

Supporting Statement – Part A
Children’s Health Insurance Program Managed Care and Supporting Regulations
CMS-10554, OMB-0938-1282

Background

Children’s Health Insurance Program (CHIP) Managed Care and Supporting Regulations Contained in 42 CFR 457.10, 457.204, 457.940, 457.950, 457.1200, 457.1201, 457.1203, 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, and 457.1285.

The Medicaid and CHIP managed care final regulation (CMS-2390-F, RIN 0938-AS25) (May 6, 2016; 81 FR 27498) implements several recent statutory provisions that apply Medicaid managed care requirements to CHIP. The regulation built 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.

This iteration is associated with our November 14, 2018, proposed rule (CMS-2408-P, RIN 0938-AT40, 83 FR 57264) which continues CMS’ efforts to streamline the Medicaid and CHIP managed care regulatory framework and reflects a broader strategy to relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care. The proposed revisions of the Medicaid and CHIP managed care regulations are intended to ensure that the regulatory framework is efficient and feasible for states to implement in a cost-effective manner and ensure that states can implement and operate Medicaid and CHIP managed care programs without undue administrative burdens. These objectives are proposed to be achieved by some revisions to the Medicaid requirements adopted by CHIP, including revising the definition of an adverse benefit determination to exclude administrative claim denials and thus eliminate the requirement for unnecessary written notices to enrollees; and eliminating the requirement to print taglines on all written materials and instead only require taglines on materials that are critical to obtaining services, among others.

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, CMS-2390-F implements section 2107(e)(1)(M) of the Act, as added by section 5006 of the American Recovery and Reinvestment Act of 2009 (ARRA). The provision applies sections 1932(a)(2)(C) and 1932(h) of the Act, which provide protections for American Indians to CHIP. The CMS-2390-F final rule also implements statutory provisions related to program integrity, specifically sections 2107(b) and 2107(e)(2)(C) through (E) of the Act.

The CMS-2408-P rule proposes revisions to the implementing regulations for CHIP managed care requirements, including related to beneficiary information and appeals and grievances requirements. The majority of the revisions are technical changes to remove certain cross-references to Medicaid managed care requirements that are not applicable to CHIP. Other revisions are necessary to clarify state requirements, including the date of compliance. In line with Medicaid, CHIP also proposes to revise provider network adequacy requirements by allowing the state to determine a quantitative standard for the required specialties and other administrative flexibilities for states and managed care plans pertaining to beneficiary notices.

2. Information Users

CHIP enrollees use the information collected and reported 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. Implementing regulations extended the availability of the EQR results to the public.

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, 457.1203, 457.1230, and 457.1240 contain requirements concerning specific reporting to CMS and will all be done electronically.

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. More specifically, this information collection does not do any of the following:

- Require respondents to report information to the agency more often than quarterly;
- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Is connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,

- Require the use of a statistical data classification that has not been reviewed and approved by OMB;
- Includes a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Require respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

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

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 are 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.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates (Hours & Wages)

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Titles and Wage Rates

Occupation Title	Occupation Code	Mean Hourly Wage(\$/hr)*	Fringe Benefit (\$/hr)	Adjusted Hourly Wage(\$/hr)
Business Operations Specialist	13-1000	35.14	35.14	70.28
Computer Programmer	15-1131	42.08	42.08	84.16
General and Operations Mgr	11-1021	59.35	59.35	118.70
Healthcare Social Worker	21-1022	27.31	27.31	54.62
Mail Clerk	43-9051	16.14	16.14	32.38
Office and Administrative Support Worker	43-9000	19.04	19.04	38.08
Registered Nurse	29-1141	35.37	35.57	71.14

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

12.2 Burden Estimates

Section 457.1201 Standard Contract Requirements Section 457.1201 contains a list of standard requirements that must be included in MCO, PIHP, PAHP, and PCCM contracts. The following burden estimate addresses the effort to amend such contracts in addition to the contract amendments associated with §§457.1203, 457.1207, 457.1208, 457.1209, 457.1210, 457.1212, 457.1218, 457.1220, 457.1222, 457.1224, 457.1226, 457.1228, 457.1230, 457.1233, 457.1240, 457.1250, 457.1260, 457.1270, and 457.1285. We estimate a one-time **state burden** of 6 hr at \$70.28/hr for a business operations specialist to amend all contracts associated with the aforementioned requirements. In aggregate, we estimate 372 hr (62 contracts x 6 hr) and \$26,144.16 (372 hr x \$70.28/hr).

Annually, we estimate **124 hr** at a cost of **\$8,714.72**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.1 (S))**

Section 457.1203 Rate development and Medical Loss Ratio Section 457.1203 applies the requirements of §438.8 to CHIP. Section 438.8(c) requires that MCOs, PIHPs, and PAHPs report to the state annually their total expenditures on all claims and non-claims related

activities, premium revenue, the calculated MLR, and, if applicable under other authority, any remittance owed.

We estimate the total number of MLR reports that MCOs, PIHPs, and PAHPs will be required to submit to the state will amount to 58 reports. 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 will be completed by a computer programmer (101 hr at \$84.16/hr), 30 percent will be completed by a business operations specialist (50 hr at \$70.28/hr), and 10 percent will be completed by a general and operations manager (17 hr at \$118.70/hr).

The first year burden amounts to 168 hr and \$14,032,06 ((101 hr x \$84.16) + (50 hr x \$70.28) + (17 hr x \$118.70)) per report or, in aggregate, **9,744 hr** (58 reports x 168 hr) and **\$813,859.48** (58 x \$13,526.92). **(Estimate 12.2 (PS))**

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 \$4,422.82 ((31.8 hr x \$84.16) (Estimate 12.5 (PS)) + (15.9 hr x \$70.28 (Estimate 12.6 (PS)) + (5.3 hr x \$118.70) (Estimate 12.7 (PS)) per report and a total of **3,074 hr** (53 hr x 58 reports) and **\$256,523.56** (58 reports x \$4,422.82). **(Estimate 12.3 (PS))**

We expect 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 provides 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 §§457.1203, 457.1207, 457.1208, 457.1209, 457.1212, 457.1214, 457.1216, 457.1220, 457.1222, 457.1224, 457.1226, 457.1230, and 457.1233. We estimate a one-time state burden of 4 hr at \$70.28 /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 \$843.36 (12 hr x \$70.28 /hr).

Annually, we estimate **4 hr** at a cost of **\$281.12**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.8 (S))**

Section 457.1207 Information Requirements Section 457.1207 applies the requirements of §438.10 to CHIP.

Section 438.10(c)(1) requires that states with separate CHIPs with managed care (25) to 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 \$70.28 /hr for a business

operations specialist to make these revisions. In aggregate, we estimate **100 hr** (25 states x 4 hr) and **\$7,028.00** (100 hr x \$70.28 /hr). **(Estimate 12.9 (S))**

Section 438.10(c)(3) requires 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 \$84.16/hr for a computer programmer to make the initial changes. In aggregate, we estimate **150 hr** (25 states x 6 hr) and **\$12,624.00** (150 hr x \$84.16/hr) **(Estimate 12.10 (S))**.

We also estimate an annual burden of 3 hr at \$84.16/hr for a computer programmer to periodically add or update documents and links on the website. In aggregate, we estimate **75 hr** (25 states x 3 hr) and **\$6,312.00** (75 hr x \$84.16/hr). **(Estimate 12.11 (S))**

Section 438.10(c)(4)(i) recommends that states develop definitions for commonly used terms to enhance consistency of the information provided to enrollees. We estimate a one-time state burden of 6 hr at \$70.28 /hr for a business operations specialist to develop these definitions. In aggregate, we estimate 150 hr (25 states x 6 hr) and \$10,542.00 (150 hr x \$70.28 /hr).

Annually, we estimate **50 hr** at a cost of **\$3,514.00**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.12 (S))**

Section 438.10(c)(4)(ii) recommends that states create model enrollee handbooks and notices. Since many states already provide model handbooks and notices to their entities, we estimate that 15 states may need to take action to comply with this provision. We estimate a one-time state burden of 40 hr at \$70.28 /hr for a business operations specialist to create these documents. In aggregate, we estimate **600 hr** (15 states x 40 hr) and **\$42,168.00** (600 hr x \$70.28/hr). **(Estimate 12.13 (S))**

We also estimate an annual state burden of 2 hr at \$70.28 /hr for a business operations specialist to maintain these documents. In aggregate, we estimate **30 hr** (15 states x 2 hr) and **\$2,108.40** (30 hr x \$70.28 /hr). **(Estimate 12.14 (S))**

Section 438.10(d)(1) requires 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 \$84.16/hr for a computer programmer to create these reports. In aggregate, we estimate 100 hr (25 states x 4 hr) and \$8,416 (100 hr x \$84.16/hr) to create these reports.

Annually, we estimate **33.3 hr** at a cost of **\$2,802.53**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.15 (S))**

We estimate no additional burden for the running of these reports as they will be put into a production schedule, and putting a report into production adds no additional burden.

Section 438.10(d)(2)(i) requires that states add taglines to all printed materials for potential enrollees explaining the availability of translation and interpreter services as well as the phone number for choice counseling assistance. We estimate a one-time state burden of 2 hr at \$70.28 /hr for a business operations specialist to create the taglines and another 4 hr to revise all document originals. In aggregate, we estimate **150 hr** (25 states x 6 hr) and **\$10,542** (150 hr x \$70.28 /hr). **(Estimate 12.16 (S))**

Proposed amendments to §438.10(d)(2) and (d)(3) would no longer require states or plans to add taglines in prevalent languages to all written materials, nor to use 18-point font size. Instead, states and plans would have the ability to include taglines only on materials critical to obtaining services and could select any font size they deem to be conspicuously visible. While we have no data indicating how many states experienced increased document length or an increase in postage costs as a result of these requirements, we believe that the proposed revision will likely reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of -\$1,983,013.15 ((-\$45,068.44= \$.005 x 9,013,687) + (-\$45,068.44= \$.005 x 9,013,687) + (-\$1,892,876.27= \$.21 x 9,013,687)). These estimates are based on commonly available prices for bulk paper and toner purchases. **(Estimate 12.16(S)).**

Section 438.10(e)(1) clarifies 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. Many states already provide similar information to potential enrollees, so we anticipate that only 15 states will need to create these materials. We estimate a one-time state burden of 40 hr at \$70.28 /hr for a business operations specialist to create the materials. In aggregate, we estimate a burden of 600 hr (15 states x 40 hr) and \$42,168 (600 hr x \$70.28 /hr) (Estimate 12.17 (S)).

Annually, we estimate **200 hr** at a cost of **\$14,056**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.17 (S))**

For existing states, we estimate 1 hr at \$70.28 /hr for a business operations specialist to update or revise existing materials. We estimate a one-time state burden of 25 hr (25 states x

1 hr) and \$1,757 (25 hr x \$70.28 /hr) to update or revise existing materials (Estimate 12.18 (S)).

Annually, we estimate **8.3 hr** at a cost of **\$583.32**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.18 (S))**

We also estimate 1 min at \$38.08/hr for an office and administrative support worker to mail the materials to 5 percent of the enrollees that are new (115,000 enrollees).

We estimate an ongoing burden of **1,916.7 hr** (115,000 enrollees x 1 min) and **\$72,986.79** (1,916.67 hr x \$38.08/hr) to mail materials. **(Estimate 12.19 (S))**

Although §438.10(g)(1) and (2) 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 will need to create a new handbook. Additionally, given the requirement in §438.10(c)(4)(ii) (which is 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 \$70.28 /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 **\$3,514.00** (50 hr x \$70.28 /hr). **(Estimate 12.20 (PS))**

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 \$70.28 /hr for a business operations specialist to update their entity’s handbook. In aggregate, we estimate **80 hr** (20 entities x 4 hr) and **\$5,622.40** (80 hr x \$70.28 /hr) to update handbooks. **(Estimate 12.21 (PS))**

Once revised, we estimate 1 min at \$38.08/hr for an office and administrative support worker to send these handbooks to 1,150,000 enrollees (50 percent of total enrollment). To send the updated handbooks, we estimate **19,166.7 hr** (1,150,000 enrollees x 1 min) and **\$729,866.79** (19,166.67 hr x \$38.08/hr). **(Estimate 12.22 (PS))**

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 115,000 enrollees (5 percent of 2,300,000) will 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 burden of 1 min at \$38.08/hr for an office and administrative support worker to mail the handbook. In aggregate, we estimate **1,916.7 hr** (115,000 enrollees x 1 min) and **\$72,986.79** (1,916.67 hr x \$38.08/hr) to send handbooks to new enrollees. **(Estimate 12.23 (PS))**

All entities will need to keep their handbook up to date. In this regard, we estimate an annual private sector burden of 1 hr at \$70.28 /hr for a business operations specialist to

update the handbook. While the updates 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 **62 hr** (62 entities x 1 hr) and **\$4,357.36** (62 hr x \$70.28 /hr). **(Estimate 12.24 (PS))**

Section 438.10(h) requires 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 private 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 is 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 \$84.16/hr for a computer programmer to update the existing directory. In aggregate, we estimate **62 hr** (62 entities x 1 hr) and **\$5,217.92** (62 hr x \$84.16/hr). Updates after creation of the original program will be put on a production schedule, which generates no additional burden. **(Estimate 12.25 (PS))**

Section 457.1209 Requirements that Apply to MCO, PIHP, PAHP, and PCCM Contracts Involving Indians, Indian Health Care Providers, and Indian Managed Care Entities

Section 457.1209 applies the requirements of §438.14 to CHIP.

Section 438.14(c) requires 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 FFS program. There are approximately 18 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 will take 1 hr at \$84.16/hr for a computer programmer to create the claims report and approximately 12 hr at \$70.28 /hr for a state business operations specialist to process the payments. We estimate that approximately 18 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 \$3,366.40 (40 hr x \$84.16/hr).

Annually, we estimate **13.3 hr** at a cost of **\$1,119.33**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.26 (PS))**

We also estimate an ongoing state burden of **216 hr** (18 states x 12 hr) and **\$15,180.48** (216 hr x \$70.28 /hr). **(Estimate 12.27 (S))**

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 IHCP at least the full amount owed under this regulation.)

Section 457.1210 Managed Care Enrollment Section 457.1210(a) requires states to establish a process for prioritizing individuals for enrollment into managed care plans. Establishing a default enrollment process requires policy changes and require the state to send notices to enrollees once they have been enrolled in a plan. We estimate that states will need to use the default enrollment process specified in §457.1210(a) for 5 percent of enrollees (115,000), and that it will take 1 min at \$38.08/hr for an office and administrative support worker to send the notice. In aggregate, we estimate **1,916.67 hr** (115,000 beneficiaries x 1 min) and **\$72,986.79** (1,916.67 hr x \$38.08/hr) to send the notices. **(Estimate 12.28 (S))**

Section 457.1210(c) requires states to send a notice to potential enrollees. We believe some states already send such notices, so that only 15 states will have to develop new notices. We estimate that it will take 4 hr at \$70.28 /hr for a business operations specialist to create the notice. We estimate a one-time burden of 60 hr (4 hr x 15 states) and \$4,216.80 (60 hr x \$70.28 /hr) to develop the notice.

Annually, we estimate **20 hr** at a cost of **\$1,405.60**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.29 (S))**

In addition, we estimate that states would need to send notices to 5 percent of enrollees (115,000) who would be new to managed care each year. We estimate it would take 1 min/enrollee 1 min at \$38.08/hr for an office and administrative support worker to mail each notice. We estimate a total annual burden of **1,916.67 hr** (115,000 beneficiaries x 1 min) and **\$72,986.79** (1,916.67 hr x \$38.08/hr) to send the notices. **(Estimate 12.30 (S))**

Section 457.1212 Disenrollment Section 457.1212 applies the requirements of §438.56 to CHIP.

To disenroll, §438.56(d)(1) requires 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 **4,791.67 hr** (28,750 enrollees x 10 min) and **4,312.5 hr** (86,250 enrollees x 3 min) for oral requests.

Section 457.1214 Conflict of Interest Safeguards Section 457.1214 applies the requirements of §438.58 to CHIP. The following requirements and burden estimates were set out in the

proposed rule and are being adopted with minor revisions to reflect BLS' updated hourly wage data. No comments were received.

Section 438.58 requires 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 will need to develop new standards to comply with this provision. We estimate a one-time state burden of 10 hr at \$70.28 /hr for a business operations specialist to develop those standards. In aggregate, we estimate 50 hr (5 states x 10 hr) and \$3,514.00 (50 hr x \$70.28 /hr).

Annually, we estimate **16.7 hr** at a cost of **\$1,173.68**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.31 (S))**

Section 457.1216 Continued Services to Beneficiaries Section 457.1216 applies the requirements of §438.62 to CHIP.

Section 438.62(b)(1) requires that states have a transition of care policy for all beneficiaries moving from FFS 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 \$70.28 /hr for a business operations specialist to develop the transition of care policy. In aggregate, we estimate 250 hr (25 states x 10 hr) and \$17,570 (250 hr x \$70.28 /hr).

Annually, we estimate **83.3 hr** at a cost of **\$5,854.32**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.32 (S))**

Section 438.62(b)(2) requires 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 will take 4 hr at \$84.16/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 ongoing 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 100 hr (25 states x 4 hr) and \$8,416 (100 hr x \$84.16/hr) to create the program that gathers and sends the FFS data to the MCOs, PIHPs, PAHPs, or PCCMs.

Annually, we estimate **33.3 hr** at a cost of **\$2,802.53**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.33 (S))**

We also estimate a one-time **private sector** burden of 248 hr (62 MCOs, PIHPs, PAHPs, or PCCMs x 4 hr) and \$20,871.68 (248 hr x \$84.16/hr) to create programs to receive and store data as well as gather and send data to other plans.

Annually, we estimate **82.67 hr** at a cost of **\$6,957.51**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.34 (PS))**

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 FFS and 5,000 may switch between plans that 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 **\$355,700.00** (5,000 hr x \$71.14/hr). **(Estimate 12.35 (PS))**

Section 457.1218 Network Adequacy Standards Section 457.1218 applies the requirements of §438.68 to CHIP.

Section 438.68(a) requires that states set network adequacy standards that each MCO, PIHP and PAHP must follow. Section 438.68(b) and (c) require that states set standards that must include time and distance standards for specific provider types and network standards for 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 will need to develop the standards. We estimate a one-time first year burden of 15 hr at \$70.28 /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 \$12,650.40 (180 hr x \$70.28 /hr).

Annually, we estimate **60 hr** at a cost of **\$4,216.80**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.36 (S))**

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 \$70.28 /hr for a business operations specialist to develop those standards. In aggregate, we estimate **50 hr** (5 states x 10 hr) and **\$3,514.00** (50 hr x \$70.28 /hr) for the development of LTSS standards. **(Estimate 12.37 (S))**

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) requires 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 \$70.28 /hr for a business operations specialist to establish an exceptions process. In aggregate, we estimate 75 hr (25 states x 3 hr) and \$5,271 (75 hr x \$70.28 /hr).

Annually, we estimate **25 hr** at a cost of **\$1,757**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.
(Estimate 12.38 (S))

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

Section 457.1220 Enrollee Rights Section 457.1220 applies the requirements of §438.100 to CHIP. The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to reflect BLS' updated hourly wage data. No comments were received.

We do not anticipate a burden associated with implementing this section because the 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 applies the requirements of §438.102 to CHIP. The following requirements and burden estimates were set out in the proposed rule and are being adopted with minor revisions to BLS' update hourly wage data. No comments were received.

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 for any particular service.

We believe the burden for providing written notice to current enrollees within 90 days of adopting the policy for a specific service, will affect no more than 3 MCOs or PIHPs annually since it will 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 are affected by this provision.

We estimate that each of the 3 MCOs or PIHPs will have such a policy change only once annually. We estimate that it will take 1 hr at \$70.28 /hr for a business operations analyst to update the policies. In aggregate, we estimate **3 hr** (3 MCOs/PIHPs x 1 hr) and **\$210.84** (3 hr x \$70.28 /hr). **(Estimate 12.39 (PS))**

We further estimate that it will take 4 hr at \$70.28/hr for a business operations specialist to create the notice and 1 min at \$38.08/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 **\$843.36** (12 hr x \$70.28 /hr) to create the notice. **(Estimate 12.40 (PS))**

To mail the notice we estimate **3,900 hr** (3 MCOs/PIHPs x 78,000 enrollees x 1 min/notice) and **\$148,512.00** (3,900 hr x \$38.08/hr). **(Estimate 12.41 (PS))**

Section 457.1224 ICRs Regarding Marketing Activities Section 457.1224 applies the requirements of §438.104 to CHIP.

Section 438.104(c) requires that the state review marketing materials submitted by managed care entities. We believe that each entity will revise its materials once every 3 years. We estimate a state burden of 3 hr at \$70.28 /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 **\$5,271** (75 hr x \$70.28 /hr). **(Estimate 12.42 (S))**

We estimate that 5 entities may need to revise and submit updated materials. We estimate a private sector burden of 2 hr at \$70.28 /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 **\$702.80** (10 hr x \$70.28). **(Estimate 12.43 (PS))**

Section 457.1230 Regarding Access Standards Section 457.1230 applies the requirements of §§438.206, 438.207, 438.208, and 438.210 to CHIP.

Section 438.206(c)(3), adopted in CHIP through §457.1230(a), requires 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 \$70.28 /hr for a business operations specialist to review and revise their network management policies and procedures. In aggregate, we estimate 174 hr (58 MCO/PIHP/PAHPs x 3 hr) and \$12,228.72 (174 hr x \$70.28 /hr).

Annually, we estimate **58 hr** at a cost of **\$4,076.24**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.44 (PS))**

Section 438.207(b), adopted in CHIP through §457.1230(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 \$70.28 /hr for a business operations specialist to compile the information necessary to meet this requirement. In aggregate, we estimate **1,160 hr** (58 entities x 20 hr) and **\$81,524.80** (1,160 hr x \$70.28 /hr). **(Estimate 12.45 (PS))**

After reviewing the documentation, §438.207(d), adopted in CHIP through §457.1230(b), 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 \$70.28 /hr for a business operations specialist to review documentation and submit the certification to CMS. In aggregate, we estimate **58 hr** (58 entities x 1 hr) and **\$4,076.24** (58 hr x \$70.28 /hr). **(Estimate 12.46 (S))**

Section 438.208(b)(2)(iii) through §457.1230(c), requires that MCOs, PIHPs and PAHPs coordinate service delivery with the services the enrollee receives in the FFS 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 (64,000) will be affected.

We estimate an annual private sector burden of 10 min/enrollee at \$54.62/hr for a healthcare social worker. In aggregate, we estimate **10,666 hr** (64,000 enrollees x 10 min) and **\$582,576.92** (10,666 hr x \$54.62/hr). **(Estimate 12.47 (PS))**

Section 438.208(b)(3), adopted in CHIP 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 (14) 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 \$70.28 /hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate 51 hr [(14 MCOs and PIHPs + 3 PAHPs) x 3 hr] and \$3,584.28 (51 hr x \$70.28 /hr).

Annually, we estimate **17 hr** at a cost of **\$1,194.76**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.48 (PS))**

We estimate that in a given year, approximately 10 percent of all enrollees are new to a managed care plan. Thus, 230,000 enrollees would be considered new and in need of an initial assessment. As PAHPs are typically a single entity within the state, we estimate that only 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 \$38.08/hr. In aggregate, we estimate an annual **private sector burden** of **38,333 hr** (230,000 enrollees x 10 min) and **\$1,459,720.64** (38,333 hr x \$38.08/hr). **(Estimate 12.49 (PS))**

Section 438.208(b)(4), adopted in CHIP through §457.1230(c), requires that MCOs, PIHPs, and PAHPs share with other MCOs, PIHPs, and PAHPs serving the enrollee the results of its identification and assessment of any enrollee with special health care needs so that those activities 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 \$84.16/hr for a computer programmer to develop the report. In aggregate, we estimate of 232 hr (58 MCOs, PIHP, and PAHPs x 4 hr) and \$19,525.12 (232 hr x \$84.16/hr).

Annually, we estimate **77.3 hr** at a cost of **\$6,505.57**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.50 (PS))**

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), adopted in CHIP through §457.1230(c), requires 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 2,300,000 (23,000) 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 \$71.14/hr for a registered nurse to complete. In aggregate, we estimate an annual private sector burden of **23,000 hr** (23,000 enrollees x 1 hr) and **\$1,636,220** (23,000 hr x \$71.14/hr). **(Estimate 12.51 (PS))**

Section 438.210(c), adopted in CHIP through §457.1230(d), requires 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 \$71.14/hr for a registered nurse to generate the notice. We estimate that each of 58 MCOs, PIHPs and PAHPs will process 20 denials/service reductions per 1,000 members. This is our best estimate based on the data available in the SEDS, conversations with states and observations of trends in Medicaid and the commercial market. 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 **45,240 hr** (58 entities x 1,560 denials or service reductions/entity x 30 min) and **\$3,218,373.60** (45,240 hr x \$71.14/hr). **(Estimate 12.52 (PS))**

Section 457.1233 Structure and Operation Standards Section 457.1233 applies the requirements of §§438.214, 438.230, 438.236, and 438.242 to CHIP.

Although we added paragraph §457.1233(d), it references an existing CHIP requirement, and will not create additional burden. Section 438.214 requires that MCOs, PIHPs, and PAHPs have policies for the selection and retention of providers. 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, adopted in CHIP through §457.1233(b), requires that MCOs, PIHPs, and PAHPs oversee subcontractors and specifies the subcontracted activities. We estimate 3 hr at \$70.28 /hr for a business operations analyst to amend appropriate contracts. We estimate a one-time private sector burden of 174 hr (58 MCOs, PIHPs, and PAHPs x 3 hr) and \$12,228.72 (174 hr x \$70.28).

Annually, we estimate **58 hr** at a cost of **\$4,076.24**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.53 (S))**

Section 438.236(c), adopted in CHIP through §457.1233(c), requires 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 \$70.28 /hr for a business operations specialist. In aggregate, we estimate **116 hr** (58 entities x 2 hr) and **\$8,152.48** (116 hr x \$70.28 /hr). **(Estimate 12.54 (PS))**

In §438.242(b)(2), adopted in CHIP through §457.1233(b), the state is 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 \$84.16/hr for a computer programmer to extract this data from an entity's system and report to the state. In aggregate, we estimate 1,100 hr (55 entities x 20 hr) and \$92,576 (1,100 hr x \$84.16/hr).

Annually, we estimate **366.7 hr** at a cost of **\$30,861.47**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.55 (PS))**

After the initial creation, the reports will 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 applies the requirements of §§438.330, 438.332, 438.334, and 438.340 to CHIP.

Section 438.330(a)(2), adopted in CHIP through §457.1240(b), specifies the process CMS will use if it elects to specify national QAPI and PIP topics, which will 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 3 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 that MMIS programming changes requires 10 hr (every 3 years) at \$84.16/hr for a computer programmer. In aggregate, we estimate an ongoing annualized state burden of **83 hr** [(25 states x 10 hr) / 3 years] and **\$6,985.28** (83 hr x \$84.16/hr). **(Estimate 12.56 (S))**

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) 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 \$70.28 /hr for a business operations specialist. In aggregate, we estimate an ongoing state burden of **0.67 hr** [(2 states x 1 hr)/3 years] and **\$47.09** (0.67 hr x \$70.28 /hr). **(Estimate 12.57 (S))**

Section 438.330(a)(2)(ii), adopted in CHIP 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(b)(3) clarifies 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 private, 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 \$70.28 /hr for a business operations specialist to establish the policies and procedures. In aggregate, we estimate 30 hr (3 PCCMs x 10 hr) and \$2,108.40 (30 hr x \$70.28 /hr).

Annually, we estimate **10 hr** at a cost of **\$702.80**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.58 (PS))**

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 **\$2,108.40** (30 hr x \$70.28 /hr) for program maintenance. **(Estimate 12.59 (PS))**

Section 438.330(c) addresses QAPI performance measurement. Section 438.330(c)(1), adopted in CHIP through §457.1240(b), requires the state to identify standard performance measures for their managed care plans, including LTSS measures if appropriate. We believe that it is standard practice for states to identify performance measures for their contracted managed care plans; therefore there is no burden associated with this paragraph.

Section 438.310(c)(2), adopted in CHIP through §457.1240(b), requires each MCO, PIHP, PAHP, and PCCM entity (described in §438.310(c)(2)) to annually measure its performance using the standard measures specified by the state in paragraph (c)(1) and to report on its performance to the state. We assume that each of the MCOs and PIHPs would report on three performance measures to the state. The use of performance measures is commonplace in private, Medicare, and Medicaid managed care markets; therefore we believe that MCOs and PIHPs already collect performance measures.

We recognize that PAHPs and PCCM entities (described in §438.310(c)(2)) may not currently engage in performance measurement as described in §438.330(c)(2), 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 3 performance measures. We estimate an annual private sector burden of 4 hr per measure at \$70.28 /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 **\$5,903.52** (84 hr x \$70.28 /hr). **(Estimate 12.60 (PS))**

Section 438.330(c)(1)(ii) requires states to identify standard performance measures in two LTSS-specific categories for managed care plans that provide LTSS. We do not know of any states that have an LTSS plan in CHIP, so there is no burden associated with the provision.

In §438.330(d), adopted in CHIP through §457.1240(b), states must ensure that each MCO, PIHP and PAHP have an ongoing program of PIPs, designed to achieve sustainable improvement, which the managed care plan will report on to the state as requested, but at least once per year. We assume that each MCO and PIHP will conduct at least 3 PIPs and each of the 3 PAHPs would conduct at least 1 PIP. 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 \$70.28 /hr for a business operations specialist to develop policies and procedures, for an aggregate burden of 6 hr (3 PAHPs x 2 hr) and \$421.68 (6 hr x \$70.28 /hr) (Estimate 12.63).

Annually, we estimate **2 hr** at a cost of **\$140.56**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.61 (PS))**

We estimate an annual burden of 8 hr to prepare a report on each PIP. In aggregate, we estimate **1,344 hr** [((55 MCOs and PIHPs x 3 PIPs) + (3 PAHPs x 1 PIP)) x 8 hr] and **\$94,456.32** (1,344 hr x \$70.28 /hr) to prepare the report. **(Estimate 12.62 (PS))**

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 \$70.28 /hr for a business operations specialist to assess the performance of a single §438.3(r) PCCM entity. In aggregate, we estimate **45 hr** (3 PCCM entities x 15 hr) and **\$3,162.60** (45 hr x \$70.28 /hr). **(Estimate 12.64 (S))**

Section 438.330(e)(1)(ii), adopted in CHIP through §457.1240(b), requires that states include outcomes and trended results of each MCO, PIHP, and PAHP's PIPs in the state's annual review of QAPI programs. We estimate a one-time state burden of 0.5 hr at \$70.28 /hr for a business operations specialist to modify the state's policies and procedures. In aggregate, we estimate 12.5 hr (25 states x 0.5 hr) and \$878.50 (12.5 hr x \$70.28 /hr) **(Estimate 12.65 (S))**.

Annually, we estimate **4.2 hr** at a cost of **\$295.18**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.65 (S))**

We also estimate an annual burden of 1 hr for the additional review. In aggregate, we estimate **25 hr** (25 states x 1 hr) and **\$1,757** (25 hr x \$70.28 /hr). **(Estimate 12.66 (S))**

Section 438.330(e)(1)(iii) sets 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 provision.

Under §438.332(a), adopted in CHIP through §457.1240(c), states must confirm the accreditation status of contracted MCOs, PIHPs, and PAHPs once a year. We estimate an annual state burden of 0.25 hr at \$70.28 /hr for a business operations specialist to review the accreditation status of each of the estimated 58 MCOs, PIHPs, and PAHPs. In aggregate, we estimate an annual burden of **14.5 hr** (0.25 hr x 58 MCOs, PIHPs, and PAHPs) and **\$1,019.06** (14.5 hr x \$70.28 /hr). **(Estimate 12.67 (S))**

Section 438.332(b), adopted in CHIP through §457.1240(c), describes the information MCOs, PIHPs, and PAHPs must authorize the private accrediting entity to release to the state regarding the plan's accreditation status. We believe that states will need to amend their MCO, PIHP, and PAHP contracts to reflect this requirement, and estimate a one-time burden of 0.25 hr per contract amendment. In aggregate, we estimate a one-time burden of 15.5 hr (0.25 hr x 58 MCOs, PIHPs, and PAHPs) and \$1,019.067 (14.5 hr x \$70.28 /hr).

Annually, we estimate **5.2 hr** at a cost of **\$365.46**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.68 (S))**

Under §438.332(c), adopted in CHIP through §457.1240(c), states will document the accreditation status of each contracted MCO, PIHP, and PAHP on the state's website, and will update this information at least annually. The burden is included in §457.1207. **(see Estimate 12.11 (S))**

Section 438.334, adopted in CHIP through §457.1240(d), requires each state that contracts with an MCO, PIHP, or PAHP to adopt a quality ratings system to generate plan ratings annually. States must either adopt the quality rating system developed by CMS in accordance with §438.334(b) or an alternative quality rating system in accordance with §438.334(c).

We assume that states will 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 17 states (with 46 MCOs, PIHPs, and PAHPs) will elect to adopt the quality rating system developed by CMS in accordance with §438.334(b), while the remainder (8 states with 16 MCOs, PIHPs, and PAHPs) will elect to use an alternative quality rating system in accordance with §438.334(c). We assume that, given the robust public engagement process CMS will use to develop the QRS in accordance with §438.334(b), states electing to adopt the CMS-developed QRS will not need to conduct additional public engagement and will require less time to develop their QRS as compared to states which elect to adopt an alternative QRS consistent with §438.334(c).

Therefore, for states adopting the CMS-developed QRS under §438.334(b), we estimate the state burden for the development and implementation of the QRS as 200 hr at \$70.28 /hr for a

business operations specialist, 100 hr at \$84.16/hr for a computer programmer, and 30 hr at \$118.70/hr for a general and operations manager. In aggregate, we estimate a one-time state burden of 5,610 hr (17 states x 330 hr) and \$442,561 [17 states x ((200 hr x \$70.28 /hr) + (100 hr x \$84.16/hr) + (30 hr x \$118.70/hr))] for the development of a state's quality rating system consistent with 438.334(b).

Annually, we estimate **1,667 hr** at a cost of **\$148,006.08**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.69 (S))**

The burden is more variable for states seeking CMS approval for the adoption of an alternative QRS per §438.334(c). A state may submit an existing QRS, may submit a modified version of an existing QRS, or may develop a new QRS. We assume that the burden for each of these options would vary by state; therefore, we estimate an average burden for the development of an alternative QRS. We believe that the average alternative QRS burden will exceed the burden to adopt the CMS-developed QRS, and will require public engagement by the state. Therefore, we estimate the average state burden for the development and implementation of an alternative QRS as 800 hr at \$70.28/hr for a business operations specialist, 400 hr at \$84.16/hr for a computer programmer, and 120 hr at \$118.70/hr for a general and operations manager. We estimate an additional 20 hr at \$38.08/hr for an office and administrative support worker for the public engagement process and an additional 50 hr at \$70.28/hr for a business operations specialist to review and incorporate public feedback. In aggregate, we estimate a one-time state burden of 11,120 hr (8 states x 1,390 hr) and \$953,100.80 [8 states x ((800 hr x \$70.28 /hr) + (400 hr x \$84.16/hr) + (120 hr x \$118.70/hr) + (20 hr x \$38.08/hr) + (50 hr x \$70.28/hr))] for the development of a state's alternative quality rating system consistent with §438.334(c).

Annually, we estimate **3,706.7 hr** at a cost of **\$289,089.44**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.70 (S))**

To elect the option under §438.334(c) to use an alternative QRS, a state will submit a request to CMS and must receive written CMS approval. We estimate a one-time state burden of 20 hr at \$70.28 /hr for a business operations specialist to seek and receive approval from CMS for the state's alternative quality rating system. In aggregate, we estimate 160 hr (8 states x 20 hr) and \$11,244.80 (160 hr x \$70.28 /hr).

Annually, we estimate **53.3 hr** at a cost of **\$3,745.92**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.77 (S))**

Section 438.334(c)(3) outlines the process for a state to make changes to an approved alternative QRS. We estimate that it will require 5 hr at \$36.54/hr for an office and administrative support worker and 25 hr at \$70.28 /hr for a business operations specialist to complete the public comment process, and an additional 5 hr at \$70.28 /hr from a business operations specialist to seek and receive approval from CMS for the change.

While we have no data to estimate how frequently a state may elect to alter an approved alternative QRS, we estimate that CMS will revise the QRS under §438.334(b) on average approximately once every 3 years. We assume that states will revise their alternative QRS on a similar frequency to ensure that the alternative QRS continues to yield substantially comparable information regarding MCO, PIHP, and PAHP performance, and apply this assumption here. Therefore, we estimate an aggregate annualized burden of **93 hr** [(8 states x 35 hr) / 3 years] and **\$6,130.13** [(8 states x ((5 hr x \$38.08/hr) + (30 x \$70.28 /hr))) / 3 years]. **(Estimate 12.78 (S))**

Under §438.334(d), each state will collect information from its MCOs, PIHPs, and PAHPs to calculate and then issue a quality rating each year. We expect that states will 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 will rate each MCO, PIHP, or PAHP with which they contract. We estimate 40 hr at \$70.28 /hr for a business operations specialist for a state to rate a MCO, PIHP, or PAHP. We believe this burden will be similar for states regardless of if they adopt the CMS-developed QRS consistent with §438.334(b) or the alternative QRS consistent with §438.334(c). In aggregate, we estimate an annual state burden of **2,320 hr** (58 MCOs, PIHPs, and PAHPs x 40 hr) and **\$163,049.60** (2,320 hr x \$70.28 /hr). **(Estimate 12.80 (S))**

Section 438.340, adopted in CHIP through §457.1240(e), requires states to have a quality strategy for managed care. In accordance with §438.340(c)(2), states will review and revise their quality strategies as needed, but no less frequently than once every 3 years. While the 25 states that contract with MCOs and/or PIHPs currently revise their quality strategies periodically, approximately half of those states (13) revise their quality strategies less frequently than what was proposed and finalized. We estimate a burden for the revision of a quality strategy of, once every 3 years, 25 hr at \$70.28 /hr for a business operations analyst to review and revise the comprehensive quality strategy, 2 hr at \$38.08/hr for an office and administrative support worker to publicize the strategy, 5 hr at \$70.28 /hr for a business operations specialist to review and incorporate public comments, and 1 hr at \$38.08/hr for an office and administrative support worker to submit the revised quality strategy to CMS. In aggregate, we estimate an ongoing annualized state burden of **143 hr** [(13 states x 33 hr) / 3 years] and **\$9,631.44** [(13 states x ((30 hr x \$70.28 /hr) + (3 hr x \$38.08/hr))) / 3 years]. **(Estimate 12.81 (S))**

The revision of a quality strategy will be a new process for the estimated three states with only PAHPs and the estimated two states with only PCCM entities. We estimate that those states need 0.5 hr at \$70.28 /hr for a business operations specialist to revise their policies and procedures. In aggregate, we estimate a one-time state burden of 2.5 hr (5 states x 0.5 hr) and \$175.70 (2.5 hr x \$70.28 /hr) to update policies and procedures.

Annually, we estimate **0.8 hr** at a cost of **\$56.22**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.85 (S))**

We assume that it will be less burdensome to revise an existing quality strategy than to draft an initial strategy. Therefore, we estimate a burden for the quality strategy revision process, once every 3 years, of 25 hr at \$70.28 /hr for a business operations analyst to review and revise the comprehensive quality strategy (see **Estimate 12.86 (S)**), 2 hr at \$38.08/hr for an office and administrative support worker to publicize the strategy (see **Estimate 12.87 (S)**), 5 hr at \$70.28 /hr for a business operations specialist to review and incorporate public comments (see **Estimate 12.88 (S)**), and 1 hr at \$38.08/hr for an office and administrative support worker to submit the revised quality strategy to CMS (see **Estimate 12.89 (S)**). In aggregate, we estimate an **ongoing annualized state burden** of **55 hr** [(5 states x (33 hr) / 3 years] and **\$3,704.40** [(5 states x ((30 hr x \$70.28 /hr) + (3 hr x \$38.08/hr)))/3 years].

Consistent with §438.340(c)(2), the review of the quality strategy will include an effectiveness evaluation conducted within the previous 3 years. We estimate the burden of this evaluation at 40 hr at \$70.28 /hr for a business operations specialist once every 3 years for all 25 states that contract with MCOs, PIHPs, PAHPs, and/or PCCM entities (described in §438.310(c)(2)). We estimate an annualized burden of **333 hr** [(25 states x 40 hr)/3 years] and **\$23,403.24** (333 hr x \$70.28 /hr) to evaluate the effectiveness of a quality strategy. (**Estimate 12.90a (S)**)

States will post the effectiveness evaluation on the state's CHIP website under §438.340(c)(2)(iii). In the proposed rule we state that while this standard was subject to the PRA, we believed that the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believed that the time, effort, and financial resources necessary to comply with the aforementioned standards will be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice. Upon further consideration, however, we determined that states today do not necessarily post the quality strategy effectiveness evaluation online. Therefore, we estimate that posting the quality strategy effectiveness evaluation online will require 0.25 hr at \$70.28 from a business operations specialist once every three years. In aggregate, we estimate an ongoing burden of **2.1 hr** [(25 states x 0.25 hr) / 3 years] and **\$147.59** (2.1 hr x \$70.28 /hr). (**Estimate 12.90b (S)**)

As described in §438.340(c)(3), states will submit to CMS a copy of the initial quality strategy and any subsequent revisions. The burden associated with this standard has been incorporated into burden estimates for initial and revised quality strategies. As this will be a new standard for the estimated 3 states with only PAHPs and the estimated 2 states with only PCCM entities, we believe that these states will need to modify their policies and procedures to incorporate this action. We estimate a burden of 0.5 hr \$70.28 /hr for a business operations specialist. In aggregate, we estimate a one-time state burden of 2.5 hr (5 states x 0.5 hr) and \$175.70 (2.5 hr x \$70.28 /hr).

Annually, we estimate **0.8 hr** at a cost of **\$56.22**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. (**Estimate 12.91a (S)**)

Finally, §438.340(d) requires states to post the final quality strategy to their CHIP websites. In the proposed rule, we stated that while this standard was subject to the PRA, we believed that the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believed that the time, effort, and financial resources necessary to comply with the aforementioned standards will be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice. Upon further consideration, however, we determined that states today do not necessarily post the final quality strategy online, though some do. Therefore, we estimate that posting the final quality strategy online will require 0.25 hr at \$70.28 from a business operations specialist once every three years. In aggregate, we estimate an ongoing burden of **2.1 hr** [(25 states x 0.25 hr) / 3 years] and **\$147.59** (2.1 hr x \$70.28 /hr). (**Estimate 12.91b (S)**)

Section 457.1250 External Quality Review Section 457.1250 applies the requirements of §§438.350, 438.352, 438.354, 438.356, 438.358, and 438.364 to CHIP.

Section 438.350, adopted in CHIP through §457.1250(a), requires that states include CHIP in their EQR. We anticipate that most states include CHIP in their Medicaid contract with the EQRO and that the burden for adding CHIP will 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 requires states to procure a new vendor.

Section 438.358, adopted in CHIP through §457.1250(a), addresses the EQR-related activities. Per §438.358(a)(1) of this section, the EQR-related activities described in paragraphs (b) and (c) of this section may be conducted by the state, its agent that is not an MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)), or an EQRO; we describe the burden assuming that the state conducts these activities, though we believe the burdens will be similar regardless of who conducts each activity.

The burden associated with the mandatory EQR-related activities described in §438.358(b) (1) is the time for a state to conduct and document the findings of the four mandatory activities: (1) the annual validation of PIPs 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 will 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 PIPs conducted, and the performance measures calculated will vary. We assume that each MCO/PIHP will conduct at least 3 PIPs, each PAHP will conduct at least 1 PIP, 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 \$70.28/hr, we estimate an annual **state burden** of 65 hr (PIP validation) (see **Estimate 12.96 (S)**), 53 hr (performance measure validation) (see **Estimate 12.97 (S)**), 361 hr (compliance review; occurs once every 3 years) (see **Estimate 12.98 (S)**), and 60 hr (validation of network

adequacy activity). In aggregate, we estimate **2,671.67 hr** (5 x [(65 hr x 3 PIPs) + (53 hr x 3 performance measures) + (361 hr/3) + 60 hr]) and **\$187,764.97** (2,671.67 hr x \$70.28 /hr).

In §438.358(b), the burden will 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 will be for preparing the information which will be performed by a business operations specialist at \$70.28 /hr while the other half will be performed by office and administrative support worker at \$38.08/hr. In aggregate, we estimate a **private sector** burden of **800 hr** (5 states x 160 hr) and **\$43,344.00** [(5 states x 80 hr x \$70.28 /hr) (see **Estimate 12.99 (PS)**) + (5 states x 80 hr x \$38.08/hr) (see **Estimate 12.100 (PS)**)].

The fourth mandatory EQR-related activity described in §438.358(b)(1)(iv) requires the validation of MCO, PIHP, and PAHP network adequacy during the preceding 12 months. States will conduct this activity for each MCO, PIHP, and PAHP. Given that this is a new activity, we do not have historic data on which to base an hourly burden estimate for the network validation process. We estimate that it will take less time than the validation of a PIP but more time than the validation of a performance measure. Therefore, we estimate an annual state burden of 60 hr at \$70.28 /hr for a business operations specialist to support the validation of network adequacy activity. In aggregate, we estimate **3,480 hr** (58 MCOs, PIHPs, and PAHPs x 60 hr) and **\$244,574.40** (3,480 hr x \$70.28 /hr) for the validation of network adequacy activity (**Estimate 12.101 (S)**).

Section 438.358(b)(2) describes the mandatory EQR-related activities which must be conducted for each PCCM entity (described in §438.310(c)(2)), specifically the activities described in paragraphs (b)(1)(ii) and (b)(1)(iii) of this section. Given that we do not have data to estimate the time required for each of these activities for these PCCM entities, we rely on the time per activity estimates used for MCOs, PIHPs, and PAHPs; we assume the validation of one performance measure per PCCM entity (described in §438.310(c)(2)). Therefore, we estimate an annual state burden of **693.2 hr** (4 PCCM entities x 173.3 hr [(53 hr x 1 performance measure) + (361 hr / 3 years)]) and **\$48,718.10** (693.2 hr x \$70.28 /hr) for the mandatory EQR-related activities for PCCM entities (described in §438.310(c)(2)). (**Estimate 12.102 (S)**)

The burden associated with §438.358(b)(1) also includes the time for an MCO, PIHP, or PAHP to prepare the information necessary for the state to conduct the mandatory EQR-related activities. We estimate that it will take each MCO, PIHP, or PAHP 200 hr to prepare the documentation for these four activities, half (100 hr) at \$70.28 /hr by a business operations specialist (see **Estimate 12.103 (PS)**) and half (100 hr) at \$38.08/hr by an office and administrative support worker (see **Estimate 12.104 (PS)**). The burden associated with §438.358(b)(2) also includes the time for a PCCM entity (described in §438.310(c)(2)) to prepare the information necessary for the state to conduct the mandatory EQR-related activities. Given the estimate of 200 hr for an MCO, PIHP, or PAHP, and that there are only 2 mandatory EQR-related activities for PCCM entities (described in §438.310(c)(2)), we estimate it will take 100 hr to prepare the documentation for these 2 activities, half (50

hr) at \$70.28 /hr by a business operations specialist (see **Estimate 12.105 (PS)**) and half (50 hr) at \$38.08/hr by an office an administrative support worker (see **Estimate 12.106 (PS)**). In aggregate, we estimate an annual **private sector** burden of **12,000 hr** [(58 MCOs, PIHPs, and PAHPs x 200 hr) + (4 PCCM entities x 100 hr)] and **\$650,160** [(6,000 hr x \$70.28 /hr) + (6,000 hr x \$38.08/hr)].

Section 438.358(c), adopted in CHIP through §457.1250(a), describes optional EQR-related activities. For the optional EQR activities, we have no data to estimate how long it will 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 PIPs and focused studies as it takes on average to validate PIPs (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 \$70.28 /hr, we estimate: (1) 16,800 hr (350 hr × 48 MCOs/PIHPs) and \$1,180,704.00 (16,800 hr x \$70.28/hr) to validate client level data (see **Estimate 12.107 (PS)**); (2) 1500 hr (50 hr × 30 MCOs/PIHPs) and \$105,420 (1500 hr x \$70.28 /hr) to validate consumer or provider surveys (see **Estimate 12.108 (PS)**); (3) 3,180 hr (159 hr × 20 MCOs/PIHPs) and \$223,490.40 (3,180 hr x \$70.28 /hr) to calculate performance measures (see **Estimate 12.109 (PS)**); (4) 5,070 hr (195 hr × 26 MCOs/PIHPs) and \$356,319.60 (5,070 hr x \$70.28 /hr) to conduct PIPs (see **Estimate 12.110 (PS)**); and (5) 8,268 hr (159 hr × 52 MCOs/PIHPs) and \$581,075.04 (8,268 hr x \$70.28 /hr) to conduct focused studies (see **Estimate 12.111 (PS)**). In aggregate, we estimate **34,818 hr** and **\$2,244,368.2** for the optional EQR-related activities.

The optional EQR-related activities described in §438.358(c) may also be conducted on PAHPs and PCCM entities (described in §438.310(c)(2)). Since neither PAHPs or PCCM entities (described in §438.310(c)(2)) have historically been subject to EQR, we do not have any data on which to base an estimate regarding how states will apply the optional EQR-related activities to these delivery systems. Section 438.358(c)(6) allows a state to contract with an EQRO to support the quality rating of MCOs, PIHPs, and PAHPs consistent with §438.334. We do not believe that the effort required to rate a plan changes based on which entity (state or EQRO) develops the plan rating. Therefore, we believe that any burden associated with this optional EQR-related activity will only offset the burden associated with §438.334(d).

Section 438.364(a), adopted in CHIP through §457.1250(a), describes the information that will be included in the annual detailed technical report that is the product of the EQR. Section 438.364(a)(1)(iii) specifies that the EQR technical report includes baseline and outcomes data regarding PIPs and performance measures. Many states already provide much of this information in their final EQR technical report. The burden of compiling this data for MCOs, PIHPs, and PAHPs is captured in §438.358. Under §438.364(a)(3), EQR technical reports will include recommendations on how the state can use the goals and objectives of its comprehensive quality strategy to support improvement in the quality, timeliness, and access to care for beneficiaries. We believe that states will amend their

EQRO contracts to address the changes to §438.364(a). We estimate a one-time state burden of 0.5 hr at \$70.28 /hr for a business operations specialist to amend the EQRO contract. In aggregate, we estimate 12.5 hr (25 states x 0.5 hr) and \$878.50 (12.5 hr x \$70.28 /hr).

Annually, we estimate **4.2 hr** at a cost of **\$295.18**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.112 (S))**

Section 438.364(c)(1), adopted in CHIP through §457.1250(a), clarifies that the EQRO will produce and finalize the annual EQR-technical report and that states may not substantively revise the report without evidence of error or omission. The April 30th deadline for the finalization and submission of EQR technical reports is consistent with existing Medicaid sub-regulatory guidance.

While we do not anticipate that these changes will pose a significant burden on states or the private sector, we estimate that this provision may necessitate a change in a state's EQRO contract for approximately 5 states. In this regard, we estimate a one-time state burden of 0.5 hr at \$70.28 /hr for a business operations specialist to modify the EQRO contract. In aggregate, we estimate 2.5 hr (5 states x 0.5 hr) and \$175.70 (2.5 hr x \$70.28 /hr).

Annually, we estimate **0.8 hr** at a cost of **\$53.72**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.113 (S))**

Section 438.364(c)(2)(ii), adopted in CHIP through §457.1250(a), requires 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 will 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 §457.1207. **(see Estimate 12.11 (S))**

We believe that by making these reports available online, states will 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 \$38.08/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 **24.1 hr** (58 MCOs/PIHPs/PAHPs x 5 requests x 5 min) and **\$917.73** (24.1 hr x \$38.08/hr). **(Estimate 12.114 (S))**

Section 457.1260 Grievances Section 457.1260 applies subpart F of part 438 to CHIP.

Section 438.400(b), adopted in CHIP through §457.1260, updates 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 \$70.28 /hr for a business operations specialist to amend all relevant documents to the new nomenclature and definitions. In aggregate, we estimate 125 hr (5 hr x 25 states) and \$8,785 (125 hr x \$70.28 /hr).

Annually, we estimate **41.7 hr** at a cost of **\$2,930.68**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.115 (S))**

Aligning the definition of “adverse benefit determination” to include medical necessity, appropriateness, health care setting, or effectiveness requires that plans provide additional hearing resources to actions previously not included. We estimate 3 hr at \$70.28 /hr for a business operations specialist and expect that each plan will provide 3 additional hearings per month (36 per year). In aggregate, we estimate an annual private sector burden of **6,264 hr** (58 MCOs, PIHPs, and PAHPs x 36 hearings x 3 hr) and **\$440,233.92** (6,264 hr x \$70.28 /hr). **(Estimate 12.116 (PS))**

Proposed amendments to §438.400(b) would revise the definition of an “adverse benefit determination” to exclude claims that do not meet the definition of “clean claim” at §447.45(b), thus eliminating the requirement for the plan to send an adverse benefit notice. While we have no data on the number of adverse benefit notices are sent due to denials of unclean claims, we believe that at least one unclean claim may be generated for half of all enrollees; thus, this proposal could reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of $-\$1,757,669.16$ ($(-\$22,534.22 = \$0.005 \times 4,506,844) + (-\$22,534.22 = \$0.005 \times 4,506,844) + (-\$1,712,600.72 = \$0.38 \times 4,506,844)$). These estimates are based on commonly available prices for bulk paper and toner purchases and bulk postage rates. **(Estimate 12.116 (PS))**

Section 438.402, adopted in CHIP through §457.1260, specifies the general requirements associated with the grievance system. More specifically, §438.402: (1) Requires MCOs, PIHPs, and PAHPs to have a grievance system; (2) sets out general requirements for the system; (3) establishes filing requirements; and (4) provides that grievances and appeals may be filed either orally or in writing. These provisions apply to 58 entities. The burden for revising the contracts for these entities is included in §457.1201. **(see Estimate 12.1 (S))**

With regard to setting up a grievance system, we estimate it will take 100 hr (10 hr at \$118.70/hr for a general and operations manager (see **Estimate 12.117 (S)**), 75 hr at \$70.28 /hr for a business operations specialist (see **Estimate 12.118 (S)**), and 15 hr at \$84.16/hr for a computer programmer (see **Estimate 12.119 (S)**)) for each entity. We estimate that the entities will 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 5,800 hr and

\$447,783.20 [58 MCOs, PIHPs, and PAHPs x ((10 x \$118.70/hr) + (75 x \$70.28 /hr) + (15 x \$84.16/hr)).

Annually, we estimate **1,933.33 hr** at a cost of **\$149,238.06**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

We also estimate an ongoing annual burden of **139,200 hr** [58 MCOs, PIHPs, and PAHPs x 400 grievances/month x 12 months x 0.5 hr/grievance] and **\$9,782,976.00** (139,200 hr x \$70.28 /hr) for processing each grievance and adverse benefit determination. **(Estimate 12.120 (PS))**

Section 438.404(a), adopted in CHIP through §457.1260, adds PAHPs as an entity that must give the enrollee timely written notice and sets 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 \$38.08/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 (115,000) of the approximately 2.3 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 **1,916.67 hr** (115,000 x 1 min) and **\$72,986.79** (1,916.67 hr x \$38.08/hr). **(Estimate 12.121 (PS))**

In §438.416, adopted in CHIP through §457.1260, the state must require that MCOs, PIHPs and PAHPs maintain records of grievances and appeals. We estimate that approximately 23,000 enrollees (1 percent) of the approximately 2.3 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 \$38.08/hr for an office and administrative support worker to record and track grievances. In aggregate, we estimate **383 hr** (23,000 grievances x 1 min) and **\$14,584.64** (383 hr x \$38.08/hr). **(Estimate 12.122 (PS))**

Section 457.1270 Sanctions Section 457.1270 applies subpart I of part 438 to CHIP.

In §438.722(a) adopted in CHIP through §457.1270, states are 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 \$70.28 /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 **\$562.24** (8 hr x \$70.28 /hr). **(Estimate 12.123 (S))**

To send the notice, we estimate an average enrollment of 30,000 beneficiaries and 1 min (per beneficiary) at \$32.38/hr for a mail clerk. In aggregate we estimate **500 hr** (30,000 beneficiaries x 1 min) and **\$16,190.00** (500 hr x \$32.38/hr). **(Estimate 12.124 (S))**

Section 438.724, adopted in CHIP through §457.1270, requires 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 will impose or lift a sanction each year and that it will take 30 min at \$70.28 /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 **\$527.10** (7.5 hr x \$70.28 /hr). **(Estimate 12.125 (S))**

Section 457.1285 Program Integrity Safeguards Section 457.1285 applies most of subpart H of part 438 to CHIP.

Section 438.602(a), adopted in CHIP through §457.1285, details 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 will need to revise their policies and implement these activities, as needed.

We estimate 50 hr at \$70.28 /hr for a business operations specialist to create and/or revise their policies for the activities set out under §438.602(a). In aggregate, we estimate a one-time state burden of 1,250 hr (25 states x 50 hr) and \$87,850.00 (1,250 hr x \$70.28 /hr).

Annually, we estimate **416.7 hr** at a cost of **\$29,285.68**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.126 (S))**

Section 438.602(b), adopted in CHIP through §457.1285, requires 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 §457.990, so there is no additional burden associated with this requirement.

Section 438.602(e), adopted in CHIP through §457.1285, requires states to conduct or contract for audits of MCO, PIHP, and PAHP encounter and financial data once every 3 years. Some states already use their EQRO to validate data. If they conduct this task at an appropriate frequency, it will 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 \$70.28 /hr for a business operations specialist. In aggregate, we estimate a one-time state burden of 7 hr (7 states x 1 hr) and \$491.96 (7 hr x \$70.28 /hr).

Annually, we estimate **2.3 hr** at a cost of **\$161.64**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.127 (S))**

A state electing to perform validation internally must develop processes and policies to support implementation. In this case, we estimate 10 hr at \$70.28 /hr for a business operations specialist to develop policy (see **Estimate 12.128 (S)**) and 100 hr at \$84.16/hr for a computer programmer to develop, test, and automate the validation processes (see **Estimate 12.129 (S)**). In aggregate, we estimate a one-time **state burden** of 770 hr (7 states x 110 hr) and \$63,831.60 [7 states x ((10 hr x \$70.28 /hr) + (100 hr x \$84.16/hr))].

Annually, we estimate **256.7 hr** at a cost of **\$21,273.58**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires.

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 \$70.28 /hr for a business operations specialist to participate in the writing, evaluating, and implementing (see **Estimate 12.130 (S)**), and 25 hr at \$118.70/hr for a general and operations manager to participate in the writing, evaluating, and implementing (see **Estimate 12.131 (S)**). In aggregate, we estimate an annual **state burden** of **1,050 hr** [7 states x (150 hr)] and **\$82,267.50** [7 states x ((125 hr x \$70.28 /hr) + (25 hr x \$118.70/hr))].

Section 438.602(g), adopted in CHIP through §457.1285, requires states to post the MCO's, PIHP's, and PAHP's contracts, data from §438.604, and audits from §438.602(e) on their website. As most of these activities will only occur no more frequently than annually, we estimate an annual state burden of 1 hr at \$84.16/hr for a computer programmer to post the documents. In aggregate, we estimate **25 hr** (25 states x 1 hr) and **\$2,104** (25 hr x \$84.16/hr). **(Estimate 12.132 (S))**

Section 438.608(a), adopted in CHIP through §457.1285, requires 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 will require 5 hr at \$70.28 /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 290 hr (58 MCOs, PIHPs, and PAHPs x 5 hr) and \$20,381.20 (290 hr x \$70.28 /hr).

Annually, we estimate **96.7 hr** at a cost of **\$6,796.08**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.133 (PS))**

Section 438.608(a)(2) and (3), adopted in CHIP through §457.1285, require reporting of overpayments and enrollee fraud. As these will 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 \$70.28 /hr. We estimate an annual burden of **116 hr** (58 MCOs, PIHPs, and PAHPs x 2 hr) and **\$8,152.48** (116 hr x \$70.28 /hr). **(Estimate 12.134 (PS))**

Section 438.608(a)(4), adopted in CHIP through §457.1285, requires 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 25 states mail to 100 enrollees each (25 x 100 = 2,500 mailings) taking 1 min at \$32.38/hr for a mail clerk. We estimate a total annual aggregate burden for **private sector** of **42 hr** (2,500 mailings x 1 min) and **\$1,359.96** (42 hr x \$32.38/hr). This burden will be significantly reduced as the use of email increases. **(Estimate 12.135 (PS))**

Section 438.608(c) and (d), adopted in CHIP through §457.1285, requires 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. **(see Estimate 12.1 (S))**

We estimate the burden to comply with the reporting to include 1 hr at \$84.16/hr for a computer programmer to create the report. In aggregate, we estimate a one-time private sector burden of 58 hr (58 MCOs, PIHPs, and PAHPs x 1 hr) and \$4,881.28 (58 hr x \$84.16/hr).

Annually, we estimate **19.3 hr** at a cost of **\$1,624.29**. We are annualizing the one-time estimate since we do not anticipate any additional burden after the 3-year approval period expires. **(Estimate 12.136 (PS))**

Once developed, the report will be put on a production schedule and add no additional burden.

12.3 Burden Summary

Summary of Annual Burden Estimates: State Government

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

Estimate No.	CFR section	# Respondents	# Responses	Burden per response (hours)	Total Hours	Labor Rate (\$/hr)	Total cost (\$)	Frequency	Respondent Type	Annualized hours*	Annualized Costs (\$)
12.1	457.1201 Contracts	62	62	6	372	70.28	26,144.16	once	R	124	8,714
12.4	457.1203 MLR	58	58	17	986	118.70	117,038.20	once	R	329	39,052
12.5	457.1203 MLR	58	58	31.8	1,844.40	84.16	155,224.70	annual	R	1,844	155,244
12.6	457.1203 MLR	58	58	15.9	922.2	70.28	64,812.22	annual	R	922	64,798
12.7	457.1203 MLR	58	58	5.3	307.4	118.70	36,488.38	annual	R	307	36,441
12.27	457.1209 Contracts	18	18	12	216	70.28	15,180.48	annual	R	216	15,180
12.29	457.1210(c) Enrollment	15	15	4	60	70.28	4,216.80	once	R	20	1,405
12.31	457.1214 Conflict	5	5	10	50	70.28	3,514	once	R	16.7	1,173
12.46	457.1230(b) Access Stds	58	58	1	58	70.28	4,076.24	annual	R	58	4,076
12.57	457.1240(b) Quality	2	2	1	0.67	70.28	47.09	annual	R	.67	47
12.63	457.1240(b) Quality	3	3	2	6	70.28	421.68	annual	R	6	421
12.64	457.1240(b) Quality	3	3	15	45	70.28	3,162.60	annual	R	45	3,162
12.65	457.1240(b) Quality	25	25	0.5	12.5	70.28	878.50	once	R	4.2	295
12.66	457.1240(b) Quality	25	25	1	25	70.28	1,757	annual	R	25	1,757
12.72	457.1240(d) Quality	8	8	800	6,400.00	70.28	449,792	once	R	2,133	149,907
12.73	457.1240(d) Quality	8	8	400	3,200.00	84.16	269,312	once	R	1,067	89,798
12.74	457.1240(d) Quality	8	8	120	960	118.70	113,952	once	R	320	37,984

12.75	457.1240(d) Quality	8	8	20	160	38.08	6,092	once	R	53	2,018
12.76	457.1240(d) Quality	8	8	50	400	70.28	28,112	once	R	133	9,347
12.77	457.1240(d) Quality	8	8	20	160	70.28	11,244.80	once	R	53	3,745
12.84	457.1240(e) Quality	13	13	1	13	38.08	495.04	annual	R	4	152
12.85	457.1240(e) Quality	5	5	0.5	2.5	70.28	175.70	annual	R	.8	56
12.86	457.1240(e) Quality	5	5	25	125	70.28	8,785	annual	R	42	2,951
12.87	457.1240(e) Quality	5	5	2	10	38.08	380.80	annual	R	3.33	126
12.88	457.1240(e) Quality	5	5	5	25	70.28	1,757	Annual	R	8	562
12.89	457.1240(e) Quality	5	5	1	5	38.08	190.40	Annual	R	2	76
12.90	457.1240(e) Quality	25	25	40	1,000.00	70.28	70,280.00	Annual	R	333	23,403
12.90b	457.1240(e) Quality	25	25	0.25	2.1	70.28	147.59	once	R	.7	49
12.91	457.1240(e) Quality	5	5	0.5	2.5	70.28	175.70	once	R	.8	56
12.91b	457.1240(e) Quality	25	25	0.25	2.1	70.28	147.59	once	R	.7	49
12.102	457.1250(a) EQR	4	4	173.3	693.2	70.28	8,718.10	Annual	R	693	48,704
12.104	457.1250(a) EQR	58	58	100	6,000	38.08	228,480	Annual	R	6,000	228,480
12.105	457.1250(a) EQR	4	4	50	200	70.28	14,056	Annual	R	50	3,514
12.106	457.1250(a) EQR	4	4	50	200	38.08	7,616	Annual	R	50	1,904
12.112	457.1250(a) EQR	25	25	0.5	12.5	70.28	878.50	Annual	R	4.2	295
12.113	457.1250(a) EQR	5	5	0.5	2.5	70.28	175.70	Annual	R	.8	53
12.125	457.1270 Sanctions	15	15	0.5	8	70.28	527.10	Annual	R	8	527
<i>Subtotal: R</i>		<i>62</i>	<i>729</i>	<i>Varies</i>	<i>24,488.57</i>	<i>Varies</i>	<i>1,654,453</i>	<i>Varies</i>	<i>R</i>	<i>14,877.9</i>	<i>935,521</i>
12.8	457.1206 Contracts	3	3	4	12	70.28	843.36	once	RK	4	281
12.12	457.1207 Information	25	25	6	150	70.28	10,542	once	RK	50	3,514
12.13	457.1207 Information	15	15	40	600	70.28	42,168	once	RK	200	14,056
12.14	457.1207 Information	15	15	2	30	70.28	2,108.40	annual	RK	30	2,108
12.15	457.1207 Information	25	25	4	100	84.16	8,416	once	RK	33	2,802
12.16	457.1207 Information	25	25	6	150	70.28	10,542	once	RK	50	3,514
12.32	457.1216 Continued	25	25	10	250	70.28	17,570	once	RK	83.3	5,854

12.33	457.1216 Continued	25	25	4	100	84.16	8,416	once	RK	33.3	2,802
12.36	457.1218 Network	12	12	15	180	70.28	12,650.40	once	RK	60	4,216.80
12.37	457.1218 Network	5	5	10	50	70.28	3,514	once	RK	17	1,194
12.38	457.1218 Network	25	25	3	75	70.28	5,271	once	RK	25	1,757
12.42	457.1224 Marketing	25	25	3	75	70.28	5,271	annual	RK	75	5,271
12.53	457.1233(b) Structure and	58	58	3	174	70.28	12,228.72	once	RK	58	4,076
12.56	457.1240(b) Quality	25	25	3.33333	83	84.16	6,985.28	annual	RK	83	6,985
12.67	457.1240(c) Quality	58	58	0.25	14.5	70.28	1,019.06	annual	RK	15	1,1019
12.68	457.1240(c) Quality	58	58	0.25	14.5	70.28	1,019.06	once	RK	5	365
12.81	457.1240(e) Quality	13	13	25	325	70.28	22,841	annual	RK	108	7,590
12.83	457.1240(e) Quality	13	13	5	65	70.28	4,568.20	annual	RK	22	1,546
12.115	457.1260 Grievances	25	25	5	125	70.28	8,785	annual	RK	41.7	2,930
12.117	457.1260 Grievances	58	58	10	580	118.7 0	68,846	once	RK	193	16,242
12.118	457.1260 Grievances	58	58	75	4,350.00	70.28	305,718	once	RK	1,450	101,906
12.119	457.1260 Grievances	58	58	15	870	84.16	73,219.20	once	RK	290	24,406
12.126	457.1285 Program Integrity	25	25	50	1,250.00	70.28	87,850	once	RK	416.7	29,285
12.128	457.1285 Program Integrity	7	7	10	70	70.28	4,919.60	once	RK	23	1,616
12.129	457.1285 Program Integrity	7	7	100	700	84.16	58,912	once	RK	233	19,609
<i>Subtotal: RK</i>		<i>58</i>	<i>688</i>	<i>Varies</i>	<i>10,393</i>	<i>Varies</i>	<i>784,223</i>	<i>Varies</i>	<i>RK</i>	<i>3,599</i>	<i>274,945</i>
12.9	457.1207 Information Requirements	25	25	4	100	70.28	7,028.00	annual	TPD	100	7,028
12.10	457.1207 Information Requirements	25	25	6	150	84.16	12,624.00	once	TPD	50	4,208
12.11	457.1207 Information Requirements	25	25	3	75	84.16	6,312.00	annual	TPD	75	6,312
12.17	457.1207 Information Requirements	15	15	40	600	70.28	42,168.00	once	TPD	200	14,056

12.18	457.1207 Information Requirements	25	25	1	25	70.28	1,757.00	once	TPD	8.3	583
12.19	457.1207 Information Requirements	25	115,000	0.01667	1,916.67	38.08	72,986.79	once	TPD	639	24,333
12.28	457.1210(a) Enrollment	25	115,000	0.01667	1,916.67	38.08	72,986.79	annual	TPD	1,917	72,999
12.30	457.1210(c) Enrollment	25	115,000	0.01667	1,916.67	38.08	72,986.79	once	TPD	639	24,333
12.69	457.1240(d) Quality	17	17	200	3,400.00	70.28	238,952.00	once	TPD	1,133	76,627
12.70	457.1240(d) Quality	17	17	100	1,700.00	84.16	143,072	once	TPD	567	47,718
12.71	457.1240(d) Quality	17	17	30	510	118.7 0	60,537.00	once	TPD	170	20,179
12.78	457.1240(d) Quality	8	8	5	35	38.08	1,523.20	annual	TPD	12	456
12.79	457.1240(d) Quality	8	8	30	240	70.28	16,867.20	annual	TPD	80	5,622
12.80	457.1240(d) Quality	58	58	40	2320	70.28	163,049.60	annual	TPD	2,320	163,049
12.82	457.1240(e) Quality	13	13	2	26	38.08	990.08	annual	TPD	9	342
12.92	457.1250(a) EQR	5	5	125	625	70.28	43,925.00	once	TPD	208	14,618
12.93	457.1250(a) EQR	5	5	50	250	84.16	21,040.00	once	TPD	83	6,985
12.94	457.1250(a) EQR	5	5	10	50	118.7 0	5,935.00	once	TPD	17	2,017
12.95	457.1250(a) EQR	5	5	2	10	70.28	702.80	once	TPD	3	210
12.96	457.1250(a) EQR	5	15	65	975	70.28	68,523.00	annual	TPD	975	68,523
12.97	457.1250(a) EQR	5	15	53	795	70.28	55,872.60	annual	TPD	795	58,872
12.98	457.1250(a) EQR	5	5	120.333	602	70.28	42,308.56	annual	TPD	602	42,308
12.99	457.1250(a) EQR	5	5	80	400	70.28	28,112.00	annual	TPD	400	28,112

12.100	457.1250(a) EQR	5	5	80	400	38.08	15,232.00	annual	TPD	400	15,232
12.101	457.1250(a) EQR	58	58	60	3480	70.28	244,574.40	annual	TPD	3,480	244,574
12.108	457.1250(a) EQR	30	30	50	1,500.00	70.28	105,420.00	annual	TPD	1,500	105,420
12.109	457.1250(a) EQR	20	20	159	3,180.00	70.28	223,490.40	annual	TPD	3,180	223,490
12.110	457.1250(a) EQR	26	26	195	5,070.00	70.28	356,319.60	annual	TPD	5,070	356,319
12.111	457.1250(a) EQR	52	52	159	8,268.00	70.28	581,075.04	annual	TPD	8,268	581,075
12.114	457.1250(a) EQR	58	290	0.08333	24.1	38.08	917.73	annual	TPD	24	914
12.123	457.1270 Sanctions	8	8	1	8	70.28	562.24	annual	TPD	8	562
12.124	457.1270 Sanctions	8	30,000	0.02	500	32.38	16,190.00	annual	TPD	500	16,190
12.127	457.1285 Program Integrity	7	7	1	7	70.28	491.96	once	TPD	2.3	161
12.130	457.1285 Program Integrity	7	7	125	875	70.28	61,495.00	annual	TPD	875	61,495
12.131	457.1285 Program Integrity	7	7	25	175	118.7 0	20,772.50	annual	TPD	175	20,773
12.132	457.1285 Program Integrity	25	25	1	25	84.16	2,104.00	annual	TPD	25	2,104
<i>Subtotal: TPD</i>		58	375,848	<i>Varies</i>	42,150	<i>Varies</i>	2,808,904	<i>Varies</i>	<i>TDP</i>	34,509	2,317,799
TOTAL		62	377,265	Varies	77,032	Varies	5,247,581	Varies	n/a	52,987	3,528,265

Summary of Annual Burden Estimates: Private Sector

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

Estimate No.	CFR section	# Respondents	# Responses	Burden per response	Total Hours	Labor Rate (\$/hr)	Total cost (\$)	Frequency	Respondent Type	Annualized hours*	Annualized Costs (\$)
12.2	457.1203 MLR	58	58	101	5858	84.16	493,009.29	once	R	1,685	141,809
12.3	457.1203 MLR	58	58	50	2,900.00	70.28	203,812.00	once	R	967	67,960

12.26	457.1209 Contracts	40	40	1	40	84.16	3,366.40	once	R	13.3	1,119
12.47	457.1230(c) Access Stds	62	64,000	0.166 67	10,666	54.62	582,576.92	annual	R	10,666	582,577
12.50	457.1230(c) Access Stds	58	58	4	232	84.16	19,525.12	once	R	77.3	6,505
12.55	457.1233(d) Structure and Operations	55	55	20	1,100.00	84.16	2,576.00	once	R	36.7	30,861
12.60	457.1240(b) Quality	7	21	4	84	70.28	5,903.52	annual	R	84	5,903
12.61	457.1240(b) Quality	3	3	2	6	70.28	421.68	once	R	2	141
12.62	457.1240(b) Quality	55	168	6	1,344.00	70.28	94,456.32	annual	R	1,344	94,456
12.103	457.1250(a) EQR	58	58	100	6,000	70.28	421,680.00	annual	R	6,000	421,680
12.136	457.1285 Program Integrity	58	58	1	58	84.16	4,881.28	once	R	19.3	1,624
<i>Subtotal: R</i>		62	64,577	Varie s	28,288	Varies	1,832,209	Varies	R	20,895	1,354,635
12.20	457.1207 Information Requirements	5	5	10	50	70.28	3,514.00	once	RK	17	1,194
12.21	457.1207 Information Requirements	20	20	4	80	70.28	5,622.40	once	RK	27	1,897
12.24	457.1207 Information Requirements	62	62	1	62	70.28	4,357.36	once	RK	21	1,476
12.35	457.1216 Continued Services	62	30,000	0.166 67	5,000.00	71.14	355,700.00	annual	RK	5,000	355,700
12.39	457.1222 Communication	3	3	1	3	70.28	210.84	annual	RK	3	211
12.43	457.1224 Marketing	5	5	2	10	70.28	702.80	once	RK	3	211
12.44	457.1230(a) Access Stds	58	58	3	174	70.28	12,228.72	once	RK	58	4,076
12.45	457.1230(b) Access Stds	58	58	20	1,160.00	70.28	81,524.80	annual	RK	1,160	81,525
12.48	457.1230(c) Access Stds	17	17	3	51	70.28	3,584.28	once	RK	17	1,195
12.49	457.1230(c) Access Stds	62	230,000	0.166 67	38,333.00	38.08	1,459,720.6 4	annual	RK	38,333	1,459,720

12.51	457.1230(c) Access Stds	62	23,000	1	23,000.00	71.14	1,636,220.00	annual	RK	23,000	1,636,220
12.58	457.1240(b) Quality	3	3	10	30	70.28	2,108.40	once	RK	10	703
12.59	457.1240(b) Quality	3	3	10	30	70.28	2,108.40	annual	RK	30	2,108
12.116	457.1260 Grievances	58	2088	3	6,264.00	70.28	440,233.92	annual	RK	6,264	440,234
12.120	457.1260 Grievances	58	278,400	0.5	139,200.00	70.28	9,782,976.00	annual	RK	139,200	9,782,976
12.133	457.1285 Program Integrity	58	58	5	290	70.28	20,381.20	once	RK	96.7	6,786.08
12.134	457.1285 Program Integrity	58	58	2	116	70.28	8,152.48	annual	RK	116	8,152
<i>Subtotal: RK</i>		62	563,838	Varies	213,853	Varies	13,819,346	Varies	RK	213,356	13,784,384
12.22	457.1207 Information Requirements	62	1,150,000	0.01667	19,166.70	38.08	729,866.79	once	TPD	6,389	243,293
12.23	457.1207 Information Requirements	62	115,000	0.01667	1,916.70	38.08	72,986.79	Annual	TPD	1,917	72,999
12.25	457.1207 Information Requirements	62	62	1	62	84.16	5,217.92	once	TPD	21	1,767
12.34	457.1216 Continued Services	62	62	4	248	84.16	20,871.68	once	TPD	82.67	6,957
12.40	457.1222 Communication	3	3	4	12	70.28	843.36	Annual	TPD	12	843
12.41	457.1222 Communication	3	234,000	0.01667	3,900.00	38.08	148,512.00	Annual	TPD	3,900	148,512
12.52	457.1230(d) Access Stds	58	90,480	0.5	45,240	71.14	3,218,373.60	Annual	TPD	45,240	3,218,374
12.54	457.1233(c) Structure and Operations	58	58	2	116	70.28	8,152.48	Annual	TPD	116	8,152
12.99	457.1250(a) EQR	5	5	80	400	70.28	28,112.00	Annual	TPD	400	28,112
12.107	457.1250(a) EQR	48	48	350	16,800.00	70.28	1,180,704.00	Annual	TPD	16,800	1,180,704
12.121	457.1260 Grievances	62	115,000	0.01667	1,916.70	38.08	72,986.79	Annual	TPD	1,917	72,999

12.122	457.1260 Grievances	62	23,000	0.016 67	383	38.08	14,584.64	Annual	TPD	383	14,585
12.135	457.1285 Program Integrity	25	2,500	0.016 67	42	32.38	1,359.96	Annual	TPD	42	1,360
<i>Subtotal: TPD</i>		62	1,730,218	<i>Varie s</i>	90,203	<i>Varies</i>	5,502,572	<i>Varies</i>	<i>TPD</i>	77,220	4,998,657
TOTAL		62	2,358,633	Varie s	332,344	Varies	21,154,127	Varies	n/a	311,470	20,137,676

Total Annual Burden Estimates

	# Respondents	# Responses	Burden per response (hours)	Total Annual Hours	Labor Rate (\$/hr)	Total cost (\$)	Frequency	Annualized hours	Annualized Costs (\$)
State	62	377,265	Varies	77,032	Varies	5,247,581	Varies	52,987	3,528,265
<i>Private Sector</i>	62	2,358,633	Varies	332,344	Varies	21,154,127	Varies	311,470	20,137,676
TOTAL	62	2,735,898	Varies	409,376	Varies	24,401,708	Varies	364,457	23,665,941

12.3 Information Collection Instruments and Associated Instructions

There are no collection instruments.

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 \$20.8 million (\$16.6 million in fixed costs + \$4.2 million variable costs).

15. Changes to Burden

This information collection request proposes the following changes in association with CMS-2408-P (RIN 0938-AT40; November 14, 2018; 83 FR 57264)

Section 457.1207 Proposed amendments to §438.10(d)(2) and (d)(3) (which apply to CHIP via 457.1207) would no longer require states or plans to add taglines in prevalent languages

to all written materials, nor to use 18-point font size. Instead, states and plans would have the ability to include taglines only on materials critical to obtaining services and could select any font size they deem to be conspicuously visible. While we have no data indicating how many states experienced increased document length or an increase in postage costs as a result of these requirements, we believe that the proposed revision will likely reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of -\$1,983,013 ($[\$.005 \times 9,013,687] + [\$0.05 \times 9,013,687] + [\$0.21 \times 9,013,687]$).

Section 457.1260 Section §438.400(b) (which applies to CHIP via 457.1260) would revise the definition of an “adverse benefit determination” to exclude claims that do not meet the definition of “clean claim” at §447.45(b), thus eliminating the requirement for the plan to send an adverse benefit notice. While we have no data on the number of adverse benefit notices are sent due to denials of unclean claims, we believe that at least one unclean claim may be generated for half of all enrollees; thus, this proposal could reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of -\$1,757,669 ($[\$.005 \times 4,506,844] + [\$0.05 \times 4,506,844] + [\$0.38 \times 4,506,844]$).

In total, we estimate a non labor savings of -\$3,740,682 ($-\$1,983,013 + -\$1,757,669$).

We are also proposing to correct (Correction #1) our currently approved time estimates which consist of 78,644 hours for states and 332,345 hours for the private sector. The total is 410,989 hours.

We are adjusting this figure by -45,279 hours (to 365,710 hr) since the ROCIS time estimates should have accounted for the annualized time estimates that was set out in currently approved Supporting Statement section 12 (365,710 hr = 53,640 hr states + 312,070 hr private sector).

We are also proposing to correct math errors (Correction #2) totaling 1,253 hours.

In total, we estimate adjustments of -46,532 hours ($-45,279 \text{ hr} + -1,253 \text{ hr}$).

16. Publication/Tabulation Dates

Most of the information submitted to CMS (with the exception of the information described in §§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.

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, PAHP or PCCM entity;

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

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

4) Recommendations for improving the quality of the services furnished by each MCO, PIHP, PAHP, and PCCM entity, including how the state can target goals and objectives in its quality strategy (required under §438.340) to support improvement in the quality, timeliness, and access to services;

5) Methodologically appropriate, comparative information about all MCOs, PIHPs, PAHPs, and PCCM entities consistent with guidance included in the EQR protocols issued in accordance with §438.352; and

6) An assessment of the degree to which each MCO, PIHP, PAHP, or PCCM entity has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

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 will use the state-provided EQR technical reports in the development of the Annual Secretary's Report on Quality of Care for Children and the Annual Secretary's Report on Quality of Care for Adults.

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

17. Expiration Date

The expiration date is displayed.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

There are no statistical methods.