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

Background

Medicaid Managed Care and Supporting Regulations Contained in 42 CFR 438.1, 438.2, 438.3, 438.4, 438.5, 438.6, 438.7, 438.8, 438.9, 438.10, 438.12, 438.14, 438.50, 438.52, 438.54, 438.56, 438.58, 438.60, 438.62, 438.66, 438.68, 438.70, 438.71, 438.74, 438.100, 438.102, 438.104, 438.106, 438.108, 438.110, 438.114, 438.116, 438.206, 438.207, 438.208, 438.210, 438.214, 438.224, 438.228, 438.230, 438.236, 438.242, 438.400, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.420, 438.424, 438.600, 438.602, 438.604, 438.606, 438.608, 438.610, 438.700, 438.702, 438.704, 438.706, 438.708, 438.710, 438.722, 438.724, 438.726, 438.730, 438.802, 438.806, 438.808, 438.810, 438.812, 438.816, and 438.818

The Medicaid managed care final rule (CMS-2390-F, RIN 0938-AS25) modernizes the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. The proposed rule was published on June 1, 2015 (80 FR 31098). The final rule (May 6, 2016; 81 FR 27498) aligns the rules governing Medicaid managed care with those of other major sources of coverage, including coverage through Qualified Health Plans and Medicare Advantage plans; implements statutory provisions; strengthens actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates; ensures appropriate beneficiary protections; and enhances expectations for program integrity.

The rule also redesignates certain provisions. For convience of aligning the final provisions with the revised designations, a 2-page crosswalk of the redesignations is attached to this package.

A. Justification

1. Need and Legal Basis:

- Section 4701 of the BBA created section 1932(a) of 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:

Sections 438.66, 438.74, 438.207, and 438.818 contain requirements concerning specific reporting to CMS and will all be done electronically. Most of the sections do not involve submitting information to any entity; those that do concern the submission of information between the State 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:

These information collection requirements (ICRs) do not duplicate similar information collections.

5. Small Businesses:

We estimate that some PAHPs, PCCMs, and PCCM entities are likely to be small entities. We estimate that most MCOs and PIHPs are 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 2012, there are 335 MCOs, 176 PIHPs, 41 PAHPs, 20 NEMT PAHPs, 25 PCCMs, and 9 PCCM entities participating in the Medicaid managed care program. 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 the approximate counts presented. Specifically, we believe that 10 to 20 PAHPs, 8 to 15 PCCMs, and 2 to 5 PCCM entities are likely to be small entities. We believe that the remaining MCOs and PIHPs 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 of these regulations on small entities, we examined the United States Census Bureau's Statistics of U.S. Businesses for 2012. According to the 2012 data, there are 4,506 direct health and medical insurance issuers with less than 20 employees and 156,408 offices of physicians or health practitioners with less than 20 employees. We believe that we are impacting less than 1 percent of the small entities that we have identified.

The primary impact on small entities will be through the standards placed on PAHPs, PCCMs, and PCCM entities through the following requirements: (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 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. We do not believe that the remaining impacts or burdens of the provisions of this final rule are great on the small entities that we have identified.

All cost estimates were derived from the Collection of Information section of the final rule. The estimated costs associated with the impacts on small entities listed above are primarily attributable to the transition of care policies for PAHPs, PCCMs, and PCCM entities, initial assessments and care coordination activities for PAHPs, and the establishment of a grievances and appeals system and process for PAHPs. The transition of care policies, initial assessments, and care coordination activities for PAHPs account for approximately $2.4 million of the cumulative $4.5 million annual impact on the 41 PAHPs. The establishment of a grievances and appeals system and process accounts for approximately $1.1 million of the cumulative $4.5 million annual impact on the 41 PAHPs. The total estimated annual burden per PAHP is less than $0.1 million, or less than 1 percent of the $38.5 million threshold. The transition of care policies for PCCMs and PCCM entities account for approximately $0.4 million of the cumulative $0.6 million annual impact on the 34 PCCMs and PCCM entities. The total estimated annual burden per PCCM or PCCM entity is less than $0.1 million, or less than 1 percent of the $11 million threshold.

These small entities must meet certain standards as identified in the provisions of this final rule; however, we believe these 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, we have determined that this final rule will not have a significant economic impact on a substantial number of small entities. In the proposed rule, we invited comment on our proposed analysis of the impact on small entities and on possible alternatives to provisions of the proposed rule that would reduce burden on small entities. We received no comments and are finalizing our analysis as proposed in this final rule.

6. Less Frequent Collection:

These ICRs were mandated by the BBA. If CMS were to collect them less frequently, we would be in violation of the law.

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 die information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation:

The NPRM published on June 1, 2015 (80 FR 31098; RIN 0938-AS25) and served as the 60-day Federal Register notice. PRA-related public comments were received. A summary of the comments and our response have been added to this package.

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. Burden Estimate:

12.1 Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Titles and Wage Rates

Occupation Title	Occupation Code	Mean Hourly Wage($/hr)*	Fringe Benefit ($/hr)	Adjusted Hourly Wage($/hr)
Actuary	15-2011	46.22	46.22	92.44
Business Operations Specialist	13-1000	32.23	32.23	64.46
Computer Programmer	15-1131	39.16	39.16	78.32
Customer Service Rep	43-4051	17.93	17.93	35.86
General and Operations Mgr	11-1021	70.40	70.40	140.80
Healthcare Social Worker	21-1022	25.77	25.77	51.54
Mail Clerk	43-9051	15.46	15.46	30.92
Office and Administrative Support Worker	43-9000	18.27	18.27	36.54
Registered Nurse	29-1141	33.46	33.46	66.92

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

12.2 Burden Estimates

Section 438.3 Standard contract requirements Section 438.3 replaces section 438.6, Contract requirements, and includes the following burden.

Section 438.3 contains a list of provisions that must be included in MCO, PIHP, PAHP, HIO, and/or PCCM contracts. While the burden associated with the implementation and operation of the contracts is set out when warranted under the appropriate CFR section, the following burden estimate addresses the effort to amend existing contracts. The estimate also includes the burden for additional contract amendments are required under:

- §438.10(c)(5) requires specific information to be provided to enrollees.
- §438.14(b) specifies requirements for Indian enrollees and providers.
- §438.110(a) requires the establishment and maintenance of member advisory committees.
- §438.210(b)(2)(iii) requires LTSS to be authorized consistent with the enrollee's needs assessment and person centered plan.
- §438.242(c) requires specific provisions for encounter data.
- §438.608 requires administrative and management arrangements and procedures to detect and prevent fraud, waste, and abuse.

We estimate a one-time state burden of 6 hr at $64.46/hr for a business operations specialist to amend all 606 (335 MCO + 176 PIHP + 61 PAHP + 34 PCCM) contracts. In aggregate, we estimate **3,636 hr** (606 contracts x 6 hr) and **$234,376.56** (3,636 hr x $64.46/hr).

Annually, we estimate **1,212 hr** at a cost of **$78,125.52**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.1)**

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 438.5 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. We estimate that most states currently certify a range as compared to the actual contract rate paid to the managed care plan. 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 10 hr at $92.44/hr for an actuary and 1 hr at $140.80/hr for a general and operations manager to comply with this requirement. In aggregate, we estimate an annual state burden of **550 hr** (50 certifications x 11 hr) and **$53,260** [50 certifications x ((10 hr x $92.44/hr) + (1 hr x $140.80/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.

While the 2002 final rule (under §438.6(c)) set out the burden per contract (15,872 hr based on 32 hr per plan), experience has shown that states do not submit certifications per plan. We believe a better estimation of the burden is associated with the development of the rate certification. In this regard, we estimate it takes 230 hr to develop each certification, consisting of 100 hr (at $92.44/hr) for an actuary, 10 hr (at $140.80/hr) for a general and operations manager, 50 hr (at $78.32/hr) for a computer programmer, 50 hr (at $64.46/hr) for a business operations specialist, and 20 hr (at $36.54/hr) for an office and administrative support worker.

The revised burden is based on a total of **16,100 hr** (230 hr x 70 certifications) which is an increase of 228 hr (16,100 hr – 15,872 hr) for all 70 certifications due to the new regulatory requirements, adjusted to 3.3 hr per certification (228 hr/70 certifications). In aggregate, we estimate an annual state burden of **$18,948.57** [70 certifications x ((1.5 hr x $92.44/hr) + (0.13 hr x $140.80/hr) + (0.73 hr x $78.32/hr) + (0.73 hr x $64.46/hr) + (0.26 hr x $36.54/hr))]. (Prorating the time of the actuary, general operations manager, computer programmer, business operations specialist, and office and administrative support worker across the 3.3 hr per certification.) **(Estimate 12.3)**

Section 438.8 Medical loss ratio standards Section 438.8, medical loss ratio standards, replaces section 438.8, Provisions that apply to PIHPs and PAHPs, with the following burden. The previous provisions in 438.8 were revised and redesignated as appropriate throughout 438.

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 estimate the total number of MLR reports that MCOs, PIHPs, and PAHPs are required to submit to states amount to 572 contracts. While the number of contracts includes 549 credible contracts and 23 non-credible contracts, all MCOs, PIHPs, and PAHPs will need to report the information required under §438.8 regardless of their credibility status.

We estimate a one-time private sector burden of 168 hr for the initial administration activities. We estimate that 60 percent of the time will be completed by a computer programmer (101 hr at $78.32/hr), 30 percent will be completed by a business operations specialist (50 hr at $64.46/hr), and 10 percent will be completed by a general and operations manager (17 hr at $140.80/hr). This amounts to $13,526.92 ((101 hr x $78.32) + (50 hr x $64.46) + (17 hr x $140.80)) per report or **96,096 hr** (168 hr x 572) and **$7,737,398.24** (572 x $13,526.92) for 572 MCOs, PIHPs, and PAHPs in 2017 (the one-time burden).

Annually, we estimate **32,032 hr** at a cost of **$2,579,132.75**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.4)**

In subsequent years, since the programming and processes established in 2017 will continue to be used, the burden will decrease from 168 hr to approximately 53 hr. Using the same proportions of labor allotment, we estimate an annual private sector burden of **30,316 hr** (572 contracts x 53 hr) $4,241.60 per report and a total of **$2,426,195.20** [572 contracts x $4,241.60 ((32 hr x $78.32/hr) + (16 hr x $64.46/hr) + (5 hr x $140.80 /hr)]. We expect that states will permit MCOs, PIHPs, and PAHPs to submit the report electronically. Since the submission time is included in our reporting estimate, we are not setting out the burden for submitting the report. **(Estimate 12.5)**

Section 438.8(m) would require 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 estimate 6 hr at $78.32/hr for a computer programmer to make the initial changes. In aggregate, we estimate a one-time state burden of **252 hr** (42 states x 6 hr) and **$19,736.64** (252 hr x $78.32/hr).

Annually, we estimate **84 hr** at a cost of **$6,578.88**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.6a)**

We also estimate 3 hr for a computer programmer to periodically add or update documents and links on the site. In subsequent years, we estimate an annual state burden of **126 hr** (42 states x 3 hr) and **$9,868.32** (126 hr x $78.32/hr). **(Estimate 12.6b)**

Section 438.10(c)(4)(i) recommends that states develop definitions for commonly used terms to enhance consistency of the information provided to enrollees. We estimate it will take 6 hr at $64.46/hr for a business operations specialist to develop these definitions. In aggregate, we estimate a one-time state burden of **252 hr** (42 states x 6 hr) and **$16,243.92** (252 hr x $64.46/hr).

Annually, we estimate **84 hr** at a cost of **$5,414.64**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.7)**

Section 438.10(c)(4)(ii)recommends that states create model enrollee handbooks and notices. Since many states already provide model handbooks and notices to their entities, we estimate 20 states may need to take action to comply with this provision. We estimate it will take 20 hr at $64.46/hr for a business operations specialist to create these documents. We also estimate 2 hr per year for a business operations specialist to revise these documents, if needed. In aggregate, we estimate a one-time state burden of **400 hr** (20 states x 20 hr) and **$25,784** (400 hr x $64.46/hr).

Annually, we estimate **133.3 hr** at a cost of **$8,594.67**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.8a)**

In subsequent years we estimate an annual burden of **40 hr** (20 states x 2 hr) and **$2,578.40** (40 hr x $64.46/hr). **(Estimate 12.8b)**

Section 438.10(d)(2)(i) requires that states add taglines to all printed materials for potential enrollees explaining the availability of translation and interpreter services as well as the phone number for choice counseling assistance. As the prevalent languages within a state do not change frequently, we are not estimating the burden for the rare updates that will be needed to update these taglines. We estimate it will take 2 hr at $64.46/hr for a business operations specialist to create the taglines and another 4 hr to revise all document originals. In aggregate, we estimate a one-time state burden of **252 hr** (42 states x 6 hr) and **$16,243.92** (252 hr x $64.46/hr).

Annually, we estimate **84 hr** at a cost of **$5,414.64**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.9)**

Section 438.10(e)(1) clarifies that states can provide required information in paper or electronic format. As this is an existing requirement, the only burden change we estimate is adding two

new pieces of information generated in §438.68 (network adequacy standards) and §438.330 (quality and performance indicators). We estimate 1 hr at $64.46/hr for a business operations specialist to update or revise existing materials and 1 min at $30.92/hr for a mail clerk to mail the materials to 5 percent of the enrollees that are new (3,135,242). In aggregate, we estimate a one-time state burden of **42 hr** (42 states x 1 hr) and **$2,707.32** (42 hr x 64.46/hr) to update/revise existing materials.

Annually, we estimate **14 hr** at a cost of **$902.44**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

The currently approved burden estimates 5 min per mailing for 65,000 total hr. By updating the enrollment count from the current burden estimate to 2,069,259 (62,704,821 total enrollees x .033 growth rate) and reducing the time from 5 min to 1 min (to acknowledge automated mailing processes), we estimate the annual state burden for mailing as -30,512 hr (**34,488 hr** – 65,000 hr) and -$943,431.04 (-30,512 hr x $30.92/hr). **(Estimate 12.10)**

Section 438.10(g)(1) requires that MCOs, PIHPs, PAHPs, and PCCMs provide an enrollee handbook. Since §438.10(g) has always required the provision of this information (although it did not specifically call it a "handbook"), we believe only new managed care entities will need to create this document. Given the requirement in §438.10(c)(4)(ii) for the state to provide a model template for the handbook, the burden on a new entity will be greatly reduced.

For existing entities that already have a method for distributing the information, we believe that 100 entities will need to modify their handbook to comply with a new model provided by the state. We estimate that 100 entities rely on a business operations specialist to spend 4 hr at $64.46/hr to update their handbook. Once revised, the handbooks need to be sent to enrollees. We estimate 1 min by a mail clerk at $32.23/hr to send handbooks to 10,659,819 enrollees (17 percent of total enrollment). To update the handbook, we estimate a one-time private sector burden of **400 hr** (100 entities x 4 hr) and **$25,784** (400 hr x $64.46/hr).

Annually, we estimate **133.3 hr** at a cost of **$8,594.67**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.11a)**

To send the handbook to existing enrollees in the 100 entities, we estimate a one-time private sector burden of **178,019 hr** (10,659,819 enrollees x 1 min) and **$5,504,346.78** (178,019 hr x $30.92/hr).

Annually, we estimate **59,339.67 hr** at a cost of **$1,834,782.26**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.11b)**

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 2,069,259 enrollees (3.3 % percent of 62,704,821) will need to receive a handbook each year. We estimate 1 min by a mail clerk at $30.92/hr to mail the handbook or **34,557 hr** (2,069,259 enrollees x 1 min). The currently approved burden estimates 5 min per mailing for 390,000 enrollees or 32,500 total hr. Updating the enrollment figure and reducing the time from 5 min to 1 min (to acknowledge current automated mailing processes), the annual private sector burden is increased by 2,057 hr (34,557 hr - 32,500 hr) and $63,602.44 (2,057 hr x $30.92/hr). **(Estimate 12.12)**

Since all of the 581 (335 MCO + 176 PIHP + 61 PAHP + 9 PCCM) entities will need to keep their handbook up to date, we estimate it will take 1 hr at $64.46/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 **581 hr** (581 entities x 1 hr) and **$37,451.26** (581 hr x $64.46/hr). **(Estimate 12.13)**

Section 438.10(h) requires that all MCO, PIHP, PAHP, and PCCM entities make a provider directory available in electronic form, and on paper upon request. Producing a provider directory is a longstanding requirement in §438.10 and in the private health insurance market. Given the time sensitive nature of provider information and the high error rate in printed directories, most provider information is now obtained via the internet or by calling a customer service representative. In this regard, the only new burden is the time for a computer programmer to add a few additional fields of data, including the provider website addresses, additional disability accommodations, and adding behavioral and long-term services and support providers.

We estimate that it takes approximately 1 hr at $78.32/hr for a computer programmer to update the existing directory. Updates after the creation of the original program will be put on a production schedule as part of usual business operations and would not generate any additional burden. In aggregate, we estimate a one-time private sector burden of **581 hr** (581 entities x 1 hr) and **$45,503.92** (581 hr x $78.32/hr).

Annually, we estimate **193.7 hr** at a cost of **$15,167.97**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.14)**

Section 438.12 Provider discrimination prohibited 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 minute to draft and furnish such notice. We estimate that on average each 572 MCOs, PIHPs, and PAHPs will need to produce 10 notices per year. In aggregate, we estimate an annual private sector burden of **95 hr** (572 entities x 10 notices x 1 min) and **$2,937.40** (95 hr x $30.92/hr). **(Estimate 12.15)**

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) 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.

We estimate it takes 1 hr at $78.32/hr for a private sector computer programmer to create the claims report and approximately 12 hr at $64.46/hr for a state business operations specialist to process the payments. We estimate that approximately 25 of the 31 states will need to use this type of arrangement. In aggregate, we estimate a one-time private sector burden of **463 hr** (463 entities x 1 hr) and **$36,262.16** (463 hr x $78.32/hr).

Annually, we estimate **154.3 hr** at a cost of **$12,087.39**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.16a)**

We also estimate an annual state burden of **300 hr** (25 states x 12 hr) and **$19,338** (300 hr x $64.46/hr). **(Estimate 12.16b)**

After the MCO, PIHP, PAHP, and PCCM report is created, it will most likely run automatically at designated times and sent electronically to the state as the normal course of business operations; therefore, no additional private sector burden is estimated after the first year. (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.)

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.

As states currently providing managed care under a State Plan developed their process for public input at the beginning of their program, this burden would only apply to states starting new programs. We estimate 5 States and 8 hours at $64.46/hr a business operations specialist to develop the process for involving the public. In aggregate we estimate a one-time State burden of **40 hr** (5 states x 8 hr) and **$2,578.40** (40 hr x $64.46/hr). **(Estimate 12.17)**

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 22,394,579 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 (839,797) we estimate 1 min per notification by a mail clerk at $30.92/hr. In aggregate, we estimate an annual state burden of **13,997 hours** (839,797 enrollees x 1 min) and **$432,787.24** (13,997 hr x $30.92/hr). **(Estimate 12.18)**

In §438.54(c)(2), our proposed rule had set out requirements and burden which would have required states having voluntary programs that use a passive enrollment process to provide a 14 day choice period before enrolling the potential enrollee into a managed care plan. To accommodate the 14 day choice period, we estimated that 15 states would have to alter the programming of their passive enrollment algorithm to delay the enrollment in a managed care plan until the enrollee makes a plan selection or the 14 day period expires. This burden estimate has been deleted because the 14 day choice period is not being finalized. This is discussed in section I.B.5.a. of the final rule.

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 Section 438.62(b)(1) requires states to have a transition of care policy for all beneficiaries moving from FFS Medicaid into a MCO, PIHP, PAHP or PCCM, or when an enrollee is moving from one MCO, PIHP, PAHP, or PCCM to another and that enrollee experiences a serious detriment to health or be at risk of hospitalization or institutionalization without continued access to services. As states are currently required to ensure services for enrollees during plan transitions, they have a policy but it may need to be revised to accommodate the requirements and to include transitions from FFS. We estimate it will take 42 states 5 hours at $64.46/hr for a state business operations specialist to revise their policies and procedures and 4 hr at $78.32/hr for a computer programmer to create a program to compile and send the data. In aggregate, we estimate a one-time state burden of **378 hr** (42 states x 9 hr) and **$26,694.36** (210 hr (42x5) x $64.46/hr + 168 hr (42x4) x $78.32/hr).

Annually, we estimate **126 hr** at a cost of **$8,898.12**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. We are not estimating additional burden for the routine running of these reports since they will be put into a normal production schedule. **(Estimate 12.19)**

Section 438.62(b)(2) requires that MCOs, PIHPs, PAHPs, and PCCMs implement their own transition of care policy that meets the requirements of §438.62(b)(1). Under current

requirements and as part of usual and customary business practice for all managed care plans, the 586 (335 MCOs + 176 PIHPs + 41 PAHPs, and 34 PCCMs) entities already exchange data with each other for this purpose. To revise their existing policies to reflect the standards in (b)(1), we estimate 1 hr at $64.46/hr for a business operations specialist. To develop computer programs to receive and store FFS data, we estimate 4 hr at $78.32/hr for a computer programmer. We are not estimating additional burden for the routine running of these reports since they will likely be put into a production schedule. In aggregate, we estimate a one-time private sector burden of **2,930 hr** (586 entities x 5 hr) and **$221,355.64** [586 entities x [(1 hr x $64.46/hr) + (4 hr x $78.32/hr)]].

Annually, we estimate **976.7 hr** at a cost of **$73,785.21**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.20)**

For transitions, we estimate 10 min (per request) at $66.92/hr for a registered nurse to access the stored data and take appropriate action. We also estimate that approximately 0.05 percent of enrollees (313,704) 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 **52,294 hr** (313,704 enrollees x 10 min) and **$3,499,545.05** (52,294 hr x $66.92/hr). **(Estimate 12.21)**

Section 438.66 State monitoring requirements Section 438.66(a) and (b) requires states with MCO, PIHP, PAHP, or PCCM programs to have a monitoring system including at least the 13 areas specified in paragraph (b). While having a monitoring system is a usual and customary business process for all of the state Medicaid agencies, including all 13 areas will require most states to make at least some revisions to their existing processes and policies. We estimate 8 hr at $64.46/hr for a business operations specialist to expand or revise existing policies and procedures. In aggregate, we estimate a one-time state burden of **336 hr** (42 states x 8 hr) and **$21,658.56** (336 hr x $64.46/hr).

Annually, we estimate **112 hr** at a cost of **$7,219.52**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.22)**

Section 438.66(c) requires states with MCO, PIHP, PAHP, or PCCM programs to utilize data gathered from its monitoring activities in 12 required areas to improve the program's performance. While all states currently utilize data for program improvement to some degree, incorporating all 12 areas will likely require some revisions to existing policies and procedures. We estimate a one-time state burden of 20 hr at $64.46/hr for a business operations specialist to revise existing or to create new policies and procedures for utilizing the collected data. In aggregate, we estimate **840 hr** (42 states x 20 hr) and **$54,146.40** (840 hr x $64.46/hr).

Annually, we estimate **280 hr** at a cost of **$18,048.80**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

(Estimate 12.23)

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 $140.80/hr) for a general and operations manager, 30 hr (at $64.46/hr) for a business operations specialist, and 5 hr (at $78.32/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 pargraph (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 **$60,588** [20 states x ((5 x $140.80/hr) +(30 x $64.46/hr) + (5 x $78.32/hr))]. **(Estimate 12.24)**

For MCO, PIHP, PAHP, or PCCM preparation and execution, we estimate 5 hr (at $140.80/hr) for a general and operations manager, 30 hr (at $64.46/hr) for a business operations specialist, and 5 hr (at $78.32/hr) for a computer programmer. In aggregate, we estimate an annual private sector burden of **800 hr** (20 entities x 40 hr) and **$60,588** [20 entities x ((5 x $140.80/hr) + (30 x $64.46/hr) + (5 x $78.32/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 $64.46/hr for a business operations specialist to compile and submit this report to CMS. In aggregate, we estimate an annual state burden of **252 hr** (42 states x 6 hr) and **$16,243.92** (252 hr x $64.46/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 standards which must include time and distance 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.

We estimate states will spend 10 hr in the first year developing the network adequacy standards for the specific provider types found in §438.68(b)(1). While 40 states have contracted with at least one MCO, PIHP or PAHP, we believe that 20 will need to develop the standards and 20 already have a network adequacy standard in place. After the network standards have been established, we estimate that the maintenance of the network standards will occur only periodically as needs dictate; therefore, we do not estimate additional burden for states after the first year.

To develop network standards meeting the specific provider types found in §438.68(b)(1), we estimate a one-time state burden of 10 hr at $64.46/hr for a business operations specialist. In aggregate, we estimate **200 hr** (20 states x 10 hr) and **$12,892** (200 hr x $64.46/hr).

Annually, we estimate **66.6 hr** at a cost of **$4,297.33**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.27)**

To develop LTSS standards, we estimate a one-time state burden of 10 additional hr at $64.46/hr for a business operations specialist to develop those standards. In aggregate, we estimate **160 hr** (16 states with MLTSS programs x 10 hr) and **$10,313.60** (160 hr x $64.46/hr).

Annually, we estimate **53.3 hr** at a cost of **$3,437.87**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.28)**

Section 438.68(d) requires that states develop an exceptions process for use by MCOs, PIHPs, and PAHPs unable to meet the network standards established in §438.68(a). We estimate a one-time state burden of 3 hr at $64.46/hr for a business operations specialist to design an exceptions process for states to use to evaluate requests from MCOs, PIHP, and PAHPs for exceptions to the network standards. With a total of 40 states contracting with at least one MCO, PIHP or PAHP, we estimate a one-time aggregate state burden of **120 hr** (40 states x 3 hr) and **$7,735.20** (120 hr x $64.46).

Annually, we estimate **40 hr** at a cost of **$2,578.40**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.29)**

The exception process should not be used very often as MCOs, PIHPs, and PAHPs meeting the established standards is critical to enrollee access to care. As such, after the exceptions process is established, we estimate that the occasional use of it will not generate any measurable burden after the first year.

States' review and reporting on exceptions granted through the process developed in §438.68(d) is estimated under §438.66 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 $64.46/hr for a business operations specialist to perform this task. In aggregate, we estimate **56 hr** (14 states x 4 hr) and **$3,609.76** (152 hr x $64.46/hr). **(Estimate 12.30)**

Section 438.71 Beneficiary support system Section 438.71(a) requires that state develop and implement a system for support to beneficiaries before and after enrollment in a MCO, PIHP, PAHP, or PCCM. This will most likely be accomplished via a call center including staff having

email capability - internal to the state or subcontracted - that will assist beneficiaries with questions. As most state Medicaid programs already provide this service, we estimate only 20 states may need to take action to address this requirement.

We estimate a state will need 150 hr to either procure a vendor for this function or add staff or train staff in an existing internal call center. The one-time state burden would consist of 125 hr (at $64.46/hr) for a business operations specialist, and 25 hr (at $140.80/hr) for a general and operations manager. In aggregate, we estimate **3,000 hr** (20 states x 150 hr) and **$231,550** [20 states x ((125 hr x $64.46/hr) + (25 hr x $140.80/hr))]. We believe this burden represents a reasonable number of hours regardless of whether a state elects procurement or use of existing staff.

Annually, we estimate **1,000 hr** at a cost of **$77,183.33**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.31)**

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.

In §438.71(d), our proposed rule had set out requirements and burden which would have required that states develop training materials for provider education on MLTSS. That requirement is not being finalized, as discussed in I.B.5.c. of the final rule.

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 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 **4,222 hr** (3 entities x 84,444 x 1 min) and **$130,544.24** (4,222 hr x $30.92/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 $64.46/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 **$5,414.64** (84hr x $64.46/hr). **(Estimate 12.33)**

Section 438.207 Assurance of adequate capacity and services Section 438.207(c) requires that the documentation required in §438.207(b) be submitted to the state at least annually. As the MCOs, PIHPs, and PAHPs will already run and review these reports periodically to monitor their networks as part of normal network management functions and as part of the provisions of §438.68, the only additional burden would possibly be (if the state doesn't already require this at least annually) for the 552 (335 MCOs + 176 PIHPs + 41 PAHPs) entities to revise their policy to reflect an annual submission. We estimate a one-time private sector burden of 1 hr at $64.46/hr for a business operations specialist to revise the policy, if needed. In aggregate, we estimate **552 hr** (552 entities x 1 hr) and **$35,581.92** (552 hr x $64.46/hr) for policy revision.

Annually, we estimate **184 hr** at a cost of **$11,860.64**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.34a)**

We also 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 (d). For compilation and submission, we estimate **1,104 hr** (552 entities x 2 hr) and **$71,163.84** (1,104 hr x $64.46/hr). **(Estimate 12.34b)**

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 5 percent of all MCO, PIHP, and PAHP enrollees (2,331,626 of 46,632,522 MCO, PIHP, and PAHP enrollees) will be affected. We estimate an ongoing private sector burden of 10 min (per enrollee) at $51.54/hr for a healthcare social worker to perform the care coordination activities. In aggregate, we estimate **457,838 hr** (2,746,476 enrollees x 10 min) and **$23,596,970.52** (457,838 hr x $51.54/hr). **(Estimate 12.35)**

Section 438.208(b)(3) requires that a MCO, PIHP or PAHP make its best effort to conduct an initial assessment of each new enrollee's needs within 90 days of the enrollment. We believe that most MCOs and PIHPs already meet this requirement and only 25 percent of the MCOs and PIHPs (84 MCOs + 44 PIHPs) will need to alter their processes; however, we do not believe this to be as common a practice among PAHPs and assume that all 41 non-NEMT PAHPs will be need to add this assessment to their initial enrollment functions. We estimate a one-time private sector burden of 3 hr at $64.46/hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate **507 hr** (169 entities x 3 hr) and **$32,681.22** (507 hr x $64.46/hr). **(Estimate 12.36)**

We estimate that in a given year, only 5 percent (726,143) of 25 percent of MCO and PIHP (10,703,220) and all (3,819,643 non-NEMT) PAHP enrollees are new to a managed care plan. We estimate an annual private sector burden of 10 min (on average) at $35.86/hr for a customer service representative to complete the screening. In aggregate, we estimate **121,024 hr** (726,143 enrollees x 10 min) and **$4,339,920.64** (121,023 hr x $35.86/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.

For 552 entities ((335 MCOs + 176 PIHPs + 41 PAHPs), we estimate a one-time burden of 4 hr at $78.32/hr for a computer programmer to develop the report. In aggregate, we estimate **2,208 hr** (556 emtities x 4 hr) and $172,930.56 (2,208 hr x $78.32/hr). However, while the currently approved burden sets out 45 min per enrollee and 399,656 annual hours, to provide more accurate estimates we are adjusting the burden by using one-time per plan estimates and recognizing the use of automated reporting. In aggregate, we estimate a one-time private sector burden of --397,448 hr (2,208 hr – 399,656 hr) and -$31,128,127 (-397,448 hr x $78.32/hr). Once put on a production schedule, no additional staff time will be needed, thus no additional burden is estimated. **(Estimate 12.38)**

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; this rule adds "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.) We believe that only enrollees in MCOs and PIHPs will require this level of assessment as most PAHPs provide limited benefit packages that do not typically warrant a separate treatment plan.

While this is an existing requirement, we estimate an additional 1 percent of the total enrollment of 42,812,879 in MCOs and PIHPs (42,812,879 x .01=428,128) given the surge in enrollment into managed care of enrollees utilizing LTSS. We estimate an annual private sector burden of 1 hr (on average) at $66.92/hr for a registered nurse to complete the assessment and treatment planning. In aggregate, we estimate an additional **428,128 hr** (428,128 enrollees x 1 hr) and **$28,650,325.76** (428,128 hr x $66.92/hr). **(Estimate 12.39)**

Section 438.208(c)(3)(v) requires that treatment plans be updated at least annually or upon request. For 552 (335 MCOs + 176 PIHPs + 41 PAHPs) entities, we estimate a one-time private sector burden of 1 hr at $64.46/hr for a business operations specialist to revise policies and procedures to reflect a compliant time frame. In aggregate, we estimate **552 hr** (552 entities x 1 hr) and **$35,581.92** (552 hr x $64.46/hr). **(Estimate 12.40)**

<u>Section 438.210 Coverage and authorization of services</u> Section 438.210(a)(4)(ii)(B) requires that MCOs, PIHPs, and PAHPs authorize services for enrollees with chronic conditions or receiving LTSS in a way that reflects the on-going nature of the service. While we expect this to already be occurring, we also expect that most MCOs, PIHPs, and PAHPs will review their policies and procedures to ensure compliance. For 572 (335 MCOs+ 176 PIHPs + 61 PAHPs) entities, we estimate a one-time private sector burden of 20 hr at $66.92/hr for a registered nurse to review and revise, if necessary, authorization policies and procedures. In aggregate, we estimate **11,440 hr** (572 entities x 20 hr) and **$765,564.80** (11,440 x $66.92/hr).

Annually, we estimate **3,813.33 hr** at a cost of **$255,188.27**. We are annualizing the one-time

estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.41)**

Section 438.210(c) currently requires that each contract provide for the MCO or PIHP to notify the requesting provider of a service authorization request denial, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. In this final rule, PAHPs are be added to this requirement.

The burden associated with sending adverse benefit determination notices is included in §438.404. While we believe PAHPs already provide notification of denials, we expect they may need to be revised to be compliant with §438.404. We estimate a one-time public sector burden of 1 hr at $64.46/hr for a business operations specialist to revise the template. In aggregate, we estimate **61 hr** (61 PAHPs x 1 hr) and **$3,932.06** (61 hr x $64.46/hr).

Annually, we estimate **20.3 hr** at a cost of **$1,310.69**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.42)**

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 438.230 Subcontractual relationships and delegation Section 438.230 would require additional provisions in MCO, PIHP, or PAHP subcontracts, other than agreements with network providers. For 572 (335 MCO+ 176 PIHPs + 61 PAHPs) entities, we estimate a one-time private sector burden of 3 hr at $64.46/hr for a business operations analyst to amend appropriate contracts. In aggregate, we estimate **1,716 hr** (572 entities x 3 hr) and **$110,613.36** (1,716 x $64.46/hr).

Annually, we estimate **572 hr** at a cost of **$36,871.12**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.43)**

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 438.242 Health information systems Section 438.242(b) and (c) currently requires MCOs and PIHPs to collect and submit to the state enrollee encounter data. This rule adds

PAHPs to the requirement. We estimate a one-time private sector burden of 20 hr at $78.32/hr for a computer programmer to extract this data from a PAHP's system and report it to the state.

In aggregate, we estimate **820 hr** (41 entities x 20 hr) and **$64,222.40** (820 hr x $78.32/hr). After creation, these reports would be set to run and sent to the state at on a production schedule.

Annually, we estimate **273.3 hr** at a cost of **$21,407.47**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.44)**

Section 438.400 Statutory basis and definitions Section 438.400(b) replaces "action" with "adverse benefit determination" and revises the definition. It also revises the definitions of "appeal" and "grievance" and add a definition for "grievance system." In response, states, MCOs and PIHPs need to update any documents where these terms are used. (PAHPs will use these updated definitions when they develop their systems in §438.402.)

For 511 (335 MCOs + 176 PIHPs) entitities, we estimate a one-time private sector burden of 5 hr at $64.46/hr for a business operations specialist to amend all associated documents to the new nomenclature and definitions. In aggregate, we estimate **2,555 hr** (511 entities x 5 hr) and **$164,695.30** (2,555 hr x $64.46/hr).

Annually, we estimate **851.7 hr** at a cost of **$54,898.43**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.45a)**

We also estimate a one-time state burden for states of **200 hr** (40 states x 5 hr) and **$12,892** (200 hr x $64.46/hr) to make similar revisions.

Annually, we estimate **66.7 hr** at a cost of **$4,297.33**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.45b)**

Section 438.402 General requirements Section 438.402(a) adds PAHPs to the existing requirement for MCOs and PIHPs to have a grievance system. There are 41 non-NEMT PAHPs that will need to have their contract amended. The burden for revising their contract is included in §438.3.

To set up a grievance system, we estimate it takes 100 hr (10 hr at $140.80/hr for a general and operations manager, 75 hr at $64.46/hr for a business operations specialist, and 15 hr at $78.32/hr for a computer programmer) for each PAHP. In aggregate, we estimate a one-time private sector burden of **4,100 hr** (41 PAHPs x 100 hr) and **$304,109.30** [41 PAHPs x ((10 hr x $140.80/hr) + (75 hr x $64.46/hr) + (15 hr x $78.32/hr))].

Annually, we estimate **1,366.7 hr** at a cost of **$101,369.77**. We are annualizing the one-time

estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.46a)**

We further estimate that the average PAHP only receives 10 grievances per month due to their limited benefit package and will only require 3 hr at $64.46/hr for a business operations specialist to process and handle grievances and adverse benefit determinations. In aggregate, we estimate an annual private sector burden of **14,760 hr** (41 PAHPs x 10 grievances x 3 hr x 12 months) and **$951,429.60** (14,760 hr x $64.46/hr). **(Estimate 12.46b)**

Section 438.402(b) limits MCOs, PIHPs, and PAHPs to one level of appeal for enrollees. This will likely eliminate a substantial amount of burden from those that currently have more than one, but we are unable to estimate that amount since we do not know how many levels each managed care plan currently utilizes. We requested comment from managed care plans to help us estimate the savings from this provision. We received no comments and have finalized this section with no estimated cost savings.

Section 438.404 Notice of action 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.

We estimate an annual private sector burden of 1 min at $30.92/hr for a mail clerk to send this notification. We also estimate that 2 percent (240,000) of the 12 million PAHP enrollees will receive one notice of adverse benefit determination per year from a PAHP. In aggregate, we estimate an annual state burden of **4,000 hr** (240,000 enrollees x 1 min) and **$123,927.36** (4,000 hr x $30.92/hr). **(Estimate 12.47)**

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) changes the time frame for appeal resolution from 45 days to 30 days. For MCOs, PIHPs, and PAHPs that have Medicare and/or QHP lines of business, this reflects a reduction in burden as this aligns Medicaid time frames with Medicare and QHP. For MCOs, PIHPs, and PAHPs that do not have Medicare and/or QHP lines of business, and whose state has an existing time frame longer than 30 days, they will need to revise their policies and procedures. Among the 200 MCOs, PIHPs, and PAHPs, we estimate a one-time private sector burden of 1 hr at $64.46/hr for a business operations specialist. In aggregate, we estimate **200 hr** (200 entities x 1 hr) and **$12,892** (200 hr x $64.46).

Annually, we estimate **66.7 hr** at a cost of **$4,297.33**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.48)**

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 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 and reporting requirements This section adds PAHPs to the requirement to maintain records of grievances and appeals. We estimate that approximately 240,000 enrollees (2 percent) of the approximately 12 million PAHP enrollees file a grievance or

appeal with their PAHP. As the required elements will be stored and tracked electronically, we estimate 1 min per grievance and appeal at $36.54/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 **4,000 hr** (240,000 grievances x 1 min) and **$146,452.32** (4,000 hr x $36.54/hr). **(Estimate 12.49)**

Maintaining records for grievances and appeals has always been required for MCOs and PIHPs. However, this rule requires specific data so a few MCOs and PIHPs (10 percent [335 MCOs + 176 PIHPs]) may have to revise their policies and systems to record the required information. We estimate 3 hr at $78.32 for a computer programmer to make necessary changes. We estimate a one-time private sector **burden of 153 hr (51 MCOs and PIHPs x 3 hr) and $11,982.96 (153 hr x $78.32/hr).**

Annually, we estimate **51 hr** at a cost of **$3,994.32**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

As the required elements will be stored and tracked electronically, we estimate 1 min per grievance and appeal at $36.54/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 **14,299 hr** (856,257 grievances (.02 x 4,394,450 (.10 x 43,944,503 MCO and PIHP enrollees) x 1 min) and **$522,503.43** (14,299 hr x $36.54/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.

For 511 (335 MCOs + 176 PIHPs) entities, we estimate a one-time private sector burden of 4 hr at $64.46/hr for a business operations specialist to revise current policies and procedures. In aggregate, we estimate **2,044 hr** (511 entities x 4 hr) and **$131,756.24** (2,044 hr x $64.46/hr). **(Estimate 12.51)**

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(a) details state responsibilities for monitoring MCO, PIHP, PAHP, PCCM or PCCM's compliance with §§438.604, 438.606, 438.608, 438.610, 438.230, and 438.808. As all of these sections are existing requirements, the

only new burden is for states to update their policies and procedures, if necessary, to reflect revised regulatory text. We estimate a one-time state burden of 6 hr at $64.46/hr for a business operations specialist to create and/or revise their policies. In aggregate, we estimate **252 hr** (42 states x 6 hr) and **$16,243.92** (252 hr x $64.46/hr).

Annually, we estimate **84 hr** at a cost of **$5,414.64**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.52)**

Section 438.602(b) requires states to screen and enroll MCO, PIHP, PAHP, PCCM and PCCM entity providers in accordance with 42 CFR part 455, subparts B and E. Given that states already comply with these subparts for their FFS programs, the necessary processes and procedures have already been implemented. Additionally, since some states require their managed care plan providers to enroll with FFS, the overlap that occurs in many states due to provider market conditions, and the exemption from this requirement for Medicare approved providers, we believe the pool of managed care providers that will have to be newly screened and enrolled by the states is small. We expect the MCOs, PIHPs, and PAHPs will need to create data files to submit new provider applications to the state for the screening and enrollment processes. As PCCMs and PCCM entities are already FFS providers, there would be no additional burden on them or the state. For 572 (335 MCOs + 176 PIHPs + 61 PAHPs) entities, we estimate a one-time private sector burden of 6 hr at $78.32/hr for a computer programmer to create the necessary programs to send provider applications/data to the state. In aggregate, we estimate **3,432 hr** (572 entities x 6 hr) and **$268,794.24** (3,432 hr x $78.32/hr).

Annually, we estimate **1,144 hr** at a cost of **$89,598.08**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. Once created, the report will likely be put on a production schedule and generate no additional burden. **(Estimate 12.53)**

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 $66.38/hr for an accountant. In aggregate, we estimate **3,680 hr** (335 MCOs + 176 PIHPs + 41 PAHPs x 20 hr)/3) and **$244,278.40** (3,680 hr x $66.38/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 $78.32/hr for a computer programmer to post the documents. In aggregate, we estimate **40 hr** (40 states x 1 hr) and **$3,132.80** (40 hr x $78.32/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.

While §438.608(a)(1) is an existing regulation, we expect all 552 (335 MCOs + 176 PIHPs + 41 PAHPs) entities review their policies and procedures to ensure that all of the above listed items are addressed. We estimate a one-time private sector burden of 2 hr at $64.46/hr for a business operations specialist to review and (if necessary) revise their policies and procedures. In aggregate, we estimate **1,104 hr** (552 entities x 2 hr) and **$71,163.84** (1,104 hr x $64.46/hr).

Annually, we estimate **368 hr** at a cost of **$23,721.28**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.56)**

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 $64.46/hr for a business operations specialist. In aggregate, we estimate **1,104 hr** (552 entities x 2 hr) and **$71,163.84** (1,104 hr x $64.46/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 $30.92/hr for a mail clerk to send each letter. In

aggregate, we estimate **333 hr** (20,000 letters x 1 min/letter) and **$10,327.28** (333 hr x $30.92/hr). This estimate will be significantly reduced as the use of email increases. **(Estimate 12.58)**

Section 438.608(b) reiterates the requirement in §438.602(b) whereby the burden is stated in section IV.C.36. of this final rule.

Section 438.608(c) and (d) requires that states include in all MCO, PIHP, and PAHP contracts, the process for the disclosure and treatment of certain types of recoveries and reporting of such activity. While the burden to amend the contracts is included in §438.3, we estimate a one-time private sector burden of 1 hr at $78.32/hr for a computer programmer to create the report. For 552 (335 MCOs + 176 PIHPs + 41 PAHPs) entities, we estimate **552 hr** (552 entities x 1 hr) and **$43,232.64** (552 hr x $78.32/hr). Once developed, the report will be put on a production schedule and add no additional burden. **(Estimate 12.59)**

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 $64.46/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 **$773.52** (12 hr x $64.46/hr). **(Estimate 12.60)**

To send the notice, we estimate 1 min (per beneficiary) at $30.92/hr for a mail clerk. We estimate an aggregate annual state burden of **18,076 hr** (12 states x 90,378 enrollees/60 mins) and **$558,909.92** (18,076 hr x $30.92/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.

A state using EQRO to validate data on less than an appropriate frequency may need to amend their EQRO contract. In this case, we estimate 1 hr at $64.46/hr for a business operations specialist. In aggregate, we estimate a one-time state burden of **9 hr** (9 states x 1 hr) and **$580.14** (9 hr x $64.46/hr).

Annually, we estimate **3 hr** at a cost of **$193.38**. We are annualizing the one-time estimate since

we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.62)**

A state electing to perform validation internally needs to develop processes and policies to support implementation. In this case, we estimate 10 hr at $64.46/hr for a business operations specialist to develop policy and 100 hr at $78.32/hr for a computer programmer to develop, test, and automate the validation processes. In aggregate, we estimate a one-time state burden of **990 hr** (9 states x 110 hr) and **$76,289.40** [9 states x ((10 hr x $64.46/hr) + (100 hr x $78.32hr))]. **(Estimate 12.63)**

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 $64.46/hr for a business operations specialist to participate in the writing, evaluating, and implementing, and 25 hr at $140.80/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 **$104,197.50** [9 states x ((125 hr x $64.46/hr) + (25 hr x $140.80/hr))]. **(Estimate 12.64)**

Section 438.818(d) would require 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.).

Summary of Annual Burden Estimates: State Government

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

Estimate #	CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Response Type	Frequency	Annualized Hours	Annualized costs ($)
12.1	438.3, Contracts	42	606	6	3,636	64.46	386.76	234,376.56	R	once	1,212	78,125.52
12.2	438.5, Rate Standards	39	50	10	500	92.44	924.40	46,220.00	R	annual	500	46,220.00
				1	50	140.80	140.80	7,040.00	R	annual	50	7,040.00
12.3	438.7, Rate Certifications	39	70	100	7,000	92.44	9,244.00	647,080.00	R	annual	7,000	647,080.00
				10	700	140.80	1,408.00	98,560.00	R	annual	700	98,560.00
				50	3,500	78.32	3,916.00	274,120.00	R	annual	3,500	274,120.00
				50	3,500	64.46	3,223.00	225,610.00	R	annual	3,500	225,610.00
				20	1,400	36.54	730.80	51,156.00	R	annual	1,400	51,156.00
12.17	438.50, State Plan requirements	5	5	8	40	64.46	515.68	2,578.40	R	once	1,400	2,578.40
12.19	438.62(b)(1), Transition of Care	42	42	5	210	64.46	322.30	13,536.60	R	once	70	4,512.20
				4	168	78.32	313.28	13,157.76	R	once	56	4,385.92
12.22	438.66(a) and (b), State Monitoring	42	42	8	336	64.46	515.68	21,658.56	R	once	112	7,219.52
12.27	438.68(a) - (c), Network Adequacy	20	20	10	200	64.46	644.60	12,892.00	R	once	66.6	4,297.33
12.28	438.68(a) - (c), Network Adequacy	16	16	10	160	64.46	644.60	10,313.60	R	once	53.3	3,437.87
12.29	438.68(d), Network Adequacy	40	40	3	120	64.46	193.38	7,735.20	R	once	40	2,578.40
12.30	438.70, MLTSS	14	14	4	56	64.46	257.84	3,609.76	R	annual	56	3,609.76

	Engagement											
12.52	438.602(a), Program Integrity	42	42	6	252	64.46	386.76	16,243.92	R	once	84	5,414.64
12.54	438.602(e), Program Integrity	42	572	6.6667	3,680	66.38	442.54	244,278.40	R	annual	3,680	244,278.40
12.55	438.602(g) Program Integrity	40	40	1	40	78.32	78.32	3,132.80	R	annual	40	3,132.80
12.63	438.818(a(2), Encounter Data	9	9	10	90	64.46	644.60	5,801.40	R	once	30	1,933.80
				100	900	78.32	7,832.00	70,488.00	R	once	300	23,496.00
12.64	438.818(a)(2), Encounter Data	9	9	125	1,125	64.46	8,057.50	72,517.50	R	annual	1,125	72,517.50
				25	225	140.80	3,520.00	31,680.00	R	annual	225	31,680.00
	SUBTOTAL: Reporting	*42*	*1,577*	--	--	--	--	--	--	--	*25,200*	*1,842,984.06*
12.6a	438.10(c)(3), Information Requirements	42	42	6	252	78.32	469.92	19,736.64	TPD	once	84	6,578.88
12.6b	438.10(c)(3), Information Requirements			3	126	78.32	234.96	9,868.32	TPD	annual	126	9,868.32
12.7	438.10(c)(4)(i), Information Requirements	42	42	6	252	64.46	386.76	16,243.92	TPD	once	84	5,414.64
12.8	438.10(c)(4) (ii), Information Requirements	20	20	20	400	64.46	1,289.20	25,784.00	TPD	once	133.3	8,594.67
				2	40	64.46	128.92	2,578.40	TPD	annual	40	2,578.40
12.9	438.10(d)(2)(i), Information Requirements	42	42	6	252	64.46	386.76	16,243.92	TPD	once	84	5,414.64
12.10	438.10(e)(1), Information Requirements	42	2,069,259	0.0167 (1 min)	34,488	30.92	0.52	1,066,368.96	TPD	annual	34,488	1,066,368.96
12.16b	438.14(c), Contracts	25	25	12	300	64.46	773.52	19,338.00	TPD	annual	300	19,338.00
12.18	438.54(c)(8), Enrollment	42	839,797	0.0167 (1 min)	13,997	30.92	0.52	432,787.24	TPD	annual	13,997	432,787.24

12.31	438.71(a), Beneficiary Support System	20	20	125	2,500	64.46	8,057.50	161,150.00	TPD	once	833.3	53,716.67
				25	500	140.80	3,520.00	70,400.00	TPD	once	166.7	23,466.67
12.60	438.722, Disenrollment Notices	12	12	1	12	64.46	64.46	773.52	TPD	annual	12	773.52
12.61	438.722 Disenrollment Notices	12	1,084,536	0.0167 (1 min)	18,076	30.92	0.52	558,909.92	TPD	annual	18,076	558,909.92
12.62	438.818(a)(2), Encounter Data	9	9	1	9	64.46	64.46	580.14	TPD	once	3	193.38
	SUBTOTAL: Third-Party Disclosure	*42*	*3,993,846*	--	--	--	--	--	--	--	*68,427.30*	*2,194,906.35*
12.23	438.66(c), State Monitoring	42	42	20	840	64.46	1,289.20	54,146.40	RK	once	280	18,048.80
12.24	438.66(d)(3), State Monitoring	20	20	5	100	140.80	704.00	14,080.00	RK	annual	100	14,080.00
				30	600	64.46	1,933.80	38,676.00	RK	annual	600	38,676.00
				5	100	78.32	391.60	7,832.00	RK	annual	100	7,832.00
12.26	438.66(e)(1) and (2), State Monitoring	42	42	6	252	64.46	386.76	16,243.92	RK	annual	252	16,243.92
12.45b	438.400(b), Definitions	40	40	5	200	64.46	322.30	12,892.00	RK	once	66.7	4,297.33
	SUBTOTAL: Recordkeeping	*42*	*144*	--	--	--	--	--	--	--	*1,398.7*	*99,178.05*
	TOTAL	**42**	**3,995,567**	--	--	--	--	--	--	--	**95,026**	**4,137,068.46**

Summary of Annual Burden Estimates: Private Sector

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

Estimate	**CFR Section**	**# Respondents**	**# responses**	**Burden per response (hours)**	**Total Annual Hours**	**Labor Rate ($/hr)**	**Cost ($) per Response**	**Total cost ($)**	**Response Type**	**Frequency**	**Annualized Hours**	**Annualized costs ($)**
12.4	438.8(c), MLR	572	572	101	57,772	78.32	7,910.32	4,524,703.04	R	once	19,257.3	1,508,234.35

				50	28,600	64.46	3,223.00	1,843,556.00	R	once	9,533.3	614,518.67
				17	9,724	140.80	2,393.60	1,369,139.20	R	once	3,241.3	456,379.73
12.5	438.8(c), MLR	572	572	32	18,304	78.32	2,506.24	1,433,569.28	R	annual	18,304	1,433,569.28
				16	9,152	64.46	1,031.36	589,937.92	R	annual	9,152	589,937.92
				5	2,860	140.80	704.00	402,688.00	R	annual	2,860	402,688.00
12.20	438.62(b)(2), Transition of Care	586	586	1	586	64.46	64.46	37,773.56	R	once	195	12,591.19
				4	2,344	78.32	313.28	183,582.08	R	once	781	61,194.03
12.21	438.62(b)(2), Transition of Care	568	313,704	0.1667 (10 min)	52,294	66.92	11.16	3,499,545.05	R	annual	52,294	3,499,545.05
12.33	438.110(a), Member Advisory Committee	14	14	6	84	64.46	386.76	5,414.64	R	annual	84	5,414.64
12.34	438.207(b) - (d), Adequate Capacity	552	552	1	552	64.46	64.46	35,581.92	R	once	184	11,860.64
				2	1,104	64.46	128.92	71,163.84	R	annual	1,104	71,163.84
12.40	438.208(c)(3) (v) Care Coordination	552	552	1	552	64.46	64.46	35,581.92	R	once	552	11,860.64
12.46a	438.402(a) Grievance System	41	41	10	410	140.80	14,058.00	57,728.00	R	once	136.7	19,242.67
				75	3,075	64.46	4,834.50	198,214.50	R	once	1,025	66,071.50
				15	615	78.32	1,174.80	48,166.80	R	once	205	16,055.60
12.46b	46b 438.402(a) Grievance System	41	410	36	14,760	64.46	2,320.56	951,429.60	R	annual	14,760	951,429.60
12.51	438.420(c)(4) Continuation of Benefits	511	511	4	2,044	64.46	257.84	131,756.24	R	once	2,044	131,756.24
12.53	438.602(b) Program	572	572	6	3,432	78.32	469.92	268,794.24	R	once	1,144	89,598.08

	Integrity											
12.59	438.608(c) - (d) Program Integrity	552	552	1	552	78.32	78.32	43,232.64	R	once	552	14,410.88
	SUBTOTAL: Reporting	*586*	*318,638*	--	--	--	--	--	--	--	*137,408.60*	*9,967,522.55*
12.11	438.10(g), Information Requirements	100	100	4	400	64.46	257.84	25,784.00	TPD	once	133.3	8,594.67
			10,659,819	0.0167 (1 min)	178,019	30.92	0.52	5,504,346.78	TPD	once	59,340	1,834,782.26
12.12	438.10(g), Information Requirements	100	2,069,259	0.0167 (1 min)	34,557	30.92	0.52	63,602.44	TPD	annual	34,557	63,602.44
12.13	438.10(g), Information Requirements	581	581	1	581	64.46	64.46	37,451.26	TPD	annual	581	37,451.26
12.14	438.10(h), Information Requirements	581	581	1	581	78.32	78.32	45,503.92	TPD	annual	193.7	15,167.97
12.15	438.12, Provider Discrimination Prohibited	568	5,680	0.0167 (1 min)	95	30.92	.52	2,937.40	TPD	annual	95	2,937.40
12.16a	438.14(c), Contracts	463	463	1	463	78.32	78.32	36,262.16	TPD	once	154	12,087.39
12.32	438.102, Provider Enrollee Communications	3	253,332	0.01667 (1 min)	4,222	30.92	.52	130,544.24	TPD	annual	4,222	130,544.24
12.35	438.208(b)(2)(iii) Care Coordination	568	2,746,476	0.1667 (10 min)	457,838	55.26	9.21	26,195,043.96	TPD	annual	457,838	26,195,043.96
12.36	438.208(b)(3) Care Coordination	169	169	3	507	64.46	193.38	32,681.22	TPD	once	507	32,681.22
12.37	438.208(b)(3) Care Coordination	168	726,143	0.1667 (10 min)	121,024	35.86	5.95	4,339,920.64	TPD	annual	121,024	4,339,920.64
12.38	438.208(b)(4) Care Coordination	552	552	4	2,208	78.32	313.28	172,930.56	TPD	once	2,208	172,930

12.42	438.210(c)	61	61	1	61	64.46	64.46	3,932.06	TPD	once	20.3	1,310.69
12.43	438.230 Subcontracts	572	572	3	1,716	64.46	193.38	110,613.36	TPD	once	572	36,871.12
12.47	438.404 Notice of Action	240,000	240,000	0.0167 (1 min)	4,000	30.92	0.52	123,680.00	TPD	annual	4,000	123,680.00
12.48	438.408(b) Appeals	200	200	1	200	64.46	64.46	12,892.00	TPD	once	66.7	4,297.33
12.57	438.608(a)(2) - (3) Program Integrity	552	552	2	1,104	64.46	128.92	71,163.84	TPD	annual	1,104	71,163.84
12.58	438.608(a)(4) Program Integrity	200	20,000	0.0167 (1 min)	333	30.92	0.52	10,327.28	TPD	annual	333	10,327.28
	SUBTOTAL: Third-Party Disclosure	581	16,724,540	--	--	--	--	--	--	--	686,949	33,093,393.71
12.25	438.66(d)(3), State Monitoring	20	20	5	100	140.80	704.00	14,080.00	RK	annual	100	14,080.00
				30	600	64.46	1,933.80	38,676.00	RK	annual	600	38,676.00
				5	100	78.32	391.60	7,832.00	RK	annual	100	7,832.00
12.39	438.208(c)(2)-(3) Care Coordination	568	428,128	1	428,128	66.92	66.92	28,650,325.76	RK	annual	428,128	28,650,325.76
12.41	438.210(a)(4)(ii)(B) Authorization of Services	572	572	20	11,440	66.92	1,338.40	765,564.80	RK	once	3,813	255,188.27
12.44	438.242(b)(2) Health Information	41	41	20	820	78.32	1,566.40	64,222.40	RK	once	273.3	21,407.47
12.45a	438.400(b) Definitions	511	511	5	2,555	64.46	322.30	164,695.30	RK	once	851.7	54,898.43
12.49	438.416 Reporting	51	240,000	0.0167 (1 min)	4,000	36.54	0.61	146,452.32	RK	annual	4,000	146,452.32
12.50	438.416 Reporting	51	51	3	153	78.32	234.96	11,982.96	RK	once	51	3,994.32
			856,257	0.0167 (1 min)	14,299	36.54	0.61	522,503.43	RK	annual	14,299	522,503.43

12.56	438.608(a)(1) Program Integrity	552	552	2	1,104	64.46	128.92	71,163.84	RK	once	368	23,721.28
	SUBTOTAL: Recordkeeping	568	1,526,132	--	--	--	--	--	--	--	452,584	29,739,079.28
	TOTAL	**586**	**18,569,310**	--	--	--	--	--	--	--	**1,276,941**	**72,799,995.54**

13. Capital Costs (Maintenance of Capital Costs):

There are no capital costs.

14. Cost to Federal Government:

Utilizing burden estimates from this final rule, Collection of Information (COI), federal costs were derived by applying the appropriate federal medical assistance percentage (FMAP). 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 this supporting statement, the annualized cost to the federal government is $35,807,519.83.

15. Program or Burden Changes:

The May 6, 2016, final rule adds hours and decreases hours for several currently approved requirements (see below). Overall, the burden has decreased by **-425,855 hours**. The number of responses has increased by **+12,751,081**.

Please note that the final rule's total burden estimates differ from what is set out in Section 12 of this Supporting Statement. The final rule's burden establishes the impact of the rule on respondents. The impact consists of added (+) or deducted (-) hours/costs since it compares/contrasts the rule's requirements and burden against what is currently approved under this control number. Section 12, on the other hand, sets out the final total burden.

The following example demonstrates that all or portions of the rule's burden would be double counted if the rule did not restrict its estimates to added (+) or deducted (-) hours/costs.

Example If requirement A is currently approved by OMB and it has a total burden of 100 hours for doctors (30 hr) and hospitals (70 hr) and a final rule published which removed the requirement for doctors, the rule's burden would be a negative number (-30 hr) associated with removing the hours associated with doctors. Here, Section 12 burden would be 70 hr.

Further, if requirement B is currently approved by OMB and it has a total burden of 500 hours for adults and a final rule adds 250 hours for children, the rule's burden would be +250 hours (impact of the rule) whereas the burden in Section 12 would be 750 hours (the total burden).

Unlike the final rule, Section 12 of this Supporting Statement sets out the final burden estimates without regard for the added or deducted hours/costs.

With regard to changes of currently approved requirements and burden, the May 2016 final rule adjusts those estimates as follows. As indicated, when considering the the rule related provisions

and the following adjustments, overall this iteration reduces respondent burden by 425,855 hours.

Section 438.10(e)(1) clarifies that states can provide required information in paper or electronic format. Our currently approved burden estimates 5 min per mailing for 65,000 total hr. By updating the enrollment count from the current burden estimate to 2,069,259 (62,704,821 total enrollees x .033 growth rate) and reducing the time from 5 min to 1 min (to acknowledge automated mailing processes and moving to mostly electronic communications), we estimate the annual state burden for mailing as **-30,512 hr** (34,488 hr – 65,000 hr) and -$943,431.04 (-30,512 hr x $30.92/hr for a mail clerk). (See **Estimate 12.10**)

The -30,512 hr impact estimate was properly accounted for in the final rule. The revised estimate of 34,488 hr is set out above in section 12.

Section 438.10(g)(1) requires that MCOs, PIHPs, PAHPs, and PCCMs 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 2,069,259 enrollees (3.3 % percent of 62,704,821) will need to receive a handbook each year. We estimate 1 min by a mail clerk at $30.92/hr to mail the handbook or 34,557 hr (2,069,259 enrollees x 1 min). The currently approved burden estimates 5 min per mailing for 390,000 enrollees or 32,500 total hr. Updating the enrollment figure and reducing the time from 5 min to 1 min (to acknowledge current automated mailing processes and moving to mostly electronic communications), the annual private sector burden is increased by **2,057 hr** (34,557 hr - 32,500 hr) and $63,602.44 (2,057 hr x $30.92/hr). (See **Estimate 12.12**)

The final rule inadverantly estimated 34,557 hr as the inpact when it should have set out 2,057 hr. The revised estimate of 34,557 hr is set out above in section 12.

Under §438.208 "Coordination and continuity of care" §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 rather than the older mailing/faxing of paper records.

While the currently approved burden sets out 45 min per enrollee and 399,656 annual hours, to provide more accurate estimates we are adjusting the burden by using one-time per plan estimates and recognizing the use of automated reporting. In aggregate, we estimate a one-time private sector burden of **-397,448 hr** (2,208 hr - 399,656 hr) and -$31,128,127 (-397,448 hr x $78.32/hr). Once put on a production schedule, no additional staff time will be needed, thus no additional burden is estimated. (See **Estimate 12.38**)

The final rule inadverantly calculated 2,272 hr when it should have estimated 2,208 hr (552 entities x 4 hr/reponse). In this regard, the impact should have read -462,574 hr (464,782 currently approved hr – 2,208 final rule hr) instead of -462,510 hr. The revised estimate of 2,208 hr is set out above in section 12.

16. Publication and Tabulation Dates:

The information submitted to CMS will not be published. 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. The rest of the information is used by States as part of their normal contracting with MCOs PIHPs, PAHPs, PCCMs, and PCCM entities and is not be published.

17. Expiration Date:

These ICRs do not lend themselves to an expiration date, as there are no forms.

18. Certification Statement:

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods.