

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****Notice of Hearing: Reconsideration of Disapproval of Ohio State Plan Amendments 05-07 and 05-020**

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

**ACTION:** Notice of hearing.

**SUMMARY:** This notice announces an administrative hearing to be held on February 28, 2006, in Suite #500, 233 N. Michigan Avenue, Minnesota Conference Room, Chicago, IL 60202, to reconsider CMS' decision to disapprove Ohio State plan amendments 05-07 and 05-020.

**Closing Date:** Requests to participate in the hearing as a party must be received by the presiding officer by February 8, 2006.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Scully-Hayes, Presiding Officer, CMS, Lord Baltimore Drive, Mail Stop LB-23-20, Baltimore, Maryland 21244. Telephone: (410) 786-2055.

**SUPPLEMENTARY INFORMATION:** This notice announces an administrative hearing to reconsider CMS' decision to disapprove Ohio State plan amendments (SPAs) 05-07 and 05-020, which were submitted on August 1, 2005, and September 1, 2005, respectively. Both SPAs were disapproved on October 28, 2005. Under SPAs 05-07 and 05-020, Ohio sought to implement the Medicaid School Program.

The amendments were disapproved because they do not comport with the requirements of section 1902(a) of the Social Security Act (the Act) and implementing regulations. The specific reasons for disapproval are identified below.

Under section 1902(a)(10) of the Act, a State plan must provide for making medical assistance available to eligible individuals. "Medical assistance," as defined in section 1905(a) of the Act, does not include habilitation services. After CMS determined that habilitation services were not properly included within the scope of the statutory category of rehabilitation services, the Omnibus Budget Reconciliation Act of 1989 (OBRA-89) "grandfathered" certain States, including Ohio, to provide habilitation services under previously approved State plan provisions as part of the Medicaid rehabilitation benefit. However, Ohio formally terminated its habilitation

services (known as the "Community Alternative Funding System," or CAFS program) in SPA 05-008 and, thus, is no longer "grandfathered" based on its previously approved State plan provision. Because there is no provision of the State's Medicaid plan as approved on or before June 30, 1989, that provides coverage of habilitation services in the State's current approved plan, the provisions of section 6411(g)(1)(A) of OBRA-89, that prohibit the Secretary from withholding, suspending, disallowing, or denying Federal financial participation for habilitation services, no longer apply.

In addition, the SPAs do not comply with the requirements of section 1902(a)(1) of the Act that services under the plan be available statewide. Under the SPAs, services would be covered only for select groups of students in participating schools but services would not be available to other eligible individuals. Because not all parts of the State may have participating schools, the SPAs violate statewide requirements. The restricted availability of services also violates the requirements of section 1902(a)(10)(B) of the Act that services available to each individual within a Medicaid eligibility group must be comparable in amount, duration, and scope (and that services available to categorically needy groups cannot be less in amount, duration, and scope than those available to the medically needy). The SPAs are not consistent with comparability requirements because the services are available only to select groups of students.

Additionally, these SPAs explicitly deny the provision of Medicaid fair hearing requests for individuals who are denied services. This provision is at variance with section 1902(a)(3) of the Act and Federal regulations at 42 CFR 431.200(a) which require that a State plan "provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly."

In addition, the State did not demonstrate that the proposed payment methodology would comply with the statutory requirements of sections 1902(a)(2), 1902(a)(30)(A), and 1903(a)(1) of the Act, which require that the State plan assure adequate funding for the non-Federal share of expenditures from State or local sources; that State or local sources have methods and procedures to assure that payments are consistent with efficiency, economy, and quality of care; and that Federal matching funds are only available for actual expenditures made by States for services under the

approved plan. The State did not respond fully to CMS' requests for information concerning State payment and funding issues. Absent such information, CMS could not determine whether the proposed SPA would operate in compliance with all applicable requirements of section 1902(a) of the Act.

Finally, for Ohio SPA 05-020 alone, the State did not show compliance with section 1902(a)(4) of the Act, which specifies that the State plan must provide for such methods of administration as are found by the Secretary to be necessary for the proper and efficient administration of the plan. Pursuant to this provision, States must include in their State plans all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation. Absent information on the methodology used to develop the fee schedules, this requirement is not met.

For the reasons cited above, and after consultation with the Secretary, as required by 42 CFR 430.15(c)(2), Ohio SPAs 05-07 and 05-020 were disapproved.

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:

Mr. Jim Petro, Office of the Attorney General, Health & Human Services Section, 30 E. Broad Street, 26th Floor, Columbus, OH 43215-3400.

Dear Mr. Petro:

I am responding to your request for reconsideration of the decision to disapprove Ohio State plan amendments (SPAs) 05-07 and 05-020, which were submitted on August 1, 2005, and September 1, 2005, respectively, and disapproved on October 28, 2005.

Under SPAs 05-07 and 05-020, Ohio was seeking to implement the Medicaid School Program.

The amendments were disapproved because they did not comport with the requirements of section 1902(a) of the Social Security Act (the Act) and implementing regulations. The specific reasons for disapproval are identified below.

Under section 1902(a)(10) of the Act, a State plan must provide for making medical assistance available to eligible individuals. "Medical assistance," as defined in section 1905(a) of the Act, does not include habilitation services. After the Centers for Medicare & Medicaid Services (CMS) determined that habilitation services were not properly included within the scope of the statutory category of rehabilitation services, the Omnibus Budget Reconciliation Act of 1989 (OBRA-89) "grandfathered" certain States, including Ohio, to provide habilitation services under previously approved State plan provisions as part of the Medicaid rehabilitation benefit. However, Ohio formally terminated its habilitation services (known as the "Community Alternative Funding System," or CAFS program) in SPA 05-008 and, thus, is no longer "grandfathered" based on its previously approved State plan provision. Because there is no provision of the State's Medicaid plan as approved on or before June 30, 1989, that provides coverage of habilitation services in the State's current approved plan, the provisions of section 6411(g)(1)(A) of OBRA-89, that prohibit the Secretary from withholding, suspending, disallowing, or denying Federal financial participation for habilitation services, no longer apply.

In addition, the SPAs do not comply with the requirements of section 1902(a)(1) of the Act that services under the plan be available statewide. Under the SPAs, services would be covered only for select groups of students in participating schools but services would not be available to other eligible individuals. Because not all parts of the State may have participating schools, the SPAs violate statewideness requirements. The restricted availability of services also violates the requirements of section 1902(a)(10)(B) of the Act that services available to each individual within a Medicaid eligibility

group must be comparable in amount, duration, and scope (and that services available to categorically needy groups cannot be less in amount, duration, and scope than those available to the medically needy). The SPAs are not consistent with comparability requirements because the services are available only to select groups of students.

Additionally, these SPAs explicitly deny the provision of Medicaid fair hearing requests for individuals who are denied services. This provision is at variance with section 1902(a)(3) of the Act and Federal regulations at 42 CFR 431.200(a) which require that a State plan "provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly."

In addition, the State did not demonstrate that the proposed payment methodology would comply with the statutory requirements of sections 1902(a)(2), 1902(a)(30)(A), and 1903(a)(1) of the Act, which require that the State plan assure adequate funding for the non-Federal share of expenditures from State or local sources; that State or local sources have methods and procedures to assure that payments are consistent with efficiency, economy, and quality of care; and that Federal matching funds are only available for actual expenditures made by States for services under the approved plan. The State did not respond fully to CMS' requests for information concerning State payment and funding issues. Absent such information, CMS could not determine whether the proposed SPA would operate in compliance with all applicable requirements of section 1902(a) of the Act.

Finally, for Ohio SPA 05-020 alone, the State did not show compliance with section 1902(a)(4) of the Act, which specifies that the State plan must provide for such methods of administration as are found by the Secretary to be necessary for the proper and efficient administration of the plan. Pursuant to this provision, States must include in their State plans all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation. Absent information on the methodology used to develop the fee schedules, this requirement is not met.

For the reasons cited above, and after consultation with the Secretary, as required by 42 CFR 430.15(c)(2), Ohio SPAs 05-07 and 05-020 were disapproved.

I am scheduling a hearing on your request for reconsideration to be held on February 28, 2006, at Suite #500, 233 N. Michigan Avenue, Minnesota Conference Room, Chicago, IL 60202, to reconsider the decision to disapprove SPA 05-07 and 05-020. 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 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,  
Mark B. McClellan, MD., PhD.  
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: January 13, 2006.

**Mark B. McClellan,**  
*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. E6-788 Filed 1-23-06; 8:45 am]  
BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0396]

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by February 23, 2006.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail,