

status, such as a change from a regular certificate to a certificate of waiver.

Required Administrative Actions

CLIA is a user-fee funded program. The registration fee paid by laboratories is intended to cover the cost of the development and administration of the program. However, when a State's application for exemption is approved, we do not charge a fee to laboratories in the State. The State's share of the costs associated with CLIA must be collected from the State, as specified in § 493.645.

The State of Washington must pay for the following:

- Costs of Federal inspection of laboratories in the State to verify that Washington State's laboratory licensure program requirements are enforced in an appropriate manner. The average Federal hourly rate is multiplied by the total hours required to perform Federal validation surveys within the State.
- Costs incurred for Federal investigations and surveys triggered by complaints that are substantiated. We will bill the State of Washington on a semiannual basis.
- The State of Washington's proportionate share of the costs associated with establishing, maintaining, and improving the CLIA computer system, a portion of those services from which the State of Washington received direct benefit or contributed to the CLIA program in the State. Thus, the State of Washington is being charged for a portion of CMS' direct and indirect costs as well as a portion of the costs incurred by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).

In order to estimate the State of Washington's proportionate share of the general overhead costs to develop and implement CLIA, we determined the ratio of laboratories in the State to the total number of laboratories nationally. Approximately 1.5 percent of the registered laboratories are in the State of Washington. We determined that a corresponding percentage of the applicable CDC, FDA, and CMS costs should be borne by the State of Washington.

The State of Washington has agreed to pay us the State's pro rata share of the overhead costs and anticipated costs of actual validation and complaint investigation surveys. A final reconciliation for all laboratories and all expenses will be made. We will reimburse the State for any overpayment or bill it for any balance.

II. Approval

In light of the foregoing, CMS grants approval of the State of Washington's laboratory licensure program under Subpart E. All laboratories located in and licensed by the State of Washington under the Medical Test Site Licensure Law, Chapter 70.42 of the Revised Code of Washington, are CLIA-exempt for all specialties and subspecialties until September 28, 2013.

Authority: Section 353(p) of the Public Health Service Act (42 U.S.C. 263a).

Dated: July 20, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Pennsylvania State Plan Amendment (SPA) 06-007

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

ACTION: Notice of Hearing.

SUMMARY: This notice announces an administrative hearing to be held on November 16, 2007, at Suite 216, The Public Ledger Building, 150 S. Independence Mall West, Conference Room 241, the Pennsylvania Room, Philadelphia, PA 19106, to reconsider CMS's decision to disapprove Pennsylvania SPA 06-007.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by October 15, 2007.

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's decision to disapprove Pennsylvania State plan amendment (SPA) 06-007 which was submitted on September 27, 2006. This SPA was disapproved on June 29, 2007.

Under this SPA, the State requested the addition of targeted case management services to low-income, first-time expectant mothers who have, or are at risk of having, a high incidence of medical or social problems. The new targeted case management services were to be provided through the Nurse

Family Partnership Program. CMS made a Request for Additional Information on December 22, 2006, to which the State responded on April 2, 2007. The information provided confirmed that the targeted case management services proposed in SPA 06-007 are currently provided to all individuals without charge.

The amendment was disapproved because CMS found that the amendment violated the statute for reasons set forth in the disapproval letter. CMS consulted with the Secretary as required by Federal regulations at 42 CFR 430.15(c)(2).

Section 1902(a)(10) of the Social Security Act (the Act) requires that States make available medical assistance which is defined at section 1905(a) of the Act, and is limited to payment of medical costs for "individuals whose income and resources are insufficient to meet all of such costs." The term "medical assistance" fundamentally excludes payment for medical services that are free to the general public, since where a service is provided without charge the individual is not in the circumstance of having insufficient income or resources to meet the cost of care. Hence, such services do not meet the definition of "medical assistance."

In addition, section 1902(a)(30) of the Act requires States to have methods and procedures in place to assure that payments are consistent with efficiency, economy, and quality of care. CMS did not find that Medicaid payments for case management for first-time expectant mothers were consistent with this requirement when these same services are available to non-Medicaid enrollees without charge. Furthermore, the State failed to provide documentation requested by CMS demonstrating that the rate methodology used to determine payments to service providers was consistent with section 1902(a)(30). The State also failed to provide documentation of the various cost elements used to determine a fee-schedule amount or to submit provider surveys conducted by the State to determine whether its proposed indirect cost rate should be applied to direct costs to calculate the final fee paid to providers.

Based on the above, and after consultation with the Secretary of the Department of Health and Human Services as required under Federal regulations at 42 CFR 430.15(c)(2), CMS disapproved Pennsylvania Medicaid SPA 06-007.

The issues to be decided at the hearing are:

- Whether Pennsylvania has demonstrated that its SPA 06-007

complies with sections 1902(a)(10) and 1902(a)(30) of the Act by limiting payment of medical assistance to payment of medical costs for individuals who lack sufficient income and resources to meet the cost of care; and

- Whether the State has provided adequate documentation to demonstrate that the State's rate methodology is consistent with the requirements of section 1902(a)(30) of the Act; specifically whether the rates paid to service providers are consistent with efficiency, economy, and quality of care.

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

Ms. Estelle B. Richman,
Secretary of Public Welfare, Commonwealth of Pennsylvania, Department of Public Welfare, Office of Medical Assistance Programs, Bureau of Policy, Budget and Planning,
P.O. Box 8046,
Harrisburg, PA 17105.

Dear Ms. Richman:

I am responding to your request for reconsideration of the decision to disapprove Pennsylvania State plan amendment (SPA) 06-007, which was submitted on September 27, 2006, and disapproved on June 29, 2007.

Under this SPA, the State requested the addition of targeted case management services for first-time, low-income expectant mothers who have, or are at risk of having, a high incidence of medical or social problems. The Centers for Medicare & Medicaid Services (CMS) disapproved the SPA because CMS found that it violated the

statute for reasons set forth in the disapproval letter.

The CMS made a Request for Additional Information on December 22, 2006, to which the State responded on April 2, 2007. The information provided confirmed that the targeted case management services proposed in SPA 06-007 are currently provided to first-time expectant mothers without charge through State grant funding and private funds.

Section 1902(a)(10) of the Social Security Act (the Act) requires that States make available medical assistance, which is defined at section 1905(a) of the Act, and is limited to payment of medical costs for "individuals whose income and resources are insufficient to meet all of such costs." The term "medical assistance" fundamentally excludes payment for medical services that are free to the general public, since where a service is provided without charge the individual is not in the circumstance of having insufficient income or resources to meet the cost of care. Hence, such services do not meet the definition of "medical assistance."

In addition, section 1902(a)(30) of the Act requires States to have methods and procedures in place to assure that payments are consistent with efficiency, economy, and quality of care. CMS did not find that Medicaid payments for case management for first-time expectant mothers were consistent with this requirement when these same services are available to non-Medicaid enrollees without charge. Furthermore, the State failed to provide documentation requested by CMS demonstrating that the rate methodology used to determine payments to service providers was consistent with section 1902(a)(30). The State failed to provide documentation of the various cost elements used to determine a fee-schedule amount or to submit provider surveys conducted by the State to determine whether its proposed indirect cost rate should be applied to direct costs to calculate the final fee paid to providers.

Based on the above, and after consultation with the Secretary of the Department of Health and Human Services as required under Federal regulations at 42 CFR 430.15(c)(2), CMS disapproved Pennsylvania Medicaid SPA 06-007.

The issues to be decided at the hearing are

- Whether Pennsylvania has demonstrated that its SPA 06-007 complies with sections 1902(a)(10) and 1902(a)(30) of the Act by limiting payment of medical assistance to payment of medical costs for individuals who lack sufficient income and resources to meet the cost of care; and

- Whether the State has provided adequate documentation to demonstrate that the State's rate methodology is consistent with the requirements of section 1902(a)(30) of the Act; specifically whether the rates paid to service providers are consistent with efficiency, economy, and quality of care.

I am scheduling a hearing on your request for reconsideration to be held on November 16, 2007, at Suite 216, The Public Ledger Building, 150 S. Independence Mall West, Conference Room 241, the Pennsylvania Room, Philadelphia, PA 19106, to reconsider

the decision to disapprove SPA 06-007. 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.)

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS-3186-PN]

Medicare and Medicaid Programs; Application by the Indian Health Service (IHS) for Continued Recognition as a National Accreditation Organization for Accrediting American Indian and Alaska Native Entities To Furnish Outpatient Diabetes Self-Management Training

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application from the Indian Health Service for continued recognition as a national accreditation organization for accrediting American Indian and Alaska Native entities that wish to furnish outpatient diabetes self-management training to Medicare beneficiaries. This notice also announces a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. October 29, 2007.