

application form. To qualify, programs must meet the minimum eligibility requirements set forth in CDC's "DPRP Draft Recognition Standards and Operating Procedures." Criteria for recognition include, but are not limited to: (1) Following an evidence-based curriculum that has been proven effective in research and demonstration projects, and (2) submitting de-identified participant process and outcome data to CDC every six months. CDC will use the process and outcome data to monitor and evaluate program effectiveness and to provide targeted technical assistance to applicant organizations. Three levels of recognition will be provided: *Pending* recognition for new applicants that have submitted an application and meet

eligibility criteria defined by DPRP standards and operating procedures; *Full* recognition for programs that have demonstrated effectiveness according to DPRP standards; and *Probationary* recognition for programs that are working towards full attainment of the standards.

Each organization that seeks recognition through the DPRP will submit an initial, online application form to CDC. There is no application deadline. The de-identified process and outcome data necessary for assessing program performance will be submitted to CDC electronically twice per year. The due dates for these submissions will be determined by the date of the organization's initial application. CDC estimates that burden to respondents

will be modest since the information requested for DPRP recognition is routinely collected by organizations that deliver lifestyle programs. To further minimize burden to respondents, CDC will accept process and outcome data submitted using any electronic format, software or method that meets the requirements established by DPRP standards and operating procedures.

OMB approval is requested for three years. CDC anticipates seeking continued OMB approval throughout the lifetime of the DPRP. Respondents will be organizational entities that offer diabetes prevention services. Participation in the DPRP is voluntary, and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Applicants for Recognition through the DPRP.	Application Form	67	1	3/60	3
	Process and Outcome Data	67	2	5/60	11
Total	14

Thelma Sims,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of California State Plan Amendments (SPAs) 08-009A; 08-009B1; 08-009B2; 08-009D; and 08-019

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on February 10, 2011, at the CMS San Francisco Regional Office, 90 7th Street, #5-300 (5W), San Francisco, California 94103 to reconsider CMS' decision to disapprove California SPAs 08-009A; 08-009B1; 08-009B2; 08-009D; and 08-019.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by January 5, 2011.

FOR FURTHER INFORMATION CONTACT:

Benjamin Cohen, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244. Telephone: (410) 786-3169.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider the decision of the Centers for Medicare & Medicaid Services (CMS) to disapprove California State plan amendments (SPAs) 08-009A; 08-009B1; 08-009B2; 08-009D; and 08-019 which were submitted on December 31, 2008, and disapproved on November 18, 2010. The SPAs proposed to reduce the reimbursement rates for certain services furnished under the approved State plan.

In the initial determination, CMS determined, after consulting with the Secretary, that it is unable to approve these SPAs because California has not demonstrated that it would meet the conditions set out in section 1902(a)(30)(A) of the Social Security Act (Act).

Section 1902(a)(30)(A) of the Act requires that State plans assure that "payments [to providers] * * * are sufficient to enlist enough providers so that care and services are available under the [State's Medicaid] plan [to recipients] at least to the extent that such care and services are available to

the general population in the geographic area."

When the SPAs were initially submitted, the State did not provide information concerning the impact of the proposed reimbursement reductions on beneficiary access to services, even though available national data indicate that this may be an issue for California. In the Requests for Additional Information (RAI) for SPAs TN 08-009A, TN 08-009B-1, TN 08-009D, (sent to the State in December 2008), and 08-019 (sent to the State in March, 2009), CMS requested information about beneficiary access to services, but California did not respond. As indicated in a January 2, 2001, letter to State Medicaid Directors, to the extent that responses to such RAIs are not received within 90 days, CMS may initiate disapproval action. In this instance, in addition, CMS had concerns that, given the time that has elapsed since these SPAs were submitted but not implemented, the cumulative effect of a retroactively effective approval of these reimbursement reductions would only serve to exacerbate beneficiary access concerns.

For these reasons, and after consulting with the Secretary as required by Federal regulations at 42 CFR 430.15(c)(2), these SPAs were disapproved.

The issues to be considered at the hearing are:

- Whether California has demonstrated that the proposed payments to providers were sufficient to enlist enough providers so that care and services were available under the State's Medicaid plan at least to the extent that such care and services are available to the general population in the geographic area as required by section 1902(a)(30)(A) of the Social Security Act.

- Whether the application of the payment rates under the SPAs retroactively, based on the proposed effective date, would be consistent with that requirement under section 1902(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 California announcing an administrative hearing to reconsider the disapproval of its SPAs reads as follows:

Mr. Toby Douglas, Chief Deputy
Director
Health Care Programs
Department of Health Care Services
1501 Capitol Avenue, 6th Floor
MS 0002
Sacramento, CA 95814

Dear Mr. Douglas:

I am responding to your request for reconsideration of the decision to disapprove the California State Plan Amendments (SPAs) 08-009A; 08-009B1; 08-009B2; 08-009D which were submitted on September 30, 2008, and 08-019 which was submitted on December 31, 2009, and disapproved on

November 18, 2010. The SPAs proposed to reduce the reimbursement rates for certain services furnished under the approved State plan.

The issues to be considered at the hearing are:

- Whether California has demonstrated that the SPAs assured that the proposed payments to providers would be sufficient to enlist enough providers so that care and services were available under the State's Medicaid plan at least to the extent that such care and services are available to the general population in the geographic area as required by section 1902(a)(30)(A) of the Social Security Act.

- Whether the application of the payment rates under the SPAs retroactively, based on the proposed effective date, would be consistent with that requirement under section 1902(a)(30)(A) of the Act.

In reviewing this issue, we note that, when the SPAs were initially submitted, the State did not provide any information concerning the impact of the proposed reimbursement reductions on beneficiary access to services, even though available national data indicated that this may be an issue for California.

In Requests for Additional Information (RAI) for SPAs TN 08-009A, TN 08-009B1, TN 08-009D (sent to the State in December 2008) and 08-019 (sent to the State in March 2009), CMS requested information about beneficiary access to services, but California never responded. As indicated in a January 2, 2001, letter to State Medicaid Directors, to the extent that responses to such RAIs are not received within 90 days, CMS may initiate disapproval action. In this instance, in addition, CMS was concerned that, given the time that had elapsed since these SPAs had been submitted but were not implemented, the cumulative effect of a retroactively effective approval of these reimbursement reductions exacerbate beneficiary access concerns.

I am scheduling a hearing on your request for reconsideration to be held on February 10, 2011, at the CMS San Francisco Regional Office, 90 7th Street, #5-300 (5W), San Francisco, California 94103-6706, in order to reconsider the decision to disapprove SPAs 08-009A; 08-009B1; 08-009B2; 08-009D; and 08-019. 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 Mr. Benjamin Cohen as the presiding officer. If these arrangements are not acceptable, please

contact the presiding officer at (410) 786-3169. 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 to provide names of the individuals who will represent the State at the hearing. Sincerely,

Donald M. Berwick, M.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: December 15, 2010.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Advisory Committees; Tentative Schedule of Meetings for 2011

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 2011. During 1991, at the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. In its final report, one of the IOM's recommendations was for the Agency to publish an annual tentative schedule of its meetings in the **Federal Register**. This publication implements the IOM's recommendation.

FOR FURTHER INFORMATION CONTACT: Teresa L. Hays, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5290, Silver Spring, MD 20993-0002, 301-796-8220.

SUPPLEMENTARY INFORMATION: The IOM, at the request of the Commissioner, undertook a study of the use of FDA's advisory committees. In its final report in 1992, one of the IOM's recommendations was for FDA to adopt a policy of publishing an advance yearly schedule of its upcoming public