DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Ohio State Plan Amendment (SPA) 07–014

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

ACTION: Notice of Hearing.

SUMMARY: This notice announces an administrative hearing to be held on April 4, 2008, at the CMS Chicago Regional Office, 233 N. Michigan Avenue, Suite 600, the Illinois Room, Chicago, IL 60601–5519, to reconsider CMS' decision to disapprove Ohio SPA 07–014.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by March 19, 2008.

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 CMS' decision to disapprove Ohio SPA 07–014, which was submitted on September 28, 2007, and disapproved on December 20, 2007.

Under this SPA, the State proposed to expand Medicaid eligibility by excluding all family income that is between 201 percent of the Federal poverty level (FPL) and 300 percent of the FPL in calculating income for purposes of determining eligibility. As a result, although the plan nominally provides for eligibility of optional targeted low-income children only for those with family income through 200 percent of the FPL, in effect, the eligibility level would rise to 300 percent of the FPL.

The amendment was disapproved because it indicated that the State will claim Federal matching funds at a rate other than the rate set forth in the Social Security Act (the Act), and thus, is not consistent with methods of administration necessary for proper and efficient operation of the plan, as required by section 1902(a)(4) of the Act.

At the hearing:

• The disapproval of this SPA will be discussed. The SPA was disapproved because the State declared its intent and was unwilling to change its intent to claim Federal matching funds at the regular matching rate, rather than the enhanced matching rate set forth in the Act, for the expanded population optional targeted low-income children, with income between 201 percent and 300 percent of the FPL.

• Section 1903(a)(1) of the Act requires that the Secretary pay the Federal medical assistance percentage (FMAP) of claimed State expenditures under the approved plan. The FMAP is defined at section 1905(b) of the Act. This section provides that the Federal matching rate for children described in section 1905(u)(2)(B) or (u)(3) of the Act ''is equal to the enhanced FMAP described in section 2105(b)'' of the Act, unless the State has exhausted its allotment under section 2104 of the Act, under the State Children's Health Insurance Program, or failed to comply with maintenance of effort and proper reporting requirements. Since none of those conditions appear to apply, and the expansion group is comprised of individuals who are described in section 1905(u)(2)(B) of the Act, the enhanced FMAP is the applicable FMAP rate, and claims at any other rate would not be consistent with proper and efficient administration of the State plan.

• The State's proposal was not consistent with methods of administration necessary for proper and efficient operation of the plan, as required by section 1902(a)(4) of the Act, because the State indicated in its overall submission that the State did not plan to submit claims at the statutorily indicated FMAP rate.

Section 1116 of the Act and Federal regulations at 42 CFR part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. 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 Ohio announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ara Mekhjian, Esq.,
Assistant Attorney General,
State of Ohio,
Health and Human Services Section,
30 E. Broad Street, 26th Floor,
Columbus, OH 43215–3400.

Dear Mr. Mekhjian:

I am responding to your request for reconsideration of the decision to disapprove the Ohio State plan amendment (SPA) 07–014, which was submitted on September 28, 2007, and disapproved on December 20, 2007.

Under this SPA, the State proposed to expand Medicaid eligibility by excluding all family income that is between 201 percent of the Federal poverty level (FPL) and 300 percent of the FPL in calculating income for purposes of determining eligibility. As a result, although the plan nominally provides for eligibility of optional targeted low-income children only for those with family income through 200 percent of the FPL, in effect, the eligibility level would rise to 300 percent of the FPL.

The amendment was disapproved because it indicated that the State will claim Federal matching funds at a rate other than the rate set forth in the Social Security Act (the Act), and thus, is not consistent with methods of administration necessary for proper and efficient operation of the plan, as required by section 1902(a)(4) of the Act.

At the hearing:

• The disapproval of this SPA will be discussed. The SPA was disapproved because the State declared its intent and was unwilling to change its intent to claim Federal matching funds at the regular matching rate, rather than the enhanced matching rate set forth in the Act, for the expanded population optional targeted low-income children, with income between 201 percent and 300 percent of the FPL.

• Section 1903(a)(1) of the Act requires that the Secretary pay the Federal medical assistance percentage (FMAP) of claimed State expenditures under the approved plan. The FMAP is defined at section 1905(b) of the Act. This section provides that the Federal matching rate for children described in section 1905(u)(2)(B) or (u)(3) of the Act ''is equal to the enhanced FMAP described in section 2105(b)'' of the Act, unless the State has exhausted its allotment under section 2104 of the Act, under the State Children's Health Insurance Program, or failed to comply with maintenance of effort and proper reporting requirements. Since none of those conditions appear to apply, and the expansion group is comprised of individuals who are described in section 1905(u)(2)(B) of the Act, the enhanced FMAP is the applicable FMAP rate, and claims at any other rate would not be consistent with proper and efficient administration of the State plan.

• The State's proposal was not consistent with methods of administration necessary for proper and efficient operation of the plan, as required by section 1902(a)(4) of the Act, because the State indicated in its overall

submission that the State did not plan to submit claims at the statutorily indicated FMAP rate.

I am scheduling a hearing at your request for reconsideration to be held on April 4, 2008, at the Centers for Medicare & Medicaid Services' Chicago Regional Office, 233 N. Michigan Avenue, Suite 600, the Illinois Room, Chicago, IL 60601–5519, to reconsider the decision to disapprove SPA 07–014. 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 by Federal regulations 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 at (410) 786–2055. 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.

Sincerely,

Kerry Weems,
Acting Administrator.

(Section 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: February 25, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–4068 Filed 3–3–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0132]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Petitions for Exemption From Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing State petitions for exemption from preemption.

DATES: Submit written or electronic comments on the collection of information by May 5, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

State Petitions for Exemption From Preemption—21 CFR 100.1(d) (OMB Control No. 0910–0277) —Extension

Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343–1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard of identity requirements. Section 100.1(d) (21 CFR 100.1(d)) sets forth the information a State is required to submit in such a petition. The information required under § 100.1(d) enables FDA to determine whether the State food labeling or standard of identity requirement satisfies the criteria of section 403A(b) of the act for granting exemption from Federal preemption.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.1(d)	1	1	1	40	40

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for § 100.1(d) is minimal because petitions for exemption from preemption are seldom submitted by States. In the last 3 years, FDA has not received any new petitions for exemption from preemption; therefore, the agency estimates that one or fewer petitions will be submitted annually. Although FDA has not received any new petitions for exemption from preemption in the last 3 years, it believes these information