

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

This package is associated with a June 1, 2015 NPRM (CMS-2390-P; RIN 0938-AS25).

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, 438.310, 438.320, 438.330, 438.332, 438.334, 438.340, 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, 438.807, 438.808, 438.810, 438.812, 438.816, and 438.818

The Medicaid managed care final rule (CMS-2104-F), published on June 14, 2002, amended the Medicaid regulations to implement the Medicaid managed care provisions of the Balanced Budget Act of 1997 (BBA). These revisions established new beneficiary protections in areas such as quality, grievance and appeal rights, and coverage of emergency services. They eliminated certain requirements viewed by State agencies as impediments to the growth of managed care programs, such as the enrollment composition requirement, the right to disenroll without cause at any time, and the prohibition on enrollee cost-sharing. They also permitted State agencies to amend their State plans to require enrollment of certain populations in managed care organizations and provide beneficiaries a choice of MCO or provider. In addition, this rule separated prepaid health plans (PHPs) into prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHP) based on the scope of services they cover, and extended most of the new MCO requirements to prepaid health plans.

CMS-2390-P, Medicaid managed care proposed rule, would modernize the Medicaid managed care regulations to reflect changes in the usage of managed care delivery systems. The proposed rule would align the rules governing Medicaid managed care with those of other major sources of coverage, including coverage through Qualified Health Plans and Medicare Advantage plans; implement statutory provisions; strengthen actuarial soundness payment provisions to promote the accountability of Medicaid managed care program rates; ensure appropriate beneficiary protections; modernize Medicaid managed care quality provisions; and enhance expectations for program integrity.

A. Justification

1. Need and Legal Basis:

- Section 4701 of the BBA created section 1932(a) of the Act, changed terminology in Title XIX of the Act and amended section 1903(m) to require that contracts and managed care organizations (MCOs) comply with applicable requirements in the new section. Section 1932(a) permits States to mandatorily enroll most groups of Medicaid beneficiaries into managed care arrangements without section 1915(b) or section 1115 waiver authority.
- Section 1932 also defines the term "managed care entity" (MCE) to include MCOs and primary care case managers (PCCMs); establishes new requirements for managed care enrollment and choice of coverage; and requires MCEs and State agencies to provide specified information to enrollees and potential enrollees.
- Section 4702 amended section 1905 to permit States to provide PCCM services without the need for waiver authority. Instead, PCCM services may be made available under a State's Medicaid plan as an optional service.
- Section 4703 eliminated a former statutory requirement that no more than 75 percent of the enrollees in an MCO be Medicaid or Medicare beneficiaries.
- Section 4704 created section 1932(b) to add increased beneficiary protections for those enrolled under managed care arrangements. These include, among other things, the use of a prudent layperson's definition of emergency medical condition when presenting at an emergency room; standards for demonstration of adequate capacity and services; grievance procedures; and protections for enrollees against liability for payment of an organization's or provider's debts in the case of insolvency.
- Section 4705 created section 1932(c), which requires States to develop and implement quality assessment and improvement strategies for their managed care arrangements.
- Section 4706 provided that with limited exceptions an MCO must meet the same solvency standards set by States for a private HMO, or be licensed or certified by the State as a risk-bearing entity.
- Section 4707 created section 1932(d) to add protections against fraud and abuse, such as restrictions on marketing and sanctions for noncompliance.
- Section 4708 added a number of provisions to improve the

administration of managed care arrangements. These include, among other things, changing the threshold amount of managed care contracts requiring the Secretary's prior approval, and permitting the same copayments in MCOs as apply to fee-for-service arrangements.

- Section 4709 allowed States the option to provide six months of guaranteed eligibility for all individuals enrolled with an MCO or PCCM.
- Section 4710 specified the effective dates for all the provisions identified in sections 4701 through 4709.
- Section 1902(a)(4) of the Social Security Act requires such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the plan.

2. Information Users:

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

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

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

3. Improved Information Technology:

Sections 438.66, 438.74, 438.207, and 438.818 contain requirements concerning specific reporting to CMS and will all be done electronically. Most of the sections do not involve submitting information to any entity; those that do concern the submission of information between the State and plans. Because this concerns disclosure to a third party, we do not dictate how the information may be disclosed.

Regarding § 438.340, the managed care component of a state's comprehensive quality strategy (CQS), submission of the CQS is addressed in CMS-10553. States will submit CQS to CMS by email. No signature, electronic or written, is required on the document.

4. Duplication of Similar Information:

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

5. Small Businesses:

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

As of 2012, there are 331 MCOs, 176 PIHPs, 41 PAHPs, 20 NEMT PAHPs, 25 PCCMs, and 9 PCCM entities participating in the Medicaid managed care program. We believe that only a few of these entities qualify as small entities. Specifically, we believe that 10 to 20 PAHPs, 8 to 15 PCCMs, and 2 to 5 PCCM entities are likely to be small entities. We believe that the remaining MCOs and PIHPs have average annual receipts from Medicaid contracts and other business interests in excess of \$38.5 million. In analyzing the scope of the impact of these regulations on small entities, we examined the United States Census Bureau's Statistics of U.S. Businesses for 2010. According to the 2010 data, there are 4,414 direct health and medical insurance carriers with less than 20 employees and 158,607 offices of physicians or health practitioners with less than 20 employees. We believe that we are impacting less than 1 percent of the small entities that we have identified.

The primary impact on small entities will be through the standards proposed to be placed on PAHPs, PCCMs, and PCCM entities through the following requirements: (1) adding PCCMs and PCCM entities, where appropriate, to the information standards in §438.10 regarding enrollee handbooks, provider directories, and formularies; (2) adding PAHPs, PCCMs, and PCCM entities in §438.62 to implement their own transition of care policies and PAHPs in §438.208 to perform initial assessments and care coordination activities; (3) adding PAHPs in §438.242 to collect data on enrollee and provider characteristics and on services furnished to enrollees through an encounter data system or other such methods; (4) adding PCCM entities to the quality assessment and performance improvement program standards in §438.330; and (5) adding PAHPs to the types of entities subject to the standards of subpart F to establish a grievances and appeals system and process. We do not believe that the remaining impacts or burdens of the provisions of this proposed rule are great on the small entities that we have identified.

All cost estimates were derived from the Collection of Information calculations, section IV of this proposed rule. The estimated costs associated with the impacts on small entities listed above are primarily attributable to the transition of care policies for PAHPs, PCCMs, and PCCM entities, initial assessments and care coordination activities for PAHPs, and the establishment of a grievances and appeals system and process for

PAHPs. The transition of care policies, initial assessments, and care coordination activities for PAHPs account for approximately \$2.4 million of the cumulative \$4.5 million annual impact on the 41 PAHPs (detailed burden estimates can be found in the Collection of Information section of this proposed rule at IV.D.10. and IV.D.17. for coordination/continuity of care). 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 (detailed burden estimates can be found in the Collection of Information section of this proposed rule at IV.D.31. – IV.D.35. for grievances and appeals). 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 (detailed burden estimates can be found in the Collection of Information section of this proposed rule at IV.D.10. and IV.D.17. for coordination/continuity of care). The total estimated annual burden per PCCM or PCCM entity is less than \$0.1 million, or less than 1 percent of the \$11 million threshold.

These small entities must meet certain standards as identified in the provisions of this proposed 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 managed care enrollees. Therefore, based on the estimates in the Collection of Information (section IV of this proposed rule); we have determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

6. Less Frequent Collection:

These ICRs (except those specified in 42 CFR 438.332 and 438.334) were mandated by the BBA. If CMS were to collect them less frequently, we would be in violation of the law.

The ICR in 42 CFR 438.332 was developed based on the accreditation process used in the private sector and Medicare advantage. The ICR in 42 CFR 438.334 was developed to align with the quality rating system developed for qualified health plans (QHPs) in the Marketplace. Less frequent collection for either would not align with industry standards.

7. Special Circumstances:

There are no special circumstances associated with this collection.

8. Federal Register Notice/Outside Consultation:

The NPRM is serving as the 60-day Federal Register notice which published on June 1, 2015 (80 FR 31098). The NPRM was placed on public inspection on May 26 whereby comments are due July 27.

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.

12. Burden Estimate:

Wage Estimates

To develop burden estimates, we used data from the U.S. Bureau of Labor Statistics' May 2013 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (at 100%) (\$/hr)	Adjusted Hourly Wage (\$/hr)
Accountant	13-2011	31.55	31.55	63.10
Actuary	15-2011	46.00	46.00	92.00
Business Operations Specialist	13-1000	29.66	29.66	53.32
Computer Programmer	15-1131	36.80	36.80	73.60
Customer Service Rep	43-4051	14.84	14.84	29.68
General and Operations Mgr	11-1021	63.86	63.86	127.72
Healthcare Social Worker	21-1022	29.60	29.60	59.20
Mail Clerk	43-9051	13.20	13.20	26.40
Office and Administrative Support Worker	43-9000	14.96	14.96	29.92
Registered Nurse	29-1141	32.70	32.70	65.40

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.

Burden Summary

Summary of Annual Burden Estimates for Private Sector

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
438.8(c) MLR	568	568	101	57,368	\$73.60	\$7,433.60	\$4,222,284.80	R	once	\$1,407,428.27
438.8(c) MLR	568	568	50	28,400	\$53.32	\$2,666.00	\$1,514,288.00	R	once	\$504,762.67
438.8(c) MLR	568	568	17	9,656	\$127.72	\$2,171.24	\$1,233,264.32	R	once	\$411,088.11
438.8(c) MLR	568	568	32	18,176	\$73.60	\$2,355.20	\$1,337,753.60	R	annual	\$1,337,753.60
438.8(c) MLR	568	568	16	9,088	\$53.32	\$853.12	\$484,572.16	R	annual	\$484,572.16
438.8(c) MLR	568	568	5	2,840	\$127.72	\$638.60	\$362,724.80	R	annual	\$362,724.80
438.10(g) Information Requirements	100	100	4	400	\$53.32	\$213.28	\$21,328.00	TPD	once	\$7,109.33
438.10(g) Information Requirements	100	10,659,819	0.0167	177,699	\$26.40	\$0.44	\$4,691,258.42	TPD	once	\$1,563,752.81
438.10(g) Information Requirements	100	2,069,259	0.0167	1,988	\$26.40	\$0.44	\$52,483.20	TPD	annual	\$52,483.20
438.10(g) Information Requirements	577	577	1	577	\$53.32	\$53.32	\$30,765.64	TPD	annual	\$30,765.64
438.10(h) Information Requirements	577	577	1	577	\$73.60	\$73.60	\$42,467.20	TPD	once	\$14,155.73
438.12 Provider Discrimination prohibited	568	5680	.0167	95	26.40	\$0.44	\$2,508	TPD	annual	\$2,508
438.14(c) Contracts	463	463	1	463	\$73.60	\$73.60	\$34,076.80	TPD	once	\$11,358.93
438.62(b)(1) Transition of Care	568	568	1	568	\$53.32	\$53.32	\$30,285.76	R	once	\$10,095.25

