

section 1902(a)(30)(A) of the Social Security Act (the Act), as implemented by the Centers for Medicare & Medicaid Services' (CMS) regulations at 42 CFR 447.272 and 447.321. The proposed methodology would increase supplemental payments to non-state government owned or operated facilities to result in aggregate payments based on 150 percent of the estimated amount that would be paid for the same services under Medicare payment principles. In accordance with the regulations at 42 CFR 447.272 and 447.321, as amended on January 18, 2002, effective May 14, 2002, aggregate payments to non-state government owned or operated hospitals may not exceed 100 percent of the reasonable estimate of the amount that would be paid for the same services under Medicare payment principles. Because the proposed payment methodology would provide for payments above the permissible level after that date, CMS concluded that the proposed methodologies are not in compliance with applicable regulations and the SPA could not be approved. Therefore, based on the reasoning set forth above, and after consultation with the Secretary as required under 42 CFR 430.15(c)(2), CMS disapproved South Carolina SPA 01-14(A).

Section 1116 of the Act and 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 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 South Carolina announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Mr. William Prince, Medicaid Director, South Carolina Department of Health and Human

Services, P.O. Box 8206, Columbia, SC 29202-8206.

Dear Mr. Prince: I am responding to your request for reconsideration of the decision to disapprove South Carolina State Plan Amendment (SPA) 01-14(A). South Carolina submitted SPA 01-14(A) on December 21, 2001. In this amendment, South Carolina proposed to revise the methodology for calculating supplemental payments for inpatient and outpatient services furnished by non-state government owned or operated facilities.

The issue is whether the State's proposed revised methodology for calculating supplemental payments for inpatient and outpatient services furnished by non-state government owned or operated facilities was consistent with the requirements of section 1902(a)(30)(A) of the Social Security Act (the Act), as implemented by the Centers for Medicare & Medicaid Services (CMS) regulations at 42 CFR 447.272 and 447.321. The proposed methodology would increase supplemental payments to non-state government owned or operated facilities to result in aggregate payments based on 150 percent of the estimated amount that would be paid for the same services under Medicare payment principles. In accordance with the regulations at 42 CFR 447.272 and 447.321, as amended on January 18, 2002, effective May 14, 2002, aggregate payments to non-state government owned or operated hospitals may not exceed 100 percent of the reasonable estimate of the amount that would be paid for the same services under Medicare payment principles. Because the proposed payment methodology would provide for payments above the permissible level after that date, CMS concluded that the proposed methodologies are not in compliance with applicable regulations and the SPA could not be approved. Based on the reasoning set forth above, and after consultation with the Secretary as required under 42 CFR 430.15(c)(2), CMS disapproved South Carolina SPA 01-14(A).

I am scheduling a hearing on your request for reconsideration to be held on December 2, 2002, at 10 a.m., Atlanta Federal Center, 61 Forsyth Street, SW., Suite 4T20, Executive Conference Room, Atlanta, Georgia 30303-8909, to reconsider our decision to disapprove South Carolina SPA 01-14(A).

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. The presiding officer may be reached at (410) 786-2055.

Sincerely,
Thomas A. Scully.

Authority: Section 1116 of the Social Security Act (42 U.S.C. section 1316); (42 CFR 430.18)

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: October 11, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0012]

Agency Information Collection Activities; Announcement of OMB Approval; Postmarketing Adverse Drug Experience Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 22, 2002 (67 FR 47821), 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 0910-0230. The approval expires on September 30, 2005. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 16, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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