

Supporting Statement – Part A  
Medicaid Managed Care and Supporting Regulations  
CMS-10855, OMB 0938-1445

The regulatory sections that support this collection of information’s requirements are set out in 42 CFR part 438 (Managed Care) under §§ 438.3 and 438.8.

Note: We intend to fold the following collection of information requirements and burden estimates under CMS-10108 (OMB 0938-0920). However, there are a number of conflicting activities that make this impractical at this time. To address those conflicts, as a stop gap measure this September 2024 iteration proposes to submit the collection of information requirements and burden estimates under CMS-10855 (OMB 0938-1445). When ready we will be folding them to their proper place under CMS-10108 (OMB 0938-0920).

**BACKGROUND**

Most Medicaid beneficiaries receive either all or part of their health care benefits through Medicaid managed care programs, including their prescription drug benefits. Because of the specialized nature of the prescription drug benefit, many of the Medicaid managed care plans (MCOs, PIHPS, or PAHPS) either own, or contract with, PBMs to administer the pharmacy benefit.

MCOs: Medicaid managed care organizations.

PIHPS: prepaid inpatient health plans.

PAHPS: prepaid ambulatory health plans.

PBMs: pharmacy benefit managers.

This collection of information request is associated with our September 26, 2024 (89 FR 79020) final rule (CMS-2434-F; RIN 0938-AU28). In § 438.3(s), Medicaid MCOs, PIHPS, and PAHPS that provide coverage of covered outpatient drugs (CODs) will be required to structure any contract that it has with any subcontractor (e.g., PBM) for the delivery or administration of the COD benefit so that the subcontractor is required to report separately the amounts related to the incurred claims described in § 438.8(e)(2) to the managed care plan. Included are (1) reimbursements for the CODs, (2) payments for other patient services, (3) dispensing or administering providers fees, and (4) subcontractor administrative fees.

The provision will ensure that medical loss ratios (MLRs) reported by MCOs, PIHPS and PAHPS that use subcontractors in the delivery of COD coverage will be more accurate and transparent.

The separate payment requirements will help States and managed care plans better understand whether they are appropriately and efficiently paying for the delivery of CODs, a significant part of which is funded by the Federal Government.

For States, we estimate a one-time burden of 40 responses/respondents, 1,000 hours, and \$91,920. For the private sector (managed care plans and PBMs) we estimate an annual burden of

564 responses/respondents, 7,614 hours, and \$699,879. Overall, we estimate a burden of 604 responses/respondents, 8,614 hours, and \$791,799.

There are no reporting instruments or instructions other than what is set out in CMS-2434-F and what is codified in the CFR.

## **A. JUSTIFICATION**

### **1. Need and Legal Basis**

While the information collection requirements are not required by statute, we believe the collection to be necessary for the proper and efficient operation of the Medicaid State Plan.

In this case, section 1902(a)(4)(A) of the Social Security Act (Act) requires that the State Plan for medical assistance comply with methods of administration that are found by the Secretary to be necessary for the proper and efficient operation of the State Plan. Greater transparency and accountability by Medicaid managed care plans (and their subcontractors including pharmacy benefit managers (PBMs)) to the States for how Medicaid benefits are paid for compared to how PBM administrative fees or services are paid are necessary for efficient and proper operation of Medicaid programs. This collection will hold Medicaid managed care plans accountable to assure that the plan's MLR calculation is limited to the true medical costs associated with the provision of CODs and are distinguishable from administrative fees and other services fees paid to PBMs.

### **2. Information Users**

Via contracts, CMS-2434-F will require that managed care plans require the subcontractor to report separately the amounts related to the incurred claims described in § 438.8(e)(2) (such as reimbursement for the COD, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a COD) from administrative costs, fees and expenses of the subcontractor will be able to accurately calculate and report its MLR.

MLR calculations are used to develop capitation rates paid to Medicaid managed care plans, thus their accuracy is critical in assuring that Medicaid payments are reasonable, appropriate and necessary for health care services when using a Medicaid managed care plan.

Managed care capitation rates must (1) be developed such that the plan would reasonably achieve an 85% MLR (§ 438.4(b)(9)) and (2) be developed using past MLR information for the plan (§ 438.5(b)(5)).

In addition to other standards outlined in §§ 438.4 through 438.7, the requirements for capitation rates related to the MLR are key to ensuring that Medicaid managed care capitation rates are actuarially sound. In addition, Medicaid managed care plans may need to pay remittances (that is, refund part of the capitation payments) to States should they not achieve the specific MLR target. Thus, the accuracy of MLR calculation is important to conserving Medicaid funds.

States are responsible for ensuring that information collected is not manipulated and erroneously published. The information is used by States as part of their normal contracting with, and monitoring of, their MCOs, PIHPs, and PAHPs and is not be published.

CMS may use the information collected and reported in an oversight role of State Medicaid managed care programs.

With regard to CMS, the reported information is reviewed as part of the agency's normal oversight activity of State Medicaid managed care programs.

### 3. Improved Information Technology

Not applicable.

### 4. Duplication of Similar Information

The information collection requirements that are set out below under section 12 do not duplicate similar information collections.

### 5. Small Businesses

For the final rule, we do not believe there will be a significant impact on small business entities. We estimated that some PAHPs, are likely to be small entities. We estimated that most MCOs and PIHPs were not small entities.

According to the Small Business Administration (SBA) and the Table of Small Business Size Standards, small entities include small businesses in the health care sector that are direct health and medical insurance carriers with average annual receipts of less than \$38.5 million and offices of physicians or health practitioners with average annual receipts of less than \$11 million. Individuals and state governments are not included in the definition of a small entity.

In CMS-2434-F, we report that there are 282 managed care entities affected by the managed care (PBM) provision. Research on publicly available records for the entities allowed us to determine that only a few of these entities qualify as small entities. Specifically, we believe that approximately 14 – 25 of these plans may be small entities.

For the requirements in section 12 of this Supporting Statement, we have determined that the burden estimates would not have a significant burden or economic impact on a substantial number of the small entities that we have identified.

### 6. Less Frequent Collection

The contract structuring requirements are a one-time activity.

The frequency of reporting of MLR by the managed care plans is required annually. The frequency of reporting MLR has not changed (§438.8).

## 7. Special Circumstances

There are no special circumstances. More specifically, this information collection does not do any of the following:

- Require respondents to report information to the agency more often than quarterly;
- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Is connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Require the use of a statistical data classification that has not been reviewed and approved by OMB;
- Includes 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
- Require respondents to 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 Notice/Outside Consultation

Serving as the 60-day notice, the proposed rule (CMS-2434-P; RIN 0938-AU28) published in the Federal Register on May 26, 2023 (88 FR 34238). While comments were received, we are not changing any of our proposed requirements, burden estimates, or assumptions in response to the NPRM's comments. Instead, CMS-2434-F finalizes the proposed requirements, burden estimates or assumptions without change. A summary of the comments and our response are included in the final rule. They are also attached to the final rule's collection of information request.

The final rule (CMS-2434-F; RIN 0938-AU28) published in the Federal Register on September 26, 2024 (89 FR 79020).

## 9. Payment/Gift to Respondent

There are no payments/gifts to respondents.

## 10. Confidentiality

Any information received by CMS as part of this provision is not confidential and its release would fall under the Freedom of Information Act.

## 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 Associated 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 ([https://www.bls.gov/oes/2023/may/oes\\_nat.htm](https://www.bls.gov/oes/2023/may/oes_nat.htm)). In this regard, the following table presents BLS’ mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our 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)
Operations Research Analyst	15-2031	45.96	45.96	91.92

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.

### *Collection of Information Requirements and Associated Burden Estimates:*

In CMS-2434-F, § 438.3(s) will require that MCOs, PIHPs, and PAHPs that provide coverage of CODs structure any contract with any subcontractor for the delivery or administration of the COD benefit to require the subcontractor to report separately the amounts related to:

- (1) The incurred claims described in § 438.8(e)(2) such as reimbursement for the COD, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a COD; and
- (2) Administrative costs, fees and expenses of the subcontractor.

We estimate that the reporting requirements will affect 282 managed care plans and 40 States. We estimate it would take 25 hours at \$91.92/hr for an operations research analyst to restructure 282 managed care contracts to require those plans to structure their subcontracts to require the subcontractor to separately report incurred claims expenses described in § 438.8(e)(2) from fees paid for administrative activities.

In aggregate, we estimate a one-time burden of 1,000 hours (40 State responses x 25 hr/response) at a cost of \$91,920 (1,000 hr x \$91.92/hr). (ESTIMATE 9.3a)

### One-time Burden Estimates: State Government

Estimate #	CFR Section	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Rate (\$/hr)	Total Cost (\$)	Response Type	Frequency
9.3a	438.3(s) and 438.8(e)(2)	40 States	40	25	1,000	91.92	91,920	TPD	Once

*(Response Type: R=reporting; RK=recordkeeping; TPD=third-party disclosure)*

For the same contract changes between the MCOs and the PBMs, we estimate a one-time private sector burden of 7,050 hours (282 managed care plans x 25 hr/response) at a cost of \$648,036 (7,050 hr x \$91.92/hr). (ESTIMATE 9.3b)

Of the 282 managed care plans' subcontractors (PBMs), we estimate that it would take approximately 2 hours at \$91.92/hr for an operations research analyst to identify the costs separately and report separately to the managed care plans claims expenses described in § 438.8(e)(2) from fees paid for administrative activities. In aggregate we estimate an annual burden of 564 hours (282 PBMs x 2 hr/response) at a cost of \$51,843 (564 hr x \$91.92/hr). (ESTIMATE 9.3c)

Estimate #	CFR Section	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Rate (\$/hr)	Total Cost (\$)	Response Type	Frequency
9.3b	438.8(e)(2)	282 managed care plans	282	25	7,050	91.92	648,036	R	Once
9.3c	438.8(e)(2)	282 subcontractors (PBMs)	282	2	564	91.92	51,843	R	Annual
<i>Subtotal: Reporting</i>		564	564	<i>Varies</i>	7,614	<i>Varies</i>	699,879	R	<i>Varies</i>

### Annual Burden Estimates: Private Sector

*(Response Type: R=reporting; RK=recordkeeping; TPD=third-party disclosure)*

### Burden Summary

#### Summary of Annual Burden Estimates: Total

Respondent Type	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Labor Rate (\$/hr)	Total Cost (\$)
State	40	40	25	1,000	91.92	91,920

Private Sector	564	564	Varies	7,614	91.92	699,879
TOTAL	604	604	Varies	8,614	91.92	791,799

*Collection of Information Instruments and Instruction/Guidance Documents*

There are no reporting instruments or instructions other than what is set out in CMS-2434-F and what is codified in the CFR.

**13. Capital Costs (Maintenance of Capital Costs)**

There are no capital costs.

**14. Annual Cost to Federal Government**

None of the contracting costs would be incurred by the Federal Government. Regardless, the following is an assessment of the costs incurred in the normal course of business operations.

CMS Central Office Staff: 1 FTE (GS-13 Step 1) working at 5% of assigned duties.

Annual Time: 104 hours (2,080 hr x 0.05)

Adjusted Hourly Wage: \$113.04/hr (\$56.52/hr + \$56.52/hr)  
(calculated from 100% of the hourly wage to account for fringe benefits and other indirect costs).

Annual Cost: = \$11,756 (\$113.04/hr x 104 hr)

\$56.52/hr is derived from OPM’s 2024 Salary Table at [chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB\\_h.pdf](https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB_h.pdf)

**15. Program and Burden Changes**

As it relates to what is active or currently approved by OMB, there are no changes as this is a new collection of information request. The new requirements and burden estimates can be found under section 12 of this Supporting Statement.

**16. Publication and Tabulation Dates**

The reported information is not published by CMS.

**17. Expiration Date**

The expiration date and PRA Disclosure Statement will be displayed.



18. Certification Statement

There are no exceptions to the certification statement.

**B. Collection of Information Employing Statistical Methods**

There are no statistical methods.