

Supporting Statement A
Annual State Report on CMS Value Based Purchasing Arrangements (VBP)
Supplemental Rebate Agreements
CMS-10722 (OMB 0938-1385)

Background

Under section 1902(a)(30)(A) of the Social Security Act, we are granted the authority to require that methods and procedures be established by states relating to the utilization of, and the payment for, care and services available under the state plan process (including but not limited to utilization review plans) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that state payments to providers of Medicaid services are consistent with efficiency, economy, and quality of care.

This 2024 information collection request updates the Annual State Report on CMS VBP Supplemental Rebate Agreements by clarifying information under the “Data Elements Defined” tab (henceforth referred to as “instructions”) and formatting changes to the Annual Report and instructions. The revisions have no impact on any of this collection’s currently approved requirements and burden estimates.

We have also adjusted our active cost estimate by using the more recent wage data.

A. Justification

1. Need and Legal Basis

The reported data is being collected to safeguard against unnecessary utilization of such care and services and to assure that state payments to providers of Medicaid services are consistent with efficiency, economy, and quality of care. CMS will collect this data to ensure that VBP programs adopted by states continue to meet these standards.

The authority to collect this data is 1902(a)(30)(A) which requires require that methods and procedures be established by states relating to the utilization of, and the payment for, care and services available under the state plan process (including but not limited to utilization review plans) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that state payments to providers of Medicaid services are consistent with efficiency, economy, and quality of care.

2. Information Users

CMS will request that the collection be in a spreadsheet format that will collect state data elements specific to the VBP arrangement that the state has entered into and the requirements as set forth in CMS-2482-F (RIN 0938–AT82). Data will be collected on an annual basis and the time period will be dependent upon the length of the VBP arrangement the state has with the manufacturer. The number of potential respondents will be 50 states plus DC and they will be responding to CMS.

CMS will use this data to assess whether the cost of entering into such agreements will save Federal and state Medicaid dollars overall thus ensuring efficient and economic operation of the Medicaid program. Specifically, CMS would like to understand if such programs (VBP arrangements under a supplemental rebate agreement) provide a true savings in the form of rebates and reduced prices given the state cost obligations under such arrangements (e.g., cost of data collection and reporting efforts). VBP arrangements offered by manufacturers to the states can range from a very simple model such as rebating a portion of the cost of an anti-psychotic drug if the patient discontinues treatment because of side effects, to a more complex arrangement such as requiring provider input on clinical outcomes, collection of patient-specific clinical data by data aggregators and reporting of that data to the manufacturer. At this time, there is no transparency into the cost to administer these programs vs. the eventual savings to the state or Federal government. By collecting this in a uniform way across all states, this form gives states and CMS the ability to understand if such programs are working to generate savings for the Medicaid program. The data can be shared nationally so that states are aware that such programs are available and approximate the savings that are generated for these programs in certain states. It also provides CMS with data to compare new programs that can produce savings compared to other traditional rebate-base models, such as those based on preferred drug status.

States will be informed of their obligation to collect the data when the state has indicated as part of their state plan that they are entering into VBP arrangements via a CMS-authorized supplemental rebate agreement. States are already required to submit a template for such arrangements to CMS as part of their state plan submission. Once they submit and CMS approves the template, they will be required to submit data on the arrangement annually.

3. Use of Information Technology

States will be asked to submit a spreadsheet with the data elements listed via email. CMS does not believe further technology will be needed for this data request. If further advances in this collection is necessary, CMS will address as part of this collection of information request.

4. Duplication of Efforts

This information cannot be collected from other sources at this time. The data being collected is specific to the VBP arrangement that the state negotiates with the manufacturer.

5. Small Businesses

N/A as this data collection applies only to the states.

6. Less Frequent Collection

The consequences of this data collection being conducted on less than an annual basis is that we will not fully understand the financial impact of such arrangements on the Medicaid program.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

Federal Register

The 60-day notice published in the Federal Register on February 9, 2024 (89 FR 9155). Although comments were due April 9, 2024, none were received.

The 30-day notice published in the Federal Register on April 25, 2024 (89 FR 31754). Comments must be received by May 28, 2024.

Outside Consultation

We also consulted with State Medicaid agency representatives regarding the collection instrument to ensure instructions were clear and simplified.

9. Payments/Gifts to Respondents

The respondents are not receiving payments or gifts for responding to his collection.

10. Confidentiality

There are no privacy issues (personally identifiable data) associated with this collection.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Collection of Information Requirements and Annual Burden Estimates

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/2023/may/oes_nat.htm). In this regard the following table presents the mean hourly wage, the cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and the adjusted hourly wage.

National Occupational Employment and Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
General Operations Mgr	11-1021	62.18	62.18	124.36

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 other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Information Collection Requirements and Burden Estimates

Under section 1902(a)(30)(A) the Act, we are granted the authority to require that methods and procedures be established by states relating to the utilization of, and the payment for, care and services available under the state plan process (including but not limited to utilization review plans) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that state payments to providers of Medicaid services are consistent with efficiency, economy, and quality of care.

To that end, as part of the state plan approval process relative to the VBP program, our CMS-2482-F final rule set out new reporting requirements that affect the 51 state Medicaid programs (the 50 states and the District of Columbia). Specifically, a State participating in value-based purchasing arrangements must report data described in § 447.518(d)(1) and (2) on an annual basis and no later than 60 days after the end of each year.

The reported data should include:
-the State name,

- National drug code(s) (for drugs covered under the VBP),
- product FDA list name,
- number of prescriptions,
- cost to the State to administer VBP (for example: systems changes, tracking evidence or outcomes-based measures, etc.), and
- the total savings generated by the supplemental rebate due to the VBP.

The reporting requirements are applicable to both FFS and MCO COD claims.

We estimate it will take 6 hours at \$124.36/hr for a general operations manager to collect the supplemental rebate agreement VBP drug utilization information, add the data to the state’s quarterly report when due annually (we will choose the quarter in which the annual data will be due), and submit the report to CMS. In aggregate we estimate an ongoing annual burden of 306 hours (6 hr/report x 1 report/year x 51 respondents) at a cost of \$38,054 (306 hr x \$124.36/hr).

Summary of Information Collection Requirements and Burden Estimates

The following table summarizes our information collection requirements and burden estimates.

Summary of Annual Requirements and Burden

Section under Title 42 of the CFR	# of Respondents	Responses (per year)	Total Responses	Time per Response (hours)	Total Time (hours)	Labor Rate (\$/hr)	Total Cost (\$)
447.518(d) (1) and (2)	51	1	51	6	306	124.36	38,054

Information Collection Instruments and Instruction/Guidance Documents

Annual State Report on CMS VBP Supplemental Rebate Agreements (Revised)

13. Capital Costs

There are no capital or start-up costs associated with this collection as it collects information on data associated with the Medicaid program that would not require additional capital.

14. Cost to Federal Government

The cost to the Federal government will only be the staff time to receive and store the collected data.

To derive average costs, we used data from OPM’s 2024 base salary for the Baltimore/Washington, D.C. region at the GS-13, step 5 level (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB_h.pdf). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and the adjusted hourly wage.

Grade (Step)	Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
GS-13 (step 5)	64.06	64.06	128.12

Our estimated cost is \$5,124.80 (40 hr x \$128.12/hr).

15. Changes to Collection of Information Requirements, Burden, and Collection of Information Instruments

The updates to the Annual Report include clarifications to the instructions and formatting changes, neither of which have an impact on the level of effort required to complete the Annual Report.

We have also adjusted our cost estimate based on using the most recent BLS wage data. Our estimate increased by \$1,903 (from \$36,151 to \$38,054). Without accounting for any adjustments, our active estimate used BLS' May 2020 mean wage of \$60.45/hr while this iteration uses BLS' May 2023 mean wage of \$62.18/hr (an increase of \$1.73/hr).

16. Publication/Tabulation Dates

There are no plans to publish the information.

17. Expiration Date

The expiration date is displayed.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods, surveys, or questionnaires associated with this collection.