

budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

- a. Current Budget Period Activities Objectives.
- b. Current Budget Period Financial Progress.
- c. New Budget Period Program Proposed Activity Objectives.
- d. Budget.
- e. Measures of Effectiveness, including progress against the numerical goals of the President's Emergency Plan for AIDS Relief for Côte d'Ivoire.

f. Additional Requested Information.

2. Annual progress report, due no more than 60 days after the end of the budget period. Reports should include progress against the numerical goals of the President's Emergency Plan for AIDS Relief for Côte d'Ivoire.

3. Financial status report, due no more than 90 days after the end of the budget period.

4. Final financial and performance reports, no more than 90 days after the end of the project period.

Recipients must mail these reports to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement. Copies of the reports must also be submitted to the Project Management Officer at the HHS/CDC Country Office in Côte d'Ivoire.

Please note: The grantee is responsible for accurate translation of all reports, and should submit French-language versions to the local HHS/CDC office in Abidjan and English-language versions to the HHS/CDC Grants Office in the U.S., by the established deadlines. See the HHS/CDC project management officer in Abidjan for more details.

VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770-488-2700.

For program technical assistance, contact: Monica Nolan, Director, HHS/CDC/Project RETRO-CI, 2010 Abidjan Place, Dulles, Virginia 20189-2010. Telephone: 225-21-25-41-89. E-mail: mnolan@cdc.gov.

For report mailing, contact: Jean-Claude Crinot, Project Management Officer, HHS/CDC /Project RETRO-CI, 01 BP 1712 Abidjan 01. Telephone: 225-21-21-42-50. E-mail: crinotj@gapcdcci.org.

For financial, grants management, or budget assistance, contact: Diane

Flournoy, Grants Management Specialist, CDC Procurement and Grants Office, U.S. Department of Health and Human Services, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770-488-2072. E-mail: dflournoy@cdc.gov.

VIII. Other Information

Applicants can find this and other HHS funding opportunity announcements on the HHS/CDC Web site, Internet address: <http://www.cdc.gov> (Click on "Funding" then "Grants and Cooperative Agreements"), and on the Web site of the HHS Office of Global Health Affairs, Internet address: <http://www.globalhealth.gov>.

Dated: August 9, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

[FR Doc. 05-16174 Filed 8-15-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Request for Application (RFA) AA112]

Implementation of Programs To Improve the Management of HIV/AIDS/STI/TB Care in the Livingstone District of the Republic of Zambia; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2005 funds for a cooperative agreement program to provide high-quality clinical care to PLWHAs in the Livingstone District of Southern Province of the Republic of Zambia. The Catalog of Federal Domestic Assistance number for this program is 93.067.

B. Eligible Applicant

Assistance will be provided only to the Southern Province Health Office of the Republic of Zambia. No other applications are solicited. The current health system structure in Zambia consists of the MOH, which has the responsibility for policy guidance and strategic planning, and the Central Board of Health, which is responsible for the translation and implementation of government health policies. The country is administratively divided into nine Provinces and 72 districts. In the health sector, the Provincial Health

Office provides technical support to the districts in the areas of management of service delivery, planning of health programs, priority setting and resource utilization. Within this framework the Southern Province Health Office is the only entity in Zambia qualified to collaborate with HHS as part of the Emergency Plan in Livingstone because it has the legal authority, expertise, and capacity to perform the key public health activities that are part of this cooperative agreement.

C. Funding

Approximately \$200,000 is available in FY 2005 to fund this award September 15, 2005 and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may change.

D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact:

Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146, telephone: 770-488-2700.

For program technical assistance, contact: Marc Bulterys, Project Officer, 1600 Clifton Road NE, MS E-04, Atlanta, GA 30333, telephone: 011 260 1 250 955, e-mail: bulterysm@cdczm.org.

Dated: August 9, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05-16175 Filed 8-15-05; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Maryland State Plan Amendment (05-06)

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on September 15, 2005, at 12 noon, in the Virginia Room 229, 150 S. Independence Mall, West, Suite 216, Philadelphia, Pennsylvania 19106, to reconsider our decision to disapprove Maryland's State Plan Amendment (SPA) 05-06.

DATES: Requests to participate in the hearing as a party must be received by the presiding officer by August 31, 2005.

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 Maryland State plan amendment (SPA) 05-06, which was submitted on January 25, 2005.

The amendment seeks approval to place what the State believes to be reasonable limits on the amounts of incurred necessary medical and remedial care expenses which must be deducted from a nursing facility resident's income under the post-eligibility treatment of income process.

Section 1902(r)(1)(A) of the Social Security Act (the Act) requires 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 permits 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. However, those reasonable limits must ensure nursing home residents are able to use their own funds to purchase necessary medical or remedial care not covered, *i.e.*, not paid for, by the State Medicaid program.

The SPA 05-06 proposes to limit the deduction of medical expenses to those incurred only during a period of eligibility for Medicaid. Thus, an individual who incurred medical expenses during the 3-month period prior to the date of application would not have any protection under the post-eligibility calculation for medical expenses incurred during that period unless he or she were determined to be eligible during that period.

In discussions with State Medicaid program staff, we confirmed this is the intent of the proposed amendment. While we believe some limitations imposed on the age of an incurred expense could be considered reasonable, we do not believe it would be reasonable for a State to exclude from post-eligibility protection an incurred medical expense that could be deducted from a person's income under the medically needy spenddown process. While the medically needy spenddown rules in Federal regulations at 42 CFR 435.831(g)(2) permit States to exclude

expenses incurred earlier than 3 months before the month of application, Maryland proposes to only permit deduction under its post-eligibility process for expenses incurred while an individual is actually eligible for Medicaid.

The State's limitation would result in an individual being able to use certain incurred medical expenses to establish eligibility for Medicaid, but not being able to deduct those same expenses under the post-eligibility process. While the statute permits the State to establish reasonable limits on the amount of non-covered expenses, we do not believe the limit is reasonable if the result were to deny the individual the ability to pay for a non-covered expense used to establish eligibility during a budget period.

The intent of section 1902(r)(1) of the Act is to afford an institutionalized individual with income the ability to actually pay non-covered medical expenses for medical and remedial care. Section 1902(r)(1) of the Act was added to the Medicaid statute by the Medicare Catastrophic Coverage Act of 1988. The Conference Report explains it was enacted to reinstate policies set forth previously in Medicaid regulations before they were revised by the Department of Health and Human Services in February 1988. Under that revised regulation, Maryland would have had the authority to implement the limits it proposes in SPA 05-06. However, by enacting section 1902(r)(1) of the Act, Congress specifically rejected that approach.

Moreover, by not protecting income to pay for non-covered expenses which were used to establish eligibility under the medically needy spenddown, the State's proposed amendment undercuts the Medicaid statute's purpose of requiring States to deduct incurred expenses under the spenddown process. To the extent that Maryland's amendment fails to protect income to enable the individual to actually pay for these incurred expenses, we view the State's proposed limit as not being reasonable. As a result, we believe the limit does not meet the requirements of section 1902(a)(17) of the Act, as refined by section 1902(r)(1) of the Act. For individuals whose post-eligibility calculation is determined using the spousal impoverishment rules, specified at section 1924 of the Act and refined by section 1902(r)(1) of the Act, we believe the limit does not meet the requirements of section 1902(a)(51) of the Act, which requires the State plan to meet the requirements of section 1924 of the Act.

The issues to be considered during the hearing are whether the amendment's limit violates the requirements of sections 1902(a)(17) and 1902(a)(51) of the Act by imposing an unreasonable limit on expenses for medical and remedial care which will be protected under the post-eligibility process.

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. The 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 in Federal regulations 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 in Federal regulations at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

Therefore, based on the reasoning set forth above, and after consultation with the Secretary as required under Federal regulations at 42 CFR 430.15(c)(2), CMS disapproved Maryland SPA 05-06. The notice to Maryland announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

*Mr. Joel L. Tornari,
Assistant Attorney General, Department of
Health and Mental Hygiene, 300 W. Preston
Street, Suite 302, Baltimore, MD 21201*

Dear Mr. Tornari: I am responding to your request for reconsideration of the decision to disapprove Maryland State plan amendment (SPA) 05-06, which was submitted on January 25, 2005.

In SPA 05-06, Maryland seeks approval to place what the State believes to be reasonable limits on the amounts of incurred necessary medical and remedial care expenses which must be deducted from a nursing facility resident's income under the post-eligibility treatment of income process.

