–03; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Oklahoma Medicaid State Plan Amendment (SPA) 02–14

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on October 7, 2003, 10 a.m.; Room 714, 1301 Young Street; CMS Dallas Regional Office; Dallas, Texas 75202 to reconsider our decision to disapprove Oklahoma State Plan Amendment 02–14.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by September 15, 2003.

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244, Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider the decision dated May 28, 2003, to disapprove Oklahoma Medicaid State Plan Amendment (SPA) 02–14.

Oklahoma submitted SPA 02–14 on October 22, 2002, and revised it on May 14, 2003. On May 28, 2003, CMS disapproved SPA 02–14, after consultation with the Secretary as required under 42 CFR 430.15(c)(2). The State requested reconsideration by letter dated July 25, 2003.

At issue is whether the proposed supplemental payment methodology contained in the SPA complies with the requirement at section 1902(a)(30)(A) of the Social Security Act (the Act) that payment methodologies must assure that ''payments are consistent with efficiency, economy and quality of care.'' The proposed payment methodology would provide supplemental payment for services rendered by doctors of medicine, osteopathy, and dentists who are State employees. The State asserted that increased payment was warranted because of the specialized services provided by these State employees. The State failed to demonstrate, however, that delivering Medicaid services through State employees generated significantly higher costs sufficient to justify the requested supplemental payment. Moreover, the supplemental payment methodology proposed by the State is not a customary method for paying physicians and other health professionals. The methodology would make it difficult to track payments for specific services and would complicate auditing processes. In sum, at issue is whether it is consistent with efficiency, economy, and quality of care to use a methodology that: (1) Is not justified by any increased costs to the State to ensure access to services for Medicaid beneficiaries; (2) is not a usual and customary payment methodology; and (3) would unduly complicate tracking and audit processes.

Section 1116 of 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. The CMS is required to publish a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

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, in accordance with the requirements contained at 42 CFR 430.76(b)(2). 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 notice to Oklahoma announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Mr. Jim Hancock, Director
Health Policy Division
Oklahoma Health Authority
4545 North Lincoln Boulevard, Suite 124
Oklahoma City, OK 73105

Dear Mr. Hancock: I am responding to your request for reconsideration of the decision to disapprove Oklahoma State Plan Amendment (SPA) 02–14.

Oklahoma submitted SPA 02–14 on October 22, 2002, and revised it on May 14, 2003. On May 28, 2003, I disapproved SPA 02–14, after consultation with the Secretary as required under 42 CFR 430.15(c)(2). You requested reconsideration by letter dated July 25, 2003.

At issue is whether the proposed supplemental payment methodology contained in the SPA complies with the requirement at section 1902(a)(30)(A) of the Social Security Act that payment methodologies must assure that ''payments are consistent with efficiency, economy and quality of care.'' The proposed payment methodology would provide supplemental payment for services rendered by doctors of medicine, osteopathy, and dentists who are State employees. The State asserted that increased payment was warranted because of the specialized services provided by these State employees. The State failed to demonstrate, however, that delivering Medicaid services through State employees generated significantly higher costs sufficient to justify the requested supplemental payment. Moreover, the supplemental payment methodology proposed by the State is not a customary method for paying physicians and other health professionals. The methodology would make it difficult to track payments for specific services and would complicate auditing processes. In sum, at issue is whether it is consistent with efficiency, economy, and quality of care to use a methodology that: (1) Is not justified by any increased costs to the State to ensure access to services for Medicaid beneficiaries; (2) is not a usual and customary payment methodology; and (3) would unduly complicate tracking and audit processes. For the above stated reasons, and after consulting with the Secretary as required by 42 CFR 430.15(c)(2), the Centers for Medicare & Medicaid Services (CMS) disapproved Oklahoma SPA 02–14.

I am scheduling a hearing on your request for reconsideration to be held on October 7, 2003, at 10 a.m., 1301 Young Street, Room 714, CMS Dallas Regional Office, Dallas, Texas 75202. 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 hearing date that has been scheduled 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,

Thomas A. Scully

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: August 25, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–22245 Filed 8–28–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Community Services

Grant to the Rural Community Assistance Program

AGENCY: Office of Community Services, Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Award announcement.

CFDA: The Catalog of Federal Domestic Assistance (CFDA) number for this program is 93.570. The title is Rural Community Development Activities Program (RF Program).

Amount of Award: $500,000.

SUMMARY: Notice is hereby given that a noncompetitive grant award is being made to the Rural Community Assistance Program, Inc. to provide training and technical assistance to small communities struggling to deal with the safety and security of small and very small community water and wastewater treatment systems. This award addresses Congressional concern that many small and very small community water and wastewater treatment systems might be most vulnerable to terrorist attack, yet the least prepared to deal with the issues.

The application is not within the scope of any existing or expected to be issued program announcement for the Fiscal Year 2003—Rural Community Development Activities Program (RF) as authorized under the Community Services Block Grant Act of 1998, as amended; sections 680(a)(3)(B) of the Community Opportunities Accountability, and Training and Educational Services (COATES) Act (Pub. L. 105–285). This application is expected to provide valuable on-site training and technical assistance to small and very small communities struggling to deal with the safety and security of small community water and wastewater treatment systems. This announcement is inviting application for a 12-month budget period and a 24 month project period.

The funds are not being competed due to the Senate appropriation language in FY 2003 that directs the Office of Community Services to support a Rural Community Assistance Program Small Community Infrastructure Safety and Training and Technical project. Congress intends the funds to go to an organization that is capable of conducting a project that is national in scope that provides State, regional and national infrastructure safety training workshops and on-site technical assistance targeted to small and very small community water and wastewater treatment systems.

FOR FURTHER INFORMATION CONTACT: Administration for Children and Families, Office of Community Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Veronica Terrell—(202) 401–5295, *vterrell@acf.hhs.gov.*

Dated: August 22, 2003.

Clarence H. Carter,

Director, Office of Community Services.

[FR Doc. 03–22099 Filed 8–28–03; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0367]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions.'' This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This guidance discusses issues related to the electronic submission of new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics licensing applications (BLAs), investigational new drug applications (INDs), master files, advertising material, and promotional labeling. The submission of these documents in electronic format should improve the agency's efficiency in processing, archiving, and reviewing them.

DATES: Submit written or electronic comments on the draft guidance by October 28, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301/594–5411, e-mail: *levinr@cder.fda.gov*, or

R. Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5349.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions.'' This draft document provides guidance to industry regarding submission of marketing applications (NDAs, ANDAs, BLAs), INDs, and related submissions (master files, advertising, and promotional