system to monitor and guide participating state health departments. Since implementation in 2010, AIRS and the technical assistance provided by CDC staff have provided states with uniform data reporting methods and linkages to other states' asthma program information and resources. Thus, AIRS has saved state resources and staff time when asthma programs embark on asthma activities similar to those done elsewhere.

In the past three years, AIRS data were used to:

- Serve as a resource to NCEH when addressing congressional, departmental and institutional inquiries.
- Help the branch align its current interventions with CDC goals and allowed the monitoring of progress toward these goals.
- Allow the NACP and the state asthma programs to make more informed decisions about activities to achieve objectives.
- Facilitate communication about interventions across states, and enable inquiries regarding interventions by populations with a disproportionate burden, age groups, geographic areas and other variables of interest.
- Provide feedback to the grantees about their performance relative to others through the distribution of two written reports and several presentations (webinar and in-person) summarizing the results.
- Customize and provide technical assistance and support materials to address implementation challenges.

There will be no cost to respondents other than their time to complete the three AIRS spreadsheets annually. The estimated annualized burden hours are 89.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State Asthma Program Awardees	AIRS Performance Measures Reporting Spreadsheets.	25	1	150/60	63
	AIRS Emergency Department Visits Reporting Form.	25	1	30/60	13
	AIRS Hospital Discharge Reporting Forms.	25	1	30/60	13
Total	.....	.....	.....	.....	89

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–26352 Filed 12–4–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–19DO; Docket No. CDC–2018–0108]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled *National Surveillance of Community Water Systems and Corresponding Populations with the Recommended Fluoridation Level.* This surveillance collects the fluoridation status of the nation's approximately 52,000 community water systems (CWS) which serve the 50 states and the District of Columbia. It also collects fluoride level testing data for those CWS which adjust naturally occurring fluoride levels. The data are analyzed and published to inform the public and to support state and local governments' efforts to monitor community water fluoridation levels relative to the US Public Health Service recommended level to prevent tooth decay.

DATES: CDC must receive written comments on or before February 4, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2018–0108 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Acting Lead, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are

publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

National Surveillance of Community Water Systems and Corresponding Populations with the Recommended Fluoridation Level—Existing Collection in use without an OMB Control Number—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Dental caries is one of the most common chronic diseases throughout the lifespan in the United States, and disproportionately affects populations with low socioeconomic status, and racial and ethnic minority populations. Dental caries can lead to infection and diminished quality of life, and cause substantial societal cost due to absence from school and work, as well as expensive treatments.

Naturally occurring fluoride is found in all surface and ground water sources, but typically is lower than the recommended concentration needed to prevent dental caries (tooth decay). Community water fluoridation is the process of adjusting the fluoride concentration of a community water system (CWS) to the level beneficial for prevention of dental caries as recommended by the US Public Health Service (PHS). CDC monitors CWS fluoride levels relative to the PHS recommended level under the Public Health Service Act. In 2000, CDC launched a Web-based data management tool—Water Fluoridation Reporting Systems (WFRS) in collaboration with the Association of State and Territorial Dental Directors. States may report their information to CDC using WFRS or via email.

Respondents to the information collection are state fluoridation managers or other state government officials designated by the state dental director or drinking water administrator. State participation in the data collection is voluntary. Respondents are asked to update fluoridation status of, and counties and populations served by, each CWS in their state annually. All 50 states respond to this portion of the collection. Washington DC is not included in the data collection because water is supplied by a CWS from Virginia and therefore Virginia will collect data. Historically collected natural fluoride concentrations are available in WFRS for all CWS; once collected, they rarely change over time. Respondents also are asked to enter the high, low, and average fluoride testing level data annually for each month for their fluoride-adjusted CWS. Currently, two-thirds of the states respond to this portion of the collection.

CDC analyzes and publishes results through interactive, public-facing web pages: (1) Biennial surveillance reports documenting the percentage of the population with fluoridated water at national, state, and local levels; and (2) My Water's Fluoride, which publishes the fluoridation status of individual CWS and some fluoride level data for states which choose to display it. CDC uses the information collection to (1) provide national fluoridation surveillance reports; (2) assist states manage their fluoride level data and monitor and improve quality of community water fluoridation programs; (3) measure national performance toward the fluoridation Healthy People objective; (4) evaluate outcomes of CDC's cooperative agreements with states; (5) facilitate creation of state-specific reports for states' programmatic and policy use. The information collection is also used to inform health care providers to determine targeted delivery of preventive care, for example, determining use of fluoride supplements for children living in fluoride-deficient areas.

CDC's collection of CWS data is not duplicative of any other federal collection, including the US Environmental Protection Agency's (EPA) Safe Drinking Water Information System (SDWIS), as SDWIS receives state reports of CWS fluoride levels that exceed 4 mg/L but not those near the beneficial level of 0.7 mg/L recommended for dental caries prevention by the PHS. Thus, CDC's system is required to assess the degree to which the nation is reaching this PHS-recommended level.

The total estimated annualized burden hours are 2,824, including (1) 1,900 hours for the validation or update of CWS fluoridation status and population served from 50 respondents, with estimated average burden hours of 38 per respondent; and (2) 924 hours for the annual entry of fluoride testing level data for fluoride-adjusted CWS conducted by 33 respondents with an estimated average burden of 28 hours per respondent. WFRS will be hosted and maintaineded by CDC. There are no maintenance costs to respondents, and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State Official	Fluoridation status and population	50	1	38	1,900
State Official	Fluoride testing data	33	1	28	924
Total					2,824

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2018–26351 Filed 12–4–18; 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 Washington Medicaid State Plan Amendment (SPA) 17–0002

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

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 December 20, 2018.

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 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.