

Dated: November 13, 2003.

Julie Brown,

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

[FR Doc. 03-29138 Filed 11-20-03; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Rhode Island State Plan Amendment 02-009

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on January 7, 2004, at 10 a.m., Government Center, JFK Federal Building, Viewstation 2350, Boston, Massachusetts 02203-0003.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by December 8, 2003.

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 Rhode Island State Plan Amendment (SPA) 02-009, submitted on September 28, 2002. The amendment would provide coverage for targeted case management services to children age 21 and under who are receiving such services from the Rhode Island Department of Children, Youth, and Families.

The issues are whether CMS properly found that SPA 02-009 is not consistent with Medicaid requirements because the proposed amendment: (1) Duplicates coverage of services that are integral components of the Federal-state child welfare programs; and (2) fails to include a payment methodology for the proposed services and thereby does not comprehensively describe the plan and provide sufficient information to determine compliance with applicable statutory and regulatory requirements.

Under section 1902(a) of the Social Security Act (the Act), states must submit plans "for medical assistance." Medical assistance is defined in sections

1905(a) and 1905(a)(19) of the Act, and includes targeted case management authorized by section 1915(g)(2) of the Act. In authorizing coverage of case management services, Congress specifically indicated that coverage for case management services must not duplicate payments made to public agencies or private entities under other program authorities for the same purpose. Congress provided an exception, in section 8435 of the Technical and Miscellaneous Revenue Act of 1988, Public Law 100-647, when the state is required to provide such services under state law, or is or was otherwise paying for the services using non-Federal funds. The case management services proposed in this SPA, however, do not come within this exception because they are provided through a Federal-state program rather than a non-Federal program operated under state law. Specifically, case management comprises an integral part of the Federal child welfare program.

At issue is whether the activities proposed under this SPA as case management services were integral and inseparable to fulfillment of a state's responsibilities under title IV of the Act.

Under title IV-B of the Act, section 422(b)(2) expressly requires that states must "provide for coordination between the services provided for children under the [state welfare] plan and the services and assistance provided under title XX, under the state program funded under part A (Title IV-A)-under the state plan approved under part E (Title IV-E) and under other state programs having a relationship to the program under this subpart." The implementing regulations specify that services be organized and "linked to a wide variety of supports and services which can be crucial to meeting families' and children's needs, for example, housing, substance abuse treatment, mental health, education, job training, child care, and informal support networks." (45 CFR section 1355.25(f))

In addition, 45 CFR section 1357.10(c)(6) requires the Child and Family Services Plan, defined at 45 CFR section 1357.10(c) as "the document, developed through joint planning, which describes the publicly-funded state child and family continuum," to include a broad spectrum of services, including foster care and child welfare services. Even though the activities in question may not always have been explicitly labeled as case management when performed under the State's title IV responsibilities, the State has provided no evidence that the activities are not the same.

Also at issue is whether SPA 02-009 comprehensively described the State program and contained sufficient information to determine whether it complied with Federal law. In the review process, CMS asked the State to submit an associated amendment to Attachment 4.19B of the State plan to describe the payment methodology that Rhode Island would use to make payments for the proposed services in accordance with the requirements of section 1902(a)(30)(A) of the Act and 42 CFR 430.10. The State did not submit the payment methodology for the proposed services. CMS concluded that without any payment methodology for the proposed services, SPA 02-009 did not comprehensively describe the State's proposed Medicaid program and did not contain sufficient information for CMS to determine that the proposed coverage was in compliance with applicable statutory and regulatory requirements.

Based on the reasoning set forth above, and after consultation with the Secretary as required under 42 CFR section 430.15(c)(2), CMS disapproved Rhode Island SPA 02-009 on August 14, 2003.

Section 1116 of the Act and 42 CFR, part 430 establishes 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 section 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

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

Ms. Jane A. Hayward, Director
Department of Human Services
600 New London Avenue
Cranston, RI 02920

Dear Ms. Hayward:

I am responding to your request for reconsideration of Rhode Island State Plan Amendment (SPA) 02-009. Rhode Island submitted SPA 02-009 on September 28, 2002. In this amendment, Rhode Island proposed to provide coverage for targeted case management services to children age 21 and under who are receiving such services from the Rhode Island Department of Children, Youth, and Families.

The issues are whether the Centers for Medicare & Medicaid Services (CMS) properly found that SPA 02-009 is not consistent with Medicaid requirements because the proposed amendment: (1) duplicates coverage of services that are integral components of the Federal-state child welfare programs; and (2) fails to include a payment methodology for the proposed services and thereby does not comprehensively describe the plan and provide sufficient information to determine compliance with applicable statutory and regulatory requirements.

Under section 1902(a) of the Social Security Act (the Act), states must submit plans "for medical assistance." Medical assistance is defined in section 1905(a) and 1905(a)(19) of the Act, and includes targeted case management authorized by section 1915(g)(2) of the Act. In authorizing coverage of case management services, Congress specifically indicated that coverage for case management services must not duplicate payments made to public agencies or private entities under other program authorities for the same purpose. Congress provided an exception, in section 8435 of the Technical and Miscellaneous Revenue Act of 1988, Public Law 100-647, when the state is required to provide such services under state law, or is or was otherwise paying for the services using non-Federal funds. The case management services proposed in this SPA, however, do not come within this exception because they are provided through a Federal-state program rather than a non-Federal program operated under state law. Specifically, case management comprises an integral part of the Federal child welfare program.

At issue is whether the activities proposed under this SPA as case management services were integral and inseparable to fulfillment of a state's responsibilities under title IV of the Act.

Under title IV-B of the Act, section 422(b)(2) expressly requires that states must "provide for coordination between the services provided for children under the [state welfare] plan and the services and assistance provided under title XX, under the state program funded under part A (Title IV-A), under the state plan approved under part E (Title IV-E), and under other state programs having a relationship to the program under this subpart." The implementing regulations specify that services be organized and "linked to a wide variety of supports and services which can be crucial to meeting families' and children's needs, for example, housing, substance abuse treatment, mental health, education, job training, child care, and informal support networks." (45 CFR section 1355.25(f))

In addition, 45 CFR 1357.10(c)(6) requires the Child and Family Services Plan, defined at 45 CFR section 1357.10(c) as "the document, developed through joint planning, which describes the publicly-funded state child and family continuum," to include a broad spectrum of services, including foster care and child welfare services. Even though the activities in question may not always have been explicitly labeled as case management when performed under the State's title IV responsibilities, the State has provided no evidence that the activities are not the same.

Also at issue is whether SPA 02-009 comprehensively described the State program and contained sufficient information to determine whether it complied with Federal law. In the review process, CMS asked the State to submit an associated amendment to Attachment 4.19B of the State plan to describe the payment methodology that Rhode Island would use to make payments for the proposed services, in accordance with requirements set forth in section 1902(a)(30)(A) of the Act and 42 CFR 430.10. The State did not submit any payment methodology for the proposed services. CMS concluded that without any payment methodology for the proposed services, SPA 02-009 did not comprehensively describe the State's proposed Medicaid program, and did not contain sufficient information for CMS to determine that the proposed coverage was in compliance with applicable statutory and regulatory requirements.

I am scheduling a hearing on your request for reconsideration to be held on January 7, 2004, at 10 a.m., Government Center, JFK Federal Building, Viewstation 2320, Boston, Massachusetts 02203-0003. 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. Ms. Scully-Hayes may be reached at (410) 786-2055.

Sincerely,
Thomas A. Scully

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)

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03-29143 Filed 11-20-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0085]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Environmental Impact Considerations" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of June 26, 2003 (68 FR 38063), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0322. The approval expires on September 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-29068 Filed 11-20-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0084]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.