Supporting Statement for Medicaid Managed Care
and Supporting Regulations Contained in
42 CFR 438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102, 438.114, 438.202, 438.204, 438.206, 438.207, 438.240, 438.242, 438.402, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.604, 437.710, 438.722, 438.724, and 438.810

A. Background:

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The implementation of HCFA-2001-F, which was published on January 19, 2001 was delayed until August 16, 2002, and withdrawn on June 14, 2002, when we published the final rule discussed above.

B. 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. 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; we do not yet have the technology for 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.

8. Federal Register Notice/Outside Consultation:

A 60-day Federal Register was published on January 12, 2007.

A proposed rule was published in the Federal Register on September 29, 1998 (66 FR 6228). The final rule, giving 30 days to comment on the ICRs, was published January 19, 2001; it set forth policies to implement provisions of the Balanced Budget Act of 1997. The effective date of this rule was delayed until August 16, 2002

On August 20, 2001, we published another proposed rule that would replace the Medicaid regulation published in the Federal Register on January19, 2001 (66 FR 6228). It contained a 60-day comment period for the ICRs. The final rule based on this proposed rule was published on June 14, 2002.

Throughout the development of the first proposed regulation, CMS consulted with State Medicaid agency representatives in order to gain more understanding of potential impacts. At the November 1997 meeting of the Executive Board of the National Association of State Medicaid Directors (NASMD), CMS discussed the process for providing initial guidance to States about the Medicaid provisions of BBA. This guidance was provided through the issuance of a series of letters to State Medicaid Directors. From October, 1997 through April, 2000, over 50 of these letters were issued. In addition, in May, 1998, the Executive Committee of NASMD was briefed on the general content of the regulation. More specific State input was obtained through discussions throughout the Spring of 1998 with the Medicaid Technical Advisory Groups (TAGs) on Managed Care and Quality. These groups are comprised of Medicaid State agency staff with notable expertise in the subject area and with CMS's regional office staff. The TAGs are staffed by the American Public Human Services Association (APHSA). Additional input was obtained from States, health plans**,** and advocates following the publication of the Final Rule in the Federal Register on January 19, 2001. Through these contacts, CMS explored with States agencies their preferences regarding policy issues and the feasibility and practicality of implementing policy under consideration.

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:

CMS solicited public comments on each of these issues for the information collection requirements discussed below. The numbers may differ from those stated in the preamble to the final rule; there were some miscalculations in that document.

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.

It is difficult to quantify the burden on States of providing information to support the actuarial soundness of the capitation rates for their risk-based, managed care contracts, because the rate setting methodologies and data sources vary widely from State to State. 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. We estimate the burden to comply with these requirements averages approximately 32 hours per contract for the 440 risk contracts, resulting in a total burden of 14,080 hours. This amount is limited to the time required for the State to compile documentation the State and its actuaries would already have developed in determining the capitation rates and submitting this documentation, as required, to CMS. Since, under this rule, States no longer need to generate a UPL (which we estimated requiring 24,640 hours {reflecting the reduction in risk contracts from 496 to 440} from our previous submission) this change results in a net reduction in burden of 10,560 hours.

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. This information is usually furnished with the rest of the information required by §438.10 and is therefore subsumed under those requirements.

There is also an implied recordkeeping requirement associated with contracts; i.e., that would be documented. Maintaining documentation is a usual and customary business practice and does not add to the burden.

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. Requirements for advance directives apply only to PIHPs and certain limited numbers of PAHPs.

PHPs (now designated as PIHPs and PAHPs) were not previously required to maintain written policies and procedures with respect to advance directives. This rule requires the PIHP and some PAHPs to provide written information to enrollees of their rights under this provision and the PIHPs policies with respect to the implementation of those rights. We project 8 hours of time for each of 107 PIHPs and 43 PAHPs to establish this policy and 2 minutes per enrollee for provision of this information, and acceptance of this right to each of approximately 13.1 million individuals enrolled in PIHPs and the specified PAHPs. The total time for this is approximately 437,866 hours.

Under the physician incentive plan provision, PIHPs and PAHPs, like MCOs, 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 are basing our projections of burden upon information published in the Federal Register on March 27, 1996 and December 31, 1996 (61 FR 13445 and 61 FR 69049) which contained the original regulatory provisions on physician incentive plans for Medicare and Medicaid HMOs. Based on those assumptions, we believe no more than 1/3 of the approximately 150 PIHPs and 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. At the projected 100 hours per response for

approximately 50 PIHPs and PAHPs the total burden would be 5,000 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 12. We estimate an additional 10 hours per plan for a total of 120 hours. Altogether, we estimate 5,120 hours of burden through imposition of this requirement on PIHPs and PAHPs.

Section 438.10 Information requirements

In summary, §438.10 requires that each State, its contracted representative, or at the option of the State, each MCO, PIHP, PAHP, and PCCM furnish information to enrollees and potential enrollees to meet the requirements of this section. Paragraph (c)(4) requires that the State and each MCO, PIHP, PAHP, and PCCM, make oral interpretation available in languages other than English. Paragraph (c)(5) requires that beneficiaries be informed how to access those services. Paragraph (d)(2) requires that all enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats. The basic information listed in paragraph (e)(2) must be provided to each potential enrollee by the State or its contracted representative.

The State, its contracted representative or the MCO, PIHP, PAHP, or PCCM must provide the information in paragraph (f)(6), and for MCOs and PIHPs, in paragraph (g) at least once a year. The information that must be provided includes the following:
(a) Information for potential enrollees:

(1) General information must be provided 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 must be provided in summary form, or in more detail, upon request of the enrollee. This includes information on benefits covered; cost sharing if any; service area; names, locations, and telephone numbers of current network providers, including at a minimum, information on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients; and 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.
(b) Information for enrollees:

(1) The State must notify enrollees of their disenrollment rights annually. The State, or the MCO, PIHP, PAHP, and PCCM, if delegated this responsibility by the State, must provide certain information to new enrollees and notify enrollees annually of their

right to request additional information. The State must give each enrollee 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 and make a good faith effort to give 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.

(c) General information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs:

(1) Names, locations, and telephone numbers of, and non-English languages spoken by, current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.

(2) Any restrictions on the enrollee's freedom of choice among network providers.

(3) Enrollee rights and responsibilities as specified in §438.100.

(4) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in §438.10(g)(i).

(5) The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.

(6) Procedures for obtaining benefits, including authorization requirements.

(7) The extent to which, and how, enrollees may obtain benefits, including family planning services from out-of-town network providers.

(8) The extent to which, and how, after-hours and emergency coverage are provided.

(9) What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in §438.114, and the fact that prior authorization is not required for emergency services.

(10) The post-stabilization care services rules set forth at §438.113(c) of this chapter.

(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) For a counseling or referral service the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, or PCCM need not furnish information on how and where to obtain the service. The State must furnish information about how and where to obtain the service.

(d) Specific information requirements for enrollees of MCOs and PIHPs:

(1) In addition to the requirements in §438.10(e), MCOs and PIHPs must provide to their enrollees the following information specified in §438.10(g):

(i) Grievance, appeal, and fair hearing procedures and timeframes, as provided in

§438.400 through 438.424, in a State-developed or State-approved description, which includes:

(ii) The right to a State fair hearing and the method for obtaining a hearing,

(iii) The rules governing representation at the hearing,

(iv) The right to file grievances and appeals

(v) The filing requirements, timeframes, and availability of assistance with the filing process,

(vi) The toll-free numbers enrollees can use to file a grievance or appeal by phone,

(vii) The fact that when requested by the enrollee, benefits will continue if the enrollee files an appeal or a request for a State fair hearing within the specified timeframes,

(viii) The possibility that the enrollee may be required to pay the cost of services furnished during the appeal process, if the final decision is adverse,

(ix) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service,

(x) Information on advance directives, as set forth in §438.6(i)(2) and physician incentive plans, as set forth in §438.6(h) and

(xi) Additional information that is available upon request, including structure and operation of the MCO or PIHP

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, as well as the time associated with distributing the materials to enrollees as specified by the regulation. We estimate that it initially takes 12 hours for each MCO, PIHP, PAHP, or PCCM system to modify existing information materials to conform to the requirements above. We further estimate that there are approximately 478 MCOs, PIHPs, PAHPs, and PCCM systems equating to an initial modification burden of approximately 5,736 hours. After the initial modification, we estimate that it takes MCOs, PIHPs, and PAHPs approximately 4 hours each to annually update the information materials, equating to an annual total burden of approximately 1,912 hours.

We estimate that that it takes MCOs, PIHPs, PAHPs, and PCCM systems approximately 5 minutes per enrollee to mail a packet of materials to potential enrollees and enrollees. We estimate that each year approximately 15 percent of the Medicaid managed care enrollee population are new enrollees. This equates to approximately 3.9 million potential enrollees a year for a total burden on the States of 65,000 hours. Mailing the annual packet of information to the 28,575,585 enrollees, at 5 minutes a packet, will result in a burden to the State, or the MCOs, PIHPs, PAHPs, and PCCMs, if delegated this responsibility by the State, of 2,381,300 hours.

We similarly estimate that it annually takes MCOs, PIHPs, PAHPs, and PCCMs 5 minutes per enrollee to supply information requested by potential enrollees and enrollees. We

estimate that 10 percent of potential enrollees and enrollees will request information each year. For the 390,000 potential enrollees requesting information, this results in a burden on States of 6,500 hours. For the 2,857,558 enrollees requesting information, this results in a burden on States, or MCOs, PIHPs, PAHPs, and PCCMs if delegated this responsibility by the State, of 238,130 hours.

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

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 the comparative chart. We estimate that it takes States approximately 8 hours each to create the comparative chart. Currently, 16 States per year have approved managed care under the State Plan Option, for a total annual burden of approximately 128 hours.

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, PIHP, and PAHP will need to produce 10 notices per year for a total of 4,420 hours.

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, including annual updates. We estimate that it takes 16 current States 40 hours per State to develop the process for involving the

public for a total burden of 640 hours. We estimate that ensuring ongoing public involvement takes another 20 hours per State annually for a total annual burden of 320 hours.

The recordkeeping burden involved in maintaining documentation that the requirements are met is a usual and customary business practice and imposes no additional burden.

Section 438.56 Disenrollment: Requirements and limitations

In order to disenroll, the beneficiary (or his or her representative) must submit an oral or written request to the State agency (or its agent) or to the MCO, PIHP, PAHP, or PCCM where permitted.

We believe that the burden associated with this requirement is the length of time it takes enrollees to submit in writing a disenrollment request, if they choose to use the written format. We estimate that il takes approximately 10 minutes per enrollee to generate a written disenrollment request. We estimate that approximately 5 percent of MCO, PIHP, PAHP, and PCCM enrollees request that they be disenrolled from an MCO, PIHP, PAHP, or PCCM. Approximately one-fourth of the enrollees choose a written rather than an oral request. This equates to an annual burden of approximately 10 minutes multiplied by 357,195 affected enrollees (one-fourth of the 1,428,779 enrollees requesting disenrollment), or approximately 59,532 hours. We estimate a burden of 3 minutes per oral request for disenrollment (for 3/4ths of the 1,071,584 enrollees, or 873,688 enrollees) for a total burden of 40,184 hours.

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 for this section is addressed in §438.10(f).

Section 438.102 Enrollee-provider communications

Section 438.102(a)(2) states that the general rule in paragraph (a)(1) of this section does not require the MCOs, PIHPs, and PAHPs 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 makes written information on these policies available to (1) prospective enrollees, before and during enrollment and, (2) current enrollees, within 90 days after adopting the policy with respect to an any particular service.

We believe the burden associated with this requirement affects no more than 3 MCOs or PIHPs annually since it applies only to the services they discontinue providing on moral or religious grounds during the contract period. We estimate that it takes 4 hours to devise a notice and 5 minutes to mail, affecting 52,000 enrollees, for a total burden of 4,345 hours. [12 hours + (52,000 x 1/12)] The burden for notification of prospective enrollees of the services not covered by the MCO, PIHP, or PAHP on these grounds is included in the overall burden arising from the Information Requirements in §438.10.

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 (34) 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. We estimate that it takes 40 hours per State to develop the proposed strategy for a total burden of 1,360 hours. We estimate that publicizing the proposed strategy takes 2 hours per State for a total burden of 68 hours. We estimate that incorporating public comments for the final strategy takes another 40 hours per State for a total burden of 1,360 hours. We estimate it takes 1 hour per State to submit an initial copy of the strategy to CMS prior to implementation and whenever significant changes are made for a total of 34 hours. We estimate it takes 40 hours per State to create and submit a report on the implementation and effectiveness of the strategy and that these reports are submitted at approximately every 3 years for a total annual burden of 453 hours. Thus the total for this provision is 3,275 hours.

Section 438.204 Elements of State Quality Strategies

In the final rule we require at §438.204(b)(2) 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.

Most States currently track race and ethnicity data in their eligibility systems. If States do not, minor changes in their software will be needed. With respect to primary language of enrollees, there will likely be additional programming needed for all States. We estimate that this requires 4 hours of programming for each of the 34 jurisdictions for a total of 136 hours.

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 has the capacity 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.

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.

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 and that the only additional burden on MCOs, PIHPs, and PAHPs is the length of time required for these entities to compile this information in the format specified by the State agency, and the length of time to mail the information to the State and to CMS. We estimate that it takes each MCO, PIHP, and PAHP approximately 20 hours to compile the information necessary to meet this requirement, for a total of 20 hours multiplied by 442 MCOs, PIHPs, and PAHPs with networks, or approximately 8,840 hours. In addition, we estimate that it takes MCOs, PIHPs, and PAHPs approximately 5 minutes each to mail the materials associated with this burden to the State for an annual burden of approximately 5 minutes multiplied by 442 of these entities, or approximately 4 hours.

We estimate that obtaining information on: (1) the numbers and types of persons with special health care needs that could be anticipated to enroll in the MCO or PIHP; (2) the types of experienced providers they would require; (3) the experience of the existing providers in the MCO's or PIHPs network; and (4) the numbers and types of additional experienced providers needed, requires an estimated 40 hours of work for each of the 442 MCOs, PIHP, and PAHP for a total estimated burden of 17,680 hours.

Section 438.208 Coordination and continuity of care

Under 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 to disclose information on enrollees. We estimated that it is necessary to disclose information on 619,709 enrollees and take it takes 45 minutes for each one, for an annual total of 464,782 hours.

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. We believe that there are approximately 100 notifications under this provision and that it takes 60 minutes to complete the notification (including writing it) per MCO or PIHP. There are approximately 292 MCOs and 107 PIHPs for a total of 399 for a total of 39,900.

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 and 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 PHAP 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. We believe that these will be rare requests and will occur infrequently.

Section 438.240 Quality assessment and performance improvement program; 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. Based on discussions with the 17 States with the largest Medicaid managed care enrollments, all 17 States are already doing so. 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 in §438.240(d), we estimate that, in any given year, each MCO and PIHP completes two projects, and will have four others underway. We further expect that States will request the status and results of each MCO's and PIHP's projects annually. Accordingly, we estimate that it takes each MCO and PIHP 5 hours to prepare its report for each project, for an annual total burden of 30 hours per MCO and PIHP. In aggregate, this burden equates to 30 hours multiplied by an estimated 399 MCOs and PIHPs, or approximately 11,970 hours.

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.

The above information collection requirement is subject to the PRA. However, we believe that the burden associated with these information collection requirements is exempt from the Act in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

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, but that oral appeals (except those with respect to expedited service authorization decisions) must be followed by a written request.

We estimate that it took approximately 5.5 hours for each MCO and PIHP to conform their existing general grievance system requirements to those in the regulation. It takes approximately 2.5 hours to create or change the filing requirements, including developing or revising templates for a notice of action and a notice of disposition or resolution. The total burden for 399 MCOs and PIHPs is 3,192 hours.

We estimate that approximately 1 percent of the approximately 27 million MCO and PIHP enrollees (270,000) annually will file a grievance with their MCO or PIHP and that approximately .5 percent (135,000) annually will file an appeal. For these cases, we estimate that the burden on the enrollee filing a grievance or appeal is approximately 20 minutes per case. The total annual burden on enrollees is 135,000 hours.

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 approximately11,250 hours.

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), Action following denial of a request for expedited resolution, 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 405,000 (1 percent) of the approximately 27 million MCO and PIHP enrollees file a grievance or appeal with their MCO or PIHP (101 per MCO or PIHP). The recording and tracking burden associated with each grievance is estimated to be 1 minute per request (1.7 hours per MCO or PIHP), for a total burden of 6,750 hours (1 minute multiplied by an estimated 405,000 enrollees who would file a grievance or appeal).

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.

W*hile 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, we are assigning 1 token hour of burden for this requirement*

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.

BB. 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.

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.

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

Section 438.730(b), Notice of Sanction, 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, Informal reconsideration, 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.

These requirements are exempt under 5 CFR 1320.4(a) because they occur as part of administrative actions.

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 3 hours per year (5 minutes multiplied by an estimated 35 enrollment broker contracts in the States using brokers).

The total burden is 3,930,093.5 hours.

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

Section 438.810 requires regional offices to review enrollment broker contracts. The cost to the Federal government associated with this information collection is the time associated with reviewing the contract.

We estimate that it takes the regional office approximately three hours to review each contract. When computed at a GS-12 step 1 salary of $26.98 per hour, the Federal cost is approximately $80.94 per review. Multiplied by the estimated 35 enrollment brokers, the total annual cost to the Federal government associated with §438.810 is approximately $2,833.

15. Program or Burden Changes:

The slight increase in burden hours are attributable to minor workload changes in the application of these managed care regulations since prior approval in 2004.

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.

C. Collection of Information Employing Statistical Methods:

These ICRs do not employ statistical methods.