In 2008, a sample of 40 hospitals will be selected for a pretest. These hospitals will not be a probability sample, but instead will be intentionally selected to include hospitals of differing size, location and other characteristics related to their service and patient clientele.

In 2010, a redesigned NHDS will be implemented and will consist of a completely new sample of approximately 240 hospitals. The redesigned NHDS will use a modified two stage design. The first stage sampling will be hospitals. The second stage of sampling will be discharges. A stratified, random sample of 120 discharges is targeted within each hospital. In the redesigned survey all data will be abstracted by trained health care staff under contract. All data will be obtained from hospital records and charts and computer systems.

The current data items will be collected with significant additional details. Patient level data items to be collected include personal identifiers such as Social Security number, name and medical record number; clinical laboratory results such as hematocrit and white blood cell count; and financial billing and record data. The survey includes detailed questions for three modules: Acute myocardial infarction; infectious disease; and end of life issues. Facility level data items include demographic information, clinical capabilities, and financial information.

Users of NHDS data include, but are not limited to the CDC; the Congressional Research Office; the Office of the Assistant Secretary for Planning and Evaluation (ASPE); American Health Care Association, Centers for Medicare and Medicaid Services (CMS), and Bureau of the Census. Data collected through the NHDS are essential for evaluating health status of the population, for the planning of programs and policy to elevate the health status of the Nation, for studying morbidity trends, and for research activities in the health field. NHDS data have been used extensively in the development and monitoring of goals for the Year 2000 and 2010 Healthy People Objectives. In addition, NHDS data provide annual updates for numerous tables in the Congressionally-mandated NCHS report, Health, United States. Other users of these data include universities, contract research organizations, many in the private sector, foundations, and a variety of users in the print media. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Hospitals	Number of respondents	Number of responses per respondent	Hours per response	Response burden (hours)
Current NHDS:				
Primary Procedure abstracting	13	250	6/60	325
Alternate (Census) Procedure (pulling & refiling records)	41	250	1/60	171
In-House Tape or Printout Hospital (programming)	29	12	13/60	75
Induction	10	1	2	20
Sub-total	.....	.....	.....	591
Redesign HDS Pre-test:				
Survey presentation to hospital	13	1	1	13
Facility questionnaire	13	1	4.1	53
Sample discharges and obtain data	13	10	14/60	30
Debrief hospital staff	13	1	1	13
Quality control	2	25	14/60	12
Sub-total	.....	.....	.....	121
Redesign Survey 2010 & 2011:				
Survey presentation to hospital	160	1	1	160
Facility questionnaire	80	1	4.1	328
Sample discharges and obtain data	160	120	14/60	4,480
Pre-testing of new data elements	13	120	5/60	130
Quality control	3	25	14/60	18
Non-response study	27	1	2	54
Sub-total	.....	.....	.....	5,170
Total	.....	.....	.....	5,882

Dated: December 27, 2007.

Maryam I. Daneshvar,

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

[FR Doc. E8–51 Filed 1–7–08; 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 California's State Plan Amendment (SPA) 06–019B

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on February 15, 2008, at the CMS San Francisco Regional Office, 90 7th Street, 5th Floor, Room 5A, San Francisco, California 94103, to reconsider CMS' decision to disapprove California's SPA 06–019B.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by January 23, 2008.

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, CMS, Lord Baltimore Drive, Mail Stop LB–23–20, Baltimore, MD 21244, Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS' decision to disapprove California's SPA #06–019B which was submitted on December 27, 2006.

Under this SPA, the State was seeking to provide direct reimbursement effective October 1, 2006, to Medicaid recipients where the recipient obtains and pays for Medicaid services after receiving a Medicaid card.

The amendment was disapproved because it did not comport with the requirements of sections 1902(a)(10), 1902(a)(32), and 1905(a) of the Social Security Act (the Act) and Federal regulations at 42 CFR 431.246, 431.250, and 447.15.

The following are the issues to be considered at the hearing:

• Would payments under the proposed SPA that would be made directly to Medicaid recipients for services furnished after the recipients have been determined to be eligible (and not during a retroactive eligibility period) be within the scope of the definition of ''medical assistance'' referenced in section 1902(a)(10) and set forth in section 1905(a) of the Act? The definition at section 1905(a) specifically limits medical assistance to payments made to providers of covered services (the ''vendor payment principle''), and contains an express statutory exception permitting direct payment to recipients only for physician and dentist services; the proposed SPA does not appear to be limited to payments for these service categories.

• Would payments under the proposed SPA that are made directly to Medicaid recipients for services furnished after the recipients have been determined eligible (and not during a retroactive eligibility period) be consistent with the requirement of section 1902(a)(32) of the Act? That section limits payment under the plan to amounts paid directly to providers (or certain assignees of those providers). This statutory requirement ensures that recipients obtain covered services from participating providers who bill the Medicaid program rather than the recipient, and accept the State's payment, including a payment of zero dollars, as payment in full. (See 42 CFR 447.15.)

• Would payments under the proposed SPA that are made directly to Medicaid recipients for services furnished after the recipients have been determined eligible (and not during a retroactive eligibility period) be within the regulatory exception at 42 CFR 431.246 and 431.250(b) to the vendor payment principle? Those sections provide for corrective payments based on a successful appeal by a recipient who, pending the appeal decision, sought and paid for covered services. Such a circumstance in the context of SPA 06–019B would exist where a recipient appealed the State's determination of the amount of the recipient's ''share of cost'' for covered services. But, SPA 06–019B does not appear to limit such payment to these exceptions to the vendor payment rule.

• Is there any binding judicial decision that would permit the Federal Government to participate in the payments contemplated in the proposed SPA? The United States was not a party to a California State Court case that apparently addressed the issues, and is not bound by that decision. Moreover, under regulations at 42 CFR 431.250 that provide for Federal participation in payments made under court order, the services must be provided within the scope of the Medicaid program under Federal law. Services that are billed directly to the recipient (and not part of a retroactive eligibility period) are outside of the Federal definition of medical assistance, and thus are not within the scope of the Federal Medicaid program.

• Is there any statutory or regulatory conflict providing a basis to conclude that the express statutory provisions establishing the vendor payment principle could not practically be applied? CMS has recognized such a conflict as the basis for permitting an exception to the vendor payment principle during a retroactive period, but such a conflict does not appear to be present in this instance.

• Are direct payments to recipients who have been determined eligible consistent with accuracy, efficiency, and effectiveness of the State Medicaid program in serving those recipients?

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 SPA reads as follows:

Mr. Stan Rosenstein, Chief Deputy Director, Health Care Program, Health and Human Services Agency, 1501 Capitol Avenue, MS 4506, P.O. Box 997413, Sacramento, CA 99859–7413.

Dear Mr. Rosenstein:

I am responding to your request for reconsideration of the decision to disapprove California's State plan amendment (SPA) 06–109B, which was submitted on December 27, 2006.

Under this SPA, the State was seeking to provide direct reimbursement, effective October 1, 2006, to Medicaid recipients where the recipient obtains and pays for Medicaid services after receiving a Medicaid card.

The amendment was disapproved because it did not comport with the requirements of sections 1902(a)(10), 1902(a)(32), and 1905(a) of the Social Security Act (the Act) and Federal regulations at 42 CFR sections 431.246, 431.250, and 447.15.

The following are the issues to be considered at the hearing:

• Would payments under the proposed SPA that would be made directly to Medicaid recipients for services furnished after the recipients have been determined to be eligible (and not during a retroactive eligibility period) be within the scope of the definition of ''medical assistance'' referenced in section 1902(a)(10) and set forth in section 1905(a) of the Act? The definition at section 1905(a) specifically limits medical assistance to payments made to providers of covered services (the ''vendor payment principle''), and contains an express statutory exception permitting direct payment to recipients only for physician and dentist services; the proposed SPA does not appear to be limited to payments for these service categories.

• Would payments under the proposed SPA that are made directly to Medicaid recipients for services furnished after the recipients have been determined eligible (and not during a retroactive eligibility period) be consistent with the requirement of section 1902(a)(32) of the Act? That section limits payment under the plan to amounts paid directly to providers (or certain assignees of those providers). This statutory requirement ensures that recipients obtain covered services from participating providers who

bill the Medicaid program rather than the recipient, and accept the State's payment, including a payment of zero dollars, as payment in full. (See 42 CFR 447.15.)

• Would payments under the proposed SPA that are made directly to Medicaid recipients for services furnished after the recipients have been determined eligible (and not during a retroactive eligibility period) be within the regulatory exception at 42 CFR 431.246 and 431.250(b) to the vendor payment principle? Those sections provide for corrective payments based on a successful appeal by a recipient who, pending the appeal decision, sought and paid for covered services. Such a circumstance in the context of SPA 06–019B would exist where a recipient appealed the State's determination of the amount of the recipient's ''share of cost'' for covered services. But, SPA 06–019B does not appear to limit such payment to these exceptions to the vendor payment rule.

• Is there any binding judicial decision that would permit the Federal Government to participate in the payments contemplated in the proposed SPA? The United States was not a party to a California State Court case that apparently addressed the issues and is not bound by that decision. Moreover, under regulations at 42 CFR 431.250 that provide for Federal participation in payments made under court order, the services must be provided within the scope of the Medicaid program under Federal law. Services that are billed directly to the recipient (and not part of a retroactive eligibility period) are outside of the Federal definition of medical assistance, and thus are not within the scope of the Federal Medicaid program.

• Is there any statutory or regulatory conflict providing a basis to conclude that the express statutory provisions establishing the vendor payment principle could not practically be applied? CMS has recognized such a conflict as the basis for permitting an exception to the vendor payment principle during a retroactive period, but such a conflict does not appear to be present in this instance.

• Are direct payments to recipients who have been determined eligible consistent with accuracy, efficiency, and effectiveness of the State Medicaid program in serving those recipients?

I am scheduling a hearing on your request for reconsideration to be held on February 15, 2008, at the CMS San Francisco Regional Office, 90 7th Street, 5th Floor, Room 5A, San Francisco, California 94103, to reconsider the decision to disapprove SPA 06–019B. 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,

Kerry Weems,

Acting Administrator.

(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: January 2, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–109 Filed 1–7–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0462]

Compliance Policy Guide Sec. 555.700 Revocation of Tolerances for Cancelled Pesticides (CPG 7120.29); Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of Compliance Policy Guide Sec. 555.700 Revocation of Tolerances for Cancelled Pesticides (CPG 7120.29) (CPG Sec. 555.700). CPG Sec. 555.700 is no longer necessary because the policy stated in the CPG is obsolete. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft revision of CPG Sec. 575.100 Pesticide Chemical Residues in Food and Feed—Enforcement Criteria (CPG 7141.01) (CPG Sec 575.100).

DATES: The withdrawal is effective January 8, 2008.

ADDRESSES: Submit written requests for single copies of CPG Sec. 555.700 to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request or fax your request to 240–632–6861.

A copy of the CPG may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD 20740–3835, 301–436–2022, FAX 301–436–2651.

SUPPLEMENTARY INFORMATION: CPG Sec. 555.700 stated FDA's policy to routinely establish action levels for pesticide chemical residues to replace tolerances that are revoked when the Environmental Protection Agency (EPA) cancels registration for the pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act. Such residues may persist in the environment for many years. Section 408(l)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(l)(4)), as amended by the Food Quality Protection Act of 1996, authorizes EPA to establish tolerances for pesticide chemical residues that will unavoidably persist in the environment. Therefore, because EPA may establish tolerances for such pesticide chemical residues, the policy set forth in CPG Sec. 555.700 is obsolete. Consequently, FDA is withdrawing CPG Sec. 555.700, in its entirety, to eliminate this obsolete policy.

Previously established action levels are listed in FDA's CPG Sec. 575.100 Pesticide Chemical Residues in Food and Feed—Enforcement Criteria (CPG 7141.01). A notice announcing availability of a draft revision of CPG Sec. 575.100 is published elsewhere in this issue of the **Federal Register**.

Dated: December 31, 2007.

Margaret O'K. Glavin,

Associate Commissioner for Regulatory Affairs.

[FR Doc. E8–127 Filed 1–7–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0463]

Draft, Revised Compliance Policy Guide Sec. 575.100 Pesticide Chemical Residues in Food—Enforcement Criteria (CPG 7141.01); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft, revised Compliance Policy Guide (CPG) Sec. 575.100 Pesticide Chemical Residues in Food—Enforcement Criteria (CPG 7141.01) (the draft CPG). The draft CPG is intended to provide guidance to FDA staff on FDA's internal enforcement processes concerning pesticide chemical residues in food.