DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval Washington Medicaid State Plan Amendment (SPA) 17-0002

AGENCY: Centers for Medicare & Medicaid Services (CMS)

ACTION: Notice of Hearing: Reconsideration of Disapproval

SUMMARY: This notice announces an administrative hearing to be held on January 15, 2019, at the Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Medicaid and Children's Health, Seattle Regional Office, 701 Fifth Avenue, Suite 1600, Seattle, WA 98104 to reconsider CMS' decision to disapprove Washington's Medicaid SPA 17-0002.

DATES: Requests to participate in the hearing as a party must be received by the presiding officer by **[insert date 15 days after publication in the Federal Register].**

FOR FURTHER INFORMATION CONTACT:

Benjamin R. 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 CMS' decision to disapprove Washington's Medicaid state plan amendment (SPA) 17-0002, which was submitted to the Centers for Medicare & Medicaid Services (CMS) on June 26, 2017 and disapproved on

September 10, 2018. This SPA requested CMS approval to: bring Washington into compliance with the pharmacy reimbursement requirements in the Covered Outpatient Drugs final rule with comment period (CMS-2345-FC) (Final Rule). Specifically, SPA 17-0002 proposed to revise the current pharmacy reimbursement methodology from reimbursing for ingredient costs based on Estimated Acquisition Cost (EAC), plus a tiered dispensing fee (High-volume pharmacies $4.24/Rx, Mid-volume pharmacies $4.56/Rx, Low-volume pharmacies $5.25/Rx, and Unit Does System $5.25/Rx), to reimbursing for ingredient cost based on Actual Acquisition Cost (AAC), using the National Average Drug Acquisition Cost (NADAC) without a change in the new requirements for a professional dispensing fee. In addition, SPA 17-0002 included proposed changes to reimbursement for 340B drugs, physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price.

The issues to be considered at the hearing are whether Washington SPA 17-0002 is inconsistent with the requirements of:

- Section 1902(a)(30)(A) of the Social Security Act (the Act) which requires, in part, that states have a state plan that provides such methods and procedures to assure that payment rates are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.
- Federal regulations at 42 CFR sections 447.502, 447.512 and 447.518 which provide that payments for drugs are to be based on the ingredient cost of the drug based on AAC and a Professional Dispensing Fee (PDF).

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 in the Federal Register 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 state Medicaid agency of additional issues that will be considered at the hearing, we will also publish that notice in the Federal Register.

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

Ms. MaryAnne Lindeblad

Director

State of Washington, Health Care Authority

626 8th Avenue PO Box 45502

Olympia, WA 98504-5050

Dear Ms. Lindeblad:

I am responding to your November 5, 2018 request for reconsideration of the decision to disapprove Washington's State Plan amendment (SPA) 17-0002. Washington SPA 17-0002 was submitted to the Centers for Medicare & Medicaid Services (CMS) on June 26, 2017, and disapproved on September 10, 2018. I am scheduling a hearing on your request for reconsideration to be held on January 15, 2019, at the Department of Health and Human Services, Centers for Medicare & Medicaid Services, Division of Medicaid and Children's Health, Seattle Regional Office, 701 Fifth Avenue, Suite 1600, Seattle, WA 98104.

I am designating Mr. Benjamin R. Cohen as the presiding officer. If these arrangements present any problems, please contact Mr. Cohen at (410) 786-3169. In order to facilitate any communication that may be necessary between the parties prior 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. If the hearing date is not acceptable, Mr. Cohen can set another date mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by federal regulations at 42 CFR Part 430.

This SPA requested CMS approval to bring Washington into compliance with the pharmacy reimbursement requirements in the Covered Outpatient Drugs final rule with comment period (CMS-2345-FC) (Final Rule). Specifically, SPA 17-0002 proposed to revise the current pharmacy reimbursement methodology from reimbursing for ingredient costs based on Estimated Acquisition Cost (EAC), plus a tiered dispensing fee (High-volume pharmacies $4.24/Rx, Mid-volume pharmacies $4.56/Rx, Low-volume pharmacies $5.25/Rx, and Unit Does System $5.25/Rx), to reimbursing for ingredient cost based on Actual Acquisition Cost (AAC), using the National Average Drug Acquisition Cost (NADAC) without a change in the new requirements

for a professional dispensing fee. In addition, SPA 17-0002 included proposed changes to reimbursement for 340B drugs, physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price.

The issues to be considered at the hearing are whether Washington SPA 17-0027 is inconsistent with the requirements of:

- Section 1902(a)(30)(A) of the Social Security Act (the Act) which requires, in part, that states have a state plan that provides such methods and procedures to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.
- Federal regulations at 42 CFR §§ 447.502, 447.512 and 447.518 which provide that payments for drugs are to be based on the ingredient cost of the drug based on AAC and a Professional Dispensing Fee (PDF).

In the event that CMS and the State come to agreement on resolution of the issues which formed the basis for disapproval, this SPA may be moved to approval prior to the scheduled hearing.

Sincerely,

Seema Verma

Administrator

cc: Benjamin R. Cohen

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: November 30, 2018

**Seema Verma**,

Administrator,

Centers for Medicare & Medicaid Services

[FR Doc. 2018-26495 Filed: 12/4/2018 8:45 am; Publication Date: 12/6/2018]