Application to Use Burden/Hours from Generic PRA Clearance:
Medicaid and CHIP State Plan, Waiver, and Program Submissions
(CMS-10398, OMB 0938-1148)

Information Collection #42 Covered Outpatient Drugs
Requirements for States (42 CFR 447.512, 447.514, and 447.518)

Center for Medicaid and CHIP Services (CMCS)
Centers for Medicare & Medicaid Services (CMS)

A. Background

The Centers for Medicare & Medicaid Services (CMS) work in partnership with States to implement Medicaid and the Children's Health Insurance Program (CHIP). Together these programs provide health coverage to millions of Americans. Medicaid and CHIP are based in Federal statute, associated regulations and policy guidance, and the approved State plan documents that serve as a contract between CMS and States about how Medicaid and CHIP will be operated in that State. CMS works collaboratively with States in the ongoing management of programs and policies, and CMS continues to develop implementing guidance and templates for States to use to elect new options available as a result of the Affordable Care Act or to comply with new statutory provisions. CMS also continues to work with States through other methods to further the goals of health reform, including program waivers and demonstrations, and other technical assistance initiatives.

B. Description of Information Collection

Our Covered Outpatient Drug final rule (February 1, 2016; 81 FR 5170) (CMS-2345-FC, RIN 0938-AQ41) added burden for states to implement new reimbursement requirements. This includes the new actual acquisition cost and professional dispensing fee requirements which are codified in 42 CFR 447.512, as well as the new requirements for the federal upper limits which are codified in 42 CFR 447.514.

The state reporting requirements are codified in 42 CFR 447.518, "State plan requirements, findings and assurances", which specifies that the state plan must describe comprehensively the agency's payment methodology for prescription drugs, including the agency's payment methodology for covered outpatient drugs, including 340B, IHS, and I/T/U.

The states' burden in revising their state plan (through a SPA submission) may include the time and cost for administrative processes and requirements such as legislative and regulatory action, operational changes, and the submission of a SPA for formal review.

C. Deviations from Generic Request

No deviations are requested.

D. Burden Hour Deduction

The total approved burden ceiling of the generic ICR is 154,104 hours, and CMS previously requested to use 70,515 hours, leaving our burden ceiling at 83,589 hours.

D.1. Wage Estimate

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the

mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage	Fringe Benefit	Adjusted Hourly Wage
Business Operations Specialist	13-1199	35.33	35.33	70.66

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

D.2. Burden Estimate

We require the states to replace the term, "estimated acquisition cost" (EAC) with "actual acquisition cost" (AAC) and to define AAC as "the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific drug manufacturers" in their state plans. We also require the states to replace the term "dispensing fee" with "professional dispensing fee" as the drug ingredient cost is only one component of the two-part formula used to reimburse pharmacies for prescribed drugs dispensed to Medicaid beneficiaries in their state plans. We further require states to reconsider the dispensing fee methodology consistent with the revised requirements. The definitions of AAC and professional dispensing fee are revised.

We have also revised the methodology we will use to calculate the FUL. Specifically, the FUL will be calculated at an amount equal to 175 percent of the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs, except where that amount is less than the average retail community pharmacies' acquisition cost for such drug products as determined by the most current national survey of such costs. In situations where the FUL is less than the average retail community pharmacies' acquisition cost, we will establish the FUL using a higher multiplier so that the FUL amount would equal the average retail community pharmacies' acquisition cost as determined by the most current national survey of such costs.

As a result of these changes, states must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing changes to either or both of these components of the reimbursement for Medicaid covered drugs to ensure that total reimbursement to the pharmacy provider is in accordance with the requirements under section 1902(a)(30)(A) of the Social Security Act. In addition, states must submit to CMS the proposed change in reimbursement and the supporting data through a SPA through the formal review process.

In addition, our definition of the term "states" has been revised to include the territories (the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa), in addition to the 50 states and the District of Columbia. Similarly, the term "United States" has been added to include the territories (the Commonwealth of Puerto Rico, the

Virgin Islands, Guam, the Northern Mariana Islands and American Samoa), in addition to the 50 states and the District of Columbia.

As a result, the territories will able to receive drug manufacturer rebates through the MDR program in the same manner that the 50 states and the District of Columbia are currently receiving rebates, beginning 1 year after the effective date of the CMS-2345-FC final rule, namely April 1, 2017.

We recognize that there will be some additional burden to the states to implement the new AAC and professional dispensing fee requirements as well as the new reimbursements for the FULs and other federal programs, such as 340B, IHS, and I/T/U. This burden may include the time and cost for administrative processes and requirements such as legislative and regulatory action, operational changes, and the submission of a SPA for formal review.

For these burdens, we believe it will take a business operations specialist 300 hours at $70.66/hr for a one-time total of 16,800 hours (56 states x 300 hours) at a cost of $1,187,088. Our 300 hour estimate is based on our experience with state plan amendments. Once the state has submitted and CMS has approved the SPA, there should be no additional burden in time or effort for the states other than that which already exists.

D.3. Information Collection Instruments and Associated Materials

Summary of Medicaid Pharmacy State Plan Requirements (dated June 13, 2016)

E. Timeline

n/a