Supporting Statement – Part A
Children's Health Insurance Program Managed Care and Supporting Regulations
CMS-10554, OCN 0938-NEW

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

Background

Children's Health Insurance Program (CHIP) Managed Care and Supporting Regulations Contained in 42 CFR 457.10, 457.204, 457.700, 457.760, 457.940, 457.950, 457.1200, 457.1201, 457.1203, 457.1205, 457.1206, 457.1207, 457.1208, 457.1210, 457.1212, 457.1214, 457.1216, 457.1218, 457.1220, 457.1222, 457.1224, 457.1226, 457.1228, 457.1230, 457.1233, 457.1240, 457.1250, 457.1260, 457.1270, 457.1280, and 457.1285.

The Medicaid and CHIP managed care proposed regulation (CMS-2390-P) implements several recent statutory provisions that apply Medicaid managed care requirements to CHIP. The regulation builds on initial guidance on the implementation of section 403 of CHIPRA provided in State Health Official (SHO) letters 09-008 and 09-013, issued on August 31, 2009 and October 21, 2009, respectively. (SHO #09-008 is available at: http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SHO083109a.pdf. SHO #09-013 is available at: http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO102109.pdf.) The SHO letters specified that all CHIP managed care contracts were to include the provisions of section 2103(f) of the Act, as amended by section 403 of CHIPRA effective July 1, 2009.

Our goal for these regulations is to align CHIP managed care standards with those of the Marketplace and Medicaid where practical. This will ensure consistency across programs. Therefore, where appropriate, we propose to align the CHIP managed care regulations with some of the proposed revisions to the Medicaid managed care rules.

A. Justification

1. Need and Legal Basis

Section 403 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) added section 2103(f)(3) to the Social Security Act (the Act). Section 2103(f)(3) of the Act applies sections 1932(a)(4), 1932(a)(5), 1932(b), 1932(c), 1932(d), and 1932(e) of the Act to CHIP. In addition, we propose to implement section 2107(e)(1)(M) of the Act, as added by section 5006 of the American Recovery and Reinvestment Act of 2009 (ARRA). This provision applies sections 1932(a)(2)(C) and 1932(h) of the Act, which provide protections for American Indians to CHIP. We also propose to implement statutory provisions related to program integrity, specifically sections 2107(b) and 2107(e)(2)(C) through (E) of the Act.

2. Information Users

General

CHIP enrollees use the information collected and reported as a result of this regulation to make informed choices regarding health care, including how to access health care services and the grievance and appeal system.

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

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

EQRO provisions

The law requires that the state agency provide to the EQRO information from the EQR-related activities, obtained through methods consistent with the Protocols specified by CMS.

The regulation extends the availability of the results of EQR to the public. In addition to responding to requests, states must post the EQR technical reports on their websites. This allows CHIP enrollees and potential enrollees to make informed choices regarding the selection of their providers. It also allows advocacy organizations, researchers, and other interested parties access to information on the quality of care provided to CHIP beneficiaries enrolled in CHIP managed care organizations (MCO), prepaid inpatient health plans (PIHP), and prepaid ambulatory health plans (PAHP).

Comprehensive quality strategy provisions

CHIP beneficiaries and stakeholders use the information collected and reported to understand the state's quality improvement goals and objectives, and to understand how the state is measuring progress on its goals.

States use this information to help monitor and assess the performance of their CHIP programs. This information may assist states in comparing the outcomes of different delivery systems and can assist them in identifying future performance improvement subjects.

3. Use of Information Technology

Sections §§457.1201, 457.1205, 457.1230, and 457.1240 contain requirements concerning specific reporting to CMS and will all be done electronically.

Pursuant to §457.760, states will post their final comprehensive quality strategies and effectiveness evaluations of their strategies, on their CHIP websites. This will ensure the public has electronic access to this information. States have discretion regarding their use of information technology for the public engagement process. While there is discretion, we expect that states will

generally submit their comprehensive quality strategies to CMS for review via email. No signature, electronic or written, is required for this document.

Most of the other 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 are not in the position to dictate how the information may be disclosed.

4. Duplication of Efforts

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

5. Small Businesses

We do not believe that these information collection requirements affect small businesses.

6. Less Frequent Collection

These ICRs were mandated by CHIPRA, ARRA, and the Affordable Care Act. If CMS were to collect them less frequently, we would be in violation of the law.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register/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. Payments/Gifts to Respondents

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.

The information collected by states under §§457.1240 and 457.1250 will be subject to state freedom of information requirements. However, as per section 1932(c)(2)(A)(iv) of the Act, the results of EQR may not be made available in a manner that discloses the identity of any individual patient.

Under §457.760, states are required to maintain the current CQS on their websites, where they must also post the findings of the CQS effectiveness evaluations conducted at least once every three years.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates (Hours & Wages)

Wage Estimates

To derive average costs, 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). Table 1 presents the median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1: Occupation Titles and Wage Rates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit (at 100%) ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialist	13-1000	29.66	$29.66	53.32
Computer Programmer	15-1131	36.80	$36.80	73.60
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.

Summary of Burden Estimates

Section in Title 42 of the CFR	Respondents	Responses	Time per Response (hr)	Total Hours	Labor Rate ($/hr)	Cost per Response ($)	Total Cost	Frequency	Annualized Hours*	Adjus Cost
457.760(a) Quality	33	33	3.333	110	53.32	178	5,864.61	annual	110	5,8
457.1201 Contracts	66	66	6	396	53.32	320	21,114.72	once	132	7,0
457.1206 Contracts	3	3	4	12	53.32	213	639.84	once	4	2
457.1207 Information Requirements	33	33	4	132	53.32	213	7,038.24	annual	132	7,0
457.1207 Information Requirements	33	33	6	198	73.60	442	14,572.80	once	66	4,8
457.1207 Information Requirements	33	33	3	99	73.60	221	7,286.40	annual	99	7,2
457.1207 Information Requirements	33	33	6	198	53.32	320	10,557.36	once	66	3,5
457.1207 Information Requirements	15	15	40	600	53.32	2,133	31,992.00	once	200	10,6
457.1207 Information Requirements	15	15	2	30	53.32	107	1,599.60	annual	30	1,5
457.1207 Information Requirements	33	33	4	132	73.60	294	9,715.20	once	44	3,2
457.1207 Information Requirements	33	33	6	198	53.32	320	10,557.36	once	66	3,5
457.1207 Information Requirements	15	15	40	600	53.32	2,133	31,992.00	once	200	10,6
457.1207 Information Requirements	33	306937	0	5,116	29.92	0	153,059.25	once	1,705	51,0
457.1207 Information Requirements	33	33	1	33	53.32	53	1,759.56	once	11	5
457.1208 Contracts	25	25	12	300	53.32	640	15,996.00	annual	300	15,9

457.1210(a) Enrollment	33	306937	0.01666667	5,116	29.92	0	153,059.25	annual	5,116	153,0
457.1214 Conflict	5	5	10	50	53.32	533	2,666.00	once	17	8
457.1216 Continued services	33	33	10	330	53.32	533	17,595.60	once	110	5,8
457.1216 Continued services	33	33	4	132	73.60	294	9,715.20	once	44	3,2
457.1218 Network	12	12	15	180	53.32	800	9,597.60	once	60	3,1
457.1218 Network	5	5	10	50	53.32	533	2,666.00	once	17	8
457.1218 Network	33	33	3	99	53.32	160	5,278.68	once	33	1,7
457.1224 Marketing	25	25	3	75	53.32	160	3,999.00	annual	75	3,9
457.1260 Grievances	33	33	5	165	53.32	267	8,797.80	annual	165	8,7
457.1270 Sanctions	8	8	1	8	53.32	53	426.56	annual	8	4
457.1270 Sanctions	30000	30000	0.02	500	26.40	0	13,200.00	annual	500	13,2
457.1270 Sanctions	15	15	1/2	8	53.32	27	399.90	annual	8	3
457.1285 Program integrity	33	33	50	1,650	53.32	2,666	87,978.00	once	550	29,3
457.1285 Program integrity	7	7	1	7	53.32	53	373.24	once	2	1
457.1285 Program integrity	7	7	10	70	53.32	533	3,732.40	once	23	1,2
457.1285 Program integrity	7	7	100	700	73.60	7,360	51,520.00	once	233	17,1
457.1285 Program integrity	7	7	125	875	53.32	6,665.00	46,655.00	annual	875	46,6

457.1285 Program integrity	7	7	25	175	127.72	3,193.00	22,351.00	annual	175	22,3
457.1285 Program integrity	33	33	1	33	73.60	73.60	2,428.80	annual	33	2,4
457.1205 MLR	62	62	101	6,262	73.60	7,434	460,883.20	once	2,087	153,6
457.1205 MLR	62	62	50	3,100	53.32	2,666	165,292.00	once	1,033	55,0
457.1205 MLR	62	62	17	1,054	127.72	2,171	134,616.88	once	351	44,8
457.1205 MLR	62	62	31.8	1,972	73.60	2,340	145,109.76	annual	1,972	145,1
457.1205 MLR	62	62	15.9	986	53.32	848	52,562.86	annual	938	52,5
457.1205 MLR	62	62	5.3	329	127.72	677	41,968.79	annual	329	41,9
457.1207 Information Requirements	5	5	10	50	53.32	533	2,666.00	once	17	8
457.1207 Information Requirements	20	20	4	80	53.32	213	4,265.60	once	27	1,4
457.1207 Information Requirements	66	3069371	0	51,156	29.92	0	1,530,593.01	once	17,052	510,1
457.1207 Information Requirements	66	306937	0	5,116	29.92	0	153,059.25	annual	5,116	153,0
457.1207 Information Requirements	66	66	1	66	53.32	53	3,519.12	once	22	1,1
457.1207 Information Requirements	66	66	1	66	73.60	74	4,857.60	once	22	1,6
457.1208 Contracts	40	40	1	40	73.60	74	2,944.00	once	13	9
457.1216 Continued services	66	66	4	264	73.60	294	19,430.40	once	88	6,4
457.1216 Continued services	30000	30000	1/6	5,000	65.40	11	327,000.00	annual	5,000	327,0

457.1222 Communication	3	3	1	3	53.32	53	159.96	annual	3	1
457.1222 Communication	3	3	4	12	53.32	213	639.84	annual	12	6
457.1222 Communication	3	234,000	0	3,900	29.92	0	116,688.00	annual	3,900	116,6
457.1224 Marketing	5	5	2	10	53.32	107	533.20	once	3	1
457.1260 Grievances	62	2232	3	6,696	53.32	160	357,030.72	annual	6,696	357,0
457.1260 Grievances	62	62	10	620	127.72	1,277	79,186.40	once	207	26,3
457.1260 Grievances	62	62	75	4,650	53.32	3,999	247,938.00	once	1,550	82,6
457.1260 Grievances	62	62	15	930	73.60	1,104	68,448.00	once	310	22,8
457.1260 Grievances	62	297,600	1/2	148,800	53.32	27	7,934,016.00	annual	148,800	7,934,0
457.1260 Grievances	306937	306937	0	5,116	29.92	0	153,059.25	annual	5,116	153,0
457.1260 Grievances	6139	6139	0	102	29.92	0	3,061.31	annual	102	3,0
457.1285 Program integrity	63	63	5	315	53.32	267	16,795.80	once	105	5,5
457.1285 Program integrity	63	63	2	126	53.32	107	6,718.32	annual	126	6,7
457.1285 Program integrity	33	3300	0	55	29.92	0	1,645.60	annual	55	1,6
457.1285 Program integrity	63	63	1	63	73.60	74	4,636.80	once	21	1,5
457.1230(a) Access Standards	63	63	3	189	53.32	160	10,077.48	once	63	3,3
457.1230(b) Access Standards	63	63	20	1,260	53.32	1,066	67,183.20	annual	1,260	67,1

457.1230(b) Access Standards	63	63	1	63	53.32	53	3,359.16	annual	63	3,3
457.1230(c) Access Standards	122775	122775	1/6	20,463	59.20	10	1,211,380.00	annual	20,463	1,211,3
457.1230(c) Access Standards	18	18	3	54	53.32	160	2,879.28	once	18	9
457.1230(c) Access Standards	613,874	613,874	1/6	102,312	29.92	5	3,061,185.01	annual	102,312	3,061,1
457.1230(c) Access Standards	63	63	4	252	73.60	294	18,547.20	once	84	6,1
457.1230(c) Access Standards	61387	61387	1	61,387	65.40	65	4,014,709.80	annual	61,387	4,014,7
457.1230(d) Access Standards	63	98280	0.5	49,140	65.40	33	3,213,756.00	annual	49,140	3,213,7
457.1233(b) Structure and Operations	63	63	3	189	53.32	160	10,077.48	once	63	3,3
457.1233(c) Structure and Operations	62	62	2	124	53.32	107	6,611.68	annual	124	6,6
457.1233(d) Structure and Operations	59	59	20	1,180	73.60	1,472	86,848.00	once	393	28,9
457.1240(b) Quality	33	33	3.33333333	110	73.60	245	8,096.00	once	37	2,6
457.1240(b) Quality	2	2	0.33	1	53.32	18	35.19	annual	1	
457.1240(b) Quality	3	3	10	30	53.32	533	1,599.60	annual	30	1,5
457.1240(b) Quality	7	21	4	84	53.32	213	4,478.88	annual	84	4,4
457.1240(b) Quality	4	4	2	8	53.32	107	426.56	once	3	1
457.1240(b) Quality	59	177	8	1,416	53.32	427	75,501.12	annual	1,416	75,5
457.1240(b) Quality	4	4	8	32	53.32	427	1,706.24	annual	32	1,7

457.1240(b) Quality	3	3	15	45	53.32	800	2,399.40	annual	45	2,3
457.1240(b) Quality	33	33	0.5	17	53.32	27	879.78	once	6	2
457.1240(b) Quality	33	33	1	33	53.32	53	1,759.56	annual	33	1,7
457.1240(c) Quality	66	66	80	1,760	53.32	4,265.60	93,843.20	annual	1,760	93,8
457.1240(c) Quality	66	66	5	110	127.72	638.60	14,049.20	annual	110	14,0
457.1240(c) Quality	66	66	5	110	29.92	149.60	3,291.20	annual	110	3,2
457.1240 Quality	66	66	40	880	53.32	2,132.80	46,921.60	annual	880	46,9
457.1240 Quality	66	66	5	110	29.92	149.60	3,291.20	annual	110	3,2
457.1240 Quality	66	66	4	88	127.72	510.88	11,239.36	annual	88	11,2
457.1240 Quality	66	66	30	1,980	53.32	1,600	105,573.60	annual	1,980	105,5
457.1240 Quality	66	66	5	330	127.72	639	42,147.60	annual	330	42,1
457.1240 Quality	66	66	5	330	29.92	150	9,873.60	annual	330	9,8
457.1240(c) Quality	16	16	N/A	N/A	N/A	70,700.00	1,131,200.00	once	N/A	377,0
457.1240(c) Quality	16	16	N/A	N/A	N/A	70,700.00	377,066.67	annual	N/A	377,0
457.1240(d) Quality	47	47	20	940	53.32	1,066.40	50,120.80	annual	940	50,1
457.1240(d) Quality	33	33	3.33333333	110	53.32	177.73	5,865.20	once	37	1,9
457.1250(a) EQR	5	5	125	625	53.32	6,665	33,325.00	once	208	11,1

457.1250(a) EQR	5	5	50	250	73.60	3,680	18,400.00	once	83	6,1
457.1250(a) EQR	5	5	10	50	127.72	1,277	6,386.00	once	17	2,1
457.1250(a) EQR	5	5	2	10	53.32	107	533.20	once	3	1
457.1250(a) EQR	5	15	65	975	53.32	3,466	51,987.00	annual	975	51,9
457.1250(a) EQR	5	15	53	795	53.32	2,826	42,389.40	annual	795	42,3
457.1250(a) EQR	5	5	120.333333	602	53.32	6,416	32,080.87	annual	602	32,0
457.1250(a) EQR	5	5	60	300	53.32	3,199	15,996.00	annual	300	15,9
457.1250(a) EQR	5	5	80	400	53.32	4,266	21,328.00	annual	400	21,3
457.1250(a) EQR	5	5	80	400	29.92	2,394	11,968.00	annual	400	11,9
457.1250(a) EQR	48	48	350	16,800	53.32	18,662	895,776.00	annual	16,800	895,7
457.1250(a) EQR	30	30	50	1,500	53.32	2,666	79,980.00	annual	1,500	79,9
457.1250(a) EQR	20	20	159	3,180	53.32	8,478	169,557.60	annual	3,180	169,5
457.1250(a) EQR	26	26	195	5,070	53.32	10,397	270,332.40	annual	5,070	270,3
457.1250(a) EQR	52	52	159	8,268	53.32	8,478	440,849.76	annual	8,268	440,8
457.1250(a) EQR	52	310	0	26	29.92	2	772.93	annual	26	7
TOTAL		5,800,642		549,704	--	--	28,595,152.65	---	494,641*	25,556,

*Private sector: 187,811 hr (reporting), 91,232 hr (recordkeeping), and 35,549 hr (third-party disclosure)
State Gov't: 107,489 hr (reporting), 52,214 hr (recordkeeping), and 20,346 hr (third-party disclosure)

Proposed Requirements and Burden Estimates

Section 457.760 CHIP Component of the State Comprehensive Quality Strategy.
Under §457.760, states would address all delivery systems for their CHIP programs as a component of the state comprehensive quality strategy under part 431, subpart I. While the majority of the burden associated with the comprehensive quality strategy is captured in part 431, subpart I, we estimate an additional burden of 10 hr (every three years) at $53.32/hr for a business operations specialist to address CHIP within the comprehensive quality strategy. In aggregate, we estimate an annualized burden of 110 hr [(33 states and territories x 10 hr) / 3 years] and $5,864.61 (110 hr x $53.32/hr).

Section 457.1201 Standard Contract Requirements
Section 457.1201 would provide a list of standard requirements that must be included in MCO, PIHP, PAHP, and primary care case management (PCCM) contracts. The following burden estimate addresses the effort to amend such contracts in addition to the contract amendments associated with §§457.1205, 457.1207, 457.1208, 457.1210, 457.1212, 457.1218, 457.1220, 457.1222, 457.1224, 457.1226, 457.1228, 457.1230, 457.1233, 457.1235, 457.1240, 457.1250, 457.1260, 457.1270, and 457.1285. We estimate a one-time state burden of 6 hr at $53.32/hr for a business operations specialist to amend all contracts associated with the aforementioned requirements. In aggregate, we estimate 396 hr (66 contracts x 6 hr) and $21,114.72 (396 hr x $53.32/hr).

Section 457.1205 Medical Loss Ratio
Section 457.1205 would apply the requirements of §438.8 to CHIP. 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 under other authority, any remittance owed.

We estimate the total number of MLR reports that MCOs, PIHPs, and PAHPs would be required to submit to the state would amount to 62 contracts. We estimate a one-time burden of 168 hr for the initial administration activities. In the first year, 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). The first year burden amounts to 168 hr and $12,270.84 ((101 hr x $73.60) + (50 hr x $53.32) + (17 hr x $127.72)) per report or, in aggregate, 10,416 hr (62 reports x 168 hr) and $760,792.086 (62 x $12,270.84).

In subsequent years, since the programming and processes established in year 1 will continue to be used, the burden will be decrease from 168 hr to an ongoing burden of approximately 53 hr. Using the same proportions of labor allotment, we estimate 53 hr and $3,865.18 ((31.8 hr x $73.60) + (15.9 hr x $53.32) + (5.3 hr x $127.72)) per report and a total of 3,127 hr (53 hr x 59 reports) and $228,045.62 (59 reports x $3,865.18). CMS expects states to permit MCOs and PIHPs 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 457.1206 Non-emergency Medical Transportation PAHPs

Section 457.1206 would provide a list of standard requirements that must be included in NEMT PAHP contracts. The following burden estimate addresses the effort to amend such contracts in addition to the contract amendments associated with §§457.1205, 457.1207, 457.1210, 457.1212, 457.1220, 457.1222, 457.1224, 457.1226, 457.1230(a), 457.1230(d), and 457.1233. We estimate a one-time state burden of 4 hr at $53.32/hr for a business operations specialist to amend all contracts associated with the aforementioned requirements. In aggregate, we estimate 12 hr (3 contracts x 4 hr) and $639.84 (12 hr x $53.32/hr).

Section 457.1207 Information Requirements

Section 457.1207 would apply the requirements of §438.10 to CHIP. Section 438.10(c)(1) would require that states provide enrollment notices, informational materials, and instructional materials in an easily understood format. We anticipate that most states already do this and will only have to make minor revisions. We estimate an annual burden of 4 hr at $53.32/hr for a business operations specialist to make these revisions. In aggregate, we estimate 132 hr (33 states x 4 hr) and $7,038.24 (132 hr x $53.32/hr).

Section 438.10(c)(3) would require that states operate a website which provides the information set out under §438.10(f). Since all states already have websites for their Medicaid programs and most also include information about their managed care program, most states will probably only have to make minor revisions to their existing website. We estimate a one-time state burden of 6 hr at $73.60/hr for a computer programmer to make the initial changes. In aggregate, we estimate 198 hr (33 states x 6 hr) and $14,572.80 (198 hr x $73.60/hr). We also estimate an annual burden of 3 hr at $73.60/hr for a computer programmer to periodically add or update documents and links on the website. In aggregate, we estimate 99 hr (33 states x 3 hr) and $7,286.40 (99 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 a one-time state burden of 6 hr at $53.32/hr for a business operations specialist to develop these definitions. In aggregate, we estimate 198 hr (33 states x 6 hr) and $10,557.36 (198 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 that 15 states may need to take action to comply with this provision. We estimate a one-time state burden of 40 hr at $53.32/hr for a business operations specialist to create these documents. In aggregate, we estimate 600 hr (15 states x 40 hr) and $31,992.00 (600 hr x $53.32/hr). We also estimate an annual state burden of 2 hr at $53.32/hr for a business operations specialist to maintain these documents. In aggregate, we estimate 30 hr (15 states x 2 hr) and $1,599.60 (30 hr x $53.32/hr).

Section 438.10(d)(1) would require that states identify prevalent non-English languages spoken in each managed care entity's service area. Given that states must already determine the prevalent non-English languages spoken in their entire Medicaid service area based on the policy guidance "Enforcement of Title VI of the Civil Rights Act of 1964 - National Origin Discrimination Against Persons With Limited English Proficiency" from the U.S. Department of Justice, we believe that

dividing the information by plan service area requires only minimal IT programming. More specifically, we estimate a one-time state burden of 4 hr at $73.60/hr for a computer programmer to create these reports. In aggregate, we estimate 132 hr (33 states x 4 hr) and $9,715.20 (132 hr x $73.60/hr) to create these reports. We estimate no additional burden for the running of these reports as they would be put into a production schedule, and putting a report into production adds no additional burden.

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. We estimate a one-time state burden of 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 198 hr (33 states x 6 hr) and $10,557.36 (198 hr x $53.32/hr). As the prevalent languages within a state do not change frequently, we are not estimating burden for the rare updates that would be needed to these taglines.

Section 438.10(e)(1) would clarify that states can provide required information in paper or electronic format. As the amount and type of information that can be provided electronically will vary greatly among the states due to enrollee access and knowledge of electronic communication methods, it is not possible to estimate with any accuracy the amount that will be able to be converted from written to electronic format. Therefore, we will use estimates for all written materials knowing that some of this burden will be alleviated as the states are gradually able to convert to electronic communication methods. In this regard, we estimate a one-time state burden of 40 hr at $53.32/hr for a business operations specialist to create the materials. Many states already provide similar information to potential enrollees, so we anticipate that only 15 states would need to create these materials. We also estimate 1 min at $29.92/hr for an office and administrative support worker to mail the materials annually. For existing states, we estimate 1 hr at $53.32/hr for a business operations specialist to update or revise existing materials and 1 min at $29.92/hr for a mail clerk to mail the materials to 5 percent of the enrollees that are new (306,937 enrollees). In aggregate, we estimate a one-time state burden of 600 hr (15 states x 40 hr) and $31,992 (600 hr x $53.32/hr) to create materials. We estimate a one-time state burden of 33 hr (33 states x 1 hr) and $1,759.56 (33 hr x $53.32/hr) to update or revise existing materials. The state will also need to mail the materials. We estimate an ongoing burden of 5,115.6 hr (306,937 enrollees x 1 min) and $153,058.75 (5,115.6 hr x $29.92/hr) to mail materials.

Although §438.10(g)(1) and (2) would require the provision of an enrollee handbook, Medicaid regulations have always required the provision of this information (although it did not specifically call it a “handbook”) so we do not anticipate that all entities would need to create a new handbook.

Additionally, given the requirement in §438.10(c)(4)(ii) (which would be adopted in CHIP through §457.1207) for the state to provide a model template for the handbook, the burden on an entity is greatly reduced. We estimate approximately 5 new managed care entities per year using 10 hr at $53.32/hr for a business operations specialist to create a handbook using their state’s model template. In aggregate, we estimate 50 hr (5 entities x 10 hr) and $2,666 (50 hr x $53.32/hr). For existing MCOs, PIHPs, PAHPs, and PCCMs that already have a method for distributing the information, we believe that 20 entities will need to modify their existing

handbook to comply with a new model provided by the state. We also estimate a one-time private sector burden of 4 hr at $53.32/hr for a business operations specialist to update their entity's handbook. Once revised, we estimate 1 min at $29.92/hr for an office and administrative support worker to send these handbooks to 3,069,371 enrollees (50 percent of total enrollment). In aggregate, we estimate 80 hr (20 entities x 4 hr) and $4,265.60 (80 hr x $53.32/hr) to update handbooks. To send the updated handbooks, we estimate 51,156.2 hr (3,069,371 enrollees x 1 min) and $1,530,593.50 (51,156.2 hr x $29.92/hr).

All new enrollees must receive a handbook within a reasonable time after receiving notice of the beneficiary's enrollment. We assume a 5 percent enrollee growth rate thus 306,937 enrollees (5 percent of 6,138,743) would need to receive a handbook each year. (Existing enrollees typically do not receive a new handbook annually unless significant changes have occurred so this estimate is for new beneficiaries only.) We estimate a private sector state burden of 1 min at $29.92/hr for an office and administrative support worker to mail the handbook. In aggregate, we estimate 5,115.6 hr (306,937 enrollees x 1 min) and $153,058.75 (5,115.6 hr x $29.92/hr) to send handbooks to new enrollees.

All entities would need to keep their handbook up to date. In this regard, we estimate an annual private sector burden of 1 hr at $53.32/hr for a business operations specialist to update the handbook. While the updates would need to be made as program changes occur, we estimate 1 hr since each change may only take a few minutes to make. In aggregate, we estimate 66 hr (66 entities x 1 hr) and $3,519.12 (66 hr x $53.32/hr).

Section 438.10(h) would require that MCOs, PIHPs, PAHPs, and PCCMs make a provider directory available in paper or electronic form. Producing a provider directory is a longstanding Medicaid requirement in §438.10 as well in the commercial health insurance market. Additionally, given the time sensitive nature of provider information and the notorious high error rate in printed directories, most provider information is now obtained via website or by calling the customer service unit. Thus, the only new burden estimated would be the time for a computer programmer to add a few additional fields of data as appropriate, specifically, provider website addresses, additional disability accommodations, and adding behavioral and long term services and support providers. We estimate a one-time private sector burden of 1 hr at $73.60/hr for a computer programmer to update the existing directory. In aggregate, we estimate 66 hr (66 entities x 1 hr) and $4,858 (66 hr x $73.60/hr). Updates after creation of the original program would be put on a production schedule, which generates no additional burden.

Section 457.1208 Requirements that Apply to MCO, PIHP, PAHP, and PCCM Contracts Involving Indians, Indian Health Care Providers, and Indian Managed Care Entities

Section 457.1208 would apply the requirements of §438.14 to CHIP. Section 438.14(c) would require states to make supplemental payments to Indian providers if the managed care entity does not pay at least the amount paid to Indian providers under the fee-for-service program. There are approximately 25 states with separate CHIPs that have federally recognized tribes. We do not know how many managed care entities have Indian providers, but estimate that it is approximately 40 entities. This type of payment arrangement typically involves the managed care entity sending a report to the state, which 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 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 states will need to use this type of arrangement. In aggregate, we estimate a one-time private sector burden of 40 hr (40 entities x 1 hr) and $2,944.00 (40 hr x $73.60/hr). We also estimate an ongoing state burden of 300 hr (25 states x 12 hr) and $15,996.00 (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 burden is estimated after the first year. (Note: this process is not necessary when the MCO, PIHP, PAHP, or PCCM entity pays the ICHP at least the full amount owed under this regulation.)

Section 457.1210 Managed Care Enrollment

Section 457.1210(a) would require states to establish a default enrollment process and §457.1210(b) would require state to establish a process for prioritizing individuals for enrollment into managed care plans. Establishing a default enrollment process would require policy changes and require the state to send notices to enrollees once they have been enrolled in a plan. We estimate that 16 states do not have a default enrollment process as would be required by §457.1210(a), and would need to develop one. We estimate that it would take 6 hr at $53.32/hr for a business operations specialist to develop the policy. In aggregate, we estimate a one-time burden of 96 hr (16 states x 6 hr) and $5,118.72 (96 hr x $53.32/hr) to develop the enrollment policy. We also estimate that states would need to use the default enrollment process specified in §457.1210(b) for 5 percent of enrollees (306,937), and that it would take 1 min at $29.92/hr for a mail clerk to send the notice. In aggregate, we estimate 5,115.6 hr (306,937 beneficiaries x 1 min) and $153,059.25 (5,115.6 hr x $29.92/hr) to send the notices.

Section 457.1212 Disenrollment

Section 457.1212 would apply the requirements of §438.56 to CHIP. To disenroll, §438.56(d)(1) would require that the beneficiary (or his or her representative) submit an oral or written request to the state agency (or its agent) or to the MCO, PIHP, PAHP, or PCCM, where permitted. We estimate that 5 percent of MCO, PIHP, PAHP, and PCCM enrollees will request that they be disenrolled from an MCO, PIHP, PAHP, or PCCM each year. We also estimate approximately one-fourth of the enrollees will choose a written rather than an oral request.

We estimate an ongoing burden of 10 min for an enrollee to generate a written disenrollment request and 3 min per oral request. In aggregate, we estimate an annual burden (written requests) of 12,789 hr (76,734 enrollees x 10 min) and 11,510.1 hr (230,202 enrollees x 3 min) for oral requests.

Section 457.1214 Conflict of Interest Safeguards

Section 457.1214 would apply the requirements of §438.58 to CHIP. Section 438.58 would require that states have in place safeguards against conflict of interest for employees or agents of the state who have responsibilities relating to the MCO, PIHP, or PAHP. We anticipate that most states already have such safeguards in place, and only 5 states would need to develop new

standards to comply with this provision. We estimate a one-time state burden of 10 hr at $53.32/hr for a business operations specialist to develop those standards. In aggregate, we estimate 50 hr (5 states x 10 hr) and $2,666.00 (50 hr x $53.32/hr).

Section 457.1216 Continued Services to Beneficiaries

Section 457.1216 would apply the requirements of §438.62 to CHIP. Section 438.62(b)(1) would require that states have a transition of care policy for all beneficiaries moving from fee-for-service CHIP 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. We estimate a one-time state burden of 10 hr at $53.32/hr for a business operations specialist to develop the transition of care policy. In aggregate, we estimate 330 hr (33 states x 10 hr) and $17,595.60 (330 hr x $53.32/hr).

Section 438.62(b)(2) would require that MCOs, PIHPs, PAHPs, or PCCMs implement their own transition of care policy that meets the requirements of §438.62(b)(1). We estimate it would take 4 hr at $73.60/hr for a computer programmer to create the program that gathers and sends the FFS data to the MCOs, PIHPs, PAHPs, or PCCMs. We also estimate each MCO, PIHP, PAHP, or PCCM will use 4 hr of a computer programmer time to create programs to receive and store data as well as gather and send data to other plans. We are not estimating additional burden for the routine running of these reports as they will be put into a production schedule. In aggregate, we estimate a one-time state burden of 132 hr (33 states x 4 hr) and $9,715.20 (132 hr x $73.60/hr) to create the program that gathers and sends the FFS data to the MCOs, PIHPs, PAHPs, or PCCMs. We also estimate a one-time private sector burden of 264 hr (66 MCOs, PIHPs, PAHPs, or PCCMs x 4 hr) and $19,430.40 (264 hr x $73.60/hr) to create programs to receive and store data as well as gather and send data to other plans.

Once a MCO, PIHP, PAHP, or PCCM receives a request or identifies a need to arrange for the transition of services, we estimate a registered nurse at the managed care plan may need 10 min, on average, to access the stored information and take appropriate action. We believe that an average of 25,000 beneficiaries will transition into managed care each year from fee-for-service and 5,000 may switch between plans that would meet the state defined standards to qualify for the transition of care policy. In aggregate, we estimate an annual for private sector burden of 5,000 hr (30,000 beneficiaries x 10 min) and $327,000.00 (5,000 hr x $65.40/hr).

Section 457.1218 Network Adequacy Standards

Section 457.1218 would apply the requirements of §438.68 to CHIP. 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 that must include time and distance standards for specific provider types and network standards for long term services and supports (LTSS) (if the MCO, PIHP or PAHP has those benefits covered through their contract).

We believe some states already comply with these requirements and that only 12 states would need to develop the standards. We estimate a one-time first year burden of 15 hr at $53.32/hr for a business operations specialist to develop network standards meeting the specific provider types

found in §438.68(b)(1). In aggregate, we estimate 180 hr (12 states x 15 hr) and $9,597.60 (180 hr x $53.32/hr).

Very few states include LTSS in CHIP, therefore we estimate only 5 states will need to develop related standards. We estimate a one-time burden of 10 additional hr at $53.32/hr for a business operations specialist to develop those standards. In aggregate, we estimate 50 hr (5 states x 10 hr) and $2,666.00 (50 hr x $53.32/hr) for the development of LTSS standards. After network standards are established, we estimate that the maintenance of the network standards will be part of usual and customary business practices and therefore, we do not estimate any burden for states after the first year.

Section 438.68(d) would require that states: (1) develop an exceptions process for plans unable to meet the state's standards and (2) review network performance for any MCO, PIHP or PAHP to which the state provides an exception. We estimate a one-time state burden of 3 hr at $53.32/hr for a business operations specialist to establish an exceptions process. In aggregate, we estimate 99 hr (33 states x 3 hr) and $5,278.68 (99 hr x $53.32/hr).

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.

Section 457.1220 Enrollee Rights

Section 457.1220 would apply the requirements of §438.100 to CHIP. We do not anticipate a burden associated with implementing this section, because the proposed requirements to provide enrollees with treatment options and alternatives, allow enrollees to participate in decisions regarding health care, ensure that enrollees are free from restraint or seclusion, are standard practice in the field. The burden associated with providing information in accordance with 45 CFR 164.524 and 164.526 is accounted for in the collection of information associated with those regulations. The burden associated with modifying contracts to comply with this regulation are accounted for under §457.1202.

Section 457.1222 Provider-enrollee Communication

Section 457.1222 would apply the requirements of §438.102 to CHIP. Section 438.102(a)(2) provides 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.

We believe the burden for providing written notice to current enrollees within 90 days of adopting the policy with respect to a specific service, would affect no more than 3 MCOs or PIHPs annually since it would apply 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.

We estimate that each of the 3 MCOs or PIHPs would have such a policy change only once annually. We estimate that it would take 1 hr at $53.32/hr for a business operations analyst to update the policies. In aggregate, we estimate 3 hr (3 MCOs/PIHPs x 1 hr) and $159.96 (3 hr x $53.32/hr). We further estimate that it would take 4 hr at $53.32/hr for a business operations specialist to create the notice and 1 min at $29.92/hr for an office and administrative support worker to mail each notice. With an average MCO/PIHP enrollment of 78,000 enrollees, we estimate a total annual burden of 12 hr (3 MCOs/PIHPs x 4 hr/notice) and $639.84 (12 hr x $53.32/hr) to create the notice. To mail the notice we estimate 3,900 hr (3 MCOs/PIHPs x 78,000 enrollees x 1 min/notice) and $116,688 (3,900 hr x $29.92/hr).

Section 457.1224 ICRs Regarding Marketing Activities

Section 457.1224 would apply the requirements of §438.104 to CHIP. Section 438.104(c) would require that the state review marketing materials submitted by managed care entities. We believe that each entity would revise its materials once every 3 years. We estimate a state burden of 3 hr at $53.32/hr for a business operations specialist to review an entity's materials. In aggregate, we estimate an annual state burden of 75 hr [3 hr x 25 entities (one third of the total entities)] and $3,999 (75 hr x $53.32/hr).

We estimate that 5 entities may need to revise and submit updated materials. We estimate a private sector burden of 2 hr at $53.32/hr for a business operations specialist to update and submit the materials. In aggregate, we estimate a one-time burden of 10 hr (5 entities x 2 hr) and $533.20 (10 hr x $53.32).

Section 457.1230 Regarding Access Standards

Section 457.1230 would apply the requirements of §§438.206, 438.207, 438.208, and 438.210 to CHIP. Section 438.206(c)(3), through 457.1230(a), would require that MCOs, PIHPs, and PAHPs ensure that providers assure access, accommodations, and equipment for enrollees with physical and/or mental disabilities. We believe that MCOs, PIHPs, and PAHPs will need to review and revise (possibly) their policies and procedures for network management to ensure compliance with this requirement.

We estimate a one-time private sector burden of 3 hr at $53.32/hr for a business operations specialist to review and revise their network management policies and procedures. In aggregate, we estimate 189 hr (63 MCO/PIHP/PAHPs x 3 hr) and $10,077.48 (189 hr x $53.32/hr). Section 438.207(b), through 457.1230(b),438.207(b) would require that each MCO, PIHP, and PAHP (where applicable) submit documentation to the state, in a format specified by the state, to demonstrate that it: (1) complies with specified requirements, and (2) has the capacity to serve the expected enrollment in its service area in accordance with the state's standards for access to care.

Section 438.207(c) would require that the documentation be submitted to the state at least annually, at the time the MCO, PIHP, or PAHP enters into a contract with the state, and at any time there has been a significant change (as defined both by the state) in the MCO, PIHP, or PAHP's operations that would affect adequate capacity and services.

We estimate an annual private sector burden of 20 hr at $53.32/hr for a business operations specialist to compile the information necessary to meet this requirement. In aggregate, we estimate 1,260 hr (63 entities x 20 hr) and $67,183.20 (1,260 hr x $53.32/hr).

After reviewing the documentation, §438.207(d), through 457.1230(a), would require that the state certify (to CMS) that the entity has complied with the state's requirements regarding the availability of services, as set forth at §438.68. We estimate an annual state burden of 1 hr/contract at $53.32/hr for a business operations specialist to review documentation and submit the certification to CMS. In aggregate, we estimate 63 hr (63 entities x 1 hr) and $3,359.16 (63 hr x $53.32/hr).

Section 438.208(b)(2)(iii), through 457.1230(c), 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 would involve using data from the state to perform the needed coordination activities. Since only a small percentage of enrollees receive carved out services and need assistance with coordination, we estimate 2 percent of all MCO, PIHP, and PAHP enrollees (122,775) will be affected.

We estimate an annual private sector burden of 10 min/enrollee at $59.20/hr for a healthcare social worker. In aggregate, we estimate 20,463hr (122,775enrollees x 10 min) and $1,211,380.00(20,463 hr x $59.20/hr).

Section 438.208(b)(3), through 457.1230(c), would require that an 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 (15) would need to alter their processes; however, we do not believe this to be as common a practice among PAHPs and assume that all 3 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 54 hr [(15 MCOs and PIHPs + 3 PAHPs) x 3 hr] and $2,879.28 (54 hr x $53.32/hr).

We estimate that in a given year, approximately 10 percent of all enrollees are new to a managed care plan. Thus, 613,874 enrollees would be considered new and in need of an initial assessment. As PAHPs are typically a single entity within the state, we will only estimate that 5 percent of their enrollees (10,000 enrollees) would need an initial assessment. In general, we believe these assessments will take 10 min on average to complete by Call Center staff at $29.92/hr. In aggregate, we estimate an annual private sector burden of 102,312.33 hr (613,874 enrollees x 10 min) and $3,061,185.01 (102,312.33 hr x $29.92/hr).

Section 438.208(b)(4), through 457.1230(c), 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 enrollees with special health care needs 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 sending that report to the other MCO, PIHP, or PAHP.

We estimate a one-time private sector burden of 4 hr at $73.60/hr for a computer programmer to develop the report. In aggregate, we estimate of 252 hr (63 MCOs, PIHP, and PAHPs x 4 hr) and $18,547.20 (288 hr x $73.60/hr). Once put into production on a schedule, no additional staff time would be needed, thus no additional burden is estimated.

Section 438.208(c)(2) and (3), through 457.1230(c), would require that the MCOs, PIHPs and PAHPs complete a comprehensive assessment and treatment plan for all enrollees that have special health care needs. The assessments and treatment plans should be completed by providers or MCO, PIHP or PAHP staff that meet the qualifications specified 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.

We estimate that 1 percent of the total enrollment of 6,138,743 (61,387) are enrolled in either a MCO, PIHP or both, and would qualify as an individual with special health care needs. The time needed for the assessment and for treatment planning will, on average, take 1 hr at $65.40/hr for a registered nurse to complete. In aggregate, we estimate an annual private sector burden of 61,387 hr (61,387 enrollees x 1 hr) and $4,014,709.80 (61,387 hr x $65.40/hr).

Section 438.210(c), through 457.1230(d), would require that each contract provide that the MCO, PIHP, or PAHP 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.

We estimate an annual private sector burden of 30 min at $65.40/hr for a registered nurse to generate the notice. We estimate that each of 63 MCOs, PIHPs and PAHPs would process 20 denials/service reductions per 1,000 members. With average enrollment of 78,000, each entity is estimated to process a total of 1,560 denials and service reductions annually. In aggregate, we estimate 49,140 hr (63 entities x 1,560 denials or service reductions/entity x 30 min) and $3,213,756.00 (49,140 hr x $65.40/hr).

Section 457.1233 Structure and Operation Standards

Section 457.1233 would apply the requirements of §§438.214, 438.230, 438.236, and 438.242 to CHIP. Section 438.214 would require that MCOs, PIHPs, and PAHPs have policies for the selection and retention of providers. As described above, we believe that the requirements in §438.214 are part of the usual course of business and will not add additional burden onto entities because the entities will have policies for selecting and retaining providers even in the absence of these regulations.

Section 438.230, through §457.1233(b), would require that MCOs, PIHPs, and PAHPs oversee subcontractors and would specify the subcontracted activities. We estimate 3 hr at $53.32/hr for a business operations analyst to amend appropriate contracts. We estimate a one-time private sector burden of 189 hr (63 MCOs, PIHPs, and PAHPs x 3 hr) and $10,077.48 (189 hr x $53.32).Section 438.236(c), through §457.1233(c), would require that each MCO, PIHP, and PAHP 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, usually by posting on their website. This is typically done annually. We estimate an annual private sector burden of 2 hr at $53.32/hr for a business operations specialist. In aggregate, we estimate 124 hr (62 entities x 2 hr) and $6,611.68 (124 hr x $53.32/hr).

In §438.242(b)(2), through §457.1233(b), the state would be required to stipulate that each MCO and PIHP 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 estimate a one-time private sector burden of 20 hr at $73.60/hr for a computer programmer to extract this data from an entity's system and report to the state. In aggregate, we estimate 1,180 hr (59 entities x 20 hr) and $86,848 (1,180 hr x $73.60/hr). After the initial creation, the reports would be set to run and sent to the state at specified times as part of a production schedule.

Section 457.1240 Quality Measurement and Improvement

Section 457.1240 would apply the requirements of §§438.330, 438.332, 438.334, and 438.340 to CHIP. Section 438.330(a)(2), through §457.1240(b), would authorize CMS to use a public notice and comment process to identify performance measures and (PIP) topics that states would include in their contracts with MCOs, PIHPs, and PAHPs. Should CMS use this process to identify specific performance measures and PIP topics at least once every 3 years, we expect that states would need to program their MMIS systems to account for the specified performance measures and PIP topics.

We estimate that MMIS programming changes would require 10 hr (every 3 years) at $73.60/hr for a computer programmer. In aggregate, we estimate an ongoing annualized state burden of 110 hr [(33 states x 10 hr) / 3 years] and $8,096 (110 hr x $73.60/hr).

Section 438.330(a)(2)(i), through §457.1240(b), allows states to select performance measures and 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) allows states to apply for an exemption from the CMS-required performance measure and PIP topic requirements 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 2 states would ask for an exemption every 3 years. We estimate that the exemption process would require 1 hr at $53.32/hr for a business operations specialist. In aggregate, we estimate an ongoing annualized state burden of 0.67 hr [(2 states x 1

hr)/3 years] and $36.72 (0.67 hr x $53.32/hr).

Section 438.330(b)(3) would clarify that MCOs, PIHPs, and PAHPs must 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.

In accordance with §438.310(c)(2), some PCCM entities (we estimate 3) will now be subject to the requirements of §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 30 hr (3 PCCMs x 10 hr) and $1,599.60 (30 hr x $53.32/hr). We also estimate an ongoing burden of 10 hr to evaluate and address the findings. In aggregate, we estimate an annual burden of 30 hr (3 PCCMs x 10 hr) and $1,599.60 (30 hr x $53.32/hr) for program maintenance.

Section 438.330(c)(1) through (3), through §457.1240(b), would require that each MCO, PIHP, and PAHP annually measure its performance using standard measures required by the state and report its performance to the state. Because the use of performance measures in managed care has become commonplace in commercial, Medicare, and Medicaid managed care, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or states.

In accordance with §438.310(c)(2), through §457.1240(b), some PCCM entities will now be subject to this requirement. We recognize that PAHPs and PCCM entities may not currently engage in performance measurement, and estimate that 7 entities might be impacted. We estimate that, in any given year, each PCCM entity and each PAHP would report to the state on at least 3 performance measures. We estimate an annual private sector burden of 4 hr per measure at $53.32/hr for a business operations specialist to prepare a report for each performance measure. In aggregate, we estimate 84 hr [(3 PAHPs + 4 PCCMs) x 3 performance measures x 4 hr] and $4,478.88 (84 hr x $53.32/hr).

In §438.330(d)(1), through §457.1240(b), states would ensure that each MCO, PIHP and PAHP have an ongoing program of PIPs. In §438.330(d)(2) each MCO, PIHP, and PAHP would be required to report the status and results of each such project to the state, as requested. We estimate that, in any given year, each of the 59 MCOs and PIHPs would conduct at least 3 PIPs and each of the 4 PAHPs would conduct at least 1 PAHP. We further expect that states will request the status and results of each entity's PIPs annually. Given that PAHPs may not currently conduct PIPs, 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, for an aggregate burden of 8 hr (4 PAHPs x 2 hr) and $426.56 (8 hr x $53.32/hr). We estimate an annual burden of 8 hr to prepare a report on each PIP. In aggregate, we estimate 1,448 hr [((59 MCOs and PIHPs x 3 PIPs) + (4 PAHPs x 1 PIP)) x 8 hr] and $77,207.36 (1,448 hr x $53.32/hr) to prepare the report.

Per §438.310(c)(2), PCCM entities specified are also subject to the requirements in §438.330(e), through §457.1240(b). 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 45 hours (3 PCCM entities x 15 hr) and $2,399.40 (45 hr x $53.32/hr).

Section 438.330(e)(1)(ii), through §457.1240(b), would require that states include outcomes and trended results of each MCO, PIHP, and PAHP's PIPs in the state's annual review of quality assessment and PIPs. 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 16.5 hr (33 states x 0.5 hr) and $879.78 (16.5 hr x $53.32/hr). We also estimate an annual burden of 1 hr for the additional review. In aggregate, we estimate 33 hr (33 states x 1 hr) and $1,759.56 (33 hr x $53.32/hr).Section 438.330(e)(1)(iii) would set out a new requirement, related to §438.330(b)(5), requiring that the state must assess the rebalancing effort results for LTSS in its annual review. We do not know of any states that have an LTSS plan in CHIP, so there is no burden associated with the proposed provision.

Under §438.332(a), through §457.1240(c), states would review and approve the performance of all CHIP MCO, PIHP, and PAHP at least once every three years. We assume that no state would set up a separate review and approval process for CHIP, and would instead follow the same process used for Medicaid managed care plans. 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 to assess a CHIP plan, which would occur at least once every 3 years. In aggregate, we estimate an annualized state burden of 1,980 hr (66 MCOs, PIHPs, and PAHPs x 90 hr / 3 years) and $157,594.80 [(66 MCOs, PIHPs, and 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 CHIP MCOs, PIHPs, and PAHPs. We estimate an annualized private sector burden of 1,078 hr [(66 MCOs, PIHPs, and PAHPs x 49 hr / 3 years) and $61,452.16 [(66 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] for CHIP MCOs, PIHPs, and PAHPs to provide the necessary information to the state for review and approval.

Section 438.332(b)(2), through §457.1240(c), would allow states to deem compliance with §438.332(a) for accredited MCOs, PIHPs, and PAHPs that authorize the private accrediting entity to release accreditation information to the state. The burden associated with operating this program at a state is captured in §438.332(b), were we assume that half of states will elect this option. We believe that approximately half of the CHIP MCOs, PIHPs, and PAHPs (17) in these states may already have received or are independently seeking accreditation, and thus would not face any additional burden associated with this requirement. The remaining 16 MCOs, PIHPs, and PAHPs (half the entities in half the states) 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 independent entities structure prices in terms of accreditation activities, not hours, an hourly burden estimate is not available) and must be renewed once every three years for the same cost. In aggregate, we estimate the one-time private sector burden for initial accreditation is $1,131,200 (16 MCOs, PIHPs, and PAHPs x $70,700), and the ongoing annualized private sector burden for accreditation renewal is $377,066.67 [(16 MCOs, PIHPs, and PAHPs x $70,700) / 3 years].

Section 438.332(c), through §457.1240(c), requires the state to document its determinations for all MCOs, PIHPs, and PAHPs on the state's website, the burden for which is included in §438.10.

Section 438.334, through §457.1240(d), would have states establish and operate a quality ratings system for MCOs, PIHPs, and PAHPs. We assume that states would utilize the same system and processes developed for CHIP managed care plans as was developed for Medicaid managed care plans. Using the assumptions developed for §438.332, we estimate that 25 states (with 47 MCOs, PIHPs, and PAHPs) will operate a quality rating systems as proposed in §438.334(a) and would rate plans each year. We estimate 20 hr at $53.32/hr for a business operations specialist in a state to rate a MCO, PIHP, or PAHP. In aggregate, we estimate an annual state burden of 940 hr (47 MCOs, PIHPs, and PAHPs x 20 hr) and $50,120.80 (940 hr x $53.32/hr). We assume the remaining 8 states (with 16 MCOs, PIHPs, and PAHPs) will utilize the flexibility at §438.334(c) to continue to use their own quality rating system. As this would not be a change from the status quo, we estimate no additional burden in these states for the quality rating system.

Section 438.340, through §457.1240(e), would describe the additional comprehensive quality strategy elements that states contracting with MCOs, PIHPs, or PAHPs would include in their comprehensive quality strategies. 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 110 hr [(33 states x 10 hr) / 3 years] and $5,865.20 (110 hr x $53.32/hr).

Section 457.1250 External Quality Review

Section 457.1250 would apply the requirements of §§438.350, 438.352, 438.354, 438.356, 438.358, and 438.364 to CHIP. Section 438.350, through §457.1250(a), would require that states include CHIP in their external quality review. We anticipate that most states would include CHIP in their Medicaid contract with the EQRO and that the burden for adding CHIP would be included in the burden for adding PAHPs to the EQRO contract. We anticipate that 5 states may contract separately for CHIP EQR services and that this would require states to procure a new vendor.

Given the wide variance in state procurement processes, the burden is conservatively estimated at 185 hr for writing an RFP, evaluating proposals, and implementing the selected proposal. More specifically, we estimate a one-time state burden of 125 hr at $53.32/hr for a business operations specialist, 50 hr at $73.60/hr for a computer programmer, and 10 hr at $127.72/hr for a general and operations manager. In aggregate, we estimate 925 hr [(125 hr +50 hr + 10 hr) x 5 states] and $58,111.00 [((125 hr x $53.32/hr) + (50 hr x $$73.60/hr) + (10 hr x $127.72/hr) x 5 states)]. Section 438.356(a)(3), through §457.1250(a), would require that states submit their EQRO contracts to CMS for review and approval prior to implementation. We estimate a one-time state burden of 2 hr at $53.32/hr for a business operations specialist to submit the contract to CMS. In aggregate, we estimate 10 hr (5 states x 2 hr) and $533.20 (10 hr x $53.32/hr).

Section 438.358, through §457.1250(a), would require that the EQRO perform certain activities. The burden associated with this provision is the time for a state to conduct and document the

findings of the four mandatory activities: (1) the annual validation of performance improvement projects conducted by the MCO/PIHP/PAHP, (2) the annual validation of performance measures calculated by the MCO/PIHP/PAHP, (3) once every 3 years, a review of MCO/PIHP/PAHP compliance with structural and operational standards; and (4) validation of MCO, PIHP, and PAHP network adequacy. Each of these activities would be conducted on the 5 MCOs/PIHPs/PAHPs that are currently providing CHIP services separately from Medicaid. The types of services provided by these managed care entities, the number of performance improvement projects conducted, and the performance measures calculated will vary. We assume that each MCO/PIHP will conduct at least 3 performance improvement projects, each PAHP will conduct at least 1 performance improvement project, and that each MCO/PIHP/PAHP will calculate at least 3 performance measures.

For a business operations specialist to conduct the mandatory EQR activities at $53.32/hr, we estimate an annual state burden of 65 hr (performance improvement project validation), 53 hr (performance measure validation), 361 hr (compliance review; occurs once every 3 years), and 60 hr (validation of network adequacy activity). In aggregate, we estimate 2,671.67hr (5 x [(65 hr x 3 performance improvement projects) + (53 hr x 3 performance measures) + (361 hr/3) + 60 hr]) and $142,453.27 (2,372 hr x $53.32/hr).

In §438.358(b), the burden would include the time for an MCO/PIHP/PAHP to prepare the information necessary for the state to conduct the three mandatory activities. We estimate that it will take each MCO/PIHP/PAHP 160 hr to prepare the documentation for these activities. We estimate that one-half of the time would be for preparing the information which will be performed by a business operations specialist at $53.32/hr while the other half will be performed by office and administrative support worker at $29.92/hr. In aggregate, we estimate a private sector burden of 800 hr (5 states x 160 hr) and $33,296.00 [(5 states x 80 hr x $53.32/hr) + (5 states x 80 hr x $29.92/hr).

Section 438.358(b)(1), through §457.1250(a), would stipulate that all of the PIPs required by the state and CMS be validated. We have added the reference to CMS-required PIPs to be consistent with our proposed provision at §438.330(a)(3). While current regulations do not specify the number of PIPs that must be validated in each state, the majority of states validate multiple PIPs for each MCO or PIHP.

Given current practice, we do not anticipate this will pose a burden on states or the private sector beyond the need to modify MCO, PIHP, PAHP, and EQRO contracts. We anticipate that most states would include CHIP in their Medicaid contract with the EQRO and that the burden for adding CHIP would be included in the burden under §438.350. The burden associated with amending MCO/PIHP/PAHP contracts is captured in §457.1202.

Section 438.358(c), through §457.1250(a), describes optional EQR-related activities. For the optional EQR activities, we have no data to estimate how long it would take to conduct these activities. We, therefore, estimate that it will take 350 hr to validate client level data and 50 hr to validate consumer or provider surveys. We estimate it will take three times as long to calculate performance measures as it takes on average to validate (159 hr) and three times as long to

conduct performance improvement projects and focused studies as it takes on average to validate performance improvement projects (195 hr). We also estimate that it will take three times as long to administer a consumer or provider survey than it takes to validate a survey (60 hr).

For a business operations specialist $53.32/hr, we estimate: (1) 16,800 hr (350 hr × 48 MCOs/PIHPs) and $895,776.00 (16,800hr x $53.32/hr) to validate client level data; (2) 1500 hr (50 hr × 30 MCOs/PIHPs) and $79,980.00 (1500 hr x $53.32/hr) to validate consumer or provider surveys; (3) 3,180 hr (159 hr × 20 MCOs/PIHPs) and $169,557.60 (3,180 hr x $53.32/hr) to calculate performance measures; (4) 5,070 hr (195 hr × 26 MCOs/PIHPs) and $270,332.40 (5,070 hr x $53.32/hr) to conduct performance improvement projects; and (5) 8,268 hr (159 hr × 52 MCOs/PIHPs) and $440,849.76 (8,268 hr x $53.32/hr) to conduct focused studies. In aggregate, we estimate 34,818hr and $1,856,495.76for the optional EQR-related activities.

We do not have any data to estimate the amount of time to prepare data and information for the optional EQR activities for PAHPs. We also do not have data regarding how states will apply these optional activities to PAHPs. Therefore, at this time, we are unable to develop a burden estimate for optional EQR-related activities for PAHPs. We welcome comment to help us develop these estimates.

Section 438.364(a)(1), through §457.1250(a), specifies that information regarding the EQR activities may include information obtained from Medicare or private accreditation reviews in accordance with §438.360. Section 438.364(a)(1)(iii) would require that the EQR technical report include baseline and outcomes data regarding PIPs and performance measures. The burden of compiling this data for MCOs, PIHPs, and PAHPs is captured in §438.358.

Section 438.364(b)(1),through §457.1250(a), would clarify that the EQRO must produce and finalize the annual EQR-technical report and that states may not substantively revise the report without evidence of error or omission, or permission from CMS. The proposed April 30th deadline for the finalization and submission of EQR technical reports is consistent with existing Medicaid sub-regulatory guidance. In an effort to ensure that the EQR process offers states timely and valuable insight into the quality of their managed care programs, we propose that the annual EQR technical report must address data collected in the previous 15 months.

We do not anticipate that these changes will pose a burden on states or the private sector. The burden associated with changing contracts for those programs that contract with EQROs with Medicaid is included under §438.364. States that contract with an EQRO separately for CHIP will include this requirement in the contract.

Section 438.364(b)(2), through §457.1250(a), would require that each state agency provide copies of technical reports, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO/PIHP/PAHP, beneficiary advocacy groups, and members of the general public. States would also be required to make the most recent EQR technical report publicly available in a manner specified by CMS. This will likely be accomplished by posting to the state's website, the burden for which is included in §457.1206.

We believe that by making these reports available online, states would be able to significantly decrease the burden associated with responding to requests from the public for this information, as it will already be easily accessible. The burden associated with this requirement is the time for a state agency to disclose copies of a given technical report to interested parties.

We estimate an annual state burden of 5 min at $15/hr for office and administrative support worker to disclose the required information per request. We also estimate that each state will receive 5 requests per MCO/PIHP/PAHP per year**.** In aggregate, we estimate 26 hr (62 MCOs/PIHPs/PAHPs x 5 requests x 5 min) and $772.93 (26 hr x $29.92/hr).

Section 457.1260 Grievances

Section 457.1260 would apply subpart F of part 438 to CHIP. We anticipate that most states currently follow the Medicaid grievance procedures, so we adopt the burden associated with the proposed changes to the Medicaid regulation.

Section 438.400(b), through §457.1260, would update the definition of "Action" to "Adverse benefit determination," clarify "appeal" and "grievance," and add the definition of "grievance system." We estimate a one-time state burden of 5 hr at $53.32/hr for a business operations specialist to amend all relevant documents to the new nomenclature and definitions. In aggregate, we estimate 165 hr (5 hr x 33 states) and $8,797.80 (165 hr x $53.32/hr).

Aligning the definition of "adverse benefit determination" to include medical necessity, appropriateness, health care setting, or effectiveness would require that plans provide additional hearing resources to actions previously not included. We estimate 3 hr at $53.32/hr for a business operations specialist and expect that each plan would provide 3 additional hearings per month (36 per year). In aggregate, we estimate an annual private sector burden of 6,696hr (62 MCOS, PIHPS, and PAHPS x 36 hearings x 3 hr) and $357,030.72 (6,696hr x $53.32/hr).

Section 438.402, through §457.1260, would specify the general requirements associated with the grievance system. More specifically, §438.402 would: (1) require MCOs, PIHPs, and PAHPs to have a grievance system (2) set out general requirements for the system, (3) establish filing requirements, and (4) provide that grievances and appeals may be filed either orally or in writing. The proposed provisions would apply to 62 entities. The burden for revising the contracts for these entities is included in §457.1201.

With regard to setting 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 entity. We estimate that the entities would receive 400 grievances per month. We estimate it will take a business operations specialist 30 min to process and handle each grievance and adverse benefit determinations.

We estimate a one-time private sector burden of 6,200 hr and $395,572.40 [62 MCOs, PIHPs, and PAHPs x ((10 x $127.72/hr) + (75 x $53.32/hr) + (15 x $73.60/hr)). We also estimate an annual burden of 148,800 hr [62 PAHPs x 400 grievances/month x 12 months x(0.5 hr/grievance x 12 months)] and $7,934,016.00 (148,800 hr x $53.32/hr) for processing each grievance and adverse

benefit determination.

Section 438.404(a), through §457.1260, would add PAHPs as an entity that must give the enrollee timely written notice and would set forth the requirements of that notice. More specifically, the enrollee must be provided timely written notice if an MCO, PIHP, or PAHP intends to: (1) deny, limit, reduce, or terminate a service; (2) deny payment; (3) deny the request of an enrollee in a rural area with one plan to go out of network to obtain a service; or (4) 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 $29.92/hr for an office and administrative support worker to provide written notice of the MCO, PIHP, or PAHP's intended action. We estimate that 5 percent (306,937) of the approximately 6 million MCO, PIHP, or PAHP enrollees will receive one notice of intended action per year from their MCO, PIHP, or PAHP. In aggregate, we estimate 5,116 hr (306,937 x 1 min) and $153,059.25 (5,116 hr x $29.92/hr).

In §438.416, through §457.1260, the state must require that MCOs, PIHPs and PAHPs maintain records of grievances and appeals. We estimate that approximately 6,139 enrollees (1 percent) of the approximately 6 million MCO and PIHP enrollees file a grievance or appeal with their MCO or PIHP. We estimate an annual private sector burden of 1 min (per request) at $29.92/hr for an office and administrative support worker to record and track grievances. In aggregate, we estimate 102 hr (6,139 grievances x 1 min) and $3,061.31 (102 hr x $29.92/hr).

Section 457.1270 Sanctions

Section 457.1270 would apply subpart I of part 438 to CHIP. In §438.722(a), through §457.1270, states would be provided the option to give MCO, PIHP, PAHP, or PCCM enrollees written notice of the state's intent to terminate its MCO, PIHP, PAHP, or PCCM contract. Notice may be provided after the state has notified the entity of its intention to terminate their contract.

States already have the authority to terminate MCO, PIHP, PAHP or PCCM contracts according to state law and have been providing written notice to the MCO, PIHP, PAHP or PCCM enrollees. While it is not possible to gather an exact figure, we estimate that 8 states may terminate 1 contract per year.

We estimate an annual state burden of 1 hr at $53.32/hr for a business operations specialist to prepare the notice to enrollees. In aggregate, we estimate 8 hr (1 hr x 8 states x 1 contract/yr.) and $426.56 (8 hr x $53.32/hr). We also estimate 1 hr at $53.32/hr for a business operations specialist to prepare the notice. In aggregate, we estimate an annual state burden of 8 hr (8 states x 1 hr) and $427 (8 hr x $53.32/hr). To send the notice, we estimate an average enrollment of 30,000 beneficiaries and 1 min (per beneficiary) at $26.40/hr for a mail clerk. In aggregate we estimate 500 hr (30,000 beneficiaries x 1 min) and $13,200.00 (500 hr x $26.40/hr).

Section 438.724, through §457.1270, would require that the state give the CMS Regional Office written notice whenever it imposes or lifts a sanction. The notice must specify the affected MCO, PIHP, PAHP, or PCCM, 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 would impose or lift a sanction each year and that it would take 30 min at $53.32/hr for a business operations specialist to give the regional office notice. In aggregate, we estimate an annual burden of 7.5 hr (15 states x 30 min) and $400 (7.5 hr x $53.32/hr).

Section 457.1280 Conditions Necessary to Contract as an MCO, PIHP, or PAHP
These requirements have not changed, they have been redesignated from another section of part 457, and so we do not estimate any additional burden.

Section 457.1285 Program Integrity Safeguards
Section 457.1285 would apply most of subpart H of part 438 to CHIP. Section 438.602(a), through §457.1285, would detail state responsibilities for monitoring MCO, PIHP, PAHP, PCCM or PCCM's compliance with other sections of part 438, screening and enrollment of providers, reviewing ownership and control information, performing periodic audits, investigating based on whistleblower information, and imposing sanctions as appropriate. States would need to revise their policies and implement these activities, as needed. Once the policies are revised, the continuing performance would be part of usual and customary business operations.

We estimate 50 hr at $53.32/hr for a business operations specialist to create and/or revise their policies for the above activities. In aggregate, we estimate a one-time state burden of 1,650 hr (33 states x 50 hr) and $87,978.00 (1,650 hr x $53.32/hr).

Section 438.602(b), through §457.1285, 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. States are already required to screen and enroll providers in both FFS and managed care in their CHIP programs through 42 CFR §457.990, so there is no additional burden associated with this requirement.

Section 438.602(e), through §457.1285, would require states to conduct or contract for audits of MCO, PIHP, and PAHP encounter and financial data once every three years. Some states already use their EQRO to validate data. If they conduct this task at an appropriate frequency, it would incur no additional burden. We estimate 12 states already use their EQRO to validate their data, so only 21 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 7 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 7 hr (7 states x 1 hr) and $373.24 (7 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 770 hr (7 states x 110 hr) and $55,252.40 [7 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 125 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 1,050 hr [7 states x (150 hr)] and $69,006.00 [7 states x ((125 hr x $53.32/hr) + (25 hr x $127.72/hr))].

Section 438.602(g), through §457.1285, 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 33 hr (33 states x 1 hr) and $2,428.80 (33 hr x $73.60/hr).

Section 438.608(a), through §457.1285, 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.

We estimate that reviewing their policies and procedures to ensure that all of the above listed items are addressed. We estimate this would require 5 hr at $53.32/hr for a business operations specialist to review and (if necessary) revise their policies and procedures. In aggregate, we estimate a one-time private sector burden of 315 hr (63 MCOs, PIHPs, and PAHPs x 5 hr) and $16,795.80 (315 hr x $53.32/hr).

Section 438.608(a)(2) and (3), through §457.1285, 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 only 2 hr per year by a business operations specialist at $53.32/hr. We estimate an annual burden of 126 hr (63 MCOs, PIHPs, and PAHPs x 2 hr) and $6,718.32 (126 hr x $53.32/hr).

Section 438.608(a)(4), through §457.1285, would require the MCO, PIHP, or PAHP to use a sampling methodology to verify receipt of services. This typically involves mailing a letter or

sending an email to the enrollee, we estimate 33 states mail to 100 enrollees each (33 x 100 = 3,300 mailings) taking 1 min at $29.92/hr for a mail clerk. We estimate a total annual aggregate burden for private sector of 55 hr (3,300 mailings x 1 min) and $1,645.60 (55 hr x $9.92/hr). This estimate will be significantly reduced as the use of email increases.

Section 438.608(c) and (d), through §457.1285, 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. The burden to amend the contracts is included in §457.1201. We estimate the burden to comply with the reporting to include 1 hr at $73.60/hr for a computer programmer to create the report. In aggregate, we estimate a one-time private sector burden of 63 hr (63 MCOs, PIHPs, and PAHPs x 1 hr) and $4,636.80 (63 hr x $73.60/hr). Once developed, the report would be put on a production schedule and add no additional burden.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

Federal costs were derived by applying the appropriate federal medical assistance percentage (FMAP). For the revisions in part 457, we applied an FMAP of 93.9, which is the average CHIP FMAP for federal fiscal years 2016-2019, to estimate the federal share of costs. For the provisions contained in this supporting statement, the annualized cost to the federal government is $24 million.

15. Changes to Burden

These regulations are new, and therefore the associated burden is new and represents an increase due to a program change (issuing of new regulations).

16. Publication/Tabulation Dates

Most of the information submitted to CMS (with the exception of the information described in §§457.760, 457.1240, and 457.1250) will not be published. Rather, that information is reviewed as part of the agency's normal oversight activity of state CHIP 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.

Pursuant to §457.1250, the EQR must, at a minimum, result in a detailed technical report that summarizes the findings on access and quality of care. This must include:

1) A description of the manner in which the data from the EQR-related activities were aggregated and analyzed, and the conclusions drawn by the EQRO regarding the quality, timeliness, and access to care provided by the MCO, PIHP, and PAHP;

2) Details for each EQR-related activity, including the objectives, technical methods of data collection and analysis, description of the data obtained (including performance measurement data for the validation of performance measures and performance improvement projects), and conclusions drawn from the data;

3) An assessment of the strength and weaknesses of each MCO, PIHP, and PAHP with respect to timeliness, access, and quality of the health care services furnished to CHIP beneficiaries;

4) Recommendations for improving the quality of the services furnished by each MCO, PIHP, and PAHP, including how the state can target goals and objectives in its comprehensive quality strategy (required under part 431, subpart I) to support improvement in the quality, timeliness, and access to services;

5) Comparative information about all MCOs, PIHPs, and PAHPs; and

6) An assessment of the degree to which each plan followed up on prior year's recommendations.

The annual EQR technical report will be submitted by the contracting EQRO to the state, which will then submit it to CMS, post it on the state's website, and provide this information upon request.

CMS intends to maintain a list of hyperlinks on Medicaid.gov to states' websites where EQR technical reports are posted in order to improve public transparency.

Pursuant to §457.760 and 457.1240, States will post current comprehensive quality strategies (CQS) on their websites. CMS will maintain a list of hyperlinks to current state CQS on Medicaid.gov. States will be required to review and revise their CQS at least once every three years; this process will include an effectiveness evaluation of the CQS, the results of which must be published on the state's website. CMS will review CQS submitted to the agency by states as a part of its normal oversight activities for the CHIP program.

17. Expiration Date

These information collection requirements do not lend themselves to an expiration date.

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.