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
438.62(b)(2) Transition of Care	568	568	4	2,272	\$73.60	\$294.40	\$167,219.20	R	once	\$55,739.73
438.62(b)(2) Transition of Care	568	313,704	0	52,294	\$65.40	\$10.90	\$3,420,057.47	R	annual	\$3,420,057.47
438.66(d)(3) State Monitoring	20	20	5	100	\$127.72	\$638.60	\$12,772.00	RK	annual	\$12,772.00
438.66(d)(3) State Monitoring	20	20	30	600	\$53.32	\$1,599.60	\$31,992.00	RK	annual	\$31,992.00
438.66(d)(3) State Monitoring	20	20	5	100	\$73.60	\$368.00	\$7,360.00	RK	annual	\$7,360.00
438.110(a) Member Advisory Committee	14	14	6	84	\$53.32	\$319.92	\$4,478.88	R	annual	\$4,478.88
438.207(b)-(d) Adequate Capacity	568	568	1	568	\$73.60	\$53.32	\$30,285.76	R	once	\$10,095.25
438.207(b)-(d) Adequate Capacity	568	568	2	1,136	\$53.32	\$106.64	\$60,571.52	R	annual	\$60,571.52
438.208(b)(2)(iii) Care Coordination	568	2,746,476	0.1667	457,746	\$59.20	\$9.87	\$27,099,105.17	TPD	annual	\$27,099,105.17
438.208(b)(3) Care Coordination	168	168	3	504	\$53.32	\$159.96	\$26,873.28	TPD	once	\$8,957.76
438.208(b)(3) Care Coordination	168	485,872	0.0167	80,980	\$29.68	\$4.95	\$2,403,494.90	RK	annual	\$2,403,494.90
438.208(b)(4) Care Coordination	568	568	4	-462,510	\$73.60	\$294.40	-\$34,040,736.00	TPD	once	-\$11,346,912.00
438.208(c)(2)-(3) Care Coordination	568	428,128	1	428,128	\$65.40	\$65.40	\$27,999,571.20	RK	annual	\$27,999,571.20
438.208(c)(3)	568	568	1	568	\$53.32	\$53.32	\$30,285.76	R	once	\$10,095.25

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
(v) Care Coordination										
438.210(a)(4)(ii)(B) Authorization of Services	568	568	20	11,360	\$65.40	\$1,308.00	\$742,944.00	RK	once	\$247,648.00
438.210(c) Authorization of Services	61	61	1.0	61	\$53.32	\$53.32	\$3,252.52	TPD	once	\$1,084.17
438.230 Subcontracts	568	568	3.0	1,704	\$53.32	\$159.96	\$90,857.28	TPD	once	\$30,285.76
438.242(b)(2) Health Information	41	41	20	820	\$73.60	\$1,472.00	\$60,352.00	RK	once	\$20,117.33
438.330(b)(3) Create PCCM Utilization Review Policies	15	15	10	150	\$53.32	\$533.20	\$7,998.00	R	once	\$2,666.00
438.330(b)(3) Operate PCCM Utilization Review Policies	15	15	10	150	\$53.32	\$533.20	\$7,998.00	R	annual	\$7,998.00
438.330(c)(1)-(3) MCO/PIHP Performance Measures	511	1,533	0.1	153	\$53.32	\$5.33	\$8,173.96	R	annual	\$8,173.96
438.330(c)(1)-(3) PAHP/PCCM Performance Measures	56	168	4	672	\$53.32	\$213.28	\$35,831.04	R	annual	\$35,831.04
438.330(c)(4) MLTSS Performance Measures	179	358	4	1,432	\$53.32	\$213.28	\$76,354.24	R	annual	\$76,354.24
438.330(d)(1)-(2) MCO/PIHP	511	1,533	8	12,264	\$53.32	\$426.56	\$653,916.48	R	annual	\$653,916.48

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
PIPs										
438.330(d)(1)-(2) Create PAHP PIP Policies	41	41	2	82	\$53.32	\$106.64	\$4,372.24	R	once	\$1,457.41
438.330(d)(1)-(2) PAHP PIPs	41	41	8	328	\$53.32	\$426.56	\$17,488.96	R	annual	\$17,488.96
438.332(a) Provide Plan Information	276	276	40	3,680	\$53.32	\$2,132.80	\$196,217.60	R	annual	\$196,217.60
438.332(a) Provide Plan Information	276	276	5	460	\$29.92	\$149.60	\$13,763.20	R	annual	\$13,763.20
438.332(a) Provide Plan Information	276	276	4	368	\$127.72	\$510.88	\$47,000.96	R	annual	\$47,000.96
438.332(b)(2) Initial Plan Accreditation	138	138	N/A	N/A	N/A	\$70,700.00	\$9,756,600.00	R	once	\$3,252,200.00
332(b)(2) Plan Accreditation Renewal	138	138	N/A	N/A	N/A	\$70,700.00	\$3,252,200.00	R	annual	\$3,252,200.00
438.400(b) Definitions	507	507	5	2,535	\$53.32	\$266.60	\$135,166.20	TPD	once	\$45,055.40
438.402(a) Grievance System	41	41	10	410	\$127.22	\$1,272.20	\$52,160.20	R	once	\$17,386.73
438.402(a) Grievance System	41	41	75	3,075	\$53.32	\$3,999.00	\$163,959.00	R	once	\$54,653.00
438.402(a) Grievance System	41	41	15	615	\$73.60	\$1,104.00	\$45,264.00	R	once	\$15,088.00
438.402(a) Grievance System	41	410	36	14,760	\$53.32	\$1,919.52	\$787,003.20	R	annual	\$787,003.20
438.404(a) Notices	507	2,140,643	0.0167	35,677	26.40	\$.044	\$941,872.80	TPD	annual	\$941,872

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
438.404(a) Notices	41	240,000	0.0167	4,000	\$26.40	\$0.44	\$105,811.20	TPD	annual	\$105,811.20
438.408(b) Appeals	200	200	1	200	\$53.32	\$53.32	\$10,664.00	R	once	\$3,554.67
438.416 Reporting	41	240,000	0.0167	4,000	\$29.92	\$0.50	\$119,919.36	RK	annual	\$119,919.36
438.416 Reporting	56	56	3	168	\$73.60	\$220.80	\$12,364.80	RK	once	\$4,121.60
438.416 Reporting	507	856,257	.0167	14,271	\$29.92	\$0.50	\$426,986.82	RK	annual	\$426,986.82
438.420(c)(4) Continuation of Benefits	507	507	4	2,028	\$53.32	\$213.28	\$108,132.96	R	once	\$36,044.32
438.602(b) Program Integrity	568	568	6	3,408	\$73.60	\$441.60	\$250,828.80	R	once	\$83,609.60
438.608(a)(1) Program Integrity	568	568	2	1,136	\$53.32	\$106.64	\$60,571.52	RK	once	\$20,190.51
438.608(a)(2)-(3) Program Integrity	568	568	2	1,136	\$53.32	\$106.64	\$60,571.52	TPD	annual	\$60,571.52
438.608(a)(4) Program Integrity	200	20,000	0.0167	333	\$26.40	\$0.44	\$8,817.60	TPD	annual	\$8,817.60
438.608(c)-(d) Program Integrity	568	568	1	568	\$73.60	\$73.60	\$41,804.80	R	once	\$13,934.93
TOTAL	602	20,224,734	---	992,469	---	---	--	--	--	66,586,961.20

(Key: R= reporting; RK= recordkeeping; TPD= third party distribution.)

Reporting:	327,150 responses	227,821 hr
Recordkeeping:	2,011,550 responses	541,663 hr
Disclosure	17,886,034 responses	222,985 hr
TOTAL	20,224,734 responses	992,469 hr

Summary of Annual Burden Estimates for State Government

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
438.3 Contracts	42	602	6	3,612	\$53.32	\$319.92	\$192,591.84	TPD	Once	\$64,197.28
438.5 Rate Standards	39	50	10	500	\$92.00	\$920.00	\$46,000.00	R	Annual	\$46,000.00
438.5 Rate Standards	39	50	1	50	\$127.72	\$127.72	\$6,386.00	R	Annual	\$6,386.00
438.7 Rate Certifications	39	70	1.50	105	\$92.00	\$138.00	\$9,660.00	R	annual	\$9,660.00
438.7 Rate Certifications	39	70	0.13	9	\$127.72	\$16.60	\$1,162.25	R	annual	\$1,162.25
438.7 Rate Certifications	39	70	0.73	51	\$73.60	\$53.73	\$3,760.96	R	annual	\$3,760.96
438.7 Rate Certifications	39	70	0.73	51	\$53.32	\$38.92	\$2,724.65	R	annual	\$2,724.65
438.7 Rate Certifications	39	70	0.26	18	\$29.92	\$7.78	\$544.54	R	annual	\$544.54
438.10(c)(3) Information Requirements	42	42	6	252	\$73.60	\$441.60	\$18,547.20	TPD	once	\$6,182.40
438.10(c)(3) Information Requirements	42	42	3	126	\$73.60	\$220.80	\$9,273.60	TPD	annual	\$9,273.60
438.10(c)(4)(i) Information Requirements	42	42	6	252	\$53.32	\$319.92	\$13,436.64	TPD	once	\$4,478.88
438.10(c)(4)(ii) Information Requirements	20	20	20	400	\$53.32	\$1,066.40	\$21,328.00	TPD	once	\$7,109.33
438.10(c)(4)(ii) Information Requirements	20	20	2	40	\$53.32	\$106.64	\$2,132.80	TPD	annual	\$2,132.80

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
438.10(d)(2)(i) Information Requirements	42	42	6	252	\$53.32	\$319.92	\$13,436.64	TPD	once	\$4,478.88
438.10(e)(1) Information Requirements	42	42	1	42	\$53.32	\$53.32	\$2,239.44	TPD	once	\$746.48
438.10(e)(1) Information Requirements	42	2,069,259	0.0167	-30,512	\$26.40	\$0.44	-\$805,516.80	TPD	annual	-\$805,516.80
438.14(c) Contracts	25	25	12	300	\$53.32	\$639.84	\$15,996.00	TPD	annual	\$15,996.00
438.50 State Plan requirements	5	5	8	40	\$53.32	\$426.56	\$2,132.80	RK	once	\$710.67
438.54(c)(2) Enrollment	15	15	2	30	\$73.60	\$147.20	\$2,208.00	TPD	once	\$736.00
438.54(c)(8) Enrollment	42	559,865	0.0167	9,350	\$26.40	\$0.44	\$246,833.28	TPD	annual	\$246,833.28
438.62(b)(1) Transition of Care	42	42	5	210	\$53.32	\$266.60	\$11,197.20	R	once	\$3,732.40
438.62(b)(2) Transition of Care	42	42	4	168	\$73.60	\$294.40	\$12,364.80	R	once	\$4,121.60
438.66(a)-(b) State Monitoring	42	42	8	336	\$53.32	\$426.56	\$17,915.52	R	once	\$5,971.84
438.66(c) State Monitoring	42	42	20	840	\$53.32	\$1,066.40	\$44,788.80	R	once	\$14,929.60
438.66(d)(3) State Monitoring	20	20	5	100	\$127.72	\$638.60	\$12,772.00	RK	annual	\$12,772.00
438.66(d)(3) State Monitoring	20	20	30	600	\$53.32	\$1,599.60	\$31,992.00	RK	annual	\$31,992.00
438.66(d)(3) State Monitoring	20	20	5	100	\$73.60	\$368.00	\$7,360.00	RK	annual	\$7,360.00
438.66(e)(1-2) State Monitoring	42	42	6	252	\$53.32	\$319.92	\$13,436.64	RK	annual	\$13,436.64
438.68(a)-(c) Network Adequacy	20	20	10	200	\$53.32	\$533.20	\$10,664.00	R	once	\$3,554.67

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
438.68(a)-(c) Network Adequacy	16	16	10	160	\$53.32	\$533.20	\$8,531.20	R	once	\$2,843.73
438.68(d) Network Adequacy	40	40	3	120	\$53.32	\$159.96	\$6,398.40	R	once	\$2,132.80
438.70(c) MLTSS Engagement	14	14	4	56	\$53.32	\$213.28	\$2,985.92	R	annual	\$2,985.92
438.71(a) Beneficiary Support System	20	20	125	2,500	\$53.32	\$6,665.00	\$133,300.00	TPD	once	\$44,433.33
438.71(a) Beneficiary Support System	20	20	25	500	\$127.72	\$3,193.00	\$63,860.00	TPD	once	\$21,286.67
438.71(b) Beneficiary Support System	42	42	3	126	\$53.32	\$159.96	\$6,718.32	TPD	once	\$2,239.44
438.71(b) Beneficiary Support System	42	42	1	42	\$53.32	\$53.32	\$2,239.44	TPD	annual	\$2,239.44
438.102 Provider Enrollee Communications	3	253,332	0.01667	4,222	\$26.40	\$0.044	\$111,466.08	TPD	annual	\$111,466.08
438.310(c)(2) State PCCM Assessment	10	10	2	20	\$53.32	\$106.64	\$1,066.40	R	once	\$355.47
438.330(a)(2) State QAPI Programming	40	40	10	133	\$73.60	\$736.00	\$9,810.88	R	annual	\$9,810.88
438.330(a)(2)(ii) State QAPI Exemption	11	11	1	4	\$53.32	\$53.32	\$197.28	R	annual	\$197.28
438.330(e) Assess PCCMs	15	15	15	225	\$53.32	\$799.80	\$11,997.00	R	annual	\$11,997.00
438.330(e)(1)(ii) Update State Policies	40	40	0.5	20	\$53.32	\$26.66	\$1,066.40	R	once	\$355.47

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
438.330(e)(1)(ii) State Review of Outcomes	40	40	1	40	\$53.32	\$53.32	\$2,132.80	R	annual	\$2,132.80
438.330(e)(1)(iii) Update State Policies	16	16	0.5	8	\$53.32	\$26.66	\$426.56	R	once	\$142.19
438.330(e)(1)(iii) State Assess LTSS	16	16	1	16	\$53.32	\$53.32	\$853.12	R	annual	\$853.12
438.332(a) State Purchase Accreditation Standards	20	20	N/A	N/A	N/A	\$20,000.00	\$133,333.33	R	annual	\$133,333.33
438.332(a) Develop State Standards	20	20	15	100	\$53.32	\$799.80	\$5,332.00	R	annual	\$5,332.00
438.332(a) Develop State Standards	20	20	5	33	\$127.72	\$638.60	\$4,257.33	R	annual	\$4,257.33
438.332(a) State Review of Plans	20	276	80	7,360	\$53.32	\$4,265.60	\$392,435.20	R	annual	\$392,435.20
438.332(a) State Review of Plans	20	276	5	460	\$127.72	\$638.60	\$58,751.20	R	annual	\$58,751.20
438.332(a) State Review of Plans	20	276	5	460	\$29.92	\$149.60	\$13,763.20	R	annual	\$13,763.20
438.332(b) State Review Deeming Process	20	20	40	267	\$53.32	\$2,132.80	\$14,220.44	R	annual	\$14,220.44
438.334(a) Create State QRS	30	30	100	3,000	\$53.32	\$5,332.00	\$159,960.00	R	once	\$53,320.00
438.334(a) Create State QRS	30	30	40	1,200	\$73.60	\$2,944.00	\$88,320.00	R	once	\$29,440.00
438.334(a) Create State	30	30	15	450	\$127.72	\$1,915.80	\$57,474.00	R	once	\$19,158.00

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
438.334(a) Create State QRS	30	30	2	60	\$29.92	\$59.84	\$1,795.20	R	once	\$598.40
438.334(a) Create State QRS	30	30	15	450	\$53.32	\$799.80	\$23,994.00	R	once	\$7,998.00
438.334(b) State Rates Plans	30	414	20	8,280	\$53.32	\$1,066.40	\$441,489.60	R	annual	\$441,489.60
438.334(c) State QRS Exemption	10	10	5	50	\$53.32	\$266.60	\$2,666.00	R	once	\$888.67
438.334(d) Use MA Rating	25	-25	20	-500	\$53.32	\$1,066.40	-\$26,660.00	R	annual	-\$26,660.00
438.340 CQS Managed Care Elements	40	40	10	133	\$53.32	\$533.20	\$7,107.56	R	annual	\$7,107.56
438.340 Removal of 438.204(b)(2)	15	-15	80	-1,200	N/A	N/A	N/A	R	once	0
438.400(b) Definitions	40	40	5	200	\$53.32	\$266.60	\$10,664.00	RK	once	\$3,554.67
438.602(a) Program Integrity	42	42	6	252	\$53.32	\$319.92	\$13,436.64	R	once	\$4,478.88
438.602(e) Program Integrity	42	568	20	3,787	\$63.10	\$1,262.00	\$238,959.70	R	annual	\$238,959.70
438.602(g) Program Integrity	40	40	1	40	\$73.60	\$73.60	\$2,944.00	R	annual	\$2,944.00
438.722 Disenrollment Notices	12	12	1	12	\$53.32	\$53.32	\$639.84	TPD	annual	\$639.84
438.722 Disenrollment Notices	12	1,084,536	0.0167	18,075	\$26.40	\$0.44	\$477,195	TPD	annual	\$477,195
438.724 Notice to CMS	15	15	0.5	112.5	\$53.32	\$26.66	\$5,998.50	TPD	annual	\$5,998.50
438.818(a)(2) Encounter Data	9	9	1	9	\$53.32	\$53.32	\$479.88	R	once	\$159.96

CFR	# Respondents	# responses	Burden per response- in hrs	Total Annual Hours	Labor Rate	Cost per Response	Total cost	Response Type	Frequency	Annualized
438.818(a)(2) Encounter Data	9	9	10	90	\$53.32	\$533.20	\$4,798.80	R	once	\$1,599.60
438.818(a)(2) Encounter Data	9	9	100	900	\$73.60	\$7,360.00	\$66,240.00	R	once	\$22,080.00
438.818(a)(2) Encounter Data	9	9	125	1,125	\$53.32	\$6,665.00	\$59,985.00	R	annual	\$59,985.00
438.818(a)(2) Encounter Data	9	9	25	225	\$127.72	\$3,193.00	\$28,737.00	R	annual	\$28,737.00
TOTAL	42	3,971,255	---	41,397	---	---	--	--	--	1,942,704.65

(Key: R= reporting; RK= record keeping; TPD= third party distribution.)

Reporting:	3,073 responses	30,371 hr
Recordkeeping:	147 responses	1,292 hr
Disclosure	3,968,035 responses	9,734 hr
TOTAL	3,971,255 responses	41,397 hr

Proposed Requirements and Burden Estimates

Section 438.3 Standard contract requirements

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

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

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

We estimate a one-time state burden of 6 hr at \$53.32/hr for a business operations specialist to amend all contracts. In aggregate, we estimate **3,612 hr** (602 contracts x 6 hr) and **\$192,591.84** (3,612 hr x \$53.32/hr).

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

Section 438.5 Rate development standards

Section 438.5 describes CMS' proposal related to the development and documentation of capitation rates paid to risk-based MCOs, PIHPs and PAHPs. Generally, we would require: the use of appropriate base data; 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; CMS 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 would place some burden on the some states. We estimate that most states currently certify a range as compared to the actual contract rate paid to the health plan. Therefore, out of the total 70 certifications submitted to CMS from 39 states, the process underlying 50 certifications will need to be modified.

We estimate it would take approximately 10 hr at \$92/hr for an actuary and 1 hr at \$127.72/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 **\$52,386** [50 certifications x ((10 hr x \$92/hr) + (1 hr x \$127.72/hr))].

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 would be in line with actuarial standards of practice and previous Medicaid managed care rules.

We estimate it would take 230 hr to develop each certification, consisting of 100 hr (at \$92/hr) for an actuary, 10 hr (at \$127.72/hr) for a general and operations manager, 50 hr (at \$73.60/hr) for a computer programmer, 50 hr (at \$53.32/hr) for a business operations specialist, and 20 hr (at \$29.92/hr) for an office and administrative support worker.

This is based on a total of 16,100 hr (230 hr x 70 certifications) which would add **228 hr** (16,100 hr – 15,872 hr) for all 70 certifications, adjusted to 3.3 hr per certification. In aggregate, we estimate an annual state burden of **\$17,852.41** [70 certifications x ((1.5 hr x \$92/hr) + (0.13 hr x \$127.72/hr) + (0.73 hr x \$73.60/hr) + (0.73 hr x \$53.32/hr) + (0.26 hr x \$29.92/hr))].

Section 438.8 Medical loss ratio standards

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

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

We estimate total number of MLR reports that MCOs and PIHPs would be required to submit to the state would amount to 568 contracts. While the number of contracts includes 545 credible contracts and 23 non-credible contracts, all MCOs and PIHPs will need to report the information required under §438.8 regardless of their credibility status.

We estimate a one-time private sector burden of 168 hr for the initial administration activities. We estimate that 60 percent of the time would be completed by a computer programmer (101 hr at \$73.60/hr), 30 percent would be completed by a business operations specialist (50 hr at \$53.32/hr), and 10 percent would be completed by a general and operations manager (17 hr at \$127.72/hr). This amounts to \$12,270.84 ((101 hr x \$73.60) + (50 hr x \$53.32) + (17 hr x \$127.72)) per report or **\$6,969,837.12** (568 x \$12,270.84) for 568 MCOs, PIHPs, and PAHPs in 2017 (the one-time burden).

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 \$3,846.92 per report and a total of **\$2,185,050.56** [568 contracts x \$3,846.92 ((32 hr x \$73.60/hr) + (16 hr x \$53.32/hr) + (5 hr x \$127.72/hr)]. CMS expects 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.

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

Section 438.10 Information Requirements

Section 438.10(c)(3) would require 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 would only have to make minor revisions to their existing website.

We estimate 6 hr at \$73.60/hr for a computer programmer to make the initial changes. We also estimate 3 hr for a computer programmer to periodically add or update documents and links on the site. In aggregate, we estimate a one-time state burden of **252 hr** (42 states x 6 hr) and **\$18,547.20** (252 hr x \$73.60/hr). In subsequent years, we estimate an annual state burden of **126 hr** (42 states x 3 hr) and **\$9,273.60** (126 hr x \$73.60/hr).

Section 438.10(c)(4)(i) would recommend that states develop definitions for commonly used terms to enhance consistency of the information provided to enrollees. We estimate it would take 6 hr at \$53.32/hr for a business operations specialist to develop these

definitions. In aggregate, we estimate a one-time state burden of **252 hr** (42 states x 6 hr) and **\$13,436.64** (252 hr x \$53.32/hr).

Section 438.10(c)(4)(ii) would recommend that states create model enrollee handbooks and notices. Since many states already provide model handbooks and notices to their entities, we estimate 20 states may need to take action to comply with this provision. We estimate it would take 20 hr at \$53.32/hr for a business operations specialist to create these documents. We also estimate 2 hr per year for a business operations specialist to revise these documents, if needed. In aggregate, we estimate a one-time state burden of **400 hr** (20 states x 20 hr) and **\$21,328** (400 hr x \$53.32/hr). In subsequent years we estimate an annual burden of **40 hr** (20 states x 2 hr) and **\$2,132.80** (40 hr x \$53.32/hr).

