

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub.L. 104-4), and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year.) We project the cost of this rule to be between \$221 and \$295 million annually. The burden of these costs will be shared between States, MCOs, PIHPs, PAHPs, PCCMs, and the Federal government. It should be noted that a large portion of these costs will be born by the Federal government through its matching payments to States for Medicaid expenditures.

This rule will implement new requirements for Medicaid managed care programs which have not been previously implemented through either the previous Part 434 of the CFR or the State Medicaid Director Letters listed in section I.A. of the Preamble, or self-implemented through the BBA. The new provisions implemented under this rule are requirements governing : (1) payments under risk contracts; (2) PIHPs and PAHPs; (3) information that must be provided to beneficiaries; quality assessment and performance improvement for managed care programs; and (4) grievances and appeals.

The RFA requires agencies to analyze options for regulatory relief of small entities. We have provided an analysis of alternatives to these rules in section V.C. of the Preamble.

This final rule primarily impacts beneficiaries, State agencies, enrollment brokers, MCOs, PIHPs, PAHPs, and PCCMs. Small entities include small businesses in the health care sector that are HMO medical centers or health practitioners as prepaid health plans with receipts of less than \$8.5 million, nonprofit organizations, and other entities. (See 65 FR 69432). For purposes of the RFA, individuals and State governments are not included in this definition. In the proposed rule we invited comments on alternatives to provisions of the proposed rule that would reduce burden on small entities. We did not receive any comments in response to this invitation.

As of June 2000, there were 339 MCOs, 123 PIHPs, 34 PAHPