DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, MD 21244-1850

September 10, 2018

Susan Birch, Director
MaryAnne Lindeblad, Medicaid Director
Washington State Health Care Authority
P.O. Box 45502
Olympia, WA 98504-5010

Dear Ms. Birch and Ms. Lindeblad:

We have reviewed the Washington State plan amendment (SPA) 17-0002, received by the Centers for Medicare & Medicaid Services (CMS) on June 26, 2017. This amendment proposes 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). Under this SPA, Washington proposes 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 dispensing fee.

In addition, this SPA includes proposed changes to reimbursement for 340B drugs, physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price.

The proposed effective date for Washington SPA 17-0002 is April 1, 2017. For reasons set forth below, we are unable to approve Washington SPA 17-0002 as submitted because it does not comply with section 1902(a)(30)(A) of the Social Security Act (the Act), and the applicable federal regulations.

Statutory and Regulatory Background & Analysis

Section 1902(a)(30)(A) of the Act 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. Under that authority, the Secretary has issued regulations to ensure that Medicaid pharmacy providers are reimbursed accordingly for covered outpatient drugs. Federal regulations at 42 CFR sections 447.502, 447.512 and 447.518 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). AAC is defined at 42 CFR section 8.502 as

the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers. The definition of PDF under 42 CFR section 447.502 is the professional fee which:

> (1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed; (2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and (3) Does not include administrative costs incurred by the state in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

The regulation at 42 CFR section 447.518(d) specifically provides that when a state proposes changes to either the ingredient cost reimbursement or PDF reimbursement, states are required to evaluate their proposed changes in accordance with the applicable regulations, and consider both the ingredient cost reimbursement and the PDF reimbursement when proposing changes to ensure that total reimbursement to the pharmacy provider is in accordance with section 1902(a)(30)(A) of the Act. Federal regulation at 42 CFR section 447.518(d) sets applicable data requirements, establishing that states must provide adequate data to support any proposed changes to either or both components of the pharmacy reimbursement methodology.

We find that the state has not documented that its PDF is consistent with these statutory and regulatory requirements because the state did not submit adequate data that demonstrates pharmacy providers are reimbursed for their professional services consistent with the requirements of the final regulation, and thus, it has not assured that the state plan complies with section 1902(a)(30)(A) of the Act. More specifically, the data requirements at 42 CFR section 447.518(d) require that, *"States must provide adequate data such as a state or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes…"*

Despite the documents submitted and arguments provided by the state under Washington SPA 17-0002, CMS finds that the state did not provide sufficient support to demonstrate that the proposed PDF is consistent with the definition of PDF at 42 CFR section 447.502. This is further evidenced by the fact that the state did not present evidence of how it calculated its PDF or how the current dispensing fee methodology is consistent with the current definition of PDF.

As stated in the Final Rule, "…states must provide information supporting any proposed change to either the ingredient cost or dispensing fee reimbursement which demonstrates that the change reflects actual costs and does not negatively impact access." (81 FR 5201). Despite our request for additional information to support the PDF, Washington did not provide documentation

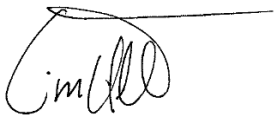
sufficient to justify its retention of its existing dispensing fee as satisfying the PDF requirements. Should the state decide in the future to provide data and documentation in a SPA sufficient to support the requirements of the Final Rule with respect to the determination of the PDF, we would be pleased to work with the state and review the data in the SPA.

Conclusion

Based on the above, and after consultation with the Secretary as required by federal regulation at 42 CFR 430.15(c)(2), I am disapproving Washington SPA 17-0002. If you are dissatisfied with this determination, you may petition for reconsideration within 60 days after receipt of this letter in accordance with the procedures set forth at 42 CFR 430.18. Your request for reconsideration should be sent to Ms. Maritza Bodon, Centers for Medicare & Medicaid Services, Center for Medicaid and CHIP Services, 7500 Security Boulevard, Mail Stop S2-26-12, Baltimore, MD 21244-1850.

If you have any questions or otherwise wish to discuss this determination, please contact John M. Coster, Ph.D., R.Ph., Director, Division of Pharmacy at (410) 786-1121.

Sincerely,



Tim Hill
Acting Director

cc: Associate Regional Administrator, David Meacham