Section 1902(r)(1)(A) of the Social Security Act (the Act) requires 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 permits 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. However, those reasonable limits must ensure that nursing home residents are able to use their own funds to purchase necessary medical or remedial care not covered; *i.e.*, not paid for, by the State Medicaid program.

The SPA 05-06 proposes to limit the deduction of medical expenses to those incurred only during a period of eligibility for Medicaid. Thus, an individual who incurred medical expenses during the 3-month period prior to the date of application would not have any protection under the post-eligibility calculation for medical expenses incurred during that period unless he or she were determined to be eligible during that period.

In discussions with State Medicaid program staff, we confirmed this is the intent of the proposed amendment. While we believe some limitations imposed on the age of an incurred expense could be considered reasonable, we do not believe it would be reasonable for a State to exclude from post-eligibility protection an incurred medical expense that could be deducted from a person's income under the medically needy spenddown process. While the medically needy spenddown rules in Federal regulations at 42 CFR 435.831(g)(2) permit States to exclude expenses incurred earlier than 3 months before the month of application, Maryland proposes to only permit deduction under its post-eligibility process for expenses incurred while an individual is actually eligible for Medicaid.

The State's limitation would result in an individual being able to use certain incurred medical expenses to establish eligibility for Medicaid, but not being able to deduct those same expenses under the post-eligibility process. While the statute permits the State to establish reasonable limits on the amount of non-covered expenses, we do not believe the limit is reasonable if the result were to deny the individual the ability to pay for a non-covered expense used to establish eligibility during a budget period.

The intent of section 1902(r)(1) of the Act is to afford an institutionalized individual with income the ability to actually pay non-covered medical expenses for medical and remedial care. Section 1902(r)(1) of the Act was added to the Medicaid statute by the Medicare Catastrophic Coverage Act of 1988. The Conference Report explains it was enacted to reinstate policies set forth previously in Medicaid regulations before they were revised by the Department of Health and Human Services in February 1988. Under that revised regulation, Maryland would have had the authority to implement the limits it proposes in SPA 05-06. However, by enacting section 1902(r)(1) of the Act, Congress specifically rejected that approach.

Moreover, by not protecting income to pay for non-covered expenses which were used to establish eligibility under the medically needy spenddown, the State's proposed amendment undercuts the Medicaid statute's purpose of requiring States to deduct incurred expenses under the spenddown process. To the extent that Maryland's

amendment fails to protect income to enable the individual to actually pay for these incurred expenses, we view the State's proposed limit as not being reasonable. As a result, we believe the limit does not meet the requirements of section 1902(a)(17) of the Act, as refined by section 1902(r)(1) of the Act. For individuals whose post-eligibility calculation is determined using the spousal impoverishment rules, specified at section 1924 of the Act and refined by section 1902(r)(1) of the Act, we believe the limit does not meet the requirements of section 1902(a)(51) of the Act, which requires the State plan to meet the requirements of section 1924 of the Act.

Based on the reasoning set forth above, and after consulting with the Secretary as required by Federal regulations at 42 CFR 430.15(c)(2), the Centers for Medicare & Medicaid Services (CMS) disapproved Maryland Medicaid SPA 05-06.

I am scheduling a hearing to be held on September 15, 2005, at 12:00 Noon in CMS' Philadelphia Regional Office, in the Virginia Room 229;150 S. Independence Mall, West; Suite 216; Philadelphia, Pennsylvania 19106, to reconsider our decision to disapprove Maryland's SPA 05-06. 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.

The issues to be considered during the hearing are whether the amendment's limit violates the requirements of sections 1902(a)(17) and 1902(a)(51) of the Act by imposing an unreasonable limit on expenses for medical and remedial care which will be protected under the post-eligibility process.

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,

Mark B. McClellan, M.D., Ph.D.

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: July 19, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05-16304 Filed 8-12-05; 1:32 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0535]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; MedWatch: Food and Drug Administration Medical Products Reporting Program

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 September 15, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

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

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

MedWatch: FDA Medical Products Reporting Program, Form FDA 3500 and Form FDA 3500A—(OMB Control Number 0910-0291)—Extension

Under sections 505, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 360b, 360c, 360e, and 393), and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the act (21 U.S.C. 352(f)(1)), it is misbranded if it fails to bear adequate warnings, and under section 502(j) of the act (21 U.S.C.