section 2102 of the Social Security Act in order to receive funds for initiating and expanding health insurance coverage for uninsured children. The Model Application Template is used to assist States in submitting a State Child Health Plan and amendments to that plan.

Frequency: Once.

Affected Public: State, local, or tribal gov't.

Number of Respondents: 42.

Total Annual Responses: 42.

Total Annual Hours: 3,360.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or e-mail your request, including your address, phone number, OMB number, and CMS 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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 21, 2002.

John P. Burke III,

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

[FR Doc. 02–6348 Filed 3–15–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of West Virginia State Plan Amendment (SPA) 01–05

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to reconsider our decision to disapprove West Virginia SPA (01–05), on April 25, 2002 at 10 a.m.; Room 339; the Public Ledger Building; 150 SouthIndependence Mall West; Philadelphia, PA 19106–3499.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by April 2, 2002.

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-HayesOffice of Hearings, Centers for Medicare & Medicaid Services, Suite L 2520 Lord Baltimore Drive, Baltimore, Maryland 21244–2670, Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove West Virginia SPA (01–05).

Section 1116 of the Social Security Act (the Act) and 42 CFR part 430 establish HHS procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. The Centers for Medicare & Medicaid Services (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 primary issue in the hearing is whether West Virginia's SPA 01–05 complies with the requirement of section 1917(b)(3) of the Act governing criteria for establishing an undue hardship under which the provisions governing mandatory estate recovery will be waived. That provision requires the State to use criteria established by the Secretary for determining whether estate recovery constitutes an undue hardship: 1. In resolving this issue, the hearing will consider whether publication in the State Medicaid Manual meets the requirements for adopting standards governing a homestead of modest value for purposes of qualifying for the undue hardship exception section 1917(b)(3); 2. The hearing will also consider if properly adopted, whether the Secretary appropriately applied these standards in disapproving the amendment.

West Virginia initially submitted SPA 01–05 on March 13, 2001. Section 1917 (b)(3) of the Act requires the state agency to establish procedures and standards to waive estate recoveries when such recoveries would cause an undue hardship as determined on the basis of criteria established by the Secretary. The State Medicaid Manual (SMM) defines one basis for an undue hardship as ''a homestead of modest value.''

The SPA proposes to exempt homestead property based on a statewide arithmetic mean appraised value of a home that is to be updated yearly by the West Virginia Department of Tax and Revenue.

The CMS has informed West Virginia that it has provided standards for determining the maximum amount which can be excluded from estate recovery as a ''homestead of modest value.'' Section 3810.C1 provides that states may not set the threshold for the market value of a homestead of modest value so high as to negate the intent of the estate recovery program. It specifically notes that ''a homestead of ''modest value'' can be defined as 50 percent or *less* of the average price of homes in the county where the homestead is located, as of the date of the beneficiary's death.'' Under West Virginia's amendment, in many counties, the $50,735 homestead of modest value exemption is greater than 100 percent of the average appraised value of homes in the county. In others it is twice that amount. Accordingly, CMS found the amendment did not comport with the standards for defining a homestead of modest value, which a state may exempt as part of its undue hardship exemption.

The CMS has noted that West Virginia's statewide homestead exemption was not included in the amendment as part of its ''undue hardship'' waiver of the mandatory estate recovery. The State included this exemption in the State plan as a separate item. Any homestead exempted must be excluded either on the basis of ''undue hardship'' or that it is not cost-effective for the State to recover.

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

Nancy V. Atkins, MSN, RNC, NP,
Commissioner, State of West Virginia,
Department of Health and Human Services,
Bureau for Medical Services, 350 Capitol
Street, Room 251, Charleston, West
Virginia 25301–3706

Dear Ms. Atkins:

I am responding to your request for reconsideration of the decision to disapprove West Virginia State Plan Amendment (SPA) 01–05.

The primary issue in the hearing is whether West Virginia's SPA 01–05 complies with the requirement of section 1917 (b)(3) of the Social Security Act (the Act) governing criteria for establishing an undue hardship

under which the provisions governing mandatory estate recovery will be waived. That provision requires the State to use criteria established by the Secretary for determining whether estate recovery constitutes an undue hardship: 1. In resolving this issue, the hearing will consider whether publication in the State Medicaid Manual meets the requirements for adopting standards governing a homestead of modest value for purposes of qualifying for the undue hardship exception Section 1917(b)(3); 2. The hearing will also consider if properly adopted, whether the Secretary appropriately applied these standards in disapproving the amendment.

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The SPA proposes to exempt homestead property based on a statewide arithmetic mean appraised value of a home that is to be updated yearly by the West Virginia Department of Tax and Revenue.

The Centers for Medicare & Medicaid Services (CMS) has informed West Virginia that it has provided standards for determining the maximum amount which can be excluded from estate recovery as a ''homestead of modest value.'' Section 3810.C1 provides that states may not set the threshold for the market value of a homestead of modest value so high as to negate the intent of the estate recovery program. It specifically notes that ''a homestead of 'modest value' can be defined as 50 percent or *less* of the average price of homes in the county where the homestead is located, as of the date of the beneficiary's death.'' Under West Virginia's amendment, in many counties, the $50,735 homestead of modest value exemption is greater than 100 percent of the average appraised value of homes in the county. In others it is twice that amount. Accordingly, CMS found the amendment did not comport with the standards for defining a homestead of modest value, which a state may exempt as part of its undue hardship exemption.

The CMS has noted that West Virginia's statewide homestead exemption was not included in the amendment as part of its ''undue hardship'' waiver of the mandatory estate recovery. The State included this exemption in the State plan as a separate item. Any homestead exempted must be excluded either on the basis of ''undue hardship'' or that it is not cost-effective for the State to recover.

I am scheduling a hearing on your request for reconsideration to be held on April 25, 2002, at 10 a.m.; Room 339; The Public Ledger Building; 150 South Independence Mall West; Philadelphia, Pennsylvania 19106–3499.

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.

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

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

Dated: March 7, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–6349 Filed 3–15–02; 8:45 am]

BILLING CODE 4160–18–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0002]

Draft Guidance for Industry on Developing Drugs To Treat Inhalational Anthrax (Post-Exposure); 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 ''Inhalational Anthrax (Post-Exposure)—Developing Antimicrobial Drugs.'' This guidance focuses on the development of antimicrobial drugs for administration to persons who have inhaled aerosolized *Bacillus anthracis*, but who do not yet have the established disease. The treatment goal would be to prevent development of the infection in such persons.

DATES: Submit written or electronic comments on the draft guidance by May 17, 2002. 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (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: Renata Albrecht, Center for Drug Evaluation and Research (HFD–590), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2336.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Inhalational Anthrax (Post-Exposure)—Developing Antimicrobial Drugs.'' This guidance focuses on the development of antimicrobial drugs for administration to persons who have inhaled aerosolized *B. anthracis*, but who do not yet have the established disease. The treatment goal would be to prevent development of the infection in such persons.

In the fall of 2001, *B. anthracis*, the bacterium that causes anthrax, was used as a bioterrorism agent and sent through the U.S. mail, resulting in cases of cutaneous and inhalational anthrax in New York, New Jersey, the District of Columbia, Florida, and Connecticut. Ciprofloxacin hydrochloride tablets, ciprofloxacin intravenous (IV) solution, ciprofloxacin IV in 5 percent dextrose, ciprofloxacin IV in 0.9 percent saline, and ciprofloxacin oral suspension, which the agency had approved in August 2000 for use in the management of patients who have been exposed to aerosolized spores of *B. anthracis*, were used to treat the potentially infected persons.

Because of the bioterrorism incident, the agency is encouraging the development of additional antimicrobial agents to be used in the event of inhalational exposure to *B. anthracis*. This guidance provides recommendations on how to develop such agents. The guidance is intended to assist applicants who wish to plan, design, conduct, and appropriately monitor the studies, including clinical studies, for drugs to treat persons exposed to *B. anthracis*. Applications submitted to the agency based on studies conducted as recommended in this guidance should yield the information necessary for the agency to determine whether the antimicrobial under study is safe and effective for use