

costs furnished to eligible individuals that are not within the statutory definition of medical assistance. It will result in State claims for FFP in expenditures as medical assistance which are not within the statutory definition of medical assistance.

Furthermore, section 1902(a)(30)(A) of the Act requires that State plan payment rates must be consistent with efficiency, economy, and quality of care. The payments that would be made under SPA 05-49 are for care or services that are not within the scope of medical assistance, and are not furnished to Medicaid-eligible individuals. Instead, the SPA would authorize a pool of funding, to subsidize health insurance that would be furnished to home health and personal care workers. The proposed payments would not be payment for identifiable covered Medicaid services, as defined under section 1905(a)(30)(A) of the Act.

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 New York announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Mr. Gregor N. Macmillan, Director, State of New York, Department of Health, Corning Tower, The Governor Nelson A. Rockefeller Empire State Plaza, Albany, NY 12237.

Dear Mr. Macmillan:

I am responding to your request for reconsideration of the decision to disapprove New York State plan amendment (SPA) 05-49, which was submitted on September 29, 2005, and disapproved on June 21, 2006. Under SPA 05-49, New York was proposing to provide supplemental funding to home care agencies for the purpose of maintaining

or subsidizing health insurance coverage for employed home care workers.

The amendment was disapproved because it did not comport with the requirements of section 1902(a)(4), 1902(a)(10)(A), 1902(a)(30)(A), and 1905(a) of the Social Security Act (the Act) and implementing regulations.

The issues in this reconsideration are whether:

(1) The proposed payments are for services to eligible individuals within the scope of the eligibility provisions of section 1902(a)(10) of the Act, as applied consistent with the limitations in the definition of medical assistance at section 1905(a) of the Act;

(2) The proposed payments are for services that are within the scope of covered medical assistance, as set forth in section 1905(a) of the Act and incorporated by section 1902(a)(10) of the Act;

(3) It is necessary for the proper and efficient operation of the plan for the State to include in the State plan a provision to provider costs that are not within the statutory definition of medical assistance; and

(4) The proposed payments are consistent with efficiency and economy as required by section 1902(a)(30)(A) of the Act.

We discuss these issues in more detail below, as set forth in the initial disapproval decision.

The proposed payments under SPA 05-49 are not for a group or category of individuals who are eligible under the statute under either section 1902(a)(10) of the Act nor as medical assistance for a covered benefit under 1905(a) of the Act. The proposed methodology would directly compensate home health and personal care employers for health insurance costs. Under the Medicaid statute, Federal funding is only available for medical assistance for individuals eligible under the approved State plan. Section 1902(a)(10) of the Act lists mandatory and optional groups of individuals who may be eligible for medical assistance. Section 1902(a)(10) must be read in concert with section 1905(a) of the Act, which defines medical assistance benefits (including additional specification of the categories of eligible individuals). For the same reasons, SPA 05-49 is not consistent with the requirements of section 1902(a)(4) of the Act. Section 1902(a)(4) of the Act requires that State Medicaid plans provide for methods of administration that are found by the Secretary to be necessary for the proper and efficient operation of the plan. It is not considered necessary for the proper and efficient operation of the plan for the State to include in the State plan a provision which would pay for provider costs furnished to eligible individuals that are not within the statutory definition of medical assistance. It will result in State claims for Federal financial participation in expenditures as medical assistance which are not within the statutory definition of medical assistance.

Furthermore, section 1902(a)(30)(A) of the Act requires that State plan payment rates must be consistent with efficiency, economy, and quality of care. The payments that would be made under SPA 05-49 are for care or

services that are not within the scope of medical assistance, and are not furnished to Medicaid-eligible individuals. Instead, the SPA would authorize a pool of funding, to subsidize health insurance that would be furnished to home health and personal care workers. The proposed payments would not be payment for identifiable covered Medicaid services, as defined under section 1905(a)(30)(A) of the Act.

I am scheduling a hearing on your request for reconsideration to be held on November 22, 2006, at 26 Federal Plaza, Room 38-110a, New York, NY, 10278, to reconsider the decision to disapprove SPA 05-49. 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, M.D., 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: September 29, 2006.

Mark B. McClellan,
Administrator.

[FR Doc. E6-17361 Filed 10-17-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Minnesota State Plan Amendment 05-015B

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

ACTION: Notice of Hearing.

SUMMARY: This notice announces an administrative hearing to be held on December 4, 2006, at 233 N. Michigan Avenue, Suite 600, the Illinois Room, Chicago, IL 60601, to reconsider CMS' decision to disapprove Minnesota State plan amendment 05-015B.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by November 2, 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 Minnesota State plan amendment (SPA) 05-015B which was submitted on September 28, 2005. This SPA was disapproved on June 12, 2006.

Under this SPA, the State proposed to limit incurred medical and remedial care expenses protected under the post eligibility process only to those expenses incurred while an individual is eligible for Medicaid.

Sections 1902(a)(17), and 1902(a)(51) in conjunction with section 1924 of the Social Security Act (the Act), as these sections are refined by section 1902(r)(1), require States to take into account, under the post eligibility process, amounts for incurred medical and remedial care expenses that are not subject to payment by a third party. Section 1902(r)(1)(A)(ii) of the Act and Federal regulations at 42 CFR 435.733(c)(4)(ii) permit States to place "reasonable" limits on the amounts of necessary medical and remedial care expenses recognized under State law but not covered under the State plan. The amendment was disapproved because CMS found that the amendment violated the statute for reasons set forth in the disapproval letter.

The issues to be decided in the hearing are:

- Whether Minnesota's SPA 05-015B impermissibly limits the amount of incurred expenses which may be deducted from an institutionalized individual's income for purposes of the post eligibility process by limiting these expenses to those incurred when the individual was Medicaid eligible; and
- Whether allowing this limitation undermines the protection of expenses which can be incurred when an individual is not Medicaid eligible, which must be considered for purposes of the medically needy spend down.

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 Minnesota announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Christine Bronson,
Medicaid Director,
Minnesota Department of Human Services,
P.O. Box 64983,
St. Paul, MN 55164-0983.

Dear Ms. Bronson: I am responding to your request for reconsideration of the decision to disapprove the Minnesota State plan amendment (SPA) 05-015B, which was submitted on September 28, 2005, and disapproved on June 12, 2006.

Under this SPA, the State proposed to limit incurred medical and remedial care expenses protected under the post eligibility process only to those expenses incurred while an individual is eligible for Medicaid.

Sections 1902(a)(17), and 1902(a)(51) in conjunction with section 1924 of the Social Security Act (the Act), as these sections are refined by section 1902(r)(1), require States to take into account, under the post eligibility process, amounts for incurred medical and remedial care expenses that are not subject to payment by a third party. Section 1902(r)(1)(A)(ii) of the Act and Federal regulations at 42 CFR 435.733(c)(4)(ii) permit States to place "reasonable" limits on the amounts of necessary medical and remedial care expenses recognized under State law but not covered under the State plan. The amendment was disapproved because CMS found that the amendment violated the statute for reasons set forth in the disapproval letter.

The issues to be decided at the hearing are:

- Whether Minnesota's SPA 05-015B impermissibly limits the amount of incurred expenses which may be deducted from an institutionalized individual's income for purposes of the post eligibility process by limiting these expenses to those incurred when the individual was Medicaid eligible; and
- Whether allowing this limitation undermines the protection of expenses which can be incurred when an individual is not Medicaid eligible, which must be considered for purposes of the medically needy spend down.

I am scheduling a hearing on your request for reconsideration to be held on December 4, 2006, at 233 N. Michigan Avenue, Suite 600, the Illinois Room, Chicago, IL 60601, to reconsider the decision to disapprove SPA 05-015B. 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,

Mark B. McClellan, M.D., PhD

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: October 5, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E6-17368 Filed 10-17-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0228]

Guidance for Industry on Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV." The guidance is intended to encourage sponsors to submit to FDA applications for fixed dose combination (FDC), co-packaged, and single-entity versions of antiretroviral drugs for the treatment of human immunodeficiency virus (HIV). The availability of a wide range of safe and effective antiretroviral products may help facilitate a wider distribution of anti-HIV drugs to better meet the demands of the global HIV/AIDS pandemic.

DATES: Submit written or electronic comments on agency guidances at any time.