Supporting Statement – Part A
Medicaid Managed Care and Supporting Regulations
CMS-10108, OMB 0938-0920

The regulatory sections that support this collection of information's requirements are set out in 42 CFR part 438 (Managed Care) as follows:

Subpart A-General Provisions

Sections 438.1, 438.2, 438.3, 438.4, 438.5, 438.6, 438.7, 438.8, 438.9, 438.10, 438.12, and 438.14

Subpart B-State Responsibilities

Sections 438.50, 438.52, 438.54, 438.56, 438.58, 438.60, 438.62, 438.66, 438.68, 438.70, 438.71, and 438.74.

Subpart C-Enrollee Rights and Protections

Sections 438.100, 438.102, 438.104, 438.106, 438.108, 438.110, 438.114, and 438.116.

Subpart D-MCO, PIHP and PAHP Standards

Sections 438.206, 438.207, 438.208, 438.210, 438.214, 438.224, 438.228, 438.230, 438.236, and 438.242.

Subpart F-Grievance and Appeal System

Sections 438.400, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.420, and 438.424.

Subpart H-Additional Program Integrity Safeguards

Sections 438.600, 438.602, 438.604, 438.606, 438.608, and 438.610.

Subpart I-Sanctions

Sections 438.700, 438.702, 438.704, 438.706, 438.708, 438.710, 438.722, 438.724, 438.726, and 438.730.

Subpart J-Conditions for Federal Financial Participation (FFP)

Sections 438.802, 438.806, 438.808, 438.810, 438.812, 438.816, and 438.818.

BACKGROUND

Our November 13, 2020, Medicaid managed care final rule (85 FR 72754) (CMS-2408-F, RIN 0938-AT40) advances CMS' efforts to streamline the Medicaid and CHIP managed care regulatory framework and reflects a broader strategy to relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care. The finalized revisions of the Medicaid and CHIP managed care regulations are intended to ensure that the regulatory framework is efficient and feasible for states to implement

in a cost-effective manner and ensure that states can implement and operate Medicaid and CHIP managed care programs without undue administrative burdens.

This collection of information request is associated with our November 13, 2020 final rule (CMS-2408-F, RIN 0938-AT40). In addition to rule-related changes, this iteration also makes burden estimates to accommodate the use of reporting templates for existing reporting requirements at 42 CFR 438.207(d) for network adequacy and access and 438.74 for medical loss ratio. State questions about these reports have demonstrated that a template would help states by articulating the specific data elements needed and by providing an easy to use format that facilitates CMS' tracking and analysis. The templates will be issued in Excel format initially and converted to an online submission method in the future. The data gathered from these reports will enable CMS to ensure state compliance with regulatory requirements. Please see Section 15 (below) for details.

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:

Medicaid enrollees use the information collected and reported to make informed choices regarding health care, including when selecting a managed care plan, how to access health care services, and the grievance and appeal system.

States use the information collected and reported as part of its contracting process with managed care entities, as well as to fulfill its compliance oversight role.

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

3. Improved Information Technology:

Section 438.10 modifies the requirements for updating the paper provider directory that would permit quarterly updates to paper directories if the managed care plan offers a mobile-enabled, electronic directory.

Sections 438.66, 438.74, 438.207, and 438.818 contain requirements concerning specific reporting to CMS and will all be done electronically. CMS is publishing templates for states to use to comply with the reporting requirements in 438.207(d) and 438.74 to ensure the receipt of consistent information that can be more easily aggregated and analyzed. Most of the other sections do not involve submitting information to any entity; those that do, concern the submission of information between states and plans. Because this concerns disclosure to a third party, we do not dictate how the information may be disclosed.

Section 438.242 requires that states ensure that each MCO, PIHP, and PAHP implement an openly published Application Programming Interface (API) that permits third-party applications to retrieve standardized data concerning adjudicated claims, encounters with sub-capitated

providers, provider remittances and enrollee cost-sharing, provider directories, and preferred drug lists. The API will make the data available to enrollees through common technologies and without special effort from enrollees. We anticipate that the standardized framework (both the API specification and data standards) would align across Medicaid and the private insurance market. These requirements will allow patients to have control of their healthcare data empowering patients to make informed decisions about their healthcare. (See CMS-9115-F for more information).

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 2016 final rule, we estimated that some PAHPs, PCCMs, and PCCM entities were 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.

As of 2017, there are approximately 680 managed care plans with the majority being MCOs. We believe that only a few of these entities qualify as small entities. Research on publicly available records for the entities allowed us to determine that approximately 30 of these may be small entities. We believe that MCOs, PIHPs, and PAHPs that have average annual receipts from Medicaid and CHIP contracts and other business interests in excess of $38.5 million. In analyzing the scope of the impact on small entities, we examined the United States Census Bureau's Statistics of U.S. Businesses for 2017. According to the 2015 data, there are 788 direct health and medical insurance issuers with less than 20 employees and 156,386 offices of physicians or health practitioners with less than 20 employees.[1] Based on the estimates in the Collection of Information (COI), we have determined that the provisions of this finalized rule will not have a significant burden or economic impact on a substantial number of the small entities we have identified.

We previously noted that the primary impact on small entities was through the standards placed on PAHPs, PCCMs, and PCCM entities through the following requirements established in the 2016 final rule: (1) adding PCCMs and PCCM entities, where appropriate, to the information standards in §438.10 regarding enrollee handbooks, provider directories, and formularies; (2) adding PAHPs, PCCMs, and PCCM entities in §438.62 to implement their own transition of care

[1] Number of Firms, Number of Establishments, Employment, Annual Payroll, and Preliminary Reciepts by Enterprise Employment Size for the United States, All Industries: 2017, accessed at https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html

policies and PAHPs in §438.208 to perform initial assessments and care coordination activities; (3) adding PAHPs in §438.242 to collect data on enrollee and provider characteristics and on services furnished to enrollees through an encounter data system or other such methods; and (4) adding PAHPs to the types of entities subject to the standards of subpart F to establish a grievances and appeals system and process.

The burden estimates associated with most of 438.10 and all of 438.62, 438.242, and Subpart F were one time estimates that have surpassed their 3-year timeframe. The remaining annual burden estimates in this rule are consistent with the nature of their business in contracting with state governments for the provision of services to Medicaid and CHIP managed care enrollees. Therefore, based on the estimates in the COI in the 2016 final rule, we have determined there will not be a significant economic impact on a substantial number of small entities.

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. In this instance we do not require respondents 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 statue 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 March 4, 2022 (87 FR 12458). No comments were received. The 30-day notice published in the Federal Register on May 11, 2022 (87 FR 28830).

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:

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage 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 and overhead, and the adjusted hourly wage.

Occupation Titles and Wage Rates

Occupation Title	Occupation Code	Mean Hourly Wage($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage($/hr)
Accountant	13-2011	39.26	39.26	78.52
Actuary	15-2011	59.22	59.22	118.44
Business Operations	13-1000	37.66	37.66	75.32

Occupation Title	Occupation Code	Mean Hourly Wage($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage($/hr)
Specialist				
Computer Programmer	15-1250	52.86	52.86	105.72
Customer Service Rep	43-4051	18.51	18.51	37.02
General and Operations Mgr	11-1021	60.45	60.45	120.90
Healthcare Social worker	21-1022	29.07	29.07	58.14
Mail Clerk	43-9051	16.20	16.20	32.40
Office and Administrative Support Worker	43-9000	18.41	18.41	36.82
Registered Nurse	29-1141	38.47	38.47	76.94

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, 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*:

Section 438.3 Standard contract requirements

Section 438.3(j) advance directives was previously designated as 438.6(i)(3). This paragraph requires that MCOs, PIHPs, and certain PAHPs provide adult enrollees with written information on advance directives policies and include a description of applicable State law. Any burden associated with this requirement is the time it takes to furnish the information to enrollees; however, it is included in the overall burden arising from the Information Requirements in §438.10.

Section 438.3(t) required states to require their managed care plans to enter into a Medicare Coordination of Benefits Agreement. Finalized amendments to §438.3(t) permit states to

choose between requiring their MCOs, PIHPs, and PAHPs to sign a COBA with Medicare, or requiring an alternative method for ensuring that each MCO, PIHP, or PAHP receives all appropriate crossover claims. If the state elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the state's remittance advice that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration. We estimate it would take 1 hour for a programmer to implement the message on the remittance advice. If 5 states elect to use an alternative method, we estimate an aggregate one-time state burden of 5 hr (5 states X 1 hour) and $529 (5 hr X $105.72/hr for a computer programmer). As this would be a one-time expense, we annualize this amount to **1.667 hr** (5 hr/3 yr) and **$176** ($529/3 yr). We are annualizing the one-time burden estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.1d)**

For the 5 states that elect to require that their plans obtain a COBA, in aggregate we estimate a one-time burden of 100 hr (25 plans x 4 hr for a business operations specialist) at a cost of $7,532 (100 hr x $75.32/hr specialist). As this will be a one-time burden, we annualize this amount to **33.33 hr** (100 hr/3 years) and **$2,510** ($7,262/3 years). We are annualizing the one-time burden estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(ESTIMATE 12.1f)**

Section 438.5 Rate development standards

Section 438.5 describes the development and documentation of capitation rates paid to risk-based MCOs, PIHPs and PAHPs. Generally, we require: the use of appropriate base data; the application of trends that have a basis in actual experience; a comprehensive description of the development of the non-benefit component of the rate; descriptions of the adjustments applied to the base data, rate, or trends; actuarial certification of the final contract rates paid to the plans; and a description of budget neutral risk adjustment methodologies.

We believe that the requirements related to the use appropriate base data and the adequate description of rate setting standards, such as trend, the non-benefit component, adjustments, and risk adjustment, are already required as part of actuarial standards of practice and accounted for in §438.7. We clarified that risk adjustment should be done in a budget neutral manner, but the manner in which risk adjustment is applied should not create additional burden on the state.

In §438.5(g), the certification of final contract rates places additional burden on the states. Therefore, out of the total 70 certifications submitted to CMS from 39 states, the process underlying 50 certifications will need to the modified.

We estimate it will take approximately 11 hr at $118.44/hr for an actuary and 1 hr at $120.90/hr for a general and operations manager to comply with this requirement. In aggregate, we estimate an annual state burden of **600 hr** (50 certifications x 12 hr) and **$71,200** (50 certifications x [(11 hr x $118.44/hr) + (1 hr x $120.90/hr)]). **(ESTIMATE 12.2)**

Section 438.7 Rate certification submission

Section 438.7 describes the submission and documentation requirements for all managed care actuarial rate certifications. The certification will be reviewed and approved by CMS concurrently with the corresponding contract(s). Section 438.7(b) details CMS' expectations 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 it takes 230 hr to develop each certification, consisting of 100 hr (at $118.44/hr) for an actuary, 10 hr (at $120.90/hr) for a general and operations manager, 50 hr (at $105.72/hr) for a computer programmer, 50 hr (at $75.32/hr) for a business operations specialist, and 20 hr (at $36.82/hr) for an office and administrative support worker.

In aggregate we estimate an annual state burden of **16,100 hr** (230 hr x 70 certifications) at a cost of **$1,611,820** [70 certifications x ((100 hr x $118.44/hr) + (10 hr x $120.90/hr) + (50 hr x $105.72/hr) + (50 hr x $75.32/hr) + (25 hr x $36.82/hr))]. **(ESTIMATE 12.3a)**

Section § 438.7(c)(3) permits CMS to require states to submit documentation attesting that any +/- 1.5% modifications to a capitation rate comply with specified regulatory requirements. We estimate that CMS will require documentation from no more than 3 states annually and that it will take a state's actuary 1 hour to prepare the documentation. For the 3 states that may be required to submit documentation. In aggregate we estimate an annual burden of **3 hr** (3 plans x 1 hr for an actuary) at a cost of **$355** (3 hr x $118.44/hr specialist). **(ESTIMATE 12.3b)**

Section 438.8 Medical loss ratio standards

Section 438.8(c) requires 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 estimated the total number of MLR reports that MCOs, PIHPs, and PAHPs were required to submit to states amount to 488 contracts. All MCOs, PIHPs, and PAHPs will need to report the information required under §438.8 regardless of their credibility status.

We estimate calculating the MLR and developing the report will take each plan approximately 53 hr, including the time to submit the report. We estimate an annual private sector burden of **25,864 hr** (488 contracts x 53 hr) and a total of **$2,534,184** [488 contracts x ((32 hr x $105.72/hr for a computer programmer) + (16 hr x $75.32/hr for a business operations specialist) + (5 hr x $120.90/hr for a general and operations manager)]. We expect that states will permit MCOs, PIHPs, and PAHPs to submit the report electronically. **(ESTIMATE 12.5)**

Section 438.8(m) requires the MCO or PIHP to recalculate its MLR for any year in which a retroactive capitation change is made. As such retroactive adjustments are not a common practice, we estimate that no more than 3 plans per year may have to recalculate their MLR do this.

Section 438.10 Information Requirements

Section 438.10(c)(3) requires states to operate a website that provides the information required in §438.10(f). Since states already have websites for their Medicaid programs and most also

include information about their managed care program, most states will only have to make minor revisions to their existing website.

We also estimate 3 hr for a computer programmer to periodically add or update documents and links on the site. We estimate an annual state burden of **123 hr** (41 states x 3 hr) and **$13,004** (123 hr x $105.72/hr). **(ESTIMATE 12.6b)**

Section 438.10(c)(4)(ii) requires that states provide model enrollee handbooks and notices. We estimate 2 hr per year for a business operations specialist to update these documents, if needed. We estimate an annual burden of **40 hr** (20 states x 2 hr) and **$3,013** (40 hr x $75.32/hr). **(ESTIMATE 12.8b)**

Section 438.10(e)(1) requires states to provide required information in paper or electronic format to prospective enrollees. We estimate 1 min (0.0167 hr) per mailing to acknowledge automated mailing processes. In aggregate we estimate an annual state burden of **36,432 hr** for 2,181,540 enrollees (66,107,287 total enrollees x 0.033 growth rate) at a cost of $**1,180,397** (36,432 hr x $32.40/hr). **(ESTIMATE 12.10b)**

Section 438.10(g)(1) requires that MCOs, PIHPs, PAHPs, and PCCMs (when required) provide an enrollee handbook. With regard to new enrollees, they must receive a handbook within a reasonable time after receiving notice of the beneficiary's enrollment. We assume a 3.3 percent enrollee growth rate thus 2,181,540 enrollees (0.033 x 66,107,287 enrollees) will need to receive a handbook each year. We estimate 1 min (0.0167 hr) by a mail clerk at $32.40/hr to mail the handbook. We estimate an annual private sector burden of **36,432 hr** (2,181,540 enrollees x 0.0167 hr) at a cost of $**1,180,397** (36,432 hr X $32.40/hr). **(ESTIMATE 12.12)**

Since all the 496 managed care plans will need to keep their handbook up to date, we estimate it will take 1 hr at $72.62/hr for a business operations specialist to update the document. While the updates are necessary when program changes occur, we estimate 1 hr since each change may only take a few minutes to make. In aggregate, we estimate an annual private sector burden of **496 hr** (496 entities x 1 hr) and **$37,359** (496 hr x $75.32/hr). **(ESTIMATE 12.13)**

<u>Section 438.12 Provider discrimination prohibited</u>

This section requires that if an MCO, PIHP, or PAHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision. The burden associated with this requirement is the time it takes the MCO, PIHP, or PAHP to furnish the providers with the requisite notice. We estimate that it takes 1 min (0.0167 hr) to draft and furnish such notice. We estimate that on average each 488 MCOs, PIHPs, and PAHPs will need to produce 10 notices per year. In aggregate, we estimate an annual private sector burden of **81 hr** (488 entities x 10 notices x 0.0167 hr) at a cost of **$2,624** (81 hr x $32.40/hr). **(ESTIMATE 12.15)**

<u>Section 438.14 Requirements that apply to MCO, PIHP, PAHP, PCCM, and PCCM entity contracts involving Indians, Indian health care providers (IHCPs), and Indian managed care entities (IMCEs)</u>

Section 438.14(c) requires states to make supplemental payments to Indian providers if the MCO, PIHP, PAHP, and PCCM entity does not pay at least the amount paid to Indian providers under the FFS program. There are approximately 31 states with 463 managed care entities with Indian providers. This type of payment arrangement typically involves the managed care entity sending a report to the state that then calculates and pays the amount owed to the Indian health care provider. Note: this process is not necessary when the MCO, PIHP, PAHP, or PCCM entity pays the ICHP at least the full amount owed under this regulation. We estimate an annual state burden of **300 hr** (25 states x 12 hr) and **$22,596** (300 hr x $75.32/hr). **(ESTIMATE 12.16b)**

Section 438.50 State Plan requirements

Each State must have a process for the design and initial implementation of the State plan that involves the public and must have methods in place to ensure ongoing public involvement once the State plan has been implemented. The burden associated with this section includes the time associated with developing the process for public involvement.

Section 438.54 Managed care enrollment

Section 438.54(c)(3) and (d)(3) requires states to notify the potential enrollee of the implications of not making an active choice during the allotted choice period. This information should be included in the notice of eligibility determination (or annual redetermination) required under §445.912, thus no additional burden is estimated here.

Section 438.54(c)(8) requires states to send a notice to enrollees in voluntary programs that utilize a passive enrollment process confirming their managed care enrollment when the enrollee's initial opportunity to select a delivery system has ended. We assume 15 states will continue using a passive enrollment process, with a total of 21,000,000 enrollees. Assuming that 5 percent of these will be new each year, and of those, approximately 75 percent will not take action within the allotted time and will remain enrolled in the managed care plan passively assigned by the state (787,500) we estimate 1 min (0.0167 hr) per notification by a mail clerk at $32.40/hr. In aggregate, we estimate an annual state burden of **13,151 hours** (787,500 enrollees x 0.0167 hr) and **$426,092** (13,151 hr x $32.40/hr). **(ESTIMATE 12.18)**

Section 438.56 Disenrollment: requirements and limitations

Under paragraph (f), a State that restricts disenrollment under this section must provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period. This information should be included in the notice of annual redetermination required under § 445.912, thus no additional burden is estimated here.

Section 438.62 Continued Services to Enrollees

For implementation of transitions of care, we estimate 10 min per request (0.1667 hr) at $74.48/hr for a registered nurse to access the stored utilization and/or claims data and take appropriate action. We also estimate that approximately 0.5 percent of enrollees (330,536 = 66,107,287 enrollees x 0.005) may meet the state defined criteria for serious detriment to health

and/or risk of hospitalization or institutionalization. In aggregate, we estimate an annual private sector burden of **55,100 hr** (330,536 enrollees x 0.1667 hr) and **$4,239,394** (55,100 hr x $76.94/hr). **(ESTIMATE 12.21)**

Section 438.66 State monitoring requirements

Section 438.66(d)(1) through (3) requires that states include a desk review of documents and an on-site review for all readiness reviews when certain events occur. For preparation and execution of the readiness review, we estimate 5 hr (at $120.90/hr) for a general and operations manager, 30 hr (at $75.32/hr) for a business operations specialist, and 5 hr (at $105.72/hr) for a computer programmer. The time and staff types are estimated for a new program or new entity review and may vary downward when the review is triggered by one of the other events listed in paragraph (d)(1). Given the varying likelihood of the 3 events listed in paragraph (d)(1), we will use an average estimate of 20 states per year having one of the triggering events. In aggregate, we estimate an annual state burden of **800 hr** (20 states x 40 hr) and **$67,880** [20 states x ((5 x $120.90/hr) +(30 x $75.32/hr) + (5 x $105.72/hr))]. **(ESTIMATE 12.24)**

For MCO, PIHP, PAHP, or PCCM preparation for and execution of a review by the state, we estimate 5 hr (at $120.90/hr) for a general and operations manager, 30 hr (at $775.32/hr) for a business operations specialist, and 5 hr (at $105.72/hr) for a computer programmer. In aggregate, we estimate an annual private sector burden of **800 hr** (20 entities x 40 hr) and **$67,880** [20 entities x ((5 x $120.90/hr) + (30 x $75.32/hr) + (5 x $105.72/hr))]. **(ESTIMATE 12.25)**

Section 438.66(e)(1) and (2) requires 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) will be used to compile this report. We estimate an annual state burden of 6 hr at $72.62/hr for a business operations specialist to compile and submit this report to CMS. In aggregate, we estimate an annual state burden of **246 hr** (41 states x 6 hr) and **$18,529** (246 hr x $75.32/hr). **(ESTIMATE 12.26)**

Section 438.68 Network adequacy standards

Section 438.68(a) requires that states set network adequacy standards that each MCO, PIHP and PAHP must follow. Section 438.68(b) and (c) would require that states set quantitative standards for specific provider types and must develop network standards for LTSS if the MCO, PIHP or PAHP has those benefits covered through their contract.

States' review and reporting on exceptions granted through the process developed in §438.68(d) is estimated under §438.68 so we do not estimate any additional burden for this requirement.

Section 438.70 Stakeholder engagement when LTSS is delivered through a managed care program

Section 438.70(c) requires that states continue to solicit and address public input for oversight purposes. Existing MLTSS programs already meet this requirement and we estimate no more than 14 new programs will be established by states.

We estimate an annual state burden of 4 hr at $75.32/hr for a business operations specialist to perform this task. In aggregate, we estimate an annual state burden of **56 hr** (14 states x 4 hr) and **$4,218** (56 hr x $75.32/hr). **(ESTIMATE 12.30)**

Section 438.71 Beneficiary support system

Section 438.71(b) requires that the system include choice counseling for enrollees, outreach for enrollees, and education and problem resolution for services, coverage, and access to LTSS. This system must be accessible in multiple ways including at a minimum, by telephone and email. Some in-person assistance may need to be provided in certain circumstances. Most states will likely use the call center created in §438.71(a) to handle the majority of these responsibilities and use existing community-based outreach/education and ombudsman staff, whether state employees or contractors, for the occasional in person request. The use of existing staff will add no additional burden as it is part of standard operating costs for operating a Medicaid program.

Section 438.74 Oversight of minimum medical loss ratio (MLR)

Section 438.74(a) requires states to submit an annual report to CMS that summarizes the MLR reports received from their managed care plans (see estimate 12.5 for managed care plan burden estimate). Section 438.74(b) requires states that collect a remittance from their plans to submit a separate report (with the report required in 438.74(a)) to CMS describing the methodology used to determine the state and federal share of the remittance. This burden estimate was omitted from the prior package as CMS did not originally intend to specify a reporting format. After receiving additional state feedback, CMS is providing a template for this report to enable states to more easily submit the needed level of detailed data to CMS for tracking, comparison, and analysis to ensure regulatory compliance. For states to complete the reporting template annually, we estimate an annual state burden of 5 hr at $75.32/hr for a business operations specialist. In aggregate, we estimate **205 hr** (41 states x 5 hr) and **$15,44**1 (205 hr x $75.32/hr). (**ESTIMATE 12.65**)

Section 438.102 Provider-enrollee communications

Section 438.102(a)(2) states that MCOs, PIHPs, and PAHPs are not required to cover, furnish, or pay for a particular counseling or referral service if the MCO, PIHP, or PAHP objects to the provision of that service on moral or religious grounds; and that written information on these policies is available to (1) prospective enrollees, before and during enrollment and, (2) current enrollees, within 90 days after adopting the policy with respect to an any particular service. The burden associated with the provisions of this information is included in the burden for 438.10(e) and 438.10(g).

Section 438.102(a)(2) specifies that MCOs, PIHPs, and PAHPs are not required to cover, furnish, or pay for a particular counseling or referral service if the MCO, PIHP, or PAHP objects to the provision of that service on moral or religious grounds; and that written information on these policies is made available to: prospective enrollees, before and during enrollment; and current enrollees, within 90 days after adopting the policy with respect to an any particular

service. We believe the burden associated with this requirement affects no more than 3 MCOs or PIHPs annually since it applies only to the services they discontinue providing on moral or religious grounds provided to a very small subset of their enrollees during the contract period. PAHPs are excluded from this estimate because they generally do not provide services that would be affected by this provision. In aggregate, we estimate an annual private sector burden of **1,253 hr** (3 entities x 25,000 x 0.0167 hr) and **$40,597** (1,253 hr x $32.40/hr). **(ESTIMATE 12.32)**

Section 438.110 Member advisory committee

Section 438.110(a) requires that each MCO, PIHP, and PAHP establish and maintain a member advisory board if the LTSS population is covered under the contract. We estimate an annual private sector burden of 6 hr at $75.32/hr for a business operations specialist to maintain the operation of the committee (hold meetings, distribute materials to members, and maintain minutes) for up to 14 new programs. Existing programs already meet this requirement. In aggregate, we estimate **84 hr** (14 states x 6 hr) and **$6,327** (84hr x $75.32/hr). **(ESTIMATE 12.33)**

Section 438.207 Assurance of adequate capacity and services

Section 438.207(b) through (c) require MCOs, PIHPs, and PAHPs to submit documentation to the state of their compliance with §438.207(a). We estimate an annual private sector burden of 2 hr to compile and submit the information necessary to meet the requirements in §438.207(b) through (c). For compilation and submission, we estimate **934 hr** (467 entities x 2 hr) and **$70,349** (934 hr x $75.32/hr). **(ESTIMATE 12.34b)**

Section 438.207(d) requires states to submit an assurance of compliance to CMS that their MCOs, PIHPs, and PAHPs meet the State's requirements for availability of services. The submission to CMS must include documentation of an analysis by the state that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP and the accessibility of covered services. This burden estimate was omitted from the prior PRA package as CMS did not intend to provide a reporting template. However, after receiving additional state feedback, CMS is providing a reporting template for states to use to fulfill this requirement to enable states to easily and consistently submit the necessary level of detailed data to CMS for tracking, analysis, and program monitoring. We estimate an annual state burden of 3 hours for a business operations specialist at $75.32/hr. Although states may need to submit a revision to this report at other times during a year (specified at 438.207(c)), we believe these submissions will be infrequent and require minimal updating to the template; therefore, the burden estimated here in inclusive of occasional revisions. In aggregate, we estimate an annual state burden of **123 hrs** (41 state x 3 hrs) and **$9,264** (123 hrs x $75.32/hr) **(ESTIMATE 12.34c)**

Section 438.208 Coordination and continuity of care.

Section 438.208(b)(2)(iii) requires that MCOs, PIHPs and PAHPs coordinate service delivery with the services the enrollee receives in the FFS program (carved out services). This involves using data from the state to perform the needed coordination activities. The exchange of data

and the reports needed to perform the coordination activity is addressed in the requirements in §438.62(b)(2). Since only a small percentage of enrollees receive carved out services and need assistance with coordination, we estimate 3,030,655 of all MCO, PIHP, and PAHP enrollees (five percent of 60,613,099 MCO, PIHP, and PAHP enrollees) will be affected. We estimate an annual private sector burden of 10 min per enrollee (0.1667 hr) at $58.14/hr for a healthcare social worker to perform the care coordination activities. In aggregate, we estimate **505,210 hr** (3,030,655 enrollees x 0.1667 hr) and **$29,372,909** (505,210 hr x $58.14/hr). **(ESTIMATE 12.35)**

We estimate that in a given year, only 3.3 percent (2,000,232) of all MCO,PIHP, and PAHPs enrollees are new to a managed care plan. We estimate an annual private sector burden of 10 min on average (0.1667 hr) at $35.88/hr for a customer service representative to complete the screening. In aggregate, we estimate **333,439 hr** (2,000,232 enrollees x 0.1667 hr) and $**12,343,912** (333,439 hr x $37.02/hr). **(ESTIMATE 12.37)**

Section 438.208(b)(4) requires that MCOs, PIHPs, and PAHPs share with other MCOs, PIHPs, and PAHPs serving the enrollee the results of its identification and assessment of any enrollee with special health care needs so that those activities are not duplicated. The burden associated with this requirement is the time it takes each MCO, PIHP or PAHP to disclose information on new enrollees to the MCO, PIHP or PAHP providing a carved-out service. This would most likely be accomplished by developing a report to collect the data and electronically posting the completed report for the other MCO, PIHP, or PAHP to retrieve.

Section 438.208(c)(2) and (3) currently require that MCOs, PIHPs and PAHPs complete an assessment and treatment plan for all enrollees that have special health care needs; the 2016 final rule added “enrollees who require LTSS” to this section. These assessments and treatment plans should be performed by providers or MCO, PIHP or PAHP staff that meet the qualifications required by the state. We believe the burden associated with this requirement is the time it takes to gather the information during the assessment. (Treatment plans are generally developed while the assessment occurs, so we are not estimating any additional time beyond the time of the assessment).

While this is an existing requirement, we estimate 1 percent of the total enrollment of 60,613,099 in MCOs and PIHPs (60,613,099 x 0.01 = 606,131) will require an assessment and treatment plan. We estimate an annual private sector burden of 1 hr (on average) at $74.48/hr for a registered nurse to complete the assessment and treatment planning. In aggregate, we estimate an additional **606,131 hr** (606,131 enrollees x 1 hr) and **$46,635,719** (606,131 hr x $76.94/hr). **(ESTIMATE 12.39)**

Section 438.214 Provider selection

Under this section, each State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of providers. The burden

associated with this requirement is the usual and customary recordkeeping collection associated with maintaining documentation**.**

Section 438.236 Practice guidelines

Under paragraph (c) of this section, each MCO, PIHP, and PAHP must disseminate guidelines to its affected providers and, upon request, to enrollees and potential enrollees.

The burden associated with this requirement is the time required to disseminate the guidelines. As this is done electronically, we estimate no additional burden here.

Section 438.404 Timely and adequate notice of adverse benefit determination

Section 438.404(a) adds PAHPs as an entity that must give the enrollee timely written notice. It also sets forth the requirements of that notice. Consistent with the requirements for MCOs and PIHPs, PAHPs must give the enrollee timely written notice if it intends to: deny, limit, reduce, or terminate a service; deny payment; deny the request of an enrollee in a rural area with one plan to go out of network to obtain a service; or fails to furnish, arrange, provide, or pay for a service in a timely manner.

Section 438.406 Handling of grievances and appeals

In summary, §438.406 states that each MCO and PIHP must acknowledge receipt of each grievance and appeal. The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.406(b)(5) modifies the language for evidence standards for appeals to mirror the private market evidence standards. This aligns the text with commercial requirements but does not alter the meaning; therefore, this imposes no additional burden.

Section 438.408 Resolution and notification: grievances and appeals

Section §438.408 states that for grievances filed in writing or related to quality of care, the MCO or PIHP must notify the enrollee in writing of its decision within specified timeframes. Except as noted below, these provisions are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

Section 438.408(b)(2) would change the timeframe an entity has to reach a determination from 45 days to 30 days to align with Medicare. Most insurers offer more than one line of business, and therefore we believe this timeframe will allow MCOs, PIHPs, and PAHPs to be consistent with their usual and customary business practices.

Section 438.408(b)(3) would change the timeframe an entity has to reach a determination in an expedited appeal from 3 days to 72 hr to align with Medicare and the private market. Most insurers offer more than one line of business, and therefore we believe this timeframe will make Medicaid consistent with usual and customary business practices.

Section 438.408(f)(1) and (2) would require that an enrollee exhaust the appeals process before proceeding to the state fair hearing process, and change the timeframe in which a beneficiary

must request a state fair hearing to 120 days. This aligns with the private market and since many insurers offer more than one line of business, we believe aligning these timeframes will make Medicaid consistent with their usual and customary business practices.

Section 438.410 Expedited resolution of appeals

Section 438.410(c) of this section requires each MCO, PIHP, and PAHP to provide written notice to an enrollee whose request for expedited resolution is denied.

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.414 Information about the grievance and appeal system to providers and subcontractors

Section 438.414 requires the MCO or PIHP to provide the information specified at §438.10(g)(2)(xi) about the grievance system to all providers and subcontractors at the time they enter into a contract. The burden for this is included in §438.10.

Section 438.416 Recordkeeping requirements

As the required elements will be stored and tracked electronically, we estimate that approximately two percent of 66,107,287 MCO, PIHP, and PAHP enrollees (66,107,287 x 0.02 = 1,322,146 grievances) file a grievance or appeal. We estimate 1 min per grievance and appeal at $35.50/hr for an office and administrative support worker to maintain each grievance and appeals record. In aggregate, we estimate an annual private sector burden of **22,080 hr** (1,322,146 grievances x 1 min) and **$812,986** (22,080 hr x $36.82/hr). **(ESTIMATE 12.50)**

Section 438.420 Continuation of benefits while the MCO, PIHP, or PAHP appeal and the State fair hearing are pending

Section 438.420(c)(4) removes the time period or service limit of a previously authorized service has been met as a criteria for defining the duration of continued benefits and adds “PAHP” as a conforming change to §438.400. This action requires that MCOs and PIHPs revise current policies and procedures to reflect having only 3 criteria instead of 4. PAHPs would incorporate the options in §438.420(c)(1) through (3) when developing their system under §438.402 and thus the elimination of §438.420 (c)(4) would have no impact on PAHPs.

Section 438.420(d) adds PAHPs to the list of entities that can recover costs if the adverse determination is upheld. PAHPs are required to include the policies and procedures necessary to recover costs when developing their system under §438.402 and thus will not incur additional burden.

Section 438.602 State responsibilities.

Section 438.602(e) requires states to conduct or contract for audits of MCO, PIHP, and PAHP encounter and financial data once every 3 years. As validation of encounter data is also required in §438.818(a), we assume no additional burden. For the financial audits, states could use internal staff or an existing contractual resource, such as their actuarial firm. For internal staff,

we estimate an annual state burden of 20 hr at $76.46/hr for an accountant. In aggregate, we estimate an annual state burden of **3,413 hr** [(512 MCOs, PIHPs, PAHPs x 20 hr)/3] and **$267,989** (3,413 hr x $78.52/hr). **(ESTIMATE 12.54)**

Section 438.602(g) requires states to post the MCO's, PIHP's, and PAHP's contracts, data from §438.604, and audits from §438.602(e) on their website. As most of these activities will only occur no more frequently than annually, we estimate an annual state burden of 1 hr at $102.88/hr for a computer programmer to post the documents. In aggregate, we estimate **40 hr** (40 states x 1 hr) and **$4,229** (40 hr x $105.72/hr). **(ESTIMATE 12.55)**

Section 438.604 Data, information, and documentation that must be submitted

This section details the type of information the state must require by contract from the MCO, PIHP, PAHP, PCCM, or PCCM entity. The burden to amend all contracts is included in 438.3.

Section 438.608 Program integrity requirements under the contract

Section 438.608(a) requires that MCOs, PIHPs, and PAHPs to have administrative and management arrangements or procedures which are designed to guard against fraud and abuse. The arrangements or procedures must include a compliance program as set forth under §438.608(a)(1), provisions for reporting under §438.608(a)(2), provisions for notification under §438.608(a)(3), provisions for verification methods under §438.608(a)(4), and provisions for written policies under §438.608(a)(5).

The compliance program under §438.608(a)(1), must include: written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable federal and state standards and requirements under the contract; the designation of a Compliance Officer; the establishment of a Regulatory Compliance Committee on the Board of Directors; effective training and education for the organization's management and its employees; and provisions for internal monitoring and a prompt and effective response to noncompliance with the requirements under the contract.

Section 438.608(a)(2) and (3) requires the reporting of overpayments and enrollee fraud. As these would be done via an email from the MCO, PIHP, or PAHP to the state and do not occur very often, we estimate an annual private sector burden of 2 hr at $72.62/hr for a business operations specialist. In aggregate, we estimate **1,104 hr** (552 entities x 2 hr) and **$83,153** (1,104 hr x $75.32/hr). **(ESTIMATE 12.57)**

Section 438.608(a)(4) requires that the MCO, PIHP, or PAHP use a sampling methodology to verify receipt of services. Given that this is already required of all states in their FFS programs, many states already require their MCOs, PIHPs, and PAHPs to do this. Additionally, many managed care plans perform this as part of usual and customary business practice. Therefore, we estimate only approximately 200 MCOs, PIHPs, or PAHPs may need to implement this as a new procedure. As this typically involves mailing a letter or sending an email to the enrollee, we estimate that 200 MCOs, PIHPs, or PAHPs will mail to 100 enrollees each. We estimate an annual private sector burden of 1 min at $31.36/hr for a mail clerk to send each letter. In aggregate, we estimate **334 hr** (20,000 letters x 0.0167 hr/letter) and **$10,822** (334 hr x

$32.40/hr). This estimate will be significantly reduced as the use of email increases. **(ESTIMATE 12.58)**

Section 438.710 Notice of sanction and pre-termination hearing

Before imposing any of the sanctions specified in subpart I, §438.710(a) would require that the state give the affected MCO, PIHP, PAHP or PCCM written notice that explains the basis and nature of the sanction. Section 438.710(b)(2) states that before terminating an MCO's, PIHP's, PAHP's or PCCM's contract, the state would be required to: (i) give the MCO or PCCM written notice of its intent to terminate, the reason for termination, the time and place of the hearing, (ii) give the entity written notice (after the hearing) of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination, and (iii) give enrollees of the MCO or PCCM notice (for an affirming decision) of the termination and information, consistent with §438.10, on their options for receiving Medicaid services following the effective date of termination. The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.722 Disenrollment during termination hearing process

After a state has notified an MCO, PIHP, PAHP or PCCM of its intention to terminate its contract, §438.722(a) provides that the state may give the entity's enrollees written notice of the state's intent to terminate its contract. States already have the authority to terminate contracts according to state law and some have previously already opted to provide written notice to MCO and PCCM enrollees when exercising this authority.

We estimate that no more than 12 states may terminate 1 contract per year. We also estimate an annual state burden of 1 hr at $72.62/hr for a business operations specialist to prepare the notice. In aggregate, we estimate a state burden of **12 hr** (12 states x 1 hr) and **$904** (12 hr x $75.32/hr). **(ESTIMATE 12.60)**

To send the notice, we estimate 1 min per beneficiary (0.0167 hr) at $31.36/hr for a mail clerk. We estimate an aggregate annual state burden of **20,040 hr** (12 states x 100,000 enrollees x 0.0167 hr) and **$649,296** (20,040 hr x $32.40/hr). **(ESTIMATE 12.61)**

Section 438.724 Notice to CMS

Section 438.724 requires that the State give the CMS written notice whenever it imposes or lifts a sanction. The notice must specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction. We anticipate that no more than 15 states impose or lift a sanction in any year. As this would be done via email, we estimate no burden for this.

Section 438.724 would require that the state provide written notice to their CMS whenever it imposes or lifts a sanction on a PCCM or PCCM entity. Given the limited scope of benefits provided by a PCCM or PCCM entity, we anticipate that no more than 3 states may impose or lift a sanction on a PCCM or PCCM entity in any year. With fewer than 10 respondents, the

information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Section 438.730 Sanction by CMS: special rules for MCOs

Section 438.730(b) would require that if CMS accepts a state agency's recommendation for a sanction, the state agency would be required to give the MCO written notice of the proposed sanction. Section 438.730(c) would require that if the MCO submits a timely response to the notice of sanction, the state agency must give the MCO a concise written decision setting forth the factual and legal basis for the decision. If CMS reverses the state's decision, the state must send a copy to the MCO.

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.810 Expenditures for enrollment broker services

Section 438.810(c) requires that a State contracting with an enrollment broker must submit the contract or memorandum of agreement (MOA) for services performed by the broker to CMS for review and approval. As this is done electronically, there is no burden estimated here.

Section 438.818 Enrollee encounter data

Section 438.818(a)(2) requires that the encounter data be validated prior to its submission. States can perform this validation activity themselves, contract it to a vendor, or contract it to their External Quality Review Organization (EQRO). In this regard, a state already using EQRO to validate its data at an appropriate frequency will incur no additional burden. Since approximately 10 states already use their EQRO to validate their data, only 27 states that use a MCO and/or PIHP may need to take action to meet this requirement. The method selected by the state will determine the amount of burden incurred. We assume an equal distribution of states selecting each method, thus 9 states per method.

For a state electing to procure a vendor, given the wide variance in state procurement processes, our burden is conservatively estimated at 150 hr for writing a proposal request, evaluating proposals, and implementing the selected proposal. We estimate 125 hr at $72.62/hr for a business operations specialist to participate in the writing, evaluating, and implementing, and 25 hr at $118.30/hr for a general and operations manager to participate in the writing, evaluating, and implementing. In aggregate, we estimate an annual state burden of **1,350 hr** (9 states x 150 hr) and **$111,942** (9 states x [(125 hr x $75.32/hr) + (25 hr x $120.90/hr)]). **(ESTIMATE 12.64)**

Section 438.818(d) requires states new to managed care and not previously submitting encounter data to MSIS to submit an Implementation plan. There are currently only 8 states that do not use managed care thus these would be the only states that may have to submit an Implementation plan should they adopt managed care in the future. With fewer than 10 respondents, the information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

12.3 Burden Summary

Summary of Annual Burden Estimates: State Government
(Response Type: R=reporting; RK=recordkeeping; TPD=third-party disclosure)

Estimate #	CFR Section	Respondents	Total Responses	Burden per Response (hr)	Total Annual Time (hr)	Labor Rate ($/hr)	Total Annual Cost ($)	Response Type	Frequency
12.2	438.5, Rate Standards	41	50	12	600	Varies (see narrative)	71,200	R	Annual
12.3a	438.7, Rate Certifications	41	70	230	16,100	Varies (see narrative)	1,611,820	R	Annual
12.3b	438.7, Rate Certifications	3	3	1	3	118.44	355	R	Annual
12.30	438.70, MLTSS Engagement	14	14	4	56	75.32	4,218	R	Annual
12.65	438.74 MLR reporting	41	41	5	205	75.32	15,441	R	Annual
12.34c	438.207(d) Access reporting	41	41	3	123	75.32	9,264	R	Annual

12.54	438.602(e), Program Integrity	40	171	20	3,413	78.52	267,989	R	Annual
12.55	438.602(g) Program Integrity	40	40	1	40	105.72	4,229	R	Annual
12.64	438.818(a)(2), Encounter Data	9	9	150	1,350	Varies (see narrative)	111,942	R	Annual
Subtotal: Reporting		*41*	*439*	*Varies*	*21,890*	*Varies*	*2,096,458*	*R*	*Annual*
12.1d	438.3(t) Std Contract Requirements	5	1.667	1	1.667	105.72	176	TPD	Once
12.6b	438.10(c), Information Requirements	41	41	3	123	105.72	13,004	TPD	Annual
12.8b	438.10(c)(4)(ii), Information Requirements	20	20	2	40	75.32	3,013	TPD	Annual

12.10b	438.10(e)(1), Information Requirements	41	2,181,540	0.0167	36,432	32.40	1,180,397	TPD	Annual
12.16b	438.14(c), Contracts	25	25	12	300	75.32	22,596	TPD	Annual
12.18	438.54(c)(8), Enrollment	41	787,500	0.0167	13,151	32.40	426,092	TPD	Annual
12.60	438.722, Disenrollment Notices	12	12	1	12	75.32	904	TPD	Annual
12.61	438.722, Disenrollment Notices	12	1,200,000	0.0167	20,040	32.40	649,296	TPD	Annual
Subtotal: Third-Party Disclosure		*41*	*4,169,140*	*Varies*	*70,100*	*Varies*	*2,295,478*	*TPD*	*Varies*
12.24	438.66(d)(3), State Monitoring	20	20	40	800	Varies (see narrative)	67,880	RK	Annual
12.26	438.66(e)(1) and (2), State Monitoring	41	41	6	246	75.32	18,529	RK	Annual
Subtotal: Recordkeeping		*41*	*61*	*Varies*	*1,046*	*Varies*	*86,409*	*RK*	*Annual*

Total State Burden (by Type)	Respondents	Total Responses	Burden per Response (hr)	Total Annual Time (hr)	Labor Rate ($/hr)	Total Annual Cost ($)
Reporting	41	439	Varies	21,890	Varies	2,096,458
Third Party Disclosure	41	4,169,140	Varies	70,100	Varies	2,295,478
Recordkeeping	41	61	Varies	1,046	Varies	86,409
TOTAL	41	4,169,640	Varies	93,036	Varies	4,478,345

Summary of Annual Burden Estimates: Private Sector
(Response Type: R=reporting; RK=recordkeeping; TPD=third-party disclosure)

Estimate #	CFR Section	Respondents	Total Responses	Burden per Response (hr)	Total Annual Time (hr)	Labor Rate ($/hr)	Total Annual Cost ($)	Response Type	Frequency
12.1f	438.3(t) Std Contract Requirements	25	8.333	4	33.33	75.32	2,510	R	Once
12.5	438.8(c), MLR	488	488	53	25,864	Varies (see narrative)	2,534,184	R	Annual
12.21	438.62(b)(2), Transition of Care	568	330,536	0.1667	55,100	76.94	4,239,394	R	Annual
12.33	438.110(a), Member Advisory Committee	14	14	6	84	75.32	6,327	R	Annual
12.34b	438.207(b) - (d), Adequate Capacity	467	467	2	934	75.32	70,349	R	Annual
Subtotal: Reporting		*568*	*331,513*	*Varies*	*82,015*	*Varies*	*6,852,764*	*R*	*Varies*
12.12	438.10(g), Information Requirements	100	2,181,540	0.0167	36,432	32.40	1,180,397	TPD	Annual

12.13	438.10(g), Information Requirements	496	496	1	496	75.32	37,359	TPD	Annual
12.15	438.12, Provider Discrimination Prohibited	488	4,880	0.0167	81	32.40	2,624	TPD	Annual
12.32	438.102, Provider Enrollee Communications	3	75,000	0.0167	1,253	32.40	40,597	TPD	Annual
12.35	438.208(b)(2)(iii) Care Coordination	488	3,030,655	0.1667	505,210	58.14	29,372,909	TPD	Annual
12.37	438.208(b)(3) Care Coordination	488	2,000,232	0.1667	333,439	37.02	12,343,912	TPD	Annual
12.57	438.608(a)(2) - (3) Program Integrity	552	552	2	1,104	75.32	83,153	TPD	Annual
12.58	438.608(a)(4) Program Integrity	200	20,000	0.0167	334	32.40	10,822	TPD	Annual
Subtotal: Third-Party Disclosure		*568*	*7,313,355*	*Varies*	*878,349*	*Varies*	*43,071,773*	*TPD*	*Annual*
12.25	438.66(d)(3), State Monitoring	20	20	40	800	Varies (see narrative)	67,880	RK	Annual
12.39	438.208(c)(2) - (3) Care Coordination	568	606,131	1	606,131	76.94	46,635,719	RK	Annual

12.50	438.416 Reporting	44	1,322,146	0.0167	22,080	36.82	812,986	RK	Annual
Subtotal: Recordkeeping		*568*	*1,928,297*	*Varies*	*629,011*	*Varies*	*47,516,585*	*RK*	*Annual*

Total Private Sector Burden (by Type)	Respondents	Total Responses	Burden per Response (hr)	Total Annual Time (hr)	Labor Rate ($/hr)	Total Annual Cost ($)
Reporting	568	331,513	Varies	82,015	Varies	6,852,764
Third Party Disclosure	568	7,313,355	Varies	878,349	Varies	43,071,773
Recordkeeping	568	1,928,297	Varies	629,011	Varies	47,516,585
TOTAL	568	9,573,165	Varies	1,589,375	Varies	97,441,122

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	41	4,169,640	Varies	93,036	Varies	4,478,345
Private Sector	568	9,573,165	Varies	1,589,375	Varies	97,441,122
TOTAL	609	13,742,805	Varies	1,682,411	Varies	101,919,467

12.4 Collection of Information Instruments and Instruction/Guidance Documents

For Estimate 12.26 and the requirement under §438.66(e), see the attached Managed Care Program Annual Report (MCPAR).

For Estimate 12.65 and the requirement under §438.74(a), see the attached MLR Reporting Tool.

For Estimate 12.34c and the requirement under §438.207(d), see the attached Network Adequacy and Access Assurances Tool.

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 $59,561,736

15. Program and Burden Changes:

Labor rates have been updated from 2019 to 2020. Additionally, two new burden estimates were added as Estimate 12.65 and Estimate 12.34c. These burden estimates accommodate the use of reporting templates for existing reporting requirements at 42 CFR 438.207(d) for network adequacy and access and 438.74 for medical loss ratio. State questions about these reports have demonstrated that a template would help states by articulating the specific data elements needed and by providing an easy to use format that facilitates CMS' tracking and analysis. The templates will be issued in Excel format initially and converted to an online submission method in the future. The data gathered from these reports will enable CMS to ensure state compliance with regulatory requirements. Estimate 12.65 and Estimate 12.34c add 328 hours and $24,705.

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.