Section 438.10(c)(7) would add PAHPs and PCCMs to the managed care entities that must have mechanisms in place to help enrollees and potential enrollees understand the requirements and benefits of managed care.

Section 438.10(d)(2)(i) would require that states add taglines to all printed materials for potential enrollees explaining the availability of translation and interpreter services as well as the phone number for choice counseling assistance. As the prevalent languages within a state do not change frequently, we are not estimating the burden for the rare updates that will be needed to update these taglines. We estimate it would take 2 hr at \$53.32/hr for a business operations specialist to create the taglines and another 4 hr to revise all document originals. In aggregate, we estimate a one-time state burden of **252 hr** (42 states x 6 hr) and **\$13,436.64** (252 hr x \$53.32/hr).

Section 438.10(e)(1) clarifies that states can provide required information in paper or electronic format. As this is an existing requirement, the only burden change we estimate is adding two new pieces of information generated in §438.68 (network adequacy standards) and §438.330 (quality and performance indicators). We estimate 1 hr at \$53.32/hr for a business operations specialist to update or revise existing materials and 1 min at \$26.40/hr for a mail clerk to mail the materials to 5 percent of the enrollees that are new (3,135,242). In aggregate, we estimate a one-time state burden of **42 hr** (42 states x 1 hr) and **\$2,239.44** (42 hr x 53.32/hr) to update/revise existing materials. The currently approved burden estimates 5 min per mailing for 65,000 total hr. By updating the enrollment figure to 2,069,259 (62,704,821 x .033) and reducing the time from 5 min to 1 min (to acknowledge automated mailing processes), we estimate the annual state burden for mailing as - **30,512 hr** (34,488 hr – 65,000 hr) and - **\$805,516.80** (- 30,512 hr x \$26.40/hr).

Section 438.10(g)(1) would require 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 would 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 would be greatly reduced. It is not possible for us to estimate how many, if any, new managed care entities may contract with a state in any year. We invite comment on an appropriate average number of new plans each year. State burden to create the template for a model handbook is set out under §438.10(c)(4)(ii).

For existing entities that already have a method for distributing the information, we believe that 100 entities will need to modify their handbook to comply with a new model provided by the state. We estimate 100 entities would rely on a business operations specialist to spend 4 hr at \$53.32/hr to update their handbook. Once revised, the handbooks need to be sent to enrollees. We estimate 1 min by a mail clerk at \$26.40/hr to send handbooks to 10,659,819 enrollees (17 percent of total enrollment). To update the handbook, we estimate a one-time private sector burden of **400 hr** (100 entities x 4 hr) and **\$21,328** (400 hr x \$53.32/hr). To send the handbook to existing enrollees in the 100 entities, we estimate a one-time private sector burden of **177,699 hr** (10,659,819 enrollees x 1 min) and **\$4,691,258.42** (177,699 hr x \$26.40/hr).

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 (5 percent of 62,704,821) would need to receive a handbook each year. We estimate 1 min by a mail clerk at \$26.40/hr to mail the handbook or **34,488 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 **1,988 hr** (34,488 hr - 32,500 hr) and **\$52,483.20** (1,988 hr x \$26.40/hr).

Since all of the MCO, PIHP, PAHP, and PCCM entities would need to keep their handbook up to date, we estimate it would take 1 hr at \$53.32/hr for a business operations specialist to update the document. While the updates would be 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 **577 hr** (577 entities x 1 hr) and **\$30,765.64** (577 hr x \$53.32/hr).

Section 438.10(h) would require that all MCO, PIHP, PAHP, and PCCM entities make a provider directory available in paper or electronic form. Producing a provider directory is a longstanding requirement in §438.10 and in the commercial 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 a computer programmer would need to add a few additional fields of data, including the provider website addresses, additional disability accommodations, and adding behavioral and long term services and support providers.

We estimate that it would take approximately 1 hr at \$73.60/hr for a computer

programmer to update the existing directory. Updates after the creation of the original program would be put on a production schedule as part of usual business operations and would not generate any additional burden. In aggregate, we estimate a one-time private sector burden of **577 hr** (577 entities x 1 hr) and **\$42,467.20** (577 hr x \$73.60/hr).

Section 438.12 Provider discrimination prohibited

This section requires that if an MCO, PIHP, or PAHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision. The burden associated with this requirement is the time it takes the MCO, PIHP, or PAHP to furnish the providers with the requisite notice. We estimate that it takes 1 minute to draft and furnish such notice. We estimate that on average each 568 MCOs, PIHPs, and PAHPs will need to produce 10 notices per year. In aggregate, we estimate an annual private sector burden of **95 hr** (568 entities x 10 notices x 1 min) and **\$2,508** (95 hr x 26.40/hr).

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) would require 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 fee-for-service program. There are approximately 31 states with 463 managed care entities with Indian providers. This type of payment arrangement typically involves the managed care entity sending a report to the state that then calculates and pays the amount owed to the Indian health care provider.

We estimate it would take 1 hr at \$73.60/hr for a private sector computer programmer to create the claims report and approximately 12 hr at \$53.32/hr for a state business operations specialist to process the payments. We estimate that approximately 25 of the 31 states will need to use this type of arrangement. In aggregate, we estimate a one-time private sector burden of **463 hr** (463 entities x 1 hr) and **\$34,076.80** (463 hr x \$73.60/hr). We also estimate an annual state burden of **300 hr** (25 states x 12 hr) and **\$15,996** (300 hr x \$53.32/hr). 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 IHCP 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. We estimate that it takes a State, providing managed care under the State plan option approximately 8 hours to develop the process for involving the public. As states

currently providing managed care under a State Plan developed their process for public input at the beginning of their program, this burden would only apply to states starting new programs. We estimate 5 States using a business operations specialist at \$53.32/hr for 8 hours to develop the process for involving the public. We estimate an aggregate one-time State burden of **40 hr** (5 states x 8 hr) and **\$2,132.80** (40 hr x \$53.32/hr).

Section 438.54 Managed care enrollment

Section 438.54(c)(2) would require states with voluntary programs that use a passive enrollment process to provide a 14 day choice period before enrolling the potential enrollee into a managed care plan. (Currently, such states enroll the potential enrollee into a managed care plan on the first day of their eligibility.) We estimate approximately 21 states have voluntary programs and approximately 75 percent of them (15) use a passive process. To accommodate the 14 day choice period, these 15 states would have to alter the programming of their passive enrollment algorithm to delay the enrollment in a managed care plan until the enrollee makes a plan selection or the 14 day period expires. We estimate it would take a computer programmer 2 hours at \$73.60/hr to complete this change. In aggregate, we estimate a one-time state burden of **30 hours** (15 states x 2 hr) and **\$2,208** (30 hours x \$73.60).

Section 438.54(c)(3) and (d)(3) would require 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) would require states to send a notice to enrollees in voluntary programs that utilize a passive enrollment process confirming their managed care enrollment when they have the opportunity to select a delivery system. We believe that by implementing the 14 day choice period, some states currently using passive enrollment process will discontinue its use. Therefore, we assume only ten states will continue using a passive enrollment process, with a total of 14,929,719 enrollees. Assuming a 5 percent of these would be new each year, and of those, that approximately 75 percent will elect managed care (559,865) we estimate 1 min per notification by a mail clerk at \$26.40/hr. In aggregate, we estimate an annual state burden of **9,350 hours** (559,865 enrollees x 1 min) and **\$246,833.28** (9350 hr x \$26.40/hr).

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) would require states to have a transition of care policy for all

beneficiaries moving from fee-for-service 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 would experience 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 proposed requirements and to include transitions from FFS. We estimate it would take a business operations specialist 5 hours at \$53.32/hr to revise their policies and procedures and 4 hr at \$73.60/hr for a computer programmer to create a program to compile and send the data. In aggregate, we estimate a one-time state burden of **378 hr** (42 states x 9 hr) and **\$23,562.00** (210 hr x \$53.32/hr + 168 hr x \$73.60/hr). We are not estimating additional burden for the routine running of these reports since they will be put into a production schedule.

Section 438.62(b)(2) would require 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 MCOs, PIHPs, PAHPs, or PCCMs already exchange data with each other for this purpose. To revise their existing policies to reflect the standards in (b) (1), we estimate 1 hr at \$53.32 for a business operations specialist. To develop computer programs to receive and store FFS data, we estimate 4 hr at \$73.60/hr for a computer programmer. We are not estimating additional burden for the routine running of these reports since they will be put into a production schedule. In aggregate, we estimate a one-time private sector burden of **568 hr** (568 MCOs, PIHPs, PAHPs, and PCCMs x 1 hr) and **\$30,285.76** (568 hr x \$53.32/hr) and **2,272 hr** (568 x 4 hr) and **\$167,219** (2,272 hr x \$73.60/hr).

For transitions, we estimate 10 min (per request) at \$65.40/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 **\$3,420,057.47** (52,294 hr x \$65.40/hr).

Section 438.66 State monitoring requirements

Section 438.66(a) and (b) would require states with MCO, PIHP, PAHP, or PCCM programs to have a monitoring system including at least the 13 areas specified in paragraph (b). While having a monitoring system is a usual and customary business process for all of the state Medicaid agencies, including all 13 areas will require most states to make at least some revisions to their existing processes and policies. We estimate 8 hr at \$53.32/hr for a business operations specialist to expand or revise existing policies and procedures. In aggregate, we estimate a one-time state burden of **336 hr** (42 states x 8 hr) and **\$17,915.52** (336 hr x \$53.32/hr).

Section 438.66(c) would require states with MCO, PIHP, PAHP, or PCCM programs to

utilize data gathered from its monitoring activities in 12 required areas to improve the program's performance. While all states currently utilize data for program improvement to some degree, incorporating all 12 areas will likely require some revisions to existing policies and procedures. We estimate a one-time state burden of 20 hr at \$53.32/hr for a business operations specialist to revise existing or to create new policies and procedures for utilizing the collected data. In aggregate, we estimate **840 hr** (42 states x 20 hr) and **\$44,788.80** (840 hr x \$53.32/hr).

Section 438.66(d)(1)-(3) would require 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 \$127.72/hr) for a general and operations manager, 30 hr (at \$53.32/hr) for a business operations specialist, and 5 hr (at \$73.60/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 (d)(1). Given the varying likelihood of the 5 events listed in (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 **\$52,124** [20 states x ((5 x \$127.72/hr) + (30 x \$53.32/hr) + (5 x \$73.60/hr))]. For MCO, PIHP, PAHP, or PCCM preparation and execution, we estimate 5 hr (at \$127.72/hr) for a general and operations manager, 30 hr (at \$53.32/hr) for a business operations specialist, and 5 hr (at \$73.60/hr) for a computer programmer. In aggregate, we estimate an annual private sector burden of **800 hr** (20 entities x 40 hr) and **\$52,124** [20 entities x ((5 x \$127.72/hr) + (30 x \$53.32/hr) + (5 x \$73.60/hr))].

Section 438.66(e)(1) and (2) would require that states submit an annual program assessment report to CMS covering the topics listed in §438.66(e)(2). The data collected for §438.66(b) and the utilization of the data in §438.66(c) will be used to compile this report. We estimate an annual state burden of 6 hr at \$53.32/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 **\$13,436.64** (252 hr x \$53.32/hr).

Section 438.68 Network adequacy standards

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

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

To develop network standards meeting the specific provider types found in §438.68(b) (1), we estimate a one-time state burden of 10 hr at \$53.32/hr for a business operations specialist. In aggregate, we estimate **200 hr** (20 states x 10 hr) and **\$10,664** (200 hr x \$53.32/hr).

To develop LTSS standards, we estimate a one-time state burden of 10 additional hr at \$53.32/hr for a business operations specialist to develop those standards. In aggregate, we estimate **160 hr** (16 states with MLTSS programs x 10 hr) and **\$8,531.20** (160 hr x \$53.32/hr).

Section 438.68(d) would require the state to develop an exceptions process for use by MCOs, PIHPs, and PAHPs unable to meet the network standards established in .68(a).

We estimate a one-time state burden of 3 hr at \$53.32/hr for a business operations specialist to design an exceptions process for states to use to evaluate requests from MCOs, PIHP, and PAHPs for exceptions to the network standards. With a total of 40 states contracting with at least one MCO, PIHP or PAHP, we estimate a one-time aggregate state burden of **120 hr** (40 states x 3 hr) and **\$6,398.40** (120 hr x \$53.32). The exception process should not be used very often as MCOs, PIHPs, and PAHPs meeting the established standards is critical to enrollee access to care. As such, after the exceptions process is established, we estimate that the occasional use of it will not generate any measureable burden after the first year.

States' review and reporting on exceptions granted through the process developed in 438.68(d) above 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(a) would require that states have a process to solicit and address viewpoints from beneficiaries, providers, and other stakeholders as part of the design, implementation, and oversight of the managed LTSS program. We estimate no more than 3 states per year would elect to move to a managed LTSS program.

Section 438.70(c) would require that states continue to solicit and address public input for oversight purposes. This must be done at least twice annually. Existing MLTSS programs already meet this requirement and we estimate no more than 14 new programs.

We estimate an annual state burden of 4 hr at \$53.32/hr for a business operations specialist to perform this task. In aggregate, we estimate **56 hr** (14 states x 4 hr) and **\$2,985.92** (152 hr x \$53.32/hr).

Section 438.71 Beneficiary support system

Section 438.71(a) would require the state to develop and implement a system for support to beneficiaries before and after enrollment in a MCO, PIHP, PAHP, or PCCM. This will

most likely be accomplished via a call center including staff having email capability - internal to the state or subcontracted - that will assist beneficiaries with questions. As most state Medicaid programs already provide this service, we estimate only 20 states may need to take action to address this requirement.

We estimate a state would need 150 hr to either procure a vendor for this function or create an internal call center. The one-time state burden would consist of 125 hr (at \$53.32/hr) for a business operations specialist, and 25 hr (at \$127.72/hr) for a general and operations manager. In aggregate, we estimate **3,000 hr** (20 states x 150 hr) and **\$197,160** [20 states x ((125 hr x \$53.32/hr) + (25 hr x \$127.72/hr))].

Section 438.71(b) would require the system to include choice counseling for enrollees, training for providers, 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.

The provider training will likely involve developing materials thus we are estimating 3 hr at \$53.32/hr for a business operations specialist to create materials specifically for provider education on MLTSS and 1 hr to update those materials (given the fluid nature of community resources). As almost all materials for providers are sent electronically, we estimate only the additional time needed to produce the materials here.

In aggregate, we estimate a one-time state burden of **126 hr** (42 states x 3 hr) and **\$6,718.32** (126 hr x \$53.32/hr). We also estimate an annual state burden of **42 hr** (42 states x 1 hr) and **\$2,239.44** (42 hr x \$53.32/hr).

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 **\$111,466.08** (4,222 hr x \$26.40/hr).

Section 438.110 Member advisory committee

Section 438.110(a) would require each MCO, PIHP, and PAHP to 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 \$53.32/hr for a business operations specialist to maintain the operation of the committee (hold meetings, distribute materials to members, and maintain minutes) for up to 14 new programs. Existing programs already meet this requirement. In aggregate, we estimate **84 hr** (14 states x 6 hr) and **\$4,478.88** (84hr x \$53.32/hr).

Section 438.207 Assurance of adequate capacity and services

Section 438.207(b) requires that each MCO, PIHP, and PAHP (where applicable) submit documentation to the State, in a format specified by the State, to demonstrate that it complies with specified requirements and that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care and meets specified requirements. Section 438.207(c) would add a requirement that the documentation required in §438.207(b) be submitted to the state at least annually. As the MCOs, PIHPs, and PAHPs would already produce 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 MCOs, PIHPs, and PAHPs to revise their policy to reflect an annual submission. We estimate a one-time private sector burden of 1 hr at \$53.32/hr for a business operations specialist to revise the policy, if needed. In aggregate, we estimate **568 hr** (568 entities x 1 hr) and **\$30,285.76** (568 hr x \$53.32/hr). We also estimate an annual private sector burden of 2 hr to compile and submit the information necessary to meet the requirements § 438.207(b) through (d). In aggregate, we estimate **1,136 hr** (568 entities x 2 hr) and **\$60,571.52** (1,136 hr x \$53.32/hr).

Section 438.208 Coordination and continuity of care

Section 438.208(b)(2) would require that MCOs, PIHPs and PAHPs coordinate an enrollee's care between settings or with services received through a different MCO, PIHP, PAHP, fee-for-service, or through community or social support services.

Section 438.208(b)(2)(i) would require discharge planning, 438.208(b)(2)(ii) would require coordination with other MCOs, PIHPs, or PAHPs providing services, and 438.208(b)(2)(iv) would require coordination with community and social support

services. Given the historical high rate of utilization of these services by the Medicaid population, Medicaid managed care plans have experience in facilitating and coordination access to these services. As these are all long standing industry practices; this text would be added to acknowledge existing industry practice.

Section 438.208(b)(2)(iii) would require that MCOs, PIHPs and PAHPs coordinate service delivery with the services the enrollee receives in the fee-for-service 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 (2,746,476) will be affected. We estimate an ongoing private sector burden of 10 min (per enrollee) at \$59.20/hr for a healthcare social worker to perform the care coordination activities. In aggregate, we estimate **457,746 hr** (2,746,476 enrollees x 10 min) and **\$27,099,105.17** (457,746 hr x \$59.20/hr).

Section 438.208(b)(3) would require 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 (127) 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 PAHPs will be need to add this assessment to their initial enrollment functions. We estimate a one-time private sector burden of 3 hr at \$53.32/hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate **504 hr** [(127 MCOs/PIHPs + 41 PAHPs) x 3 hr] and **\$26,873.28** (504 hr x \$53.32/hr).

We estimate that in a given year, only 5 percent (485,872) of 25 percent of MCO and PIHP and all PAHP enrollees are new to a managed care plan. We estimate an annual private sector burden of 10 min (on average) at \$29.68/hr for a customer service representative to complete the assessment. In aggregate, we estimate **80,980 hr** (485,872 enrollees x 10 min) and **\$2,403,494.90** (80,980 hr x \$29.68/hr).

Section 438.208(b)(4) would require 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 need not be 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 posting the completed report for the other MCO, PIHP, or PAHP to retrieve.

We estimate a one-time burden of 4 hr at \$73.60/hr for a computer programmer to develop the report. In aggregate, we estimate 2,272 hr (568 MCOs, PIHPs, and PAHPs x

4 hr) and \$167,219 (2,272 hr x \$73.60/hr). However, while the currently approved burden sets out 45 min per enrollee and 464,782 annual hours, to provide more accurate estimates we are adjusting the burden by using one-time per plan estimates and recognizing the use of automated reporting. In aggregate, we estimate a one-time private sector burden of **-462,510 hr** (2,272 hr - 464,782 hr) and **-\$34,040,736** (-462,510 hr x \$73.60/hr). Once put on a production schedule, no additional staff time would be needed, thus no additional burden is estimated.

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; we propose to add “enrollees who require LTSS” to this section. These assessments and treatment plans should be performed by providers or MCO, PIHP or PAHP staff that meet the qualifications required by the state. We believe the burden associated with this requirement is the time it takes to gather the information during the assessment. (Treatment plans are generally developed while the assessment occurs so we are not estimating any additional time beyond the time of the assessment.) We believe that only enrollees in MCOs and PIHPs will require this level of assessment as most PAHPs provide limited benefit packages that do not typically warrant a separate treatment plan.

While this is an existing requirement, we estimate an additional 1 percent of the total enrollment of 42,812,879 (428,128) given the surge in enrollment into managed care of enrollees utilizing LTSS. We estimate an annual private sector burden of 1 hr (on average) at \$65.40/hr for a registered nurse to complete the assessment and treatment planning. In aggregate, we estimate an additional **428,128 hr** (428,128 enrollees x 1 hr) and **\$27,999,571.20** (428,128 hr x \$65.40/hr).

Section 438.208(c)(3)(v) would add a requirement that treatment plans be updated at least annually or upon request. We estimate a one-time private sector burden of 1 hr at \$53.32/hr for a business operations specialist to revise policies and procedures to reflect a compliant time frame. In aggregate, we estimate **568 hr** (568 MCOs, PIHPs, PAHPs x 1 hr) and **\$30,285.76** (568hr x \$53.32/hr).

Section 438.210 Coverage and authorization of services

Section 438.210(a)(4)(ii)(B) would require 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 would expect that most MCOs, PIHPs, and PAHPs would review their policies and procedures to ensure compliance. We estimate a one-time private sector burden of 20 hr at \$65.40/hr for a registered nurse to review and revise, if necessary, authorization policies and procedures. In aggregate, we estimate **11,360 hr** (568 MCOs, PIHPs, and PAHPs x 20 hr) and **\$742,944** (11,360 x \$65.40/hr).

Section 438.210(b) would require contracts with MCOs, PIHPs, or PAHPs and its subcontractors to have written policies and procedures for the processing of requests for

initial and continuing authorizations of services. The burden associated with this requirement is the time required to develop the policies and procedures which is part of usual and customary business practice for managed care plans.

Section 438.210(c) currently requires that each contract provide for the MCO or PIHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. In this NPRM, PAHPs would be added to this requirement. The burden associated with sending adverse benefit determination notices is included in § 438.404. While we believe PAHPs already provide notification of denials, we expect they may need to be revised to be compliant with §438.404. We estimate a one-time public sector burden of 1 hr at \$53.32/hr for a business operations specialist to revise the template. In aggregate, we estimate **61 hr** (61 PAHPs x 1 hr) and **\$3,252.52** (61 hr x \$53.32/hr).

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. We estimate a one-time private sector burden of 3 hr at \$53.32/hr for a business operations analyst to amend appropriate contracts. In aggregate, we estimate **1,704 hr** (568 MCO, PIHP, or PAHP x 3 hr) and **\$90,857.28** (1,704 x \$53.32/hr).

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)(2) currently requires MCOs and PIHPs to collect data on enrollee and provider characteristics as specified by the state, and on services furnished to enrollees, through an encounter data system or other such methods as may be specified by the state. We propose to add PAHPs to the requirement. We estimate a one-time private sector burden of 20 hr at \$73.60/hr for a computer programmer to extract this data from a PAHP's system and report it to the state.

In aggregate, we estimate **820 hr** (41 entities x 20 hr) and **\$60,352** (820 hr x \$73.60/hr). After creation, these reports would be set to run and sent to the state at on a production

schedule.

Section 438.310 Basis, scope, and applicability

Section 438.310 describes the statutory basis for section 438 subpart E, the scope of this subpart, and its application.

Section 438.310(c)(2) is new and would have states assess the performance of each PCCM entity described in § 438.3(r). Section 438.3(r) describes a specific subset of PCCM entities; therefore we estimate that this change will affect 10 states, or approximately 15 PCCM entities. At a minimum, the assessment would include the elements in § 438.330(b)(3), (c), and (e).

We estimate a one-time state burden of 2 hr at \$53.32/hr for a business operations specialist to address the performance assessment of PCCM entities specified at §438.3(r) by revising a state's policies and procedures. In aggregate, we estimate **20 hr** (10 states x 2 hr) and **\$1,066.40** (20 hr x \$53.32/hr).

Section 438.330 Quality assessment and performance improvement program

This section describes the quality assessment and performance improvement programs that states must require each contract MCO, PIHP, and PAHP to establish and implement, which includes both performance measurement and performance improvement projects. It also describes the annual review which the state must undertake to assess the impact and effectiveness of each MCO's, PIHP's, and PAHP's quality assessment and performance improvement program.

Section 438.330(a)(2) alters the process CMS would use to specify performance measures and PIP topics to include a public notice and comment process. Assuming that we do use this process to identify performance measures and PIP topics at least once every three years, the burden for states will be altered. Some may experience a decrease in the time spent selecting performance measures and PIP topics while others might experience a slight increase in the form of programming their MMIS systems to account for the specified performance measures and PIP topics.

We estimate an annual state burden of 10 hr (every 3 years) at \$73.60/hr for a computer programmer to make the MMIS programming changes. In aggregate, we estimate an annualized burden of **133.3 hr** [(40 states x 10 hr) / 3 years] and **\$9,810.88** (133.3 hr x \$73.60/hr). We cannot estimate the amount of possible decrease in burden as we have no way to know the average amount of time a state expended on selecting performance measures or PIP topics and how this might change based on this revision.

Section 438.330(a)(2)(i) would allow states to select performance measures and performance improvement projects (PIPs) in addition to those specified by CMS under § 438.330(a)(2). Since this language continues the flexibility available to states today, we do not believe this creates any change in burden for states or the private sector.

Section 438.330(a)(2)(ii) would allow states to apply for an exemption from the CMS-specified performance measures and PIP topics established under §438.330(a)(2). While we have no data on how many states would take advantage of this option, given that the performance measures and PIP topics under §438.330(a)(2) would be identified through a public notice and comment process, we estimate that 25 percent of states (11 states) would ask for an exemption every 3 years. We estimate an annual state burden of 1 hr at \$53.32/hr for a business operations specialist to comply with the exemption process. In aggregate, we estimate an annualized burden of **3.7 hr** [(11 states x 1 hr)/3 years] and **\$197.28** (3.7 hr x \$53.32/hr).

Section 438.330(b)(3) clarifies that MCOs, PIHPs, and PAHPs would have an approach to evaluate and address findings regarding the underutilization and overutilization of services. Because utilization review in managed care has become commonplace in the commercial, Medicare, and Medicaid settings, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or PAHPs. However, in accordance with § 438.310(c)(2), some PCCM entities (we estimate 15) would now be subject to this operational component.

We recognize that PCCM entities may not currently have in place mechanisms to assess and address underutilization and overutilization of services in accordance with §438.330(b)(3). We estimate a one-time private sector burden of 10 hr at \$53.32/hr for a business operations specialist to establish the policies and procedures. In aggregate, we estimate **150 hr** (15 PCCM entities x 10 hr) and **\$7,998** (150 hr x \$53.32/hr) for program establishment. We also estimate an annual burden of 10 hr to evaluate and address the findings. In aggregate, we estimate **150 hr** (15 PCCM entities x 10 hr) and **\$7,998** (150 hr x \$53.32/hr) for program maintenance.

Section 438.330(c)(1) through (3) would include conforming changes, specifically the addition of PAHPs to the list of affected managed care entities and updated citations. The section states that each MCO and PIHP annually measures its performance using standard measures specified by the state and reports its performance to the state. We assume that each of the 335 MCOs and 176 PIHPs would report on three performance measures to the state. The use of performance measures is commonplace in commercial, Medicare, and Medicaid managed care markets; therefore we believe that MCOs and PIHPs already collect performance measures.

For MCOs (335) and PIHPs (176), we estimate an annual private sector burden of 0.1 hr at \$53.32/hr for a business operations specialist to report on a single performance measure to the state. In aggregate, we estimate **153.3 hr** (511 MCOs and PIHPs x 3 performance measures x 0.1 hr) and **\$8,173.96** (153.3 hr x \$53.32/hr).

In accordance with § 438.310(c)(2), some PCCM entities would now be subject to the performance measurement standards under §438.330(c). We recognize that PAHPs and

PCCM entities may not currently engage in performance measurement as described in §438.330(c). We estimate that each PCCM entity and each PAHP would report to the state on 3 performance measures annually. For the 15 PCCM entities and 41 PAHPs, we estimate an annual private sector burden of 4 hr (per measure) at \$53.32/hr for a business operations specialist to collect, calculate, and submit each performance measure to the state. In aggregate, we estimate **672 hr** (56 PAHPs and PCCMs x 3 performance measures x 4 hr) and **\$35,831.04** (672 hr x \$53.32/hr).

In § 438.330(c)(4) we propose that, in addition to the performance measures otherwise specified under § 438.330(c)(1) through (3), MCOs, PIHPs, and PAHPs that provide LTSS services would collect and report on two categories of measures specific to LTSS. Assuming that each of the 179 MLTSS plans reports on at least one measure per category and a burden of 4 hr (per measure) at \$53.32/hr for a business operations specialist to collect, calculate, and submit each LTSS performance measure to the state, we estimate an aggregated private sector burden of **1,432 hr** (179 MLTSS plans x 2 performance measures x 4 hr) and **\$76,354.24** (1,432 hr x \$53.32/hr).

Section 438.330(d)(1) would have states ensure that each MCO and PIHP has an ongoing program of PIPs. In §438.330(d)(2), each MCO and PIHP would report the status and results of each such PIP to the state as requested. With respect to the standards for ongoing PIPs in §438.240(d), we estimate that each MCO and PIHP would conduct at least 3 PIPs in any given year. We further expect that states would request the status and results of each entity's PIPs annually. The currently approved burden under this control number estimates that each of 539 MCOs and PIHPs conducts 3 PIPs, for a burden of 12,936 hr (539 MCOs and PIHPs x 3 PIPs x 8 hr). However, this figure overestimates the number of MCOs and PIHPs. Therefore, we estimate an annual private sector burden of 8 hr at \$53.32/hr for a business operations specialist to report on each PIP. In aggregate, we estimate **12,264 hr** (511 MCOs and PIHPs x 8 hr x 3 PIPs) and **\$653,916.48** (12,264 hr x \$53.32/hr).

Section 438.330(d)(1) and (2) would add PAHPs to the list of affected managed care entities. While we recognize that PAHPs may not currently be conducting PIPs, we assume that each PAHP would conduct at least one PIP each year. We expect that states would request the status and results of each PAHP's PIP annually. We estimate a one-time private sector burden of 2 hr at \$53.32/hr for a business operations specialist to develop policies and procedures. In aggregate, we estimate **82 hr** (41 PAHPs x 2 hr) and **\$4,372.24** (82 hr x \$53.32/hr). We also estimate an annual private sector burden of 8 hr to prepare a PIP report. In aggregate, we estimate **328 hr** (41 PAHPs x 1 PIP x 8 hr) and **\$17,488.96** (328 hr x \$53.32/hr).

Per §438.310(c)(2), PCCM entities specified at §438.3(r) would also be subject to the program components in §438.330(e). We estimate an annual state burden of 15 hr at \$53.32/hr for a business operations specialist to assess the performance of a single §438.3(r) PCCM entity. In aggregate, we estimate **225 hours** (15 PCCM entities x 15 hr)

and **\$11,997** (225 hr x \$53.32/hr).

Under section 438.330(e)(1)(ii) states would include outcomes and trended results of each MCO, PIHP, and PAHP's PIPs in the state's annual review of quality assessment and performance improvement programs. We estimate a one-time state burden of 0.5 hr at \$53.32/hr for a business operations specialist to modify policies and procedures for the 40 states with MCOs, PIHPs and PAHPs. In aggregate, we estimate **20 hr** (40 states x 0.5 hr) and **\$1,066.40** (20 hr x \$53.32/hr). We also estimate an annual state burden of 1 hr to conduct the additional annual review of the outcomes and trended results for MCOs, PIHPs, and PAHPs. In aggregate, we estimate **40 hr** (40 states x 1 hr) and **\$2,132.80** (40 hr x \$53.32/hr).

Section 438.330(e)(1)(iii) is a new program component, related to §438.330(b)(5), which would have a state (in its annual review) assess the results of any efforts to support state goals to promote community integration of beneficiaries using LTSS in place at the MCO, PIHP, or PAHP. We estimate that the 16 states with MLTSS plans would need to modify their policies and procedures regarding the annual review of quality assessment and performance improvement programs in their managed care entities. We estimate a one-time state burden of 0.5 hr at \$53.32/hr for a business operations specialist to modify the state's policies and procedures. In aggregate, we estimate **8 hr** (16 states x 0.5 hr) and **\$426.56** (8 hr x \$53.32/hr). We also estimate an annual burden of 1 hr for the assessment of rebalancing efforts. In aggregate, we estimate **16 hr** (16 states x 1 hr) and **\$853.12** (16 hr x \$53.32/hr) for the assessment.

Section 438.332 State review and approval of MCOs, PIHPs, and PAHPs

Under this new section, states would review and approve MCO, PIHP, and PAHP performance at least once every three years, in accordance with standards at least as strict as those used by a private accrediting entity that is approved or recognized by CMS under the existing Marketplace and Medicare Advantage programs, as a condition of contracting with the state. It would also grant states the option of allowing MCOs, PIHPs, and PAHPs to meet this standard by presenting proof of accreditation by a private accrediting entity recognized by CMS. MCOs, PIHPs, and PAHPs would maintain state approval for the duration of participation in the Medicaid program. State approval of MCOs, PIHPs, and PAHPs would be renewed every 3 years.

A number of states already either include accreditation by a private accrediting entity as a component of their managed care contracting process or recognize such accreditation. We estimate that half of states (20 states) would elect to establish their own state review and approval process (per §438.332(a)) and the remainder (20 states) will elect to use the accreditation deeming option (per §438.332(b)). We further estimate that half (276) of the total number of MCOs, PIHPs, and PAHPs (552) will be subject to each process.

Section 438.332(a) would establish that in order to enter into a contract with the state, the performance of each MCO, PIHP, and PAHP would be reviewed and approved by the

state, using a set of standards that are at least as stringent as those used by a private accrediting entity recognized by CMS either for Medicare Advantage or Qualified Health Plan accreditation. It would also define maintenance of state approval as a condition of its contract. While we are aware of at least one state that operates its own accreditation process, we do not have any data regarding the costs of this type of review and approval system and thus estimate all burdens associated with this process.

We expect that states would have to purchase the accreditation standards of a private accrediting entity recognized by CMS in order to determine if its standards for MCOs, PIHPs, and PAHPs are at least as stringent as those used by a private accrediting entity. We estimate that this would cost \$20,000 per state, and that states would have to purchase these standards at least once every three years. In aggregate, we estimate an ongoing annualized state burden of **\$133,333.33** [(20 states x \$20,000) / 3 years] for the purchase of the accreditation standards of a private accrediting entity.

After purchasing these standards, the state would use them to develop its own standards which are at least as stringent as those used by the private accrediting entity. We estimate that states would conduct this process at least once every three years. We estimate an annual state burden of 15 hr at \$53.32/hr for a business operations specialist and 5 hr at \$127.72/hr for a general and operations manager. In aggregate, we estimate an annualized burden of **133.3 hr** [(20 states x 20 hr) / 3 years] and **\$9,589.33** [(20 states x 15 hr x \$53.32/hr) + (20 states x 5 hr x \$127.72/hr)) / 3 years].

The state would then use its standards to review and approve the performance of each plan at least once every three years. For plan review and approval, we estimate an annual state burden of 80 hr at \$53.32/hr for a business operations specialist, 5 hr at \$127.72/hr for a general and operations manager, and 5 hr at \$29.92/hr for an office and administrative support worker. In aggregate, we estimate an annualized state burden of **8,280 hr** (276 MCOs, PIHPs, and PAHPs x 90 hr / 3 years) and **\$464,949.60** [(276 MCOs/PIHPs/PAHPs x [(80 hr x \$53.32/hr) + (5 hr x \$127.72/hr) + (5 hr x \$29.92/hr)]) / 3 years] to review and approve MCOs, PIHPs, and PAHPs.

For the state to review and approve a plan, the MCO, PIHP, or PAHP would have to provide certain information to the state. As a condition of contracting with the states, plans would have to maintain state approval (a process which we estimate will occur at least once every three years); therefore plans would provide this information to the state at least once every three years. We estimate a burden of 40 hr at \$53.32/hr for a business operations specialist, 5 hr at \$29.92/hr for an office and administrative support worker, and 4 hr at \$127.72/hr for a general and operations manager to compile and provide this information. In aggregate we estimate an annualized private sector burden of **4,508 hr** [(276 MCOs, PIHPs, and PAHPs x 49 hr) / 3 years] and **\$256,981.76** [(276 MCOs, PIHPs, and PAHPs x [(40 hr x \$53.32/hr) + (5 hr x \$29.92/hr) + (4 hr x \$127.72/hr)]) / 3 years].

Section 438.332(b) would allow states to deem compliance with the process in §438.332(a) for MCOs, PIHPs, and PAHPs that provide proof and documentation of accreditation by a private accrediting entity recognized by CMS. We estimate the burden for the operation of the state deeming process as 40 hr at \$53.32/hr for a business operations specialist to oversee and collect private accreditation information from MCOs, PIHPs, and PAHPs. In aggregate, we estimate an annualized state burden of **266.7 hr** [(20 states x 40 hr) / 3 years] and **\$14,220.44** (266.7 hr x \$53.32/hr) for the oversight and operation of the accreditation deeming process.

Under section 438.332(b)(2), MCOs, PIHPs, and PAHPs would authorize the private accrediting entity to release accreditation information to the state in order to deem compliance with §438.332(a). We believe that an indeterminate number (estimated to be half, or 138 MCOs, PIHPs, and PAHPs) of these entities may already have received or are independently seeking accreditation, and thus would not face any additional burden associated with this section.

The remaining 138 MCOs, PIHPs, and PAHPs would have to seek initial accreditation from a private accrediting entity. The burden for accreditation varies widely, depending on a number of factors including the type of managed care entity, the size of its population, and the accrediting body. We estimate that initial accreditation costs \$70,700 per plan (given that private accrediting entities structure prices in terms of accreditation activities, not hours, an hourly burden estimate is not available) and would be renewed once every three years for the same cost. In aggregate, we estimate the one-time private sector burden for initial accreditation is **\$9,756,600** (138 MCOs, PIHPs, and PAHPs x \$70,700) and an annualized private sector burden of **\$3,252,200** [(138 MCOs, PIHPs, and PAHPs x \$70,700) / 3 years] for accreditation renewal.

Section 438.332(c) would have the state document its determinations for all MCOs, PIHPs, and PAHPs on the state's website. The burden is included in §438.10.

Section 438.334 Medicaid managed care quality rating system

Section 438.334 (a) would have each state which contracts with an MCO, PIHP or PAHP establish a quality rating system to generate plan ratings. These quality ratings would: (1) be based on the three specified components (clinical quality management, member experience, and plan efficiency, affordability, and management), (2) use outcomes data from the CMS-specified performance measures in 438.330(a)(3), and (3) be prominently displayed by the state on its website.

We assume each state would create a single quality rating system for all its MCOs, PIHPs, and PAHPs. Section 438.334(c) would provide states with the option to use their own quality rating system in place of the system proposed under this section; therefore, we estimate that 30 states would have to create quality rating systems. We further estimate that 75 percent (414) of MCOs, PIHPs, and PAHPs operate in these 30 states. We also assume that each state would utilize a public engagement process to solicit

feedback on its quality rating system.

We estimate the burden for the development of a state quality rating system as 100 hr at \$53.32/hr for a business operations specialist, 40 hr at \$73.60/hr for a computer programmer, and 15 hr at \$127.72/hr for a general and operations manager. We estimate an additional 2 hr at \$29.92/hr for an office and administrative support worker for the public engagement process and an additional 15 hr at \$53.32/hr for a business operations specialist to review and incorporate public feedback. In aggregate, we estimate a one-time state burden of **5,160 hr** (30 states x 172 hr) and **\$331,543.20** [30 states x ((100 hr x \$53.32/hr) + (40 hr x \$73.60/hr) + (15 hr x \$127.72/hr) + (2 hr x \$29.92/hr) + (15 hr x \$53.32/hr))] for the development of a state's quality rating system.

Under section 438.334(b) each state would collect information from its MCOs, PIHPs, and PAHPs in order to calculate and then issue a quality rating. We expect that states would rely on information and data already provided to them by their MCOs, PIHPs, and PAHPs; therefore, we do not expect this data collection to pose an additional burden on the private sector. However, each year states would rate each MCO, PIHP, or PAHP with which they contract. We estimate 20 hr at \$53.32/hr for a business operations specialist for a state to rate a MCO, PIHP, or PAHP. In aggregate, we estimate an annual state burden of **8,280 hr** (414 MCOs, PIHPs, and PAHPs x 20 hr) and **\$441,489.60** (8,280 hr x \$53.32/hr).

To elect the option under § 438.334(c) for states to use their own quality rating system in place of the system under § 438.334(a), a state would submit a request to CMS and receive written CMS approval. Knowing that some states already operate their own quality rating systems, we estimate that one quarter (10) of states will elect to use their own quality rating system. We estimate a one-time state burden of 5 hr at \$53.32/hr for a business operations specialist to seek and receive approval from CMS for the state's own quality rating system. In aggregate, we estimate **50 hr** (10 states x 5 hr) and **\$2,666** (50 hr x \$53.32/hr).

Section 438.334(d) would provide states with the option to use the Medicare Advantage five-star rating, instead of the quality rating system established under this section, for plans that serve only dual eligibles. We estimate that states may utilize this option for 25 MCOs, PIHPs, or PAHPs. This option would reduce the burden under §438.334(b) by - **500 hr** (-25 MCOs, PIHPs, and PAHPs x 20 hr) and **-\$26,660** (-500 hr x \$53.32/hr).

Section 438.334(e) would have states prominently display quality rating information for plans on the state website described in § 438.10. The burden associated with this process is captured in § 438.10.

Section 438.340 Managed care elements of State comprehensive quality strategies

This section describes the additional items that must be included in a state's comprehensive quality strategy (established in part 431 subpart I) when a state contracts

with MCOs, PIHPs, and/or PAHPs.

Section 438.340 would identify the additional items which states that contract with MCOs, PIHPs, and/or PAHPs would include in the comprehensive quality strategy under § 431.502. To include the additional managed care-related items in their comprehensive quality strategies, we estimate a state burden of 10 hr at \$53.32/hr for a business operations specialist each time a state revises its comprehensive quality strategy (once every three years, per §431.504(b)). In aggregate, we estimate an annualized burden of **133.3 hr** [(40 states x 10 hr) / 3 years] and **\$7,107.56** (133.3 hr x \$53.32/hr).

Section 438.400 Statutory basis and definitions

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

We estimate a one-time private sector burden of 5 hr at \$53.32/hr for a business operations specialist to amend all associated documents to the new nomenclature and definitions. In aggregate, we estimate **2,535 hr** (507 MCO and PIHP entities x 5 hr) and **\$135,166.20** (2,535 hr x \$53.32/hr). We also estimate a one-time state burden for states of **200 hr** (40 states x 5 hr) and **\$10,664** (200 hr x \$53.32/hr) to make similar revisions.

Section 438.402 General requirements

Section 438.402, general requirements, is revised with the following burden.

Section 438.402(a) would add PAHPs to the existing requirement for MCOs and PIHPs to have a grievance system. There are 41 non-NEMT PAHPs that would need to have their contract amended. The burden for revising their contract is included in §438.3. To set up a grievance system, we estimate it would take 100 hr (10 hr at \$127.72/hr for a general and operations manager, 75 hr at \$53.32/hr for a business operations specialist, and 15 hr at \$73.60/hr for a computer programmer) for each PAHP. In aggregate, we estimate a one-time private sector burden of **4,100 hr** (41 PAHPs x 100 hr) and **\$261,383.20** [41 PAHPs x ((10 hr x \$127.72/hr) + (75 hr x \$53.32/hr) + (15 hr x \$73.60/hr))].

We further estimate that the average PAHP would only receive 10 grievances per month due to their limited benefit package and will only require 3 hr at \$53.32/hr for a business operations specialist to process and handle grievances and adverse benefit determinations. In aggregate, we estimate an annual private sector burden of **14,760 hr** (41 PAHPs x 10 grievances x 3 hr x 12 months) and **\$787,003.20** (14,760 hr x \$53.32/hr)

Section 438.402(b) would limit 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.

Section 438.404 Notice of action

Section §438.404 states that if an MCO or PIHP intends to deny, limit, reduce, or terminate a service; deny payment; deny the request of an enrollee in a rural area with one MCO or PIHP to go out of network to obtain a service; or fails to furnish, arrange, provide, or pay for a service in a timely manner, the MCO or PIHP must give the enrollee timely written notice and sets forth the requirements of that notice.

We estimate that the burden associated with this requirement is the length of time it takes an MCO or PIHP to provide written notice of an intended action. We estimate that it takes MCOs and PIHPs 1 minute per action to make this notification. We estimate that approximately 5 percent (2,140,643) of the 42,812,879 MCO and PIHP enrollees will receive one notice of intended action per year from their MCO or PIHP. In aggregate, we estimate an annual private sector burden of **35,677 hr** (2,140,643 x 1 min) and **\$941,872.80** (35,677 hr x \$26.4/hr)

Section 438.404(a) would add 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 \$26.40/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 **\$105,811.20** (4,000 hr x \$26.40/hr).

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) would modify 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 not 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) would change 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 would align 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 would need to revise their policies and procedures. Among the 200 MCOs, PIHPs, and PAHPs, we estimate a one-time private sector burden of 1 hr at \$53.32/hr for a business operations specialist. In aggregate, we estimate **200 hr** (200 MCOs, PIHPs, and PAHPs x 1 hr) and **\$10,664** (200 hr x \$53.32).

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 would add 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 \$29.92/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 **\$119,919.36** (4,000 hr x \$29.92/hr).

Maintaining records for grievances and appeals has always been required for MCOs and PIHPs. However, we propose specific data so MCOs and PIHPs will have to revise their policies and systems to record the required information. We estimate 3 hr at \$73.60 for a computer programmer to make necessary changes. We estimate a one-time private sector burden of **168 hr** (56 MCOs and PIHPs x 3 hr) and **\$12,364.80** (168 hr x \$73.60/hr). As the required elements will be stored and tracked electronically, we estimate 1 min per grievance and appeal at \$29.92/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 **14,271 hr** (856,257 grievances x 1 min) and **\$426,986.82** (14,271 hr x \$29.92/hr).

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) would remove 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 would add “PAHP” as a conforming change to §438.400. This action would require 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 paragraph (c)(4) would have no impact on PAHPs.

For MCOs and PIHPs, we estimate a one-time private sector burden of 4 hr at \$53.32/hr for a business operations specialist to revise current policies and procedures. In aggregate, we estimate **2,028 hr** (507 MCOs and PIHPs x 4 hr) and **\$108,132.96** (2,028 hr x \$53.32/hr).

Section 438.420(d) would add PAHPs to the list of entities that can recover costs if the adverse determination is upheld. PAHPs would include the policies and procedures necessary to recover costs when developing their system under §438.402 and thus would incur no additional burden.

Section 438.602 State responsibilities

Section 438.602(a) would detail state responsibilities for monitoring MCO, PIHP, PAHP, PCCM or PCCM’s compliance with 438.604, 438.606, 438.608, 438.610, 438.230, and 438.808. As all of these sections are existing requirements, the only new burden is for states to update their policies and procedures, if necessary, to reflect revised regulatory

text. We estimate a one-time state burden of 6 hr at \$53.32/hr for a business operations specialist to create and/or revise their policies. In aggregate, we estimate **252 hr** (42 states x 6 hr) and **\$13,436.64** (252 hr x \$53.32/hr).

Section 438.602(b) would require states to screen and enrollee 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. As such, we estimate a one-time private sector burden of 6 hr at \$73.60/hr for a computer programmer to create the necessary programs to send provider applications/data to the state. In aggregate, we estimate **3,408 hr** (568 MCOs, PIHPs, and PAHPs x 6 hr) and **\$250,828.80** (3,408 hr x \$73.60/hr). Once created, the report would be put on a production schedule.

Section 438.602(e) would require states to conduct or contract for audits of MCO, PIHP, and PAHP encounter and financial data once every three 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 \$63.10/hr for an accountant. In aggregate, we estimate **3,787 hr** (568 MCOs, PIHPs, and PAHPs x 20 hr)/3) and **\$238,959.70** (3,787 hr x \$63.10/hr).

Section 438.602(g) would require 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 \$73.60/hr for a computer programmer to post the documents. In aggregate, we estimate **40 hr** (40 states x 1 hr) and **\$2,944** (40 hr x \$73.60/hr).

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) would require that MCOs, PIHPs, and PAHPs have administrative and management arrangements or procedures that 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 must include: written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable federal and state standards and requirements under the contract; the designation of a Compliance Officer; the establishment of a Regulatory Compliance Committee on the Board of Directors; effective training and education for the organization's management and its employees; and provisions for internal monitoring and a prompt and effective response to noncompliance with the requirements under the contract.

While §438.608(a)(1) is an existing regulation, we expect all MCOs, PIHPs, and PAHPs review their policies and procedures to ensure that all of the above listed items are addressed. We estimate a one-time private sector burden of 2 hr at \$53.32/hr for a business operations specialist to review and (if necessary) revise their policies and procedures. In aggregate, we estimate **1,136 hr** (568 MCOs, PIHPs, and PAHPs x 2 hr) and **\$60,571.52** (1,136 hr x \$53.32/hr).

Section 438.608(a)(2) and (3) require reporting of improper payments 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 \$53.32/hr for a business operations specialist. In aggregate, we estimate **1,136 hr** (568 MCOs, PIHPs, and PAHPs x 2 hr) and **\$60,571.52** (1,136 hr x \$53.32/hr).

Section 438.608(a)(4) would require the MCO, PIHP, or PAHP to 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 health 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 would mail to 100 enrollees each. We estimate an annual private sector burden of 1 min at \$26.40/hr for a mail clerk to send each letter. In aggregate, we estimate **333 hr** (20,000 letters x 1 min/letter) and **\$8,817.60** (333 hr x \$26.40/hr). This estimate will be significantly reduced as the use of email increases.

Section 438.608(b) reiterates the requirement in §438.602(b) whereby the burden is stated above.

Section 438.608(c) and (d) would require states to include in all MCO, PIHP, and PAHP contracts, the process for the disclosure and treatment of certain types of recoveries and reporting of such activity. While the burden to amend the contracts is included in §438.3, we estimate a one-time private sector burden of 1 hr at \$73.60/hr for a computer

programmer to create the report. In aggregate, we estimate **568 hr** (568 MCOs, PIHPs, and PAHPs x 1 hr) and **\$41,804.80** (568 hr x \$73.60/hr). Once developed, the report would be put on a production schedule and add no additional burden.

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) would provide 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 they have already opted to provide written notice to MCO and PCCM enrollees.

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 \$53.32/hr for a business operations specialist to prepare the notice. In aggregate, we estimate a one-time state burden of **12 hr** (12 states x 1 hr) and **\$639.84** (12 hr x \$53.32/hr).

To send the notice, we estimate 1 min (per beneficiary) at \$26.40/hr for a mail clerk. We estimate an aggregate annual state burden of **18,075 hr** (12 states x 90,378 enrollees/60 mins) and **\$477,195** (18,075 hr x \$26.40/hr).

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) would require 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 would incur no additional burden. Since approximately 10 states already use their EQRO to validate their data, only 27 states may need to take action to meet this requirement. The method selected by the state will determine the amount of burden incurred. We assume an equal distribution of states selecting each method, thus 9 states per method.

A state using EQRO to validate data on less than an appropriate frequency may need to amend their EQRO contract. In this case, we estimate 1 hr at \$53.32/hr for a business operations specialist. In aggregate, we estimate a one-time state burden of **9 hr** (9 states x 1 hr) and **\$479.88** (9 hr x \$53.32/hr).

A state electing to perform validation internally would need to develop processes and policies to support implementation. In this case, we estimate 10 hr at \$53.32/hr for a business operations specialist to develop policy and 100 hr at \$73.60/hr for a computer programmer to develop, test, and automate the validation processes. In aggregate, we estimate a one-time state burden of **990 hr** (9 states x 110 hr) and **\$71,038.80** [9 states x ((10 hr x \$53.32/hr) + (100 hr x \$73.60/hr))].

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 75 hr at \$53.32/hr for a business operations specialist to participate in the writing, evaluating, and implementing, 50 hr at \$53.32/hr for a business operations specialist to participate in the writing, evaluating, and implementing, and 25 hr at \$127.72/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 **\$88,722** [9 states x ((125 hr x \$53.32/hr) + (25 hr x \$127.72/hr))].

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

13. Capital Costs (Maintenance of Capital Costs):

There are no capital costs.

14. Cost to Federal Government:

Utilizing burden estimates from section IV of this proposed 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 \$39,273,939.

15. Program or Burden Changes:

Adjustments have been made to CMS-10108 to account for: (1) proposed changes to the regulations per CMS-2390-P (see detailed description in Section 12), (2) estimate revisions to update data from current supporting statement, and (3) updated BLS job titles and wages. Due to the magnitude of revisions in 42 CFR part 438, many of the burden estimates in section B.12. of the previous supporting statement were extensively revised. The chart below summarizes, at the section level, the annualized changes to hour and cost burdens as compared to the most recent available supporting statement estimates.

Section	hours			costs			Reason
	Previous	Revised	difference	Previous	Revised	difference	
6 Special contract provisions related to payment	16,224	785	-15,440	\$2,072,129	\$70,238	-\$2,001,891	Revisions to provisions
10 Information Standards	488,538	152,103	-336,435	\$13,013,208	\$897,337	-\$12,115,871	Revisions to provisions
12 Provider discrimination prohibited	6,220	95	-6,125	\$164,208	\$2,508	-\$161,700	Revisions to provisions
50 State plan requirements	88	40	48	\$4,692	\$2,132	-\$2,560	Revisions to provisions
62 Continued services to enrollees	0	55,512	55,512	\$0	\$3,493,746	\$3,493,746	Existing section but no previous burden
102 Provider -enrollee communications	6,727	4,222	2,505	\$179,208	\$111,466	-\$67,742	Revisions to provisions
207 Assurance of adequate capacity and services	12,440	1,704	-10,736	\$684,200	\$70,666	-\$613,534	Revisions to provisions
208 Coordination and continuity of care	547,231	505,416	-41,815	\$40,276,201	\$46,174,312	\$5,898,111	Revisions to provisions
210 Coverage and Authorization of services	497,600	11,421	-486,179	\$36,623,360	\$248,732	-\$36,374,628	Revisions to provisions
230 Contractual relationships and	0	1,704	1,704	\$0	\$90,857	\$90,857	Existing section but no previous burden

Section	hours			costs			Reason
	Previous	Revised	difference	Previous	Revised	difference	
delegation							
242 Health Information systems	129,360	820	-128,540	\$9,520,896	\$20,117	-\$9,500,779	Revisions to provisions
438.310 Basis, scope, and applicability	0	7	7	\$0	\$355	\$355	Regulatory change: application of certain quality regulations to PCCM entities
438.320 Definitions	---	---	N/A	---	---	N/A	N/A
402 General requirements	0	18,860	18,860	\$0	\$874,130	\$874,130	no previous burden
404 Timely and adequate notice of adverse benefit determination	11,250	39,685	28,435	\$297,000	\$941,872	\$644,872	revisions to provisions
408 Resolution and notification: grievances and appeals	0	200	200	\$0	\$3,554	\$3,554	no previous burden
416 Recordkeeping requirements	6,833	25,610	18,777	\$293,819	\$765,360	\$471,541	revisions to provisions
420 Continuation of benefits pending appeal	0	2,028	2,028	\$0	\$36,044	\$36,044	no previous burden
602	0	7,487	7,487	\$0	\$329,992	\$329,992	no previous

Section	hours			costs			Reason
	Previous	Revised	difference	Previous	Revised	difference	
State responsibilities							burden
608 Program integrity requirements under the contract	0	2,038	2,038	\$0	\$83,324	\$83,324	no previous burden
722 Disenrollment during termination process	51,730	18,091	-33,639	\$1,366,049	\$477,931	-\$888,118	revisions to provisions
New sections 438	.3, .4, 5, .7, .9, .14, .54, .68, .70, .71, .74, .110, .330, .332, .334, .340, .807, .816, and .818						
Deleted sections 438	.202, .204, .218, .240, and .226						
Replaced section number 438	.8 Description of change: Section 438.8, medical loss ratio standards, replaces section 438.8, Provisions that apply to PIHPs and PAHPs. The previous provisions in 438.8 were revised and redesignated as appropriate throughout 438.						

16. Publication and Tabulation Dates:

The information submitted to CMS (excluding the information described in § 438.340) 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 or PCCMs. The rest of the information is used by States as part of their normal contracting with MCOs PIHPs, PAHPs, and PCCMs and is not be published.

The information submitted to CMS under § 438.340, the managed care component of the comprehensive quality strategy, may be made publicly available by CMS. CMS intends to maintain a list of hyperlinks on Medicaid.gov to states' websites where comprehensive quality strategies are posted in order to improve public transparency.

17. Expiration Date:

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

18. Certification Statement:

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

A statistical analysis of the collected information is not applicable.