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 2016 Medicaid managed care final rule (81 FR 27498) (CMS-2390-F, RIN 0938-AS25) modernized the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. The 2016 final rule aligned the rules governing Medicaid managed care with those of other major sources of coverage, included coverage through Qualified Health Plans and Medicare Advantage plans; implemented statutory provisions; strengthened actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates; ensured appropriate beneficiary protections; and enhanced expectations for program integrity. This proposed rule advances CMS' efforts to streamline the Medicaid and CHIP managed care regulatory framework and reflects a broader strategy to relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care. The proposed revisions of the Medicaid and CHIP managed care regulations are intended to ensure that the regulatory framework is efficient and feasible for states to implement in a cost-effective manner and ensure that states can implement and operate Medicaid and CHIP managed care programs without undue administrative burdens.

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:

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

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

between states and plans. Because this concerns disclosure to a third party, we do not dictate how the information may be disclosed.

Section 438.242 requires that states ensure that each MCO, PIHP, and PAHP implement an openly published Application Programming Interface (API) that permits third-party applications to retrieve standardized data concerning adjudicated claims, encounters with sub-capitated providers, provider remittances and enrollee cost-sharing, provider directories, and preferred drug lists. The API will make the data available to enrollees through common technologies and without special effort from enrollees. We anticipate that the standardized framework (both the API specification and data standards) would align across Medicaid, Medicare, and the private insurance market. These requirements will allow patients to have control of their healthcare data empowering patients to make informed decisions about their healthcare. (See CMS-9115-P for more information).

4. Duplication of Similar Information:

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

5. Small Businesses:

For 2016 final rule, we estimated that some PAHPs, PCCMs, and PCCM entities were likely to be small entities. We estimated that most MCOs and PIHPs were not small entities. According to the Small Business Administration (SBA) and the Table of Small Business Size Standards, small entities include small businesses in the health care sector that are direct health and medical insurance carriers with average annual receipts of less than $38.5 million and offices of physicians or health practitioners with average annual receipts of less than $11 million. Individuals and state governments are not included in the definition of a small entity.

As of 2016, there are 337 MCOs, 130 PIHPs and or PAHPS, 21 NEMT PAHPs, 18 PCCMs, and 8 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. Previously, for the 2016 final rule, we estimated that 10 to 20 PAHPs, 8 to 15 PCCMs, and 2 to 5 PCCM entities were likely to be small entities. We still believe these estimates to be accurate. 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 on small entities, we examined the United States Census Bureau's Statistics of U.S. Businesses for 2015. According to the 2015 data, there are 3,461 direct health and medical insurance issuers with less than 20 employees and 147,862 offices of physicians or health practitioners with less than 20 employees.[1] Based on the estimates in the Collection of Information (COI), we have determined that the provisions of this proposed rule will not have a significant burden or economic impact on a substantial number of the small entities we have identified.

[1] Number of Establishments with Corresponding Employment Change by Employment Size of the Enterprise for the United States, Industries (4-digit NAICS): 2014-2015, accessed at https://www.census.gov/data/tables/2015/econ/susb/2015-susb-employment.html

We previously noted that the primary impact on small entities was through the standards placed on PAHPs, PCCMs, and PCCM entities through the following requirements established in the 2016 final rule: (1) adding PCCMs and PCCM entities, where appropriate, to the information standards in §438.10 regarding enrollee handbooks, provider directories, and formularies; (2) adding PAHPs, PCCMs, and PCCM entities in §438.62 to implement their own transition of care 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 estimated the following costs, derived from the COI section of the 2016 final rule, associated with the impacts on small entities. The costs were 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 the 2016 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 in the 2016 final rule, we have determined there will be a significant economic impact on a substantial number of small entities. In the 2015 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 finalized our analysis as proposed in the 2016 final rule.

6. Less Frequent Collection:

Many of the ICRs were mandated by the BBA. If CMS were to collect them less frequently, we would be in violation of the law. While others are not required by statute, we believe them necessary for program administration and have set them at frequencies as low as possible.

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 November 14, 2018 (83 FR 57264), proposed rule (CMS-2408-P, RIN 0938-AT40) served as the 60-day Federal Register notice.

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 Estimates:

12.1 Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for Direct Health and Medical Insurance Carriers (NAICS 524114) (https://www.bls.gov/oes/current/naics5_524114.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)
Accountant	13-2011	35.23	35.23	70.46
Actuary	15-2011	49.81	49.81	99.62
Business Operations Specialist	13-1000	34.11	34.11	68.22
Computer Programmer	15-1131	43.42	43.42	86.84
Customer Service Rep	43-4051	19.05	19.05	38.10
General and Operations Mgr	11-1021	72.51	72.51	145.02
Healthcare Social Worker	21-1022	26.07	26.07	52.14
Mail Clerk	43-9051	16.14	16.14	32.38
Office and Administrative Support Worker	43-9000	19.04	19.04	38.08
Registered Nurse	29-1141	35.57	35.57	71.14

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:

The currently approved PRA package contained one-time burden estimates that were annualized over three years. For this proposed rule, because there is one year remaining on this PRA

package, all burden estimates reflect only one year of burden and have been updated with current wage rates, enrollment totals, and managed care plan counts.

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 estimated **6 hr** at $78.32/hr for a computer programmer to make the initial changes. In aggregate, we estimated a one-time state burden of **252 hr** (42 states x 6 hr) and **$19,736.64** (252 hr x $78.32/hr). As this is a one-time burden, we estimate the remaining annualized burden of **2 hr** at $68.22/hr for a business operations specialist to amend all 514 (337 MCOs, 151 PIHPs and or PAHPS, and 26 PCCMs) contracts. In aggregate, we estimate **1,028 hr** (514 contracts x 2 hr) and **$70,130.16** (1,028 hr X $68.22). We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.1a)**

In this proposed rule, amendments to §438.3(t) would permit states to choose between requiring their MCOs, PIHPs, and PAHPs to sign a coordination of benefits agreement with Medicare, or requiring an alternative method for ensuring that each MCO, PIHP, or PAHP receives all appropriate crossover claims. We estimate it would take **1 hr** for a programmer to implement the message on the remittance advice. If 20 states elect to pursue an alternative method, we estimate an aggregate one-time state burden of $**1,736.80** (20 states x 1 hour x $86.84 for a computer programmer). **(Estimate 12.1b)**

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

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

choose between requiring their MCOs, PIHPs, and PAHPs to sign a COBA with Medicare, or requiring an alternative method for ensuring that each MCO, PIHP, or PAHP receives all appropriate crossover claims. If the state elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the state's remittance advice that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration. We estimate it would take 1 hour for a programmer to implement the message on the remittance advice. If 10 states elect to pursue an alternative method, we estimate an aggregate one-time state burden of 10 hrs (10 states X 1 hour) and $860.84 (10 hrs X $86.84 for a computer programmer). As this would be a one-time expense, we annualize this amount to 3.33 hrs and $286.95. **(Estimate 12.1c)**

Additionally, for states that elect to require an alternative method, the proposed amendments to §438.3(t) would also alleviate managed care plans in those states of the burden of obtaining a COBA. We estimate 6 states with 25 plans may elect this option and save 4 hours per plan by a Business Operations Specialist -100 hrs (25 plans x 4 hrs) and -$6,822 (100 hrs x $68.22/hr). As this would be a one-time savings, we annualize this amount to -1.33 hrs and -$2,274. **(Estimate 12.1d)**

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 $99.62/hr for an actuary and **1 hr** at $145.02/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 **$57,061.00** [50 certifications x ((10 hr x $99.62.44/hr) + (1 hr x $145.02/hr))]. **(Estimate 12.2)**

Section 438.6(c) Proposed amendments to §438.6(c) would remove the requirement for states to obtain prior approval for directed payment arrangements that utilize a state approved FFS fee schedule. To obtain prior approval, states submit a preprint (OMB control # 0938-1148 (CMS-10398 #52)) to CMS. We estimate that 20 states may elect annually to request approval for 40

directed payments that utilize a state approved FFS fee schedule. By eliminating the requirement that states submit a preprint for each arrangement, we estimate that a state could save 1 hour per directed payment arrangement for a Business Operations Specialist at $68.22/hr. We estimate an annual savings of -40 hours (20 states x 2 preprints each x 1 hour per preprint) and -$2,728.80 (40 hours x $68.22/hr). **(Estimate 12.65)**

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 estimated it takes **230 hr** to develop each certification, consisting of **100 hr** (at $99.62/hr) for an actuary, **10 hr** (at $145.02/hr) for a general and operations manager, **50 hr** (at $86.84/hr) for a computer programmer, **50 hr** (at $68.22/hr) for a business operations specialist, and **20 hr** (at $38.08/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 was an increase of **228 hr** (16,100 hr – 15,872 hr) for all 70 certifications due to new regulatory requirements, adjusted to **3.3 hr** per certification (228 hr/70 certifications). In aggregate, we estimate an annual state burden of **$20,396.40** [70 certifications x ((1.5 hr x $99.62/hr) + (0.13 hr x $145.02/hr) + (0.73 hr x $86.84/hr) + (0.73 hr x $68.22/hr) + (0.26 hr x $38.08/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(c) requires that MCOs, PIHPs, and PAHPs report to the state annually their total expenditures on all claims and non-claims related activities, premium revenue, the calculated MLR, and, if applicable, any remittance owed.

We estimated the total number of MLR reports that MCOs, PIHPs, and PAHPs were required to submit to states amount to 572 contracts. All MCOs, PIHPs, and PAHPs will need to report the information required under §438.8 regardless of their credibility status.

We estimated a one-time private sector burden of **168 hr** per report or a total of **96,096 hr** (168 hr x 572) and **$7,737,398.24** (572 x $13,526.92). As this is a one-time burden, we estimate the remaining annualized burden of **56 hr** for the initial administration activities per report. We estimate that 60 percent of the time will be completed by a computer programmer (33.67 hr x 488 contracts) for **16,341 hr**, 30 percent would be completed by a business operations specialist (16.67 hr x 488 contracts) for **8,135 hr**, and 10 percent would be completed by a general and operations manager (5.67 hr x 488 contracts) for **2,767 hr** for a total of **27,333 hrs** and

$2,375,291.20 (488 x $4,867.40 per report) for 488 MCOs, PIHPs, and PAHPs. We do not anticipate any additional burden after the previous 3-year approval 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 **27,189 hr** (488 contracts x 53 hr) $4,595.50 per report and a total of **$2,242,604** [488 contracts x $4,595.50 ((32 hr x $86.84/hr) + (16 hr x $68.22/hr) + (5 hr x $145.02 /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) requires the MCO or PIHP to recalculate its MLR for any year in which a retroactive capitation change is made. As such retroactive adjustments are not a common practice, we estimate that no more than 3 plans per year may have to recalculate their MLR do this.

Section 438.10 Information Requirements Section 438.10(c)(3) requires states to operate a website that provides the information required in §438.10(f). Since states already have websites for their Medicaid programs and most also include information about their managed care program, most states will only have to make minor revisions to their existing website.

We estimated **6 hr** at $78.32/hr for a computer programmer to make the initial changes. In aggregate, we estimated a one-time state burden of **252 hr** (42 states x 6 hr) and **$19,736.64** (252 hr x $78.32/hr). As this is a one-time burden, we estimate the remaining annualized burden of **2 hr** at $86.84/hr for a computer programmer to make the initial changes. In aggregate, we estimate **84 hr** (42 states x 2 hr) and **$7,294.56** (84 hr x $78.32/hr). We do not anticipate any additional burden after the previous 3-year approval 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 **$10,941.84** (126 hr x $86.84/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 estimated it would take **6 hr** at $64.46/hr for a business operations specialist to develop these definitions. In aggregate, we estimated a one-time state burden of **252 hr** (42 states x 6 hr) and **$16,243.92** (252 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of **2 hr** at $68.22/hr for a business operations specialist to develop these definitions. In aggregate, we estimate **84 hr** (42 states x 2 hr) and **$5,730.48** (84 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval 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 would need to take action to comply with this provision. We estimated it would take **20 hr** at $64.46/hr for a business operations specialist to create these documents. We also estimated **2**

hr per year for a business operations specialist to revise these documents, if needed. In aggregate, we estimated a one-time state burden of **400 hr** (20 states x 20 hr) and **$25,784** (400 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of **6.66 hr** at $68.22/hr for a business operations specialist to create these documents. In aggregate, we estimate a burden of **133.3 hr** (20 states x 6.66 hr) and **$9,093.73** (133.3 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.8a)**

In subsequent years, we estimate an annual burden of **40 hr** (20 states x 2 hr) and **$2,728.80** (40 hr x $68.22/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 did not estimate the burden for the rare updates that would be needed to update these taglines. We estimated it would 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 estimated a one-time state burden of **252 hr** (42 states x 6 hr) and **$16,243.92** (252 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of **.67 hr** at $68.22/hr for a business operations specialist to create the taglines and another **1.33 hr** to revise all document originals. In aggregate, we estimate **84 hr** (42 states x 2 hr) and **$5,730.48** (84 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.9)**

Proposed amendments to §438.10(d)(2) and (d)(3) would no longer require states or plans to add taglines in prevalent languages to all written materials, nor to use 18-point font size. Instead, states and plans would have the ability to include taglines only on materials critical to obtaining services and could select any font size they deem to be conspicuously visible. While we have no data indicating how many states experienced increased document length or an increase in postage costs as a result of these requirements, we believe that this proposed revision will likely reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of -$12,009,380.89 ((-$272,940.47= $.005 x 54,588,095) + (-$272,940.47= 0.005 x 54,588,095) + (-$11,463,499.95 = $.21 x 54,588,095)). These estimates are based on commonly available prices for bulk paper and toner purchases. **(Estimate 12.10c).**

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 estimated was adding two new pieces of information generated in §438.68 (network adequacy standards) and §438.330 (quality and performance indicators). We estimated **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 estimated 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. As this is a one-time burden, we estimate the remaining annualized burden of **14 hr** (42 states x .333 hr) and **$955.08** (14 hr x 64.46/hr) to update/revise

existing materials. We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.10a)**

The previously approved burden estimated 5 min per mailing for 65,000 total hr. By updating the enrollment count 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 estimated a savings in the previously approved package of -30,512 hr (**34,488 hr** – 65,000 hr) and -$943,431.04 (-30,512 hr x $30.92/hr). The currently approved burden estimates **1 min** per mailing for **34,488 hr** for 2,069,259 enrollees (62,704,821 total enrollees x .033 growth rate) at **1 min** (to acknowledge automated mailing processes), we estimate the annual state burden for mailing as $**1,116,721.44** (34,488 hr x $32.38/hr). **(Estimate 12.10b)**

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 believed that 100 entities would need to modify their handbook to comply with a new model provided by the state. We estimated that 100 entities relied 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 estimated **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 estimated a one-time private sector burden of **400 hr** (100 entities x 4 hr) and **$25,784** (400 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of **1.333 hr** at $68.22/hr for a business operations specialist to spend to update their handbook for 100 entities. In aggregate, we estimate **133.3 hr** (100 entities x 1.333 hr) and **$9,093**.73(133.3 hr X $68.22). We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.11a)**

Once revised, the handbooks need to be sent to enrollees. We estimate **20 seconds** by a mail clerk at $32.38/hr to send handbooks to 10,659,819 enrollees (17 percent of total enrollment). In aggregate, we estimate **59,695 hr** (10,659,819 enrollees x 20 secs (.0056)) and **$1,932,923.66** (59,695 hr X $32.28). We do not anticipate any additional burden after the previous 3-year approval 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 $32.38/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 **$66,399.96** (2,057 hr x $32.38/hr). We estimate the annual state burden to be **1,118,955.66** (34,557 hr X 32.38/hr). **(Estimate 12.12)**

Since all the 496 (337 MCO + 151 PIHPs or PAHPs + 8 PCCM) entities will need to keep their handbook up to date, we estimate it will take **1 hr** at $68.22/hr for a business operations specialist to update the document. While the updates are necessary when program changes occur, we estimate **1 hr** since each change may only take a few minutes to make. In aggregate, we estimate an annual private sector burden of **496 hr** (496 entities x 1 hr) and **$33,837.12** (496 hr x $68.22/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 estimated that it takes approximately **1 hr** at $78.32/hr for a computer programmer to update the existing directory. In aggregate, we estimated a one-time private sector burden of **581 hr** (581 entities x 1 hr) and **$45,503.92** (581 hr x $78.32/hr). As this is a one-time burden, we estimate the remaining annualized burden of .**33 hr** at $86.84/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 **164 hr** (496 entities x .33 hr) and **$14,241.76**(496 hr x $86.84/hr). We do not anticipate any additional burden after the previous 3-year approval 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 min** to draft and furnish such notice. We estimate that on average each 488 MCOs, PIHPs, and PAHPs will need to produce 10 notices per year. In aggregate, we estimate an annual private sector burden of **81 hr** (488 entities x 10 notices x 1 min) at a cost of **$ 2,622.78** (81 hr x $32.38/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 estimated it would take **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 estimated that approximately 25 of the 31 states will need to use this type of arrangement. In aggregate, we estimated a one-time private sector burden of **463 hr** (463 entities x 1 hr) and **$36,262.16** (463 hr x $78.32/hr). As this is a one-time burden, we estimate the remaining annualized burden of **.333 hr** at $86.84/hr for a private sector computer programmer to create the claims report we estimate **154 hr** (463 x .333) and (**$13,373.36)** (154 hr x $86.84). We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.16a)**

We also estimate an annual state burden of **300 hr** (25 states x 12 hr) and **$20,466.60** (300 hr x $68.22/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 estimated 5 states and **8 hr** at $64.46/hr a business operations specialist to develop the process for involving the public. In aggregate we estimated a one-time state burden of **40 hr** (5 states x 8 hr) and **$2,578.40** (40 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of **2.66 hr** at $68.22/hr for a business operations specialist to develop the process for involving the public. In aggregate, we estimate **13.3 hr (**5 states x 2.66 hr) and **$907.33** (13.3 hr X $68.22). We do not anticipate any additional burden after the previous 3-year approval expires. **(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 $32.38/hr. In aggregate, we estimate an annual state burden of **13,997 hours** (839,797 enrollees x 1 min) and **$453,222.86** (13,997 hr x $32.38/hr). **(Estimate 12.18)**

Section 438.56 Disenrollment: requirements and limitations Under paragraph (f), a State that restricts disenrollment under this section must provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period. This information should be included in the notice of annual redetermination required under § 445.912, thus no additional burden is estimated here.

Section 438.62 Continued services to enrollees 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 estimated it would take 42 states **5 hr** 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 estimated a one-time state burden of **378 hr** (42 states x 9 hr) and **$26,694.36** (210 hr (42 x 5) x $64.46/hr + 168 hr (42 x 4) x $78.32/hr). As this is a one-time burden, we estimate the remaining annualized burden of **1.67 hr** at $68.22/hr for a state business operations specialist to revise their policies and procedures and **1.33 hr** at $86.84/hr for a computer programmer to create a program to compile and send the data. In aggregate, we estimate **126 hr** (42 states x 3 hr) and **$9,638.44** [(70 hr X $68.22) + (56 hr X $86.84)]. We do not anticipate any additional burden after the previous 3-year approval 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 estimated **1 hr** at $64.46/hr for a business operations specialist. To develop computer programs to receive and store FFS data, we estimated **4 hr** at $78.32/hr for a computer programmer. In aggregate, we estimated 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)]]. As this is a one-time burden, we estimate the remaining annualized burden for 493 (337 MCOs + 130 PIHPs and or PAHPS + and 26 PCCMs) entities to revise their existing policies at **.33 hr** at $68.22/hr for a business operations specialist. To develop computer programs to receive and store FFS data, we estimate **1.33 hr** at $86.84/hr for a computer programmer. We did not estimate additional burden for the routine running of these reports since they will likely be put into a production schedule. In aggregate, we estimate **819 hr** (493 entities x 1.66 hr) and **$68,086.90** [(163 hr x

$68.22/hr) + (656 hr x $86.84/hr)]]. We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.20)**

For transitions, we estimate **10 min** (per request) at $71.14/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 **$3,720,195.16** (52,294 hr x $71.14/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. In aggregate, we estimated a one-time state burden of **336 hr** (42 states x 8 hr) and **$21,658.56** (336 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of **2.66 hr** at $68.82/hr for a business operations specialist to expand or revise existing policies and procedures. In aggregate, we estimate **112 hr** (42 states x 2.66 hr) and **$7,640.64** (112 hr x $68.22). We do not anticipate any additional burden after the previous 3-year approval 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 would likely require some revisions to existing policies and procedures. We estimated 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 estimated **840 hr** (42 states x 20 hr) and **$54,146.40** (840 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of **6.66 hr** at $68.22/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 **280 hr** (42 states x 6.66 hr) and **$19,101.60** (280 hr x $68.22). We do not anticipate any additional burden after the previous 3-year approval 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 $145.02/hr) for a general and operations manager, **30 hr** (at $68.22/hr) for a business operations specialist, and **5 hr** (at $86.84/hr) for a computer programmer. The time and staff types are estimated for a new program or new entity review and may vary downward when the review is triggered by one of the other events listed in paragraph (d)(1). Given the varying likelihood of the 3 events listed in paragraph (d)(1), we will use an average estimate of 20 states per year having one of the triggering events. In aggregate, we estimate an annual state burden of **800 hr** (20 states x 40 hr) and **$64,118** [20 states x ((5 x $145.02/hr) +(30 x $68.22/hr) + (5 x $86.84/hr))]. **(Estimate 12.24)**

For MCO, PIHP, PAHP, or PCCM preparation and execution, we estimate **5 hr** (at $145.02/hr) for a general and operations manager, **30 hr** (at $68.22/hr) for a business operations specialist, and **5 hr** (at $86.84/hr) for a computer programmer. In aggregate, we estimate an annual private sector burden of **800 hr** (20 entities x 40 hr) and **$64,118** [20 entities x ((5 x $145.02/hr) + (30 x $68.22/hr) + (5 x $86.84/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 $68.22/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 **$17,191.44** (252 hr x $68.22/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 estimated states would 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 believed that 20 would 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 would occur only periodically as needs dictate; therefore, we did 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 estimated a one-time state burden of **10 hr** at $64.46/hr for a business operations specialist. In aggregate, we estimated **200 hr** (20 states x 10 hr) and **$12,892** (200 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of **3.33 hr** at $68.22/hr for a business operations specialist. In aggregate, we estimate **66.6 hr** (20 states x 3.33 hr) and **$4,543.45** (66.6 hr X $68.22). We do not anticipate any additional burden after the previous 3-year approval expires.

Proposed amendments to §438.68(a) would eliminate a requirement that states develop time and distance standards for provider types set forth in §438.68(b)(1) and for LTSS providers if covered in the MCO, PIHP, or PAHP contract; the proposal would replace the requirement to adopt time and distance standards with a requirement to adopt a quantitative standard to evaluate network adequacy Since time and distance is a quantitative network adequacy standard, for states that used time and distance prior to the 2016 final rule or for those that have adopted time and distance in order to comply with the 2016 final rule, discontinuing the use of time and distance is merely an option that they may elect. We believe the proposed change increases flexibility for states without affecting burden on states. **(Estimate 12.27)**

To develop LTSS standards, we estimated a one-time state burden of **10 hr** at $64.46/hr for a business operations specialist to develop those standards. In aggregate, we estimated **160 hr** (16 states with MLTSS programs x 10 hr) and **$10,313.60** (160 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of 3.33 **hr** at $68.22/hr for a business operations specialist to develop those standards. In aggregate, we estimate **53.3 hr** (16 states with MLTSS programs x 3.33 hr) and **$3,636.13.76** (53.3 hr X $68.22). We do not anticipate any additional burden after the previous 3-year approval 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 estimated 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 estimated a one-time aggregate state burden of **120 hr** (40 states x 3 hr) and **$7,735.20** (120 hr x $64.46). As this is a one-time burden, we estimate the remaining annualized burden of **1 hr** at $68.22/hr for a business operations specialist to design an exceptions process. With a total of 40 states contracting with at least one MCO, PIHP or PAHP, we estimate **40 hr** (40 states x 1 hr) and **$2,728.80** (40 hr X $68.22). We do not anticipate any additional burden after the previous 3-year approval 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 estimated 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 $68.22/hr for a business operations specialist to perform this task. In aggregate, we estimate **56 hr** (14 states x 4 hr) and **$3,820.32** (152 hr x $68.22/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 would 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 estimated only 20 states may need to take action to address this requirement.

We estimated a state would 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 estimated **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 believed this burden represented a reasonable number of hours regardless of whether a state elects procurement or use of existing staff. As this is a one-time burden, we estimate the remaining annualized burden of 50 **hr** to either procure a vendor for this function or add staff or train staff in an existing internal call center consisting of **41.66 hr** (at $68.82/hr) for a business operations specialist, and **8.34 hr** (at $145.02/hr) for a general and operations manager. In aggregate, we estimate **1,000 hr** (20 states x 50 hr) and **$81,066.07** [(833 hr x $68.22) + (167 hr x $145.02)]. We do not anticipate any additional burden after the previous 3-year approval 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.

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 **$136,708.36** (4,222 hr x $32.28/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 $68.22/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 **$5,730.48** (84hr x $68.22/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 estimated 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 estimated **552 hr** (552 entities x 1 hr) and **$35,581.92** (552 hr x $64.46/hr) for policy revision.

As this is a one-time burden, we estimate the remaining annualized burden of **.33 hr** at $68.22/hr for a business operations specialist to revise the policy for 467 entities (337 MCOs + 107 PIHPs + 23 PAPHs) to be **154 hr** and **$10,505.88** (154 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval 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 **934 hr** (467 entities x 2 hr) (337 MCOs and 130 PIHPs or PAHPs) and **$63,717.48** (9344 hr x $68.22/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 (2,731,359 of 54,627,180 MCO, PIHP, and PAHP enrollees) will be affected. We estimate an ongoing private sector burden of 10 min (per enrollee) at $52.14/hr for a healthcare social worker to perform the care coordination activities. In aggregate, we estimate **457,318 hr** (2,731,359 enrollees x 10 min) and **$ 23,844,560** (457,318 hr x $52.14/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 needing to add this assessment to their initial enrollment functions. We still believe that only 25 percent of the MCOs and PIHPs (84 MCOs + 27 PIHPs) will need to continue to alter their processes. As this is a one-time burden, we estimate the remaining annualized burden of **1 hr** at $68.22/hr for a business operations specialist to revise their policies and procedures. In

aggregate, we estimate **132 hr** (132 entities x 1 hr) and **$9,005.04** (132 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.36)**

We estimate that in a given year, only 5 percent (1,352,486) of 25 percent of MCO and PIHP (13,656,795) and all (13,392,943 non-NEMT) PAHP enrollees are new to a managed care plan. We estimate an annual private sector burden of 10 min (on average) at $38.10/hr for a customer service representative to complete the screening. In aggregate, we estimate **225,459 hr** (1,352,486enrollees x 10 min) and $ 8,589,987 (225,459hr x $38.10/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 previously estimated a one-time burden of **4 hr** at $78.32/hr for a computer programmer to develop the report. In aggregate, we estimated **2,208 hr** (552 entities x 4 hr) and $172,930.56 (2,208 hr x $78.32/hr). As this was a one-time burden, we estimate the remaining annualized burden for 467 entities ((337 MCOs + 130 PIHPs and or PAHPs) of **1.33 hr** at $78.32/hr for a computer programmer to develop the report. In aggregate, we estimate **621 hr** (467 entities x 1.33 hr) and **$53,927.64** (621 hr x $86.84/hr). However, while the previously approved burden set out 45 min per enrollee and 399,656 annual hours, to provide more accurate estimates we adjusted the burden by using one-time per plan estimates and recognizing the use of automated reporting. In aggregate, we estimated 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. As this was a one-time burden that resulted in a savings, we estimate the remining annualized burden of **-132,483 hr** and **-$11,504,823.72** (-132,483 x 86.84). We do not anticipate any additional burden after the previous 3-year approval expires. **(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; the 2016 final rule added “enrollees who require LTSS” to this section. These assessments and treatment plans should be performed by providers or MCO, PIHP or PAHP staff that meet the qualifications required by the state. We believe the burden associated with this requirement is the time it takes to gather the information during the assessment. (Treatment plans are generally developed while the assessment occurs, so we are not estimating any additional time beyond the time of the assessment). 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 54,627,180 in MCOs and PIHPs (54,627,180 x .01=546,272) 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 $71.14/hr for a registered nurse to complete the assessment and treatment planning. In aggregate, we estimate an additional **546,272 hr** (546,272 enrollees x 1 hr) and **$38,861790** (546,272 hr x $71.14/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 estimated 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 estimated **552 hr** (552 entities x 1 hr) and **$35,581.92** (552 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden for 467 (337 MCOs + 130 PIHPs and or PAHPs) entities, of .33 hr at $68.22/hr for a business operations specialist to revise policies and procedures to reflect a compliant time frame. In aggregate, we estimate **154.11 hr** (467 entities x .33 hr) and **$ 10,513.38** (162 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.40)**

Section 438.210 Coverage and authorization of services 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 estimated 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 estimated **11,440 hr** (572 entities x 20 hr) and $765,564.80 (11,440 x $66.92/hr). As this is a one-time burden, we estimate the remaining annualized burden for 513 (343 MCOs + 149 PIHPs and PAHPs + 21 NEMT PAHPs) entities, of **6.67 hr** at $71.14/hr for a registered nurse to review and revise, if necessary, authorization policies and procedures. In aggregate, we estimate **3,422 hr** (513 entities x 6.67 hr) and **$243,441.08** (3,3,422 x $71.14/hr). We do not anticipate any additional burden after the previous 3-year approval 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 the 2016 final rule, PAHPs were 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 estimated 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 estimated **61 hr** (61 PAHPs x 1 hr) and **$3,932.06** (61 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of .333 hr at $68.22/hr for a business operations specialist to revise the template. In aggregate, we estimate **15 hr** (44 PAHPs x .333

hr) and **$1,023.30** (15 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval 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 estimated 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 estimated **1,716 hr** (572 entities x 3 hr) and **$110,613.36** (1,716 x $64.46/hr). As this is one-time burden, we estimate the remaining annualized burden for 488 (337 MCOs + 130 PIHPs and PAHPs + 21 NEMT PAHPs) entities of **1 hr** at $68.22/hr for a business operations analyst to amend appropriate contracts. In aggregate, we estimate **513 hr** (488 entities x 1 hr) and **$33, 291.36** (488 x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval 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. The 2016 final rule added PAHPs to the requirement. We estimated 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 estimated **820 hr** (41 entities x 20 hr) and **$64,222.40** (820 hr x $78.32/hr). As this is a one-time burden, we estimate the remaining annualized burden of **154 hr** (23 entities x 6.67 hr) and **$ 13,286.52** (154 hr x $86.84/hr). After creation, these reports would be set to run and sent to the state at on a production schedule. We do not anticipate any additional burden after the previous 3-year approval 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) entities, we estimated 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 estimated **2,555 hr** (511 entities x 5 hr) and **$164,695.30** (2,555 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining

annualized burden for 444 (337 MCOs + 107 PIHPs) entities of **1.67 hr** at $68.22/hr for a business operations specialist to amend all associated documents to the new nomenclature and definitions. In aggregate, we estimate **741 hr** (444 entities x 1.67 hr) and **$50,551.02** (741 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.45a)**

We also estimated 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. As this is a one-time burden, we estimate the remaining annualized burden of **66.7 hr** (40 states x 1.67 hr) and **$4,550.27** (66.7 hr x $68.22/hr) to make similar revisions. We do not anticipate any additional burden after the previous 3-year approval expires.

Proposed amendments to §438.400(b) would revise the definition of an "adverse benefit determination" to exclude claims that do not meet the definition of "clean claim" at §447.45(b), thus eliminating the requirement for the plan to send an adverse benefit notice. While we have no data on the number of adverse benefit notices are sent due to denials of unclean claims, we believe that at least one unclean claim may be generated for half of all enrollees; thus, this proposal could reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of -$10,644,678.32 ((-$136,470.23= $.005 x 27,294,047) + (-$136,470.23 = 0.005 x 27,294,047) + (-$10,371,737.86 = $.38 x 27,294,047)). These estimates are based on commonly available prices for bulk paper and toner purchases and bulk postage rates. **(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 estimated 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 estimated 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))]. As this is a one-time burden, we estimate the remaining annualized burden to set up a grievance system of **33.33 hr, 3.33 hr** at $145.02/hr for a general and operations manager, **25 hr** at $68.22/hr for a business operations specialist, and **5 hr** at $86.84/hr for a computer programmer) for each PAHP. In aggregate, we estimate **767 hr** (23 PAHPs x 33.33 hr) and **$60,379.64** [(77 hr x $145.02/hr) + (575 hr x $68.22/hr) + (115 hr x $86.84/hr))]. We do not anticipate any additional burden after the previous 3-year approval 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 $68.22/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 **8,280 hr** (23 PAHPs x 10 grievances x 3 hr x 12 months) and **$564,861.60** (8,280 hr x $68.22/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 finalized this section with no estimated cost savings.

Section 402(c) Proposed amendments to §§438.402(c)(3)(ii) and 438.406(b)(3) would no longer require enrollees to follow up an oral appeal with a written appeal. This change would alleviate the burden on plans to follow up with enrollees that do not submit the written appeal. We estimate that plans may have an Office and Administrative Support Worker spend up to **2 hrs** per appeal calling or sending letters to enrollees in an effort to receive the written appeal. We estimate that 300 plans in 20 states have an average of 200 oral appeals that are not followed up with a written appeal. We estimate an aggregate annual private sector burden reduction of -120,000 hours (300 plans X 200 appeals X 2 hrs) and **-$4,569,600** (- 120,000 hrs x $38.08/hour). **(Estimate 12.46c)**

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 $32.38/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 **$129,520.00** (4,000 hr x $32.38/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 estimated a one-time private sector burden of **1 hr** at $64.46/hr for a business operations specialist. In aggregate, we estimated **200 hr** (200 entities x 1 hr) and **$12,892** (200 hr x $64.46). As this is a one-time burden, we estimate the remaining annualized burden of **.33 hr** at $68.22/hr for a business operations specialist. In aggregate, we estimate **66.7 hr** (200 entities x .33 hr) and **$4,550.27** (66.7 hr x $68.22). We do not anticipate any additional burden after the previous 3-year approval 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 $38.08/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 **$152,320.00** (4,000 hr x $38.08/hr). **(Estimate 12.49)**

Maintaining records for grievances and appeals has always been required for MCOs and PIHPs. However, the 2016 final rule required specific data so we estimated that 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 estimated **3 hr** at $78.32 for a computer programmer to make necessary changes. We estimated 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)**.** As this is a one-time burden, we estimate the remaining annualized burden for 10 percent [337 MCOs + 107 PIHPs] of organizations to revise their policies and systems to record the required information of 1 **hr** at $86.84 for a computer programmer to make necessary changes. In aggregate, we estimate **44 hr** (44 MCOs and PIHPs x 1 hr) and **$3,820.96** (44 hr x $86.84/hr). We do not anticipate any additional burden after the previous 3-year approval expires.

As the required elements will be stored and tracked electronically, we estimate **1 min** per grievance and appeal at $38.08/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 **$544,505.92** (14,299 hr x $38.08/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 estimated 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 estimated **2,044 hr** (511 entities x 4 hr) and $131,756.24 (2,044 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden for 444 (337 MCOs + 107 PIHPs) entities of **1.33 hr** at $68.22/hr for a business operations specialist to revise current policies and procedures. In aggregate, we estimate **591 hr** (444entities x 1.33 hr) and **$40,318.02** (591hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval expires. **(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 estimated 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 estimated **252 hr** (42 states x 6 hr) and **$16,243.92** (252 hr x $64.46/hr). As this is a one-time burden, we estimate the remaining annualized burden of **2 hr** at $68.22/hr for a business operations specialist to create and/or revise their policies. In aggregate, we estimate **84 hr** (42 states x 2 hr) and $**5,730.48** (84 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval 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 estimated 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 estimated **3,432 hr** (572 entities x 6 hr) and **$268,794.24** (3,432 hr x $78.32/hr). As this is a one-time burden, we estimate the remaining annualized burden for 488 (337 MCOs + 130 PIHPs and or PAHPs + 21 NEMT PAHPs) entities of **2 hr** at $86.84/hr for a computer programmer to create the necessary programs to send provider applications/data to the state. In aggregate, we estimate **976 hr** (488 entities x 2 hr) and **$ 84,755.84** (1,026 hr x $86.84/hr). We do not anticipate any additional burden after the previous 3-year approval expires. **(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 $70.46/hr for an accountant. In aggregate, we estimate **3,420 hr** (343 MCOs + 170PIHPs or PAHPs x 20 hr)/3) and **$240,973.20**(3,420 hr x $70.46/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 $86.84/hr

for a computer programmer to post the documents. In aggregate, we estimate **40 hr** (40 states x 1 hr) and **$3,473.60** (40 hr x $86.84/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 expected 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 estimated 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 estimated **1,104 hr** (552 entities x 2 hr) and **$71,163.84** (1,104 hr x $64.46/hr). As this is a one-time burden we estimate the remaining annualized burden for 488 (337 MCOs + 130 PIHPs and or PAHPs + 21 NEMT PAHPs) entities to review their policies and procedures to ensure that all of the above listed items are addressed. We estimate a burden of **.67 hr** at $68.22/hr for a business operations specialist to review and (if necessary) revise their policies and procedures. In aggregate, we estimate **327 hr** (488 entities x .67 hr) and **$ 23,307.94** (327 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval 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 $68.22/hr for a business operations specialist. In aggregate, we estimate **1,104 hr** (552 entities x 2 hr) and **$75,314.88** (1,104 hr x $68.22/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 $32.38/hr for a mail clerk to send each letter. In aggregate, we estimate **333 hr** (20,000 letters x 1 min/letter) and **$10,782.54** (333 hr x $32.38/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 estimated 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 estimated **552 hr** (552 entities x 1 hr) and **$43,232.64** (552 hr x $78.32/hr). As this is one-time burden, we estimate the remaining annualized burden for 467 (337 MCOs + 130 PIHPs and or PAHPs) entities of .**33 hr** at $86.84/hr for a computer programmer to create the report. In aggregate, we estimate **154 hr** (467entities x .33 hr) and **$13,373.36** (154hr x $86.84/hr). We do not anticipate any additional burden after the previous 3-year approval expires. **(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 $68.22/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 **$818.64** (12 hr x $68.22/hr). **(Estimate 12.60)**

To send the notice, we estimate **1 min** (per beneficiary) at $32.38/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 **$585,300.88** (18,076 hr x $32.38/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 estimated **1 hr** at $64.46/hr for a business operations specialist. In aggregate, we estimated a one-time state burden of **9 hr** (9 states x 1 hr) and

$580.14 (9 hr x $64.46/hr). As this is a one-time burden, we estimate a remaining annualized burden of 3 **hr** (9 states x .33 hr) and **$204.66** (3 hr x $68.22/hr). We do not anticipate any additional burden after the previous 3-year approval expires. **(Estimate 12.62)**

A state electing to perform validation internally needs to develop processes and policies to support implementation. In that case, we estimated **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 estimated 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))]. As this is a one-time burden, we estimate the remaining annualized burden of **3.33 hr** at $68.22/hr for a business operations specialist to develop policy and **33.33 hr** at $86.84/hr for a computer programmer to develop, test, and automate the validation processes. In aggregate, we estimate **330 hr** (9 states x 36.66 hr) and **$28,098.60** [9 states x ((3.33 hr x $68.22/hr) + (33.33 hr x $86.84/hr. We do not anticipate any additional burden after the previous 3-year approval expires. **(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 $68.22/hr for a business operations specialist to participate in the writing, evaluating, and implementing, and **25 hr** at $145.02/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 **$109,377.00** [9 states x ((125 hr x $68.22/hr) + (25 hr x $145.02/hr))]. **(Estimate 12.64)**

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

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
12.1a	438.3, Contracts	42	514	2	1,028	68.22	136.44	70,130.16	R	Once
12.2	438.5, Rate Standards	39	50	11	550	99.62	1095.82	54,791.00	R	Annual
				1	50	145.02	145.02	7,251.00	R	Annual
12.3	438.7, Rate Certifications	39	70	100	7,000	99.62	9,962.00	697,340.00	R	Annual
				10	700	145.02	1,450.20	101,514.00	R	Annual
				50	3,500	86.84	4,342.00	303,940.00	R	Annual
				50	3,500	68.22	3,411.00	238,770.00	R	Annual
				20	1,400	38.08	761.60	53,312.00	R	Annual
12.17	438.50, State Plan requirements	5	5	2.66	13.3	68.22	181.47	907.33	R	Once
12.19	438.62(b)(1), Transition of Care	42	42	1.67	70	68.22	113.70	4,775.40	R	Once
				1.33	56	86.84	115.79	4,863.04	R	Once
12.22	438.66(a) and (b), State Monitoring	42	42	2.66	112	68.22	181.92	7,640.64	R	Once
12.27	438.68(a) - (c), Network Adequacy	20	20	3.33	66.6	68.22	227.17	4,543.45	R	Once
12.28	438.68(a) - (c), Network Adequacy	16	16	3.33	53.3	68.22	227.26	3,636.13	R	Once
12.29	438.68(d), Network Adequacy	40	40	1	40	68.22	68.22	2,728.80	R	Once
12.30	438.70, MLTSS Engagement	14	14	4	56	68.22	272.88	3,820.32	R	Annual

Estimate #	CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Response Type	Frequency
12.52	438.602(a), Program Integrity	42	42	2	84	68.22	136.44	5,730.48	R	Once
12.54	438.602(e), Program Integrity	42	512	6.43	3,420	70.46	470.65	240,973.20	R	Annual
12.55	438.602(g) Program Integrity	40	40	1	40	86.84	86.84	3,473.60	R	Annual
12.63	438.818(a)(2), Encounter Data	9	9	3.33	30	68.22	227.17	2,046.60	R	Once
				33.33	300	86.84	2,894.38	26,052.00	R	Once
12.64	438.818(a)(2), Encounter Data	9	9	125	1,125	68.22	8,527.50	76,747.50	R	Annual
				25	225	145.02	3,625.50	32,629.50	R	Annual
	SUBTOTAL: Reporting	*42*	*1,425*	--	*23,419*	--	--	*1,947,616.15*	--	--
12.1c	§438.3(t) Contracts	10	10	1	10	$86.84	$86.84	$860.84	TPD	Once
12.6a	438.10(c)(3), Information Requirements	42	42	2	84	86.84	173.68	7,294.56	TPD	once
12.6b				3	126	86.84	260.52	10,941.84	TPD	Annual
12.7	438.10(c)(4)(i), Information Requirements	42	42	2	84	68.22	136.44	5,730.48	TPD	Once
12.8	438.10(c)(4)(ii), Information Requirements	20	20	6.66	133.3	68.22	454.69	9,093.73	TPD	Once
				2	40	68.22	136.44	2,728.80	TPD	Annual
12.9	438.10(d)(2)(i), Information Requirements	42	42	2	84	68.22	136.44	5,730.48	TPD	Once
12.10a	438.10(e)(1), Information	42	42	0.33	14	68.22	22.74	955.08	TPD	Once

Estimate #	CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Response Type	Frequency
	Requirements									
12.10b	438.10(e)(1), Information Requirements	42	2,069,259	0.0167 (1 min)	34,488	32.38	0.54	1,116,721.44	TPD	Annual
12.16b	438.14(c), Contracts	25	25	12	300	68.22	818.66	20,466.60	TPD	Annual
12.18	438.54(c)(8), Enrollment	42	839,797	0.0167 (1 min)	13,997	32.38	0.54	453,222.86	TPD	Annual
12.31	438.71(a), Beneficiary Support System	20	20	41.66	833.3	68.22	2,842.39	56,847.73	TPD	Once
				8.33	167	145.02	1,210.92	24,218.34	TPD	Once
12.60	438.722, Disenrollment Notices	12	12	1	12	68.22	68.22	818.64	TPD	Annual
12.61	438.722 Disenrollment Notices	12	1,084,536	0.0167 (1 min)	18,076	32.38	0.54	585,300.88	TPD	Annual
12.62	438.818(a)(2), Encounter Data	9	9	0.33	3	68.22	22.74	204.66	TPD	Once
	SUBTOTAL: Third-Party Disclosure	*42*	*3,993,856*	--	*68,451.60*	--	--	*2,301,136.36*	--	--
12.23	438.66(c), State Monitoring	42	42	6.66	280	68.22	454.80	19,101.60	RK	Once
12.24	438.66(d)(3), State Monitoring	20	20	5	100	145.02	725.10	14,502.00	RK	Annual
				30	600	68.22	2,046.60	40,932.00	RK	Annual
				5	100	86.84	434.20	8,684.00	RK	Annual

Estimate #	CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Response Type	Frequency
12.26	438.66(e)(1) and (2), State Monitoring	42	42	6	252	68.22	409.32	17,191.44	RK	Annual
12.45b	438.400(b), Definitions	40	40	1.66	66.7	68.22	113.76	4,550.27	RK	Once
	SUBTOTAL: Recordkeeping	*42*	*144*	--	*1,398.70*	--	--	*104,961*	--	--
	TOTAL	42	3,995,472	Varies	93,269.5	Varies	Varies	4,353,714	--	--

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
12.4	438.8(c), MLR	488	488	33.67	16,341	86.84	2,907.89	1,419,052.44	R	Once
				16.67	8,135	68.22	1,137.23	554,969.70	R	Once
				5.67	2,767	145.02	822.28	401,270.34	R	Once
12.5	438.8(c), MLR	488	488	32	15,616	86.84	2,778.88	1,356,093.44	R	Annual
				16	7,808	68.22	1,091.52	532,661.76	R	Annual
				5	2,440	145.02	725.10	353,848.80	R	Annual
12.20	438.62(b)(2), Transition of Care	493	493	0.33	163	68.22	22.56	11,119.86	R	Once
				1.33	656	86.44	115.55	56,967.04	R	Once
12.21	438.62(b)(2), Transition of Care	568	313,704	0.1667 (10 min)	52,294	71.14	11.85	3,720,195.16	R	Annual
12.33	438.110(a),	14	14	6	84	68.22	409.32	5,730.48	R	Annual

Estimate	CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Response Type	Frequency
	Member Advisory Committee									
12.34	438.207(b) - (d), Adequate Capacity	467	467	0.33	154	68.22	22.50	10,505.88	R	Once
12.34	438.207(b) - (d), Adequate Capacity	512	512	2	1,026	68.22	136.71	69,993.72	R	Annual
12.40	438.208(c)(3)(v) Care Coordination	492	492	0.33	162	68.22	22.46	11,051.64	R	Once
12.46a	438.402(a) Grievance System	23	23	3.33	77	145.02	485.50	11,166.54	R	Once
				25	575	68.22	1,705.50	39,226.50	R	Once
				5	115	86.84	434.20	9,986.60	R	Once
12.46b	46b 438.402(a) Grievance System	23	230	36	8,280	68.22	2,455.92	564,861.60	R	Annual
12.51	438.420(c)(4) Continuation of Benefits	444	444	1.33	591	68.22	90.81	40,318.02	R	Once
12.53	438.602(b) Program Integrity	488	488	2	976	86.84	173.72	84,755.84	R	Once
12.59	438.608(c) - (d) Program Integrity	467	467	.033	154	86.84	28.64	13,373.36	R	Once
	SUBTOTAL: Reporting	*568*	*318,310*	Varies	*118,414*	Varies	Varies	*9,267,149*	--	--
12.11	438.10(g), Information	100	100	1.33	133.3	68.22	90.93	9,093.73	TPD	Once

Estimate	CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Response Type	Frequency
		100	10,659,819	0.0056 (20 sec)	59,695	32.38	0.18	1,932,923.66	TPD	Once
12.12	438.10(g), Information Requirements	100	2,069,259	0.0167 (1 min)	34,557	32.38	0.54	1,118,955.66	TPD	Annual
12.13	438.10(g), Information Requirements	496	496	1	496	68.22	68.22	33,837.12	TPD	Annual
12.14	438.10(h), Information Requirements	496	496	.33	164	86.84	28.71	14,241.76	TPD	Annual
12.15	438.12, Provider Discrimination Prohibited	488	488	0.0167 (1 min)	81	32.38	0.54	2,622.78	TPD	Annual
12.16a	438.14(c), Contracts	463	463	0.33	154	86.84	28.88	13,373.36	TPD	Once
12.32	438.102, Provider Enrollee Communications	3	253,332	0.01667 (1 min)	4,222	32.38	0.54	136,708.36	TPD	Annual
12.35	438.208(b)(2)(iii) Care Coordination	568	2,731,359	0.1667 (10 min)	457,318	52.14	8.69	23,844,560.52	TPD	Annual
12.36	438.208(b)(3) Care Coordination	169	169	1	169	68.22	68.22	11,529.18	TPD	Once
12.37	438.208(b)(3) Care Coordination	168	1,352,486	0.1667 (10 min)	225,459	38.10	6.35	8,589,987.90	TPD	Annual
12.38	438.208(b)(4)	467	467	1.33	621	86.84	115.48	53,927.66	TPD	Once

Estimate	CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Response Type	Frequency
	Care Coordination									
12.42	438.210(c)	44	44	0.33	15	68.22	23.26	1,023.30	TPD	Once
12.43	438.230 Subcontracts	488	488	1	488	68.22	68.22	33,291.36	TPD	Once
12.47	438.404 Notice of Action	240,000	240,000	0.0167 (1 min)	4,000	32.38	0.54	129,520.00	TPD	Annual
12.48	438.408(b) Appeals	200	200	0.33	66.7	68.22	22.75	4,550.27	TPD	Once
12.57	438.608(a)(2) - (3) Program Integrity	552	552	2	1,104	68.22	136.44	75,314.88	TPD	Annual
12.58	438.608(a)(4) Program Integrity	200	20,000	0.0167 (1 min)	333	32.38	0.54	10,782.54	TPD	Annual
	SUBTOTAL: Third-Party Disclosure	568	17,330,218	Varies	789,076	Varies	Varies	36,016,244	--	--
12.25	438.66(d)(3), State Monitoring	20	20	5	100	145.02	725.10	14,502.00	RK	Annual
				30	600	68.22	2,046.65	40,932.00	RK	Annual
				5	100	86.84	432.20	8,684.00	RK	Annual
12.39	438.208(c)(2)-(3) Care Coordination	568	546,272	1	546,272	71.14	71.14	38,861,790.08	RK	Annual
12.41	438.210(a)(4)(ii)(B)	513	513	6.67	3,422	71.14	474.54	243,441.08	RK	Once

Estimate	CFR Section	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Cost ($) per Response	Total cost ($)	Response Type	Frequency
	Authorization of Services									
12.44	438.242(b)(2) Health Information	23	23	6.67	153	86.84	577.67	13,286.52	RK	Once
12.45b	§438.400(b) Definitions	444	444	1.67	741	68.22	113.85	50,551.02	RK	Once
12.49	438.416 Reporting	51	240,000	0.0167 (1 min)	4,000	38.08	0.63	152,320.00	RK	Annual
12.50	438.416 Reporting	44	44	1	44	86.84	86.84	3,820.96	RK	Once
		44	856,257	0.0167 (1 min)	14,299	38.08	0.63	544,505.92	RK	Annual
12.56	438.608(a)(1) Program Integrity	488	488	0.67	327	68.22	45.71	22,307.94	RK	Once
	SUBTOTAL: Recordkeeping	568	1,644,061	Varies	570,058	Varies	Varies	39,956,142	--	--
	TOTAL	568	19,292,589	Varies	**1,477,548**	Varies	Varies	**85,239,534.28**	--	--

Summary of Annual Burden Estimates: Total

Respondent Type	# Respondents	# responses	Burden per response (hours)	Total Annual Hours	Labor Rate ($/hr)	Total cost ($)
State Government	42	3,995,472	Varies	93,270	Varies	4,353,714.42
Private Sector	568	19,292,589	Varies	1,477,548	Varies	85,239,534.28
TOTAL	**610**	**23,288,061**	**Varies**	**1,570,818**	**Varies**	**89,593,250**

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 $49,813,989.09

15. Program or Burden Changes*:*

This proposed rule adds/decreases the number of responses and hours for several of our currently approved requirements (see below). Overall, the burden has increased by 723,184 responses and 198,849 hours. For States, we estimate a decrease of 95 responses and 1,757 hours. For the private sector we estimate an increase of 723,184 responses and 198,849 hours.

Section 438.3(t), permits states to choose between requiring their MCOs, PIHPs, and PAHPs to sign a coordination of benefits agreement with Medicare, or requiring an alternative method for ensuring that each MCO, PIHP, or PAHP receives all appropriate crossover claims. To comply with these requirements, we estimate it would take 1 hour for a programmer to implement the message on the remittance advice. If 20 states elect to pursue an alternative method, we estimate an aggregate one-time state burden of $1,736.80 (20 states x 1 hour x $86.84 for a computer programmer).

Additionally, for states that elect to require an alternative method, the proposed amendments to §438.3(t) would also alleviate managed care plans in those states of the burden of obtaining a COBA. We estimate 6 states with 25 plans may elect this option and save 4 hours per plan by a Business Operations Specialist -100 hrs (25 plans x 4 hrs) and -$6,822 (100 hrs x $68.22/hr). As this would be a one-time savings, we annualize this amount to -1.33 hrs and -$2,274.

Section §438.6(c) would remove the requirement for states to obtain prior approval for directed payment arrangements that utilize a state approved FFS fee schedule. To obtain prior approval, states submit a preprint (OMB control # 0938-1148 (CMS-10398 #52)) to CMS. We estimate that 20 states may elect annually to request approval for 40 directed payments that utilize a state approved FFS fee schedule. By eliminating the requirement that states submit a preprint for each arrangement, we estimate that a state could save 1 hour per directed payment arrangement for a Business Operations Specialist at $68.22/hr. We estimate an annual savings of -40 hours (20 states x 2 preprints each x 1 hour per preprint) and -$2,728.80 (40 hours x $68.22/hr).

Section §438.10(d)(2) and (d)(3) would no longer require states or plans to add taglines in prevalent languages to all written materials, nor to use 18-point font size. Instead, states and plans would have the ability to include taglines only on materials critical to obtaining services and could select any font size they deem to be conspicuously visible. While we have no data indicating how many states experienced increased document length or an increase in postage costs as a result of these requirements, we believe that this proposed revision will likely reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of -$12,009,380.89 ((-$272,940.47= $.005 x 54,588,095) + (-$272,940.47= 0.005 x 54,588,095) + (-$11,463,499.95= $.21 x 54,588,095)).

Section §438.400(b) would revise the definition of an "adverse benefit determination" to exclude claims that do not meet the definition of "clean claim" at §447.45(b), thus eliminating the requirement for the plan to send an adverse benefit notice. While we have no data on the number of adverse benefit notices are sent due to denials of unclean claims, we believe that at least one unclean claim may be generated for half of all enrollees; thus, this proposal could reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of -$10,644,678.32 ((-$136,470.23= $.005 x 27,294,047) + (-$136,470.23 = 0.005 x 27,294,047) + (-$10,371,737.86 = $.38 x 27,294,047)).

Section 438.402(c)(3)(ii) no longer requires enrollees to follow up an oral appeal with a written appeal. This change would alleviate the burden on plans to follow up with enrollees that do not submit the written appeal. We estimate that plans may spend up to 2 hours per appeal calling or sending letters to enrollees in an effort to receive the written appeal. We estimate that 300 plans in 20 states have an average of 200 oral appeals that are not followed up with a written appeal. We estimate an aggregate annual private sector burden reduction of -$4,569,600 (300 plans x 200 appeals x $38.08/hour x 2hr) for an office and administrative support worker).

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. Some information must be published on a state or managed care plan website, while the rest of the information is used by States as part of their normal contracting with, and monitoring of, their MCOs PIHPs, PAHPs, PCCMs, and PCCM entities and is not be published.

17. Expiration Date*:*

The expiration date and PRA Disclosure Statement are displayed.

18. Certification Statement:

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods.