

Supporting Statement – Part A
Medicaid Managed Care and Supporting Regulations
CMS-10856, OMB 0938-TBD

The regulatory sections that support this collection of information request are set out in 42 CFR part 438 (Medicaid Managed Care). See section 12 of this Supporting Statement for details.

BACKGROUND

The changes in this August 2023 iteration would advance CMS' efforts to improve access to care, quality and health outcomes, and better address health equity issues for Medicaid managed care enrollees. The changes include standards for timely access to care and States' monitoring and enforcement efforts, enhanced quality as well as fiscal and program integrity standards for state directed payments (SDPs), new standards that would apply when States use in lieu of services and settings (ILOSs) to promote effective utilization and specify the scope and nature of ILOS, and specify medical loss ratio (MLR) requirements.

A. JUSTIFICATION

1. Need and Legal Basis:

Section 4701 of the Bipartisan Budget Act (BBA) of 1997 created section 1932(a) of the Social Security Act (the Act), changed terminology in Title XIX of the Act and amended section 1903(m) to require that contracts and managed care organizations (MCOs) comply with applicable requirements in the new section. Section 1932(a) permits States to mandatorily enroll most groups of Medicaid beneficiaries into managed care arrangements without section 1915(b) or section 1115 waiver authority.

- Section 1932 also defines the term "managed care entity" (MCE) to include MCOs and primary care case managers (PCCMs); establishes new requirements for managed care enrollment and choice of coverage; and requires MCEs and State agencies to provide specified information to enrollees and potential enrollees.
- Section 4702 amended section 1905 to permit States to provide PCCM services without the need for waiver authority. Instead, PCCM services may be made available under a State's Medicaid plan as an optional service.
- Section 4703 eliminated a former statutory requirement that no more than 75 percent of the enrollees in an MCO be Medicaid or Medicare beneficiaries.
- Section 4704 created section 1932(b) to add increased beneficiary protections for those enrolled under managed care arrangements. These include, among other things, the use of a prudent layperson's definition of emergency medical condition when presenting at an emergency room; standards for demonstration of adequate capacity and services; grievance

procedures; and protections for enrollees against liability for payment of an organization's or provider's debts in the case of insolvency.

- Section 4705 created section 1932(c), which requires States to develop and implement quality assessment and improvement strategies for their managed care arrangements.
- Section 4706 provided that with limited exceptions an MCO must meet the same solvency standards set by States for a private HMO, or be licensed or certified by the State as a risk-bearing entity.
- Section 4707 created section 1932(d) to add protections against fraud and abuse, such as restrictions on marketing and sanctions for noncompliance.
- Section 4708 added a number of provisions to improve the administration of managed care arrangements. These include, among other things, changing the threshold amount of managed care contracts requiring the Secretary's prior approval, and permitting the same copayments in MCOs as apply to fee-for-service arrangements.
- Section 4709 allowed States the option to provide six months of guaranteed eligibility for all individuals enrolled with an MCO or PCCM.
- Section 4710 specified the effective dates for all the provisions identified in sections 4701 through 4709.
- Section 1902(a)(4) of the Social Security Act requires such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the plan.

2. Information Users:

Reporting: Information required to be reported as specified in 42 CFR part 438 regulations and as indicated the burden estimates in Section 12 below, is used by states for program administration as well as reported to CMS for program compliance monitoring and policy development. The three templates included in this Supporting Statement are used by states for reporting: Managed Care Program Annual Report (MCPAR), Medical Loss Ratio (MLR) Reporting Template, and Network Adequacy and Access Assurances Tool are used for state reporting to CMS. Some of the information reported by States is collected from their contracted managed care plans, as indicated in the Private Sector burden estimates in Section 12.

Third Party Disclosures: States are required as specified in 42 CFR part 438 regulations and as indicated the burden estimates in Section 12 below, to include certain requirements in their contracts with their managed care plans. Managed care plans' contracts specify their obligations to the State Medicaid agency. Managed care plans and states must distribute certain information to their enrollees (ex. handbooks and notices) and providers (ex. practice guidelines and notices). Enrollees use this information to understand their rights under the program and how to access care. Providers use the information to understand their rights and obligations as a Medicaid and managed care plan provider.

3. Improved Information Technology:

Section 438.10 would provide new standards for state operated websites.

Sections 438.3(a), 438.6(c), 438.66(e), 438.74, 438.207(d) and (f) would provide requirements concerning specific reporting to CMS and would all be done electronically. CMS has published templates for states to use to comply with the reporting requirements in §§ 438.66(e), 438.207(d), and 438.74 to ensure the receipt of consistent information that can be more easily aggregated and analyzed. With the exception of §§ 438.3(a), 438.6, 438.66(e), 438.74, 438.207(d), the other sections do not involve submitting information to any entity other than between states and plans. Because this concerns disclosure to a third party, we do not dictate how the information may be disclosed.

4. Duplication of Similar Information:

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

5. Small Businesses:

As of 2020, there were 467 MCOs, 162 PIHPs or PAHPs, 21 non-emergency transportation PAHPs, and 26 PCCM entities participating in the Medicaid managed care program. 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. We have determined that there is no significant economic impact on a substantial number of small entities for the requirements in section 12 of this Supporting Statement.

6. Less Frequent Collection:

Many of the information collection requirements that are set out below under section 12 are mandated by the BBA. If CMS were to collect them less frequently, we would be in violation of the law. While others are not required by statute, we believe them necessary for program administration and have set them at frequencies as low as possible. None of the respondents are required to report information more often than quarterly.

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:

The 60-day notice published in the Federal Register on August 28, 2023 (88 FR 58588). Comments must be received by October 27, 2023.

9. Payment/Gift to Respondent:

There is no payment/gift to respondents.

10. Confidentiality:

The information received by CMS 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:

The regulatory sections that support our collection of information's requirements are set out in 42 CFR part 438 (Managed Care). The requirements and burden follow.

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs, and our adjusted hourly wage.

National Occupation Titles and Wage Rates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
All Occupations	00-0000	28.01	n/a	n/a
Accountant	13-2011	40.37	40.37	80.74
Actuary	15-2011	60.24	60.24	120.48
Business Operations Specialist, All Other	13-1199	38.64	38.64	77.28
Computer Programmer	15-1251	54.68	54.68	109.36
Customer Service Rep	43-4051	18.79	18.79	37.58
Database Administrator	15-1242	49.25	49.25	98.50
General and Operations Manager	11-1021	55.41	55.41	110.82
Medical Records Specialist	29-2072	23.23	23.23	46.46
Office Clerk, General	43-9061	18.98	18.98	37.96
Statistician	15-2041	47.81	47.81	96.62
Registered Nurse	29-1141	39.78	39.78	79.56
Web Developer	15-1245	39.09	39.09	78.18

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.

12.2 Collection of Information Requirements and Associated Burden Estimates:

Subpart A-General Provisions

Subpart A specifies requirements for states and managed care plans including contract requirements and payment.

Section 438.3 Standard contract requirements

Changes to §§ 438.3(i) would require that MCOs, PIHPs, and PAHPs report provider incentive payments based on standard metrics for provider performance. Changes to § 438.8(e)(2) would

define the provider incentive payments that could be included in the MLR calculation; however, the administrative burden for these changes is attributable to the managed care contracting process, so we are attributing these costs to the contracting requirements in § 438.3(i). Approximately 315 MCO, PIHP, and PAHP contracts would require modification to reflect these changes. For the contract modifications, we estimate it would take 2 hours at \$77.28/hr for a business operations specialist and 1 hour at \$110.82/hr for a general operations manager. In aggregate for § 438.3(i), we estimate a one-time State burden of 945 hours (315 contracts x 3 hr) at a cost of \$83,595 [315 contracts x ((2 hr x \$77.28/hr) + (1 hr x \$110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 315 hours and \$9,288. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.1g)**

To report provider incentive payment based on standard metrics, MCOs, PIHP, and PAHPs would need to select standard metrics, develop appropriate payment arrangements, and then modify the affected providers' contracts. We estimate it would take 120 hours consisting of: 80 hours x \$77.28/hr for a business operations specialist and 40 hours x \$110.82/hr for a general and operations manager. In aggregate for § 438.3(i), we estimate a one-time private sector burden of 37,800 hours (315 contracts x 120 hr) at a cost of \$3,343,788 [315 contracts x ((80 hr x \$77.28/hr) + (40 hr x \$110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 12,600 hours and \$1,114,596. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.1h)**

Section 438.6 Special Contract Provisions Related to Payment

Changes to § 438.6(c)(2) would require all SDP expenditures under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) (that is, the SDPs that require prior written approval) must be submitted and have written approval by CMS prior to implementation. We estimate that, initially, 38 States would submit 50 new proposals for minimum/maximum fee schedules, value-based payment, or uniform fee increases. We estimate that it would take 2 hours at \$120.48/hr for an actuary, 6 hours at \$77.28/hr for a business operations specialist, and 2 hours at \$110.82/hr for a general and operations manager for development and submission. We estimate an annual State burden of 500 hours (50 proposals x 10 hr) at a cost of \$46,314 [50 proposals x ((2 hr x \$120.48/hr) + (6 hr x \$77.28/hr) + (2 hr x \$110.82/hr))]. **(ESTIMATE 70)**

Thereafter, we estimate that 38 States would submit 150 renewal or amendment proposals per year. We estimate also it would take 1 hour at \$77.28/hr for a business operations specialist, 1 hour at \$120.48/hr for an actuary, and 1 hour at \$110.82/hr for a general and operations manager for any proposal updates or renewals. In aggregate, we estimate an annual State burden of 450 hours (150 proposals x 3 hr) and \$46,287 [150 renewal/amendment proposals x ((1 hr x \$77.28/hr) + (1 hr x \$110.82/hr) + (1 hr x 120.48/hr))]. **(ESTIMATE 70a)**

Changes to § 438.6(c)(2)(iii) would require that all SDPs subject to prior approval under paragraphs (c)(1)(i) through (iii) for inpatient hospital services, outpatient hospital services, nursing facility services, and qualified practitioner services at an academic medical center, include a written analysis, showing that the total payment for such services does not exceed the average commercial rate. We estimate that 38 States will develop and submit 60 of these SDPs that include a written analysis to CMS. We also estimate it would take 6 hours at \$120.48/hr for an actuary, 3 hours at \$110.82/hr for a general and operations manager, and 6 hours at \$109.36/hr for a computer programmer for each analysis. In aggregate we estimate an annual State burden of 900 hours (60 SDPs x 15 hr) and at a cost of \$102,690 [60 certifications x ((6 hr x \$120.48/hr) + (3 hr x \$110.82/hr) + (6 hr x \$109.36/hr))]. **(ESTIMATE 70b)**

Section 438.6(c)(2)(iv) would require that SDPs under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) must prepare and submit a written evaluation plan to CMS. The evaluation plan must include specific components and is intended to measure the effectiveness of those State directed payments in advancing at least one of the goals and objectives in the quality strategy on an annual basis and whether specific performance targets are met. We estimate that 38 States would submit 50 written evaluation plans for new proposals. We also estimate it would take 5 hours at \$109.36/hour for a computer programmer, 2.5 hours at \$110.82/hr for a general and operations manager, and 2.5 hours at \$77.28/hr for a business operations specialist for each new evaluation plan. In aggregate, we estimate an annual State burden of 500 hours (50 evaluation plans x 10 hr) and at a cost of \$50,853 [50 evaluation plans x ((5 hr x 109.36/hr) + (2.5 hr x \$110.82) + (2.5 hr x \$77.28/hr))]. **(ESTIMATE 70c)**

Thereafter, we estimate that 38 States would prepare and submit 150 written evaluation plans for amendment and renewal proposals. We also estimate it would take 2 hours at \$109.36/hr for a computer programmer, 2 hours at \$110.82/hr for a general and operations manager and 2 hours at \$77.28/hr for a business operations specialist for each evaluation plan amendment and renewal. In aggregate we estimate an annual State burden of 900 hours (150 evaluation plans x 6 hr) at a cost of \$89,238 [150 evaluation plans x ((2 hr x 109.36/hr) + (2 hr x \$110.82) + (2 hr x \$77.28/hr))]. **(ESTIMATE 70d)**

Section 438.6(c)(2)(v) would require for all SDPs under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) that have an actual Medicaid managed care spending percentage greater than 1.5 must complete and submit an evaluation report using the approved evaluation plan to demonstrate whether the SDP results in achievement of the State goals and objectives in alignment with the State's evaluation plan. We estimate 38 States will submit 47 evaluation reports. We also estimate it would take 3 hours at \$109.36/hr for a computer programmer, 1 hour at \$110.82/hour for a general and operations manager, and 2 hours at \$77.28/hr for a business

operations specialist for each report. In aggregate we estimate an annual State burden of 282 hours (47 reports x 6 hr) at a cost of \$27,893 [47 reports x ((3 hr x \$109.36/hr) + (1 hr x \$110.82/hr) + (2 hr x \$77.28/hr))]. **(ESTIMATE 70e)**

Changes to § 438.6(c)(7) would require States to submit a final SDP cost percentage as a separate actuarial report concurrently with the rate certification only if a State wishes to demonstrate that the final SDP cost percentage is below 1.5 percent. We anticipate that 10 States would need: 5 hours at \$120.48/hr for an actuary, 5 hours at \$109.36/hr for a computer programmer, and 7 hours at \$77.28/hr for a business operations specialist. In aggregate, we estimate an annual State burden of 170 hours (17 hr x 10 States) at a cost of \$16,902 (10 States x [(5 hr x \$120.48/hr) + (5 hr x \$109.36/hr) + (7 hr x \$77.28/hr)]). **(ESTIMATE 70f)**

Section 438.7 Rate certification submission

Changes to § 438.7 set out revisions to the submission and documentation requirements for all managed care actuarial rate certifications. The certification would be reviewed and approved by CMS concurrently with the corresponding contract(s). Currently, § 438.7(b) details certain requirements for documentation in the rate certifications. We believe these requirements are consistent with actuarial standards of practice and previous Medicaid managed care rules.

We estimate that 44 States would develop 225 certifications at 250 hours for each certification. Of the 250 hours, we estimate that it would take 110 hours at \$120.48/hr for an actuary, 15 hours at \$110.82/hr for a general and operations manager, 53 hours at \$109.36/hr for a computer programmer, 52 hours at \$77.28/hr for a business operations specialist, and 20 hours at \$37.96/hr for an office and administrative support worker. In aggregate we estimate an annual State burden of 56,250 hours (250 hr x 225 certifications) at a cost of \$5,735,012 [225 certifications x ((110 hr x \$120.48/hr) + (15 hr x \$110.82/hr) + (53 hr x \$109.36/hr) + (52 hr x \$77.28/hr) + (20 hr x \$37.96/hr))]. **(ESTIMATE 12.3c)**

Section 438.8 Medical loss ratio standards

Changes to §§ 438.8 would require that MCOs, PIHPs, and PAHPs report to the State annually their total expenditures on all claims and non-claims related activities, premium revenue, the calculated MLR, and, if applicable, any remittance owed.

We estimate the total number of MLR reports that MCOs, PIHPs, and PAHPs were required to submit to States amount to 629 Medicaid contracts. All MCOs, PIHPs, and PAHPs need to report the information specified under §§ 438.8 regardless of their credibility status.

Changes to § 438.8(k) would require that MCOs, PIHPs, and PAHPs include expenditures for State directed payments on a separate line in their annual report to the State. We anticipate that the one-time system change would take 4 hr at \$77.28/hr for a business operations specialist and 2 hr at \$109.36/hr for a computer programmer. In aggregate for § 438.8(k), we estimate a one-time private sector burden of 3,774 hours (629 contracts x 6 hr) at a cost of \$332,011 [629 contracts x ((4 hr x \$77.28/hr) + (2 hr x \$109.36/hr))]. As this would be a one-time requirement,

we annualize our time and cost estimates to 1,258 hours and \$110,670. The annualization divides our estimate by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.5b)**

Changes to §§ 438.8(k)(1)(vii) would require that MCOs, PIHPs, and PAHPs develop their annual MLR reports compliant with the expense allocation methodology.¹ To meet this requirement we anticipate it would take: 1 hr at \$80.74/hr for an accountant, 1 hr at \$77.28/hr for a business operations specialist, and 1 hr at \$110.82/hr for a general operations manager. In aggregate for § 438.8(k)(1)(vii), we estimate an annual private sector burden of 1,887 hours (629 contracts x 3 hr) at a cost of \$169,100 [629 contracts x ((1 hr x \$80.74/hr) + (1 hr x \$77.28/hr) + (1 hr x \$110.82/hr))]. **(ESTIMATE 12.5c)**

To do the annual reconciliations needed to make the incentive payments (438.3(i)) and include the expenditures in their annual report required by 438.8(k), we estimate MCOs, PIHPs, and PAHPs would take 1 hour at \$77.28/hr for a business operations specialist. In aggregate we estimate an annual private sector burden of 315 hours (315 contracts x 1 hr) at a cost of \$24,343 (315 contracts x 1 hr x \$77.28/hr). **(ESTIMATE 12.5a)**

Section 438.10 Information Requirements

Changes to §§ 438.10(c)(3) would require States to operate a website that provides the information required in § 438.10(f). States would be required to include required information on one page, use clear labeling, and verify correct functioning and accurate content at least quarterly. We anticipate it would take 20 hours at \$109.36/hr once for a computer programmer to place all required information on one page and ensure the use of clear and easy to understand labels on documents and links. In aggregate for § 438.10(c)(3), we estimate a one-time State burden of 900 hours (45 States x 20 hr) at a cost of \$98,424 (900 hr x \$109.36/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 300 hours and \$32,808. As this would be a one-time requirement, we annualize our time and cost estimates to 213 hours and \$23,294. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.6c)**

We also anticipate that it would take 40 hr at \$109.36/hr for a computer programmer to periodically add and verify the function and content on the site at least quarterly (10 hours/quarter). In aggregate for we estimate an annual State burden of 1,800 hours (45 States x 40 hr) at a cost of \$196,848 (1,800 hr x \$109.36/hr). **(ESTIMATE 12.6d)**

Section 438.16 In Lieu of Services and Settings

Changes to §§ 438.16 would require States that provide ILOSs, with the exception of short term IMD stays, to comply with additional information collection requirements. 44 States utilize MCOs, PIHPs and PAHPs in Medicaid managed care programs. We do not have current data readily available on the number of States that utilize ILOSs and the types of ILOSs in Medicaid

¹ Methodology(ies) for allocation of expenditures as described at 45 CFR 158.170(b).

managed care. We believe it is a reasonable estimate to consider that half of the States with MCOs, PIHPs and PAHPs (22 States) may choose to provide non-IMD ILOSs.

Changes to § 438.16(c)(4)(i) would require States to submit a projected ILOS cost percentage to CMS as part of the rate certification. The burden for this proposal is accounted for in ICR #2 (above) for § 438.7 Rate Certifications.

Changes to § 438.16(c)(5)(ii) would require States to submit a final ILOS cost percentage and summary of actual MCO, PIHP and PAHP ILOS costs as a separate actuarial report concurrently with the rate certification. We anticipate that 22 States would need: 5 hours at \$120.48/hr for an actuary, 5 hours at \$109.36/hr for a computer programmer, and 7 hours at \$77.28/hr for a business operations specialist. In aggregate, we estimate an annual State burden of 374 hours (17 hr x 22 States) at a cost of \$37,184 (22 States x [(5 hr x \$120.48/hr) + (5 hr x \$109.36/hr) + (7 hr x \$77.28/hr)]). **(ESTIMATE 12.66a)**

Proposals at §§ 438.16(d)(1) would require States that elect to use ILOS to include additional documentation requirements in their managed care plan contracts. We anticipate that 22 States would need 1 hour at \$77.28/hr for a business operations specialist to amend 327 Medicaid MCO, PIHP, and PAHP contracts annually. In aggregate for § 438.16(d)(1), we estimate an annual State burden of 327 hours (327 contracts x 1 hr) at a cost of \$25,271 (327 hr x \$77.28/hr). **(ESTIMATE 12.66b)**

Proposals at §§ 438.16(d)(2) would require some States to provide to CMS additional documentation to describe the process and supporting data the State used to determine each ILOS to be a medically appropriate and cost-effective substitute. This additional documentation would be required for States with a projected ILOS cost percentage greater than 1.5 percent. We anticipate that approximately 5 States may be required to submit this additional documentation. We estimate it would take 2 hours at \$77.28/hr for a business operations specialist to provide this documentation. In aggregate for § 438.16(d)(2), we estimate an annual State burden of 10 hours (5 States x 2 hr) at a cost of \$773 (10 hr x \$77.28/hr). **(ESTIMATE 12.66c)**

Proposals at §§ 438.16(e)(1) would require States with a final ILOS cost percentage greater than 1.5 percent to submit an evaluation for ILOSs to CMS. We anticipate that approximately 5 States may be required to develop and submit an evaluation. We estimate it would take 25 hours at \$77.28/hr for a business operations specialist. In aggregate for § 438.16(e)(1), we estimate an annual State burden of 125 hours (5 States x 25 hr) at a cost of \$9,660 (125 hr x \$77.28/hr). **(ESTIMATE 12.66d)**

An ILOS may be terminated by either a State, a managed care plan, or by CMS. Proposals at §§ 438.16(e)(2)(iii) would require States to develop an ILOS transition of care policy. We believe all States with non-IMD ILOSs should proactively prepare a transition of care policy in case an ILOS is terminated. We estimate both a one-time burden and an annual burden for these proposals. We believe there is a higher one-time burden as all States that currently provide non-IMD ILOSs would need to comply with this proposed requirement by the applicability date, and an annual burden is estimated for States on an on-going basis. We estimate for a one-time burden, it would take: 2 hours at \$109.36/hr for a computer programmer and 2 hours at \$77.28/hr for a business and operations specialist for initial development of a transition of care policy. In

aggregate for § 438.16(e)(2)(iii), we estimate a one-time State burden 88 hours (22 States x 4 hr) at a cost of \$8,212 (22 States x [(2 hr x \$109.36/hr) + (2 hr x \$77.28/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 30 hours and \$2,799. As this would be a one-time requirement, we annualize our time and cost estimates to 21 hours and \$1,991. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.66e)**

For updates to reflect specific ILOSs, we also estimate that this proposed ILOS transition of care policy would have an annual burden of 1 hour at \$77.28/hr for a business operations specialist per State. In aggregate for § 438.16(e)(2)(iii), we estimate an annual State burden of 22 hours (22 States x 1 hr) at a cost of \$1,700 (22 hr x \$77.28/hr). **(ESTIMATE 12.66f)**

For MCOs, PIHPs, or PAHPs that would need to implement a transition policy when an ILOS is terminated, we estimate that on an annual basis, 20 percent of managed care plans (65 plans) may need to implement this policy. We estimate an annual managed care plan burden of 2 hours at \$77.28/hr for a business operations specialist to implement the policy. In aggregate for § 438.16(e)(2)(iii)(B) we estimate an annual burden of 130 hours (65 plans x 2 hr) at a cost of \$10,046 (130 hr x \$77.28/hr). **(ESTIMATE 12.66g)**

Subpart B-State Responsibilities

Subpart B specifies requirements for states in the design and operation of their managed care programs.

Section 438.66 State monitoring requirements

Changes to § 438.66(c) would require States to conduct, or contract for, an enrollee experience survey annually. We believe most, if not all, States will use a contractor for this task and base our burden estimates on that assumption. In the first year, for procurement, contract implementation and management, and analysis of results, we estimate 85 hours at \$77.28/hr for a business operations specialist and 25 hours at \$110.82/hr for general operations manager. In aggregate for § 438.66(c), we estimate a one-time State burden of 5,390 hours (49 States x 110 hr) at a cost of \$457,626 (49 States x [(85 hr x \$77.28/hr) + (25 hr x \$110.20)]). As this would be a one-time requirement, we annualize our time and cost estimates to 1,796 hours and \$152,542. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.26a)**

In subsequent years, for contract management and analysis of experience survey results, we estimate 50 hours at \$77.28/hr for a business operations specialist and 15 hours at \$110.82/hr for general operations manager. In aggregate, we estimate an annual State burden of 3,185 hr (49 States x 65 hr) at a cost of \$270,789 (49 States x [(50 hr x \$77.28/hr) + (15 hr x \$110.20/hr)]). **(ESTIMATE 12.26b)**

Amendments to § 438.66(e)(1) and (2) would require that States submit an annual program assessment report to CMS covering the topics listed in § 438.66(e)(2). The data collected for §

438.66(b) and the utilization of the data in § 438.66(c), including reporting as proposed in § 438.16, would be used to complete the report. We anticipate it would take 80 hours at \$77.28/hr for a business operations specialist to compile and submit this report to CMS. In aggregate, we estimate an annual State burden of 3,920 hours (49 States x 80 hr) at a cost of \$302,938 (3,920 hr x \$77.28/hr). **(ESTIMATE 12.26c)**

Section 438.68 Network adequacy standards

Sections 438.68(e) would require States with MCO, PIHP, and PAHPs to develop appointment wait time standards for four provider types. We anticipate it would take: 20 hours at \$77.28/hr for a business operations specialist for development and 10 hours at \$77.28/hr a business operations specialist for ongoing enforcement of all network adequacy standards. In aggregate for § 438.68(e), we estimate a one-time State burden of 880 hours (44 States x 20 hr) at a cost of \$68,006 (880 hr x \$77.28/hr) and an annual State burden of 440 hours (44 States x 10 hr) at a cost of \$34,003 (440 hr x \$77.28/hr). **(ESTIMATE 12.67)**

Amendments to §§ 438.68(f) would require States with MCO, PIHPs, or PAHPs to contract with an independent vendor to perform secret shopper surveys of plan compliance with appointment wait times and accuracy of provider directories and send directory inaccuracies to the State within three days of discovery. In the first year, for procurement, contract implementation, and management, we anticipate it would take: 85 hours at \$77.28/hr for a business operations specialist and 25 hours at \$110.82/hr for general operations manager. In aggregate for § 438.68(f), we estimate a one-time State burden of 4,840 hours (44 States x 110 hr) at a cost of \$410,929 (44 States x [(85 hr x \$77.28/hr) + (25 hr x \$110.82/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 1,614 hours and \$136,976. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.67a)**

In subsequent years, for contract management and analysis of results, we anticipate it would take 50 hours at \$77.28/hr for a business operations specialist and 15 hours at \$110.82/hr for general operations manager. In aggregate for § 438.68(c), we estimate an annual State burden of 2,860 hours (44 States x 65 hr) at a cost of \$243,157 (44 States x [(50 hr x \$77.28/hr) + (15 hr x \$110.82)]). **(ESTIMATE 12.67b)**

Section 438.74 State Oversight of the MLR requirement

Changes to §§ 438.74 would require States to comply with data aggregation requirements for their annual reports to CMS. We estimate that only 5 States would need to resubmit MLR reports to comply with the proposed data aggregation changes. We anticipate that it would take 5 hours x \$77.28/hr for a business operations specialist. In aggregate, for § 438.74, we estimate a one-time State burden of 25 hours (5 States x 5 hr) at a cost of \$1,932 (5 States x 5 hr x \$77.28/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 8 hours and \$644. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.65b)**

Changes to § 438.74 would require States to submit a summary report of the State directed payment data submitted by their managed care plans under § 438.8(k). The proposed changes to § 438.74 would apply to 43 States. To accommodate the new data from plans resulting from proposed changes to § 438.74, we anticipate it would take 4 hours at \$77.28/hr for a business operations specialist to implement the proposed SDP reporting changes in their MLR summary reports. In aggregate, we estimate an annual State burden of 172 hours (43 States x 4 hr) at a cost of \$13,292 (43 States x 4 hr x \$77.28/hr). **(ESTIMATE 12.65c)**

Subpart D-MCO, PIHP and PAHP Standards

Subpart D specifies requirements for managed care plans in a managed care program including for access to services and data collection and reporting.

Section 438.207 Assurance of adequate capacity and services

Changes to §§ 438.207(b) would require MCOs, PIHPs, and PAHPs to submit documentation to the State of their compliance with § 438.207(a). As we propose in this rule to add a reimbursement analysis at § 438.207(b)(3), we estimate a one-time plan burden of: 50 hours at \$77.28/hr for a business operations specialist, 20 hours at \$110.82/hr for a general operations manager, and 80 hours at \$109.36/hr for a computer programmer. In aggregate for § 438.207(b), we estimate a one-time private sector burden of 94,350 hours (629 MCO, PIHPs, and PAHPs x 150 hr) at a cost of \$9,327,567 (629 MCOs, PIHPs, and PAHPs x [(50 hr x \$77.28/hr) + (20 hr x \$110.20/hr) + (80 hr x \$109.36/hr)]). As this would be a one-time requirement, we annualize our time and cost estimates to 31,450 hours and \$3,460,800. The annualization divides our estimates by three (3) years to reflect OMB's likely approval period. We are annualizing the one-time burden estimates since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.34d)**

For ongoing analyses and submission of information that would be required by amendments to § 438.207(b), we estimate it would take: 20 hours at \$77.28/hr for a business operations specialist, 5 hours at \$110.82/hr for a general operations manager, and 20 hours at \$109.36/hr for a computer programmer. In aggregate we estimate a one-time private sector burden of 28,305 hours (629 MCO, PIHPs, and PAHPs x 45 hr) at a cost of \$2,696,460 (629 MCO, PIHPs, and PAHPs x [(20 hr x \$77.28/hr) + (5 hr x \$110.20/hr) + (20 hr x \$109.36/hr)]). **(ESTIMATE 12.34e)**

Subpart H- Additional Program Integrity Standards

Section 438.608 Program integrity requirements under the contract

Changes to §§ 438.608 would require States to update all MCO, PIHP, and PAHP contracts to require managed care plans to report overpayments to the State within 10 business days of identifying or recovering an overpayment. We estimate that the proposed changes to the timing of overpayment reporting (from timeframes that varied by State to 10 business days for all States) would apply to 654 MCO, PIHP, and PAHP contracts. We estimate it would take: 2 hours at \$77.28/hr for a business operations specialist and 1 hour at \$110.82/hr for a general and

operations manager to modify State contracts with plans. In aggregate for § 438.608, we estimate a one-time State burden of 1,962 hours (654 contracts x 3 hr) at a cost of \$173,559 [654 contracts x ((2 hr x \$77.28/hr) + (1 hr x \$110.82/hr))]. As this would be a one-time requirement, we annualize our time and cost estimates to 654 hours and \$57,853. **(ESTIMATE 12.57a)**

We also estimate that it would take MCOs, PIHPs, and PAHPs 1 hour at \$109.36/hr for a computer programmer to update systems and processes already used to meet the previous requirement for “prompt” reporting. In aggregate for § 438.608, we estimate a one-time private sector burden of 654 hours (654 contracts x 1 hr) at a cost of \$71,521 (654 hr x \$109.36/hr). As this would be a one-time requirement, we annualize our time and cost estimates to 218 hours and \$23,840. The annualization divides our estimates by three (3) years to reflect OMB’s likely approval period. We are annualizing the one-time burden estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.57b)**

12.3 Burden Summary

Summary of Annual Burden Estimates: State Government

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

Estimate #	CFR section	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate (\$/hr)	Total cost (\$)	Response Type	Frequency
12.70	438.6(c)(2)(ii) State directed payments	38	50	2	100	120.48	12,048	R	Annual
12.70	438.6(c)(2)(ii) State directed payments	38	50	6	300	77.28	23,184	R	Annual
12.70	438.6(c)(2)(ii) State directed payments	38	50	2	100	110.82	11,082	R	Annual
12.70a	438.6(c)(2)(ii) State directed payments	38	150	1	150	110.82	16,623	R	Annual
12.70a	438.6(c)(2)(ii) State directed payments	30	150	1	150	120.48	18,072	R	Annual
12.70a	438.6(c)(2)(ii) State directed payments	38	150	1	150	77.28	11,592	R	Annual
12.70b	438.6(c)(2)(iii) State directed payments	38	60	6	360	120.48	43,373	R	Once
12.70b	438.6(c)(2)(iii) State directed payments	38	60	3	180	110.82	19,948	R	Once
12.70b	438.6(c)(2)(iii) State directed payments	38	60	6	360	109.36	39,370	R	Once
12.70c	438.6(c)(2)(iv) State directed payments	38	50	5	250	109.36	27,340	R	Annual
12.70c	438.6(c)(2)(iv) State directed payments	38	50	2.5	125	110.82	13,853	R	Annual
12.70c	438.6(c)(2)(iv) State directed payments	38	50	2.5	125	77.28	9,660	R	Annual
12.70d	438.6(c)(2)(iv) State directed payments	38	150	2	300	109.36	32,808	R	Annual
12.70d	438.6(c)(2)(iv) State directed payments	38	150	2	300	110.82	33,246	R	Annual

Estimate #	CFR section	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate (\$/hr)	Total cost (\$)	Response Type	Frequency
12.70d	438.6(c)(2)(iv) State directed payments	38	150	2	300	77.28	23,184	R	Annual
12.70e	438.6(c)(2)(v) State directed payments	38	47	3	141	109.36	15,420	R	Annual
12.70e	438.6(c)(2)(v) State directed payments	38	47	1	47	110.82	5,209	R	Annual
12.70e	438.6(c)(2)(v) State directed payments	38	47	2	94	77.28	7,264	R	Annual
12.70f	438.6(c)(7) State directed payments	10	10	5	15	120.48	6,024	R	Annual
12.70f	438.6(c)(7) State directed payments	10	10	5	15	109.36	5,468	R	Annual
12.70f	438.6(c)(7) State directed payments	10	10	7	70	77.28	5,410	R	Annual
12.3c	438.7(b) Rate certifications	44	225	110	24,750	120.48	2,981,880	R	Annual
12.3c	438.7(b) Rate certifications	44	225	15	3,375	110.82	374,018	R	Annual
12.3c	438.7(b) Rate certifications	44	225	53	11,925	109.36	1,304,118	R	Annual
12.3c	438.7(b) Rate certifications	44	225	52	11,700	77.28	904,176	R	Annual
12.3c	438.7(b) Rate certifications	44	225	20	4,500	37.96	170,820	R	Annual
12.5b	438.8(k) Reporting requirements	629	629	4	2,516	77.28	194,437	R	Once
12.5b	438.8(k) Reporting requirements	629	629	2	1,258	109.36	137,575	R	Once
12.5c	438.8(k) Reporting requirements	629	629	1	629	80.74	50,785	R	Annual
12.5c	438.8(k) Reporting requirements	315	315	1	315	77.28	24,343	R	Annual
12.5c	438.8(k) Reporting requirements	629	629	1	629	110.82	69,706	R	Annual
12.5a	438.8(k) Reporting requirements	629	629	1	629	77.28	48,609	R	Annual
12.66a	438.16(c)(5)(ii) Basic rules	22	22	5	110	120.48	13,253	R	Annual

Estimate #	CFR section	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate (\$/hr)	Total cost (\$)	Response Type	Frequency
12.66a	438.16(c)(5)(ii) Basic rules	22	22	7	154	77.28	11,901	R	Annual
12.66a	438.16(c)(5)(ii) Basic rules	22	22	5	110	109.36	12,030	R	Annual
12.66b	438.16(d)(1) Documentation requirements	22	327	1	327	77.28	25,271	R	Annual
12.66c	438.16(d)(2) Documentation requirements	5	5	2	10	77.28	773	R	Annual
12.66d	438.16(e)(1) Monitoring, Evaluation, and Oversight	5	5	25	125	77.28	9,660	R	Annual
12.66e	438.16(e)(2)(iii) Monitoring, Evaluation, and Oversight	22	22	2	44	77.28	3,400	R	Once
12.66e	438.16(e)(2)(iii) Monitoring, Evaluation, and Oversight	22	22	2	44	109.36	4,812	R	Once
12.66f	438.16(e)(2)(iii) Monitoring, Evaluation, and Oversight	22	22	1	44	77.28	1,700	R	Annual
12.66g	438.16(e)(2)(iii) Monitoring, Evaluation, and Oversight	65	65	2	130	77.28	10,046	R	Annual
12.26a	438.66(c) Monitoring requirements	49	49	85	4,165	77.28	321,871	R	Once
12.26a	438.66(c) Monitoring requirements	49	49	25	1,225	110.82	135,755	R	Once
12.26b	438.66(c) Monitoring requirements	49	49	50	2,450	77.28	189,336	R	Annual
12.26b	438.66(c) Monitoring requirements	49	49	15	735	110.82	81,453	R	Annual
12.26c	438.66(e) Monitoring requirements	49	49	80	3,920	77.28	302,938	R	Annual
12.67	438.68(e) Appointment wait time standards	44	44	20	880	77.28	68,006	R	Once
12.67	438.68(e) Appointment wait time standards	44	44	10	440	77.28	34,003	R	Annual
12.67a	438.68(f) Secret shopper surveys	44	44	85	3,740	77.28	289,027	R	Once
12.67a	438.68(f) Secret shopper surveys	44	44	25	1,100	110.82	121,902	R	Once

Estimate #	CFR section	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate (\$/hr)	Total cost (\$)	Response Type	Frequency
12.67b	438.68(f) Secret shopper surveys	44	44	50	2,200	77.28	170,016	R	Annual
12.67b	438.68(f) Secret shopper surveys	44	44	15	660	110.82	73,141	R	Annual
12.65b	438.74 State oversight of MLR	5	5	5	25	77.28	1,932	R	Once
12.65c	438.74 State oversight of MLR	43	43	4	172	77.28	13,292	R	Annual
12.57a	438.608(a)(2) Administrative and management arrangements or procedures to detect and prevent fraud, waste, and abuse	654	654	2	1308	77.28	101,082	R	Once
12.57a	438.608(a)(2) Administrative and management arrangements or procedures to detect and prevent fraud, waste, and abuse	654	654	1	654	110.82	72,476	R	Once
12.57b	438.608(a)(2) Administrative and management arrangements or procedures to detect and prevent fraud, waste, and abuse	654	654	1	654	109.36	71,521	R	Once
Subtotal Reporting		654	9,189	Varies	91,284	Varies	8,781,242	R	Varies
12.1g	438.3(i) Physician incentive plans	315	315	2	630	77.28	48,686	TPD	Once
12.1h	438.3(i) Physician incentive plans	315	315	1	315	110.82	34,908	TPD	Once
12.6c	438.10(c)(3) Basic rules	45	45	20	900	109.36	98,424	TPD	Once
12.6d	438.10(c)(3) Basic rules	45	45	40	1800	109.36	196,848	TPD	Annual
Subtotal Third Party Distribution		315	720	Varies	3645	Varies	378,866	TPD	Varies

Total State Burden (by Type)	Respondents	Total Responses	Burden per Response (hr)	Total Annual Time (hr)	Labor Rate (\$/hr)	Total Annual Cost (\$)
Reporting	654	9,189	Varies	91,284	Varies	8,781,242

Third Party Disclosure	315	720	Varies	3,645	Varies	378,866
TOTAL	969	9,909	Varies	94,929	Varies	9,160,108

Summary of Annual Burden Estimates: Private Sector

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

Estimate #	CFR section	# of Respondents	Total # of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate (\$/hr)	Total cost (\$)	Response Type	Frequency
12.5a	438.8(k) MLR reporting requirements	315	315	80	25,200	77.28	1,947,456	R	Once
12.5a	438.8(k) MLR reporting requirements	315	315	40	12,600	110.82	1,396,332	R	Once
12.34d	438.207(b)(3) Nature of supporting documentation	629	629	50	31,450	77.28	3,485,289	R	Once
12.34d	438.207(b)(3) Nature of supporting documentation	629	629	20	12,580	110.82	1,394,116	R	Once
12.34d	438.207(b)(3) Nature of supporting documentation	629	629	80	50,320	109.36	5,502,995	R	Once
12.34e	438.207(b)(3) Nature of supporting documentation	629	629	20	12,580	77.28	972,182	R	Annual
12.34e	438.207(b)(3) Nature of supporting documentation	629	629	5	3,145	110.82	348,529	R	Annual
12.34e	438.207(b)(3) Nature of supporting documentation	629	629	20	12,580	109.36	1,375,749	R	Annual
Subtotal Reporting		629	4,404	Varies	160,455	Varies	16,422,648	R	Varies
Total		629	4,404	Varies	160,455	Varies	16,422,648	R	Varies

Summary of Annual Burden Estimates: Total

Respondent Type	Respondents	Total Responses	Burden per Response (hr)	Total Annual Time (hr)	Labor Rate (\$/hr)	Total Annual Cost (\$)
State	969	9,909	Varies	94,929	Varies	9,160,108
Private Sector	629	4,404	Varies	160,455	Varies	16,422,648
TOTAL	1,598	14,313	Varies	255,384	Varies	25,582,756

12.4 Collection of Information Instruments and Instruction/Guidance Documents

None.

13. Capital Costs (Maintenance of Capital Costs):

There are no capital costs.

14. Cost to Federal Government:

For the revisions in part 438, we applied a weighted FMAP of 58.44 percent (weighted for enrollment) to estimate the federal share of private sector costs. This was done to account for private sector costs that are passed to the federal government through the managed care capitation rates.

For the provisions contained in section 12 of this supporting statement, the annualized cost to the federal government is \$14,950,562 ($25,582,756 \times .5844$)

15. Program and Burden Changes:

n/a

16. Publication and Tabulation Dates:

The majority of information submitted to CMS will not be published by CMS. Rather, that information is reviewed as part of the agency's normal oversight activity of State Medicaid managed care programs. The majority of the information collection is undertaken by States. Accordingly, States are responsible for ensuring that information collected is not manipulated and erroneously published. Much of the information (e.g., the information requirements under § 438.10) is provided directly to beneficiaries by the States, MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities. Some information must be published on a state or managed care plan website, while the rest of the information is used by States as part of their normal contracting with, and monitoring of, their MCOs PIHPs, PAHPs, PCCMs, and PCCM entities and is not be published.

17. Expiration Date:

The expiration date and PRA Disclosure Statement are displayed.

18. Certification Statement:

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods.