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

Background

Medicaid Managed Care and Supporting Regulations Contained in 42 CFR 438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102, 438.202, 438.204, 438.207, 438.208, 438.210, 438.214, 438.230, 438.236, 438.240, 438.242, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.604, 438.608, 438.710, 438.722, 438.724, 438.730, and 438.810

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

The implementation of CMS-2104-F, which was published on January 19, 2001 was delayed until August 16, 2002, and withdrawn on June 14, 2002, when the final rule discussed above was published.

A. Justification

1. Need and Legal Basis:

Section 4701 of the BBA created section 1932(a) of the Act, changed terminology in Title XIX of the Act and amended section 1903(m) to require that contracts and managed care organizations (MCOs) comply with applicable requirements in the new section.

- Section 1932(a) permits States to mandatorily enroll most groups of Medicaid beneficiaries into managed care arrangements without section 1915(b) or section 1115 waiver authority. Under the law prior to the BBA, a State agency was required to obtain Federal authority to waive beneficiary free choice of providers in order to restrict their coverage to managed care arrangements.

- Section 1932 also defines the term "managed care entity" (MCE) to include MCOs and primary care case managers (PCCMs); establishes new requirements for managed care enrollment and choice of coverage; and requires MCEs and State agencies to provide specified information to enrollees and potential enrollees.

Section 4702 amended section 1905 to permit States to provide PCCM services without the need for waiver authority. Instead, PCCM services may be made available under a State's Medicaid plan as an optional service.

Section 4703 eliminated a former statutory requirement that no more than 75 percent of the enrollees in an MCO be Medicaid or Medicare beneficiaries.

Section 4704 created section 1932(b) to add increased beneficiary protections for those enrolled under managed care arrangements. These include, among other things, the use of a prudent layperson's definition of emergency medical condition when presenting at an emergency room; standards for demonstration of adequate capacity and services; grievance procedures; and protections for enrollees against liability for payment of an organization's or provider's debts in the case of insolvency.

Section 4705 created section 1932(c), which requires States to develop and implement quality assessment and improvement strategies for their managed care arrangements and to provide for external, independent review of managed care activities.

Section 4706 provided that with limited exceptions an MCO must meet the same solvency standards set by States for a private HMO, or be licensed or certified by the State as a risk-bearing entity.

Section 4707 created section 1932(d) to add protections against fraud and abuse, such as restrictions on marketing and sanctions for noncompliance.

Section 4708 added a number of provisions to improve the administration of managed care arrangements. These include, among other things, changing the threshold amount of managed care contracts requiring the Secretary's prior approval, and permitting the same copayments in MCOs as apply to fee-for-service arrangements.

Section 4709 allowed States the option to provide six months of guaranteed eligibility for all individuals enrolled with an MCO or PCCM.

Section 4710 specified the effective dates for all the provisions identified

in sections 4701 through 4709.

2. Information Users:

Medicaid 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 its contracting process with managed care entities, as well as its compliance oversight role. CMS uses the information collected and reported in an oversight role of State Medicaid managed care programs.

3. Improved Information Technology:

Only §§438.202 and 438.207 contain requirements concerning reporting to CMS. Most of the other sections do not involve submitting information to any entity; those that do concern 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.

States may furnish the information required by §438.202 electronically. The certification required by §438.207 requires a signature; in some but not all cases, this information can be sent with electronic signatures.

4. Duplication of Similar Information:

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

5. Small Businesses:

The RFA requires agencies to analyze options for regulatory relief of small entities affected by these ICRs. The rule implemented Medicaid provisions as directed by the BBA of 1997. The statute does not permit significant regulatory alternatives. Thus, we are not able to consider significant alternatives for reducing the burden on small entities.

6. Less Frequent Collection:

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

7. Special Circumstances:

There are no special circumstances associated with this collection.

8. Federal Register Notice/Outside Consultation:

The 60-day Federal Register notice published on April 19, 2013 (78 FR 23566).

No comments were received.

9. Payment/Gift To Respondent:

There is no payment/gift to respondents.

10. Confidentiality:

The information received by CMS is not confidential and its release would fall under the Freedom of Information Act.

11. Sensitive Questions:

There are no sensitive questions.

12. Burden Estimate:

Section 438.6 Contract requirements

Section 438.6(c) modified the rules governing payments to MCOs, PIHPs, and PAHPs by doing the following: (1) eliminating the upper payment limit (UPL) requirement; (2) requiring actuarial certification of capitation rates; (3) specifying data elements that must be included in the methodology used to set capitation rates; (4) requiring states to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims in developing rates; (5) requiring states to provide explanations of risk sharing or incentive methodologies; and (6) imposing special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements.

Under the requirements for actuarial soundness, states need to provide an actuarial certification and additional documentation not previously required, including: specific data elements used to set capitation rates; methodologies to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims; explanations of risk sharing or incentive methodologies; and documentation supporting special contract provisions. These requirements are only applied to states who contract with MCOs, PIHPs and PAHPs on a risk basis. There are 507 risk contracts in effect with a burden for each estimated to be 32 hours.

- 507 risk contracts x 32 hours/contract = 16,224 hours for states.

Section 438.6(i)(3) Advance directives

This paragraph requires that MCOs, PIHPs, and certain PAHPs provide adult enrollees with written information on advance directives policies and include a description of applicable State law.

The burden associated with this requirement is the time it takes to furnish the information to enrollees; however, it is included in the overall burden arising from the Information Requirements in §438.10.

Section 438.8 Provision that apply to PIHPs and PAHPs

This section specifies which of the contract requirements contained in §438.6 apply to PIHPs and which apply to PAHPs.

- PIHPs and some PAHPs are required to comply with the information requirements of § 438.10.

The burden associated with this requirement is included in the overall burden arising from the Information Requirements in §438.10.

- PIHPs and PAHPs are required to provide descriptive information to states and CMS to determine whether or not there is substantial financial risk in their subcontracts. In addition, enrollees must be surveyed and provided information on the risk arrangements when substantial risk exists.

We estimate that no more than 1/3 of the approximately 306 PIHPs and PAHPs (or 102 PIHPs/PAHPs) use incentive or risk payment arrangements with their subcontracting providers. Affected PIHPs and PAHPs are required to provide detailed responses to State surveys regarding their payment mechanisms and amounts. We project that providing those responses requires 30 hours per PIHP or PAHP

- 102 PIHPs/PAHPs (306/3) x 30 hours = 3,060 hours

- For those PIHPs and PAHPs with substantial financial risk, there are other requirements such as stop/loss insurance and beneficiary surveys. We believe there is minimal additional burden as a result of these requirements (because many already comply with these requirements) and that this would apply to no more than ¼ of those PIHPs and PAHPs with risk or incentive payments, or a total of 26 (102/4). We estimate an additional 10 hours of work for those PIHPs and PAHPs.

  - 26 PIHPs/PAHPs (102/4) x 10 hours = 260 additional hours

Altogether, we estimate 3,780 hours of burden for this requirement.

- 3,060 hours + 260 hours = 3,320 hours for the private sector

Section 438.10 Information requirements

§438.10 requires that each State, or its contracted representative, provide information to potential managed care enrollees in order to assist them in selecting a managed care plan. Additionally, each MCO, PIHP, PAHP, and PCCM must provide the same information to their new enrollees to meet the requirements of this section.

The information that must be provided includes the following:

(1) General information about the basic features of managed care, which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in an MCO or PIHP, and MCO and PIHP responsibilities for coordination of enrollee care.
(2) Information specific to each MCO, PIHP, PAHP, and PCCM serving an area that encompasses the potential enrollee's service area, including provider network information.
(3) An enrollee's right to disenroll (provided annually).
(4) Written notice of any change (that the State defines as "significant") in the information specified at least 30 days before the intended effective date of the change.
(5) Written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.
(6) Any restrictions on the enrollee's freedom of choice among network providers.
(7) Enrollee rights and responsibilities.
(8) Grievance and fair hearing procedures, and for MCO and PIHP enrollees, state fair hearing rights.
(9) The amount, duration, and scope of benefits available under the contract.
(10) Procedures for obtaining benefits, including authorization requirements.
(11) Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.
(12) Cost sharing, if any.
(13) How and where to access any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.
(14) How and where to obtain a counseling or referral service the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections.
(15) Information on advance directives and physician incentive plans

We believe the burden placed on states, MCOs, PIHPs, PAHPs, and PCCMs, and enrollment brokers as a result of these requirements is the time associated with modifying

the content of existing information materials, developing new materials if a new contractor with a State, as well as the time associated with distributing the materials to potential enrollees and enrollees.

State (or enrollment broker) burden

- Mailing materials to potential enrollees

We estimate that that it takes states approximately 5 minutes per potential enrollee to mail a packet of materials. We estimate that each year approximately 5 percent of Medicaid managed care enrollment (58,725,513) are new enrollees. This equates to approximately 2.9 million potential new enrollees. Total burden to the State is estimated to be 241,667 hours.

  - 2.9 million new enrollees x 5 minutes = 14,500,000 minutes/60 = 241,667 hours for states

- Notifying all enrollees of their right to disenroll annually

This responsibility is assumed to be part of the State's existing workload in redetermining Medicaid beneficiaries' eligibility each year. Therefore, there is no additional burden from this requirement.

MCO/PIHP/PAHP/PCCM burden

- Developing materials

We estimate that it initially takes 36 hours for each new MCO, PIHP, PAHP, or PCCM to develop information materials which conform to the requirements above. We estimate that there are 2 new MCOs, 40 PIHPs, 15 PAHPs, and 12 PCCMs each year. Accordingly, they will collectively spend approximately 2,484 hours.

  - (2+40+15+12) * 36 hours = 2,484 initial hours for the private sector

- Updating materials annually

After the initial development, we estimate that it takes MCOs, PIHPs, PAHPs, and PCCMs approximately 4 hours each to annually update the information materials, equating to an annual total burden of approximately 2,720 hours.

  - 680 MCOs, PIHPs, PAHPS and PCCMs x 4 hours = 2,720 total annual hours for the private sector

- Mailing materials to new enrollees

Like the State, we similarly estimate that each year it takes MCOs, PIHPs, PAHPs, and PCCMs 5 minutes per new enrollee to mail the required materials upon enrollment. We estimate that each year approximately 5 percent of Medicaid managed care enrollment (58,725,513) represents new enrollees. This equates to approximately 2.9 million new enrollees. Total burden to the MCOs/ PIHPs/PAHPS/PCCMs is estimated to be 244,690 hours.

- 2.9 million new enrollees x 5 minutes = 14,500,000 minutes/60 = 241,667 hours for the private sector

Altogether, we estimate hours of burden for this requirement.

- 241,667 hours + 2,484 hours + 2,720 hours + 241,667 hours = 488,538 hours

<u>Section 438.10(i), Special rules: States with mandatory enrollment under State plan authority</u>

Under (h), if the State plan provides for mandatory MCO or PCCM enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must provide information in a comparative, chart-like format, to potential enrollees. The information must include the MCO's or PCCM's service area, the benefits covered under the contract, any cost sharing imposed by the MCOs or PCCMs and, to the extent available, quality and performance indicators, including but not limited to disenrollment rates and enrollee satisfaction.

For the requirement to provide information in a chart-like format, we believe that the additional burden on states (i.e., not yet captured in the above provisions) is the length of time associated with creating initially and updating annually the comparative chart.

- Create initial chart

We estimate that it takes a State, which starts providing managed care under the State plan option approximately 16 hours to create the comparative chart. The 22 states using this authority have already created a chart; thus, this burden would only apply to a new state that implements managed care using the1932(a) authority.

- Updating chart annually

We estimate that it takes each State which provides managed care under the State

plan option approximately 4 hours to update the chart annually. Currently, 22 states use State plan authority to provide managed care, for an annual burden of 88 hours.

- 22 states x 4 hours/each = 88 annual hours for states

Section 438.12 Provider discrimination prohibited

This section requires that if an MCO, PIHP, or PAHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

The burden associated with this requirement is the time it takes the MCO, PIHP, or PAHP to draft and furnish the providers with the requisite notice. We estimate that it takes 1 hour to draft and furnish any given notice. We estimate that on average each MCO (316), PIHP (223), and PAHP (83) will need to produce 10 notices per year for a total of 6,620 hours.

- (316 + 223 + 83) x 10 notices x 1 hour = 6,220 annual hours for the private sector

Section 438.50(b) State plan information

Each State must have a process for the design and initial implementation of the State plan that involves the public and must have methods in place to ensure ongoing public involvement once the State plan has been implemented.

The burden associated with this section includes the time associated with developing the process for public involvement and updating that process annually.

- Developing public involvement process

We estimate that it takes a State, providing managed care under the State plan option approximately 8 hours to develop the process for involving the public. As states currently providing managed care under a State Plan developed their process for public input at the beginning of their program, this burden would only apply to states starting new programs.

- Ensuring ongoing public involvement

We estimate that it takes each State which provides managed care under the State plan option approximately 4 hours annually to continue to involve the public. Currently, 22 states use State plan authority to provide managed care, for an annual burden of 88 hours.

- 22 states x 4 hours/each = 88 annual hours for states

Section 438.56(f)

Under paragraph (f), a State that restricts disenrollment under this section must provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

The burden associated with this requirement is included in the overall burden arising from the Information Requirements in §438.10.

Section 438.102 Enrollee-provider communications

Section 438.102(a)(2) states that MCOs, PIHPs, and PAHPs are not required to cover, furnish, or pay for a particular counseling or referral service if the MCO, PIHP, or PAHP objects to the provision of that service on moral or religious grounds; and that written information on these policies is available to (1) prospective enrollees, before and during enrollment and, (2) current enrollees, within 90 days after adopting the policy with respect to an any particular service.

- Written information to prospective enrollees

The burden associated with this requirement is included in the overall burden arising from the Information Requirements in §438.10.

- Written notice to current enrollees within 90 days of adopting the policy with respect to a specific service.

We believe the burden associated with this requirement affects no more than 20 MCOs or PIHPs annually since it applies only to the services they discontinue providing on moral or religious grounds during the contract period. PAHPs are excluded from this estimate because they generally do not provide services that would be affected by this provision.

Therefore, we estimate that each of the 20 MCO or PIHPs would have only once occurrence of such a policy change during each contract period. We further estimate that it takes approximately 3 hours for each plan to create the notice and 5 minutes to mail it to each enrollee.

With an average MCO/PIHP enrollment of 80,000 enrollees, the total annual burden is 6,727 hours.

- (20 MCOs/PIHPs x 3 hours/notice) x 1 notice annually = 60 hours annually for development of the written information

- 80,000 average enrollees x 5 minutes/notice x 1 notice = 400,000 minutes/60 = 6, 667 hours.
- 60 hours + 6,667 hours = 6,727 annual hours for the private sector

Section 438.202 State responsibilities

Each State contracting with an MCO or PIHP must have a written strategy for assessing and improving the quality of managed care services offered by the MCO or PIHP, make it available for public comment before adopting it in final, and conduct periodic reviews to evaluate the effectiveness of the strategy. We estimate that states conduct these periodic reviews every 3 years. Each State must also submit to CMS a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, states are required to submit to CMS regular reports on the implementation and effectiveness of the strategy, consistent with the State's own periodic review of its strategy's effectiveness.

The burden associated with this section is limited to those states offering managed care through MCOs or PIHPs and includes the time associated with developing the proposed strategy, publicizing the proposed strategy, incorporating public comments, submitting an initial copy of the strategy to CMS prior to its implementation and whenever significant changes are made, and submitting regular reports on the implementation and effectiveness of the strategy.

For each of the 37 states which offer managed care through MCOs or PIHPs, we estimate the following:

- Developing the proposed strategy takes 80 hours
- Publicizing the proposed strategy takes 2 hours
- Incorporating public comments into the strategy takes 15 hours
  - (80+2+15) hours x 37 states = 3,589 hours per completed strategy

- Submitting initial strategy to CMS prior to implementation and when changes are made takes 1 hour for a total of 37 hours

- Creating and submitting a report to CMS on the implementation and effectiveness of the strategy takes 40 hours per State; however, this is done approximately every 3 years.

  - (40 hours x 37 states)/3 = 493 annual hours.

  - 3,589 hours + 37 hours + 493 hours = 4,119 total annual hours for states

Section 438.204 Elements of State Quality Strategies

§438.204(b)(2) requires that a State identify the race, ethnicity, and primary language spoken by each MCO and PIHP enrollee and report this information to each MCO and PIHP in which each beneficiary enrolls at the time of their enrollment.

The 37 states which use MCOs or PIHPs have already made whatever system changes were necessary to comply with this provision, and are providing this information upon enrollment to MCOs and PIHPs. Any of the 15 states not currently using MCOs or PIHPs would have to make those system changes to capture enrollee race, ethnicity and primary language spoken. We estimate that burden to be 80 hours of programming per State.

Section 438.207 Assurances of Adequate Capacity and Services

Section 438.207(b) requires that each MCO, PIHP, and PAHP (where applicable) submit documentation to the State, in a format specified by the State, to demonstrate that it complies with specified requirements and that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care and meets specified requirements. Section 438.207(c) requires that this documentation be submitted to the State 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 and this regulation) in the MCO's, PIHP's, or PAHPs operations that would affect adequate capacity and services.

We believe that MCOs, PIHPs, and PAHPs already collect and provide this information to State agencies as part of their customary and usual business practices; therefore, there is no additional burden from these requirements.

Section 438.207(d) requires the State, after reviewing the MCO's, PIHP's, or PAHP's documentation, to certify to CMS that the MCO, PIHP, or PAHP has complied with the State's requirements for availability of services, as set forth at §438.206.

MCOs, PIHPs, and PAHPs have to compile this information in the format specified by the State agency, and mail it to the State and to CMS. We estimate that it takes approximately 20 hours each contract year to compile the information necessary to meet this requirement; with 622 MCOs, PIHPs, and PAHPs under contract with states, the annual burden is 12,440 hours.

- 20 hours x 622 entities = 12,440 annual hours for the private sector

Section 438.208 Coordination and continuity of care

Paragraph (b)(3) of this section requires MCOs, PIHPs, and PAHPs to 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 information collection requirement is the time it takes each MCO, PIHP or PAHP to disclose information on enrollees with special health care needs to the enrollees' new MCO, PIHP or PAHP. We estimated that approximately 25 percent of the 43.7 million enrollees in states with more than one MCO, PIHP or PAHP serving those enrollees have special health care needs, and that only 5 percent of those enrollees actually switch to another MCO, PIHP or PAHP, thereby triggering this information-sharing requirement. For each of those 547,231 enrollees, it takes approximately 1 hour to gather and share the required information for an annual burden of 547,231 hours.

- 43.7 million x .25 = 10,944,616 enrollees with special health care needs
- 10,944,616 enrollees x .05 = 547,231 enrollees with special health care needs who switch plans annually
- 547,231 affected enrollees x 1 hour each = 547,231 total annual hours for the private sector

Section 438.210 Coverage and authorization of services

Under paragraph (b) of this section, for the processing of requests for initial and continuing authorizations of services, each contract must require that the MCO, PIHP, or PAHP and its subcontractors have in place written policies and procedures.

The burden associated with this requirement is the time required to develop the policies and procedures. We do not believe that this requirement increases an entity's burden as it part of usual and customary business practices.

Under paragraph (c) of this section, each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested.

The burden associated with this requirement is the time required to notify the requesting provider and the enrollee for each denial and service reduction. We estimate that each of 622 MCOs, PIHPs and PAHPs process 20 denials/service reductions per 1,000 members. With average enrollment of 80,000, each entity is estimated to process a total of 1,600 denials and service reductions annually. With the notification to both the provider and enrollee of each occurrence taking approximately 30 minutes, the total annual burden is estimated to be 497,600 hours.

- 622 entities x 1,600 denials/service reductions/entity x 30 minutes = 29,856,000 minutes/60 = 497,600 annual hours for the private sector

Section 438.214 Provider selection

Under this section, each State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of providers.

The burden associated with this requirement is the usual and customary recordkeeping collection associated with maintaining documentation.

Section 438.230 Subcontractual relationships and delegation

Under paragraph (b), there must be a written agreement that specifies the activities and report responsibilities delegated to the subcontractor and provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

The burden associated with this requirement is the time required to write the agreement and the time required to maintain documentation of the agreement. We believe that these activities are part of an entity's usual and customary business practices and do not affect the entities' burden.

Section 438.236 Practice guidelines

Under paragraph (c) of this section, each MCO, PIHP, and PAHP must disseminate guidelines to its affected providers and, upon request, to enrollees and potential enrollees.

The burden associated with this requirement is the time required to disseminate the guidelines. As part of a comprehensive quality program, we believe that each of the 622 entities will do this annually. We estimate this will take approximately 5 hours per entity, for a total annual burden of 3,110 hours.

- 622 entities x 5 hours = 3,110 annual hours for the private sector

Section 438.240 Quality assessment and performance improvement program, including performance improvement projects

Section 438.240(c) states that each MCO and PIHP must annually measure its performance using standard measures required by the State and report its performance to the State. In addition to using and reporting on measures of its performance,

§438.240(d)(1) requires states to ensure that each MCO and PIHP have an ongoing program of performance improvement projects. In §438.240(d)(2) each MCO and PIHP is required to report the status and results of each such project to the State as requested.

This regulation requires states to require each MCO and PIHP to have an ongoing program of performance improvement. Because the use of performance measures in managed care has become commonplace in commercial, Medicare, and Medicaid managed care, we do not believe that this regulatory provision imposes any new burden on MCOs, PIHPs, or states.

With respect to the requirements for ongoing performance improvement projects (PIPs) in §438.240(d), we estimate that, in any given year, each MCO and PIHP will be conducting at least three PIPs. We further expect that states will request the status and results of each entity's PIPs annually. Accordingly, we estimate that it takes an MCO or PIHP 8 hours to prepare a report on each PIP; with three PIPs, the burden is 24 hours per MCO or PIHP. For the 539 MCOs and PIHPs, this represents an annual burden of approximately 12,936 hours.

- 3 PIPs x 8 hours x 539 entities = 12,936 annual hours for the private sector

Section 438.242 Health information systems

Section 438.242(b)(1) requires the State to require each MCO and PIHP to collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees, through an encounter data system or other such methods as may be specified by the State. Paragraph (3) requires that the data be made available to the State and, upon request, to CMS.

We believe that collecting encounter data on enrollees and the services they have used is part of an entity's usual and customary business practice and therefore imposes no additional burden.

However, the requirement that the data be provided to the State does represent a burden. We estimate that extracting this data from an entity's system and transmitting it to the State takes 20 hours each month, for an annual burden of 240 hours. Therefore, the total annual burden for the 539 MCOs and PIHPs is 129,360 hours.

- 20 hours/month x 12 months x 539 entities = 129,360 annual hours for the private sector

Section 438.402 General requirements

In summary, §438.402 requires each MCO and PIHP to have a grievance system, sets out general requirements for the system, and establishes filing requirements. It provides that grievances and appeals may be filed either orally or in writing.

The burden associated with this requirement is the time required to develop a grievance and appeal system. We do not believe that this requirement increases an entity's burden as it part of usual and customary business practices.

Section 438.404 Notice of action

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

We estimate that the burden associated with this requirement is the length of time it takes an MCO or PIHP to provide written notice of an intended action. We estimate that it takes MCOs and PIHPs 30 seconds per action to make this notification. We estimate that approximately 5 percent (1,350,000) of the approximately 27 million MCO and PIHP enrollees will receive one notice of intended action per year from their MCO or PIHP for a total burden of approximately 11,250 hours for the private sector.

- 1,350,000 x 5 minutes = 11,250 annual hours for the private sector

Section 438.406 Handling of grievances and appeals

In summary, §438.406 states that each MCO and PIHP must acknowledge receipt of each grievance and appeal.

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.408 Resolution and notification: grievances and appeals

In summary, §438.408 states that for grievances filed in writing or related to quality of care, the MCO or PIHP must notify the enrollee in writing of its decision within specified timeframes. The notice must also specify that the enrollee has the right to seek further review by the State and how to seek it. All decisions on appeals must be sent to the enrollee in writing within specified timeframes and for notice of expedited resolution, the MCO or PIHP must also provide oral notice. The decision notice must include the MCO or PIHP contact for the appeal and the results of the process and the date it was completed. For an oral grievance that does not relate to quality of care, the

MCO or PIHP may provide oral notice unless the enrollee request that it be written.

The above information collection requirements are not subject to the PRA. They are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

Section 438.410 Expedited resolution of appeals

Paragraph (c) of this section requires each MCO and PIHP to provide written notice to an enrollee whose request for expedited resolution is denied.

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.414 Information about the grievance system to providers and subcontractors.

Under this section, the MCO or PIHP must provide the information specified at §438.10(g)(i) about the grievance system to all providers and subcontractors at the time they enter into a contract.

The burden associated with this requirement is the time required to include the necessary language in the contract. We believe that this is usual and customary business practice and does not add any burden.

Section 438.416 Record keeping and reporting requirements

This section requires the State to require MCOs and PIHPs to maintain records of grievances and appeals.

We estimate that approximately 410,000 (1 percent) of the approximately 41 million MCO and PIHP enrollees file a grievance or appeal with their MCO or PIP. The recording and tracking burden associated with each grievance is estimated to be 1 minute per request, for a total burden of 6,833 hours.

- 410,000 grievances x 1 minute = 6,833 annual hours for the private sector

Section 438.604 Data that must be certified

The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

While the requirement for MCOs and PIHPs is to certify all documents required

by the State, the burden associated with these requirements is captured during the submission of such information. Therefore, there is no additional burden.

Section 438.608 Program integrity requirements.

Under this section, the MCO or PIHP must have administrative and management arrangements or procedures that are designed to guard against fraud and abuse. The arrangements or procedures 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 the designation of a compliance officer and a compliance committee that are accountable to senior management.

The burden associated with this requirement is the time required to file a copy of the written procedures. We believe that this is a normal business practice and does not add any burden.

Section 438.710 Due process: Notice of sanction and pre-termination hearing

Section 438.710(a) states that before imposing any of the sanctions specified in this subpart, the State must give the affected MCO or PCCM written notice that explains the basis and nature of the sanction.

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.710 (b)(2) Due process: notice of sanction and pre-termination hearing

Section 438.710(b)(2) states that before terminating an MCO's or PCCM's contract, the State must:

(i) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, the time and place of the hearing;

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with §438.10, on their options for receiving Medicaid services following the effective date of termination.

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.722 Disenrollment during termination hearing process

Section 438.722(a) states that after a State has notified an MCO or PCCM of its

intention to terminate the MCO's or PCCM's contract, the State may give the MCO's or PCCM's enrollees written notice of the State's intent to terminate the MCO's or PCCM's contract.

States already had the authority to terminate MCO or PCCM contracts according to State law and have been providing written notice to the MCOs or PCCMs. States are now given, at their discretion, the option of notifying the MCO's or PCCM's enrollees of the State's intent to terminate the MCO's or PCCM's contract. While it is not possible to gather an exact figure, we estimate that no more than 8 states may terminate 1 contract per year. We estimate that it takes states 1 hour to prepare the notice to enrollees, for a total burden of 8 hours. In addition, we estimate that it takes states approximately 5 minutes per beneficiary to notify them of the termination, equating to a burden of 5 minutes multiplied by 8 states multiplied by 77,583 beneficiaries per MCO or PCCM, for a burden of approximately 51,722 hours. The total burden of preparing the notice and notifying enrollees is 51,730 for states.

- 8 states x 1 hour = 8 annual hours.
- 8 states x 5 minutes x 77,583 beneficiaries = 51,722 annual hours

- 8 hours + 51,722 hours = 51,730 total annual hours for states

Section 438.724 Notice to CMS

Section 438.724 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, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

We anticipate that no more than 15 states impose or lift a sanction in any year and that it takes each one 30 minutes to give the regional office notice. Thus the annual burden would be 7.5 hours for states.

- 15 states x .5 hours = 7.5 annual hours for states

Section 438.730 Sanction by CMS: Special rules for MCOs with risk contracts

Section 438.730(b) requires that if CMS accepts a State agency's recommendation for a sanction, the State agency gives the MCO written notice of the proposed sanction. Paragraph (c) of this section requires that if the MCO submits a timely response to the notice of sanction, the State agency gives the MCO a concise written decision setting forth the factual and legal basis for the decision. In addition, if CMS reverses the State's decision, the State sends a copy to the MCO.

The above information collection requirement is not subject to the PRA. It is

exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Section 438.810 Expenditures for Enrollment Broker Services

Section 438.810(c) requires that a State contracting with an enrollment broker must submit the contract or memorandum of agreement (MOA) for services performed by the broker to CMS for review and approval.

The burden associated with this requirement is the length of time for a State to mail each contract to CMS for review. We estimated that the burden associated with this requirement is 5 minutes per enrollment broker contract, for a total annual burden of approximately 1.6 hours per year for states (5 minutes multiplied by an estimated 19 enrollment broker contracts in the states using brokers).

- 19 contracts x 5 minutes = 1.6 annual hours for states

The total burden for states is 313,925 hours; the total burden for the private sector is 1,483,898 hours.

Summary of Annual Burden Estimates for Private Sector

CFR Section	Respondents	Total Responses	Burden per response (hrs)	Total Annual burden (hrs)	Labor cost ($/per hr)	Cost per Response ($)	Total Cost ($)	Response Type
438.8	102	102	30	3,060	77	2,310	235,620	R
438.8	26	26	10	260	77	770	20,020	R
438.10	69	69	36	2,484	43	1,548	106,812	TPD
438.10	680	680	4	2,720	43	172	116,960	TPD
438.10	622	2.9M	0.083333	241,667	20	2	4,833,340	TPD
438.12	622	6,220	1	6,220	55	55	342,100	TPD
438.102	20	20	3	60	43	129	2,580	TPD
438.102	20	80,000	0.083333	6,667	20	2	133,340	TPD
438.207	622	622	20	12,440	55	1,100	684,200	R
438.208	622	547,231	1	547,231	55	55	30,097,705	TPD
438.210	622	995,200	0.5	497,600	55	28	27,368,000	TPD
438.236	622	622	5	3,110	43	215	133,730	TPD
438.240	539	1,617	8	12,936	55	440	711,480	R
438.242	539	539	240	129,360	55	13,200	7,114,800	R
438.404	539	1.35M	0.0083333	11,250	20	.16	225,000	TPD
438.416	539	410,000	0.017	6,833	43	1	293,819	RK
TOTAL		**6,292,948**		**1,483,898**			**72,419,506**	

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

Summary of Annual Burden Estimates for State government

CFR Section	Respondents	Total Responses	Burden per response (hrs)	Total Annual burden (hrs)	Labor cost ($/per hr)	Cost per Response ($)	Total Cost ($)	Response Type
438.6	37	507	32	16,224	77	2,464	1,249,248	R
438.10	37	2.9M	0.083333	241,667	20	2	4,833,340	TPD
438.10(i)	22	22	4	88	43	172	3,784	TPD
438.50(b)	22	22	4	88	55	220	4,840	TPD
438.202	37	37	97	3,589	77	7,469	276,353	TPD
438.202	37	37	1	37	55	55	2,035	R
438.202	37	37	13.33333	493	77	1,027	37,961	R
438.722	8	8	1	8	55	55	440	TPD
438.722	8	620,664	0.083333	51,722	20	2	1,034,440	TPD
438.724	15	15	0.5	7.5	77	39	578	R
438.810	19	19	0.083333	1.6	43	4	69	R
TOTAL		**3,521,368**		**313,925**			**7,443,088**	

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

13. Capital Costs (Maintenance of Capital Costs):

There are no capital costs.

14. Cost to Federal Government:

Most of the time associated with the review of information collected under this rule is imposed on States. New cost to the Federal government will be generated with respect to §438.810, which requires regional offices to review and approve enrollment broker contracts. The cost to the Federal government associated with this information collection is the time associated with reviewing and approving the contract.

We estimate that it takes the regional office approximately 24 hours to review and approve each contract. When computed at a GS-12 step 1 salary of $32.97 per hour, the Federal cost is approximately $791.28 per review. To review and approve the 19 enrollment broker contracts, the total annual cost to the Federal government associated with §438.810 is approximately $15,034.32.

15. Program or Burden Changes:

In the past, this package had included burden associated with Individuals/Households. While this may have been appropriate at one time, in this current request we have determined that this package does not contain any requirements

or burden on Individuals/Households. Consequently, we are removing that burden (1,635,883 responses and 228,250 hr) from this package. Beside the deletion of the Individual/Household burden, this ICR does not propose any new/revised program requirements.

We are also correcting several typographical and mathematical errors (in Supporting Statement section 12) as follows:

438.8: originally read: "76 PIHPS/PAHPS". It should read, "26 PIHPS/PAHPS". Also, originally read: "3,060 hrs + 760 hrs = 3,780 hrs", but should read, "3,060 hrs + 260 hrs = 3,320 hrs".

438.10: originally read: "14,681,378 minutes". It should read, "14,500,000 minutes". Also, originally read, "2.9 million new enrollees x 5 minutes = 14,500,000 minutes/60 = 241,690 hours", but should read, "2.9 million new enrollees x 5 minutes = 14,500,000 minutes/60 = 241,667 hours".

438.202: originally read: "3,367 hours". It should read, "3,589 hours". Also, originally read: "…3,897 total hours", but should read, "4,119".

438.**416**: originally read: "…total burden of 6,750". It should read, "…total burden of 6,833".

Pg. **20**: originally read: "The total burden is 5,872,255.1". It should read, "The total burden for states is 313,925 hours; the total burden for the private sector is 1,483,898 hours."

Finally, to make our calculations more user-friendly, we have added Plan and State burden tables in Supporting Statement section 12. We are also adding cost data which was inadvertently excluded from earlier PRA packages.

16. Publication and Tabulation Dates:

The information submitted to CMS will not be published. Rather, that information is reviewed as part of the agency's normal oversight activity of State Medicaid managed care programs. The majority of the information collection is undertaken by States. Accordingly, States are responsible for ensuring that information collected is not manipulated and erroneously published. Much of the information (i.e., the information requirements under § 438.10) is mailed directly to beneficiaries by the States, MCOs, PIHPs, PAHPs or PCCMs. The rest of the information is used by States as part of their normal contracting with MCOs PIHPs, PAHPs, and PCCMs and is not be published.

17. Expiration Date:

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

18. Certification Statement:

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods:

This ICR does not employ any statistical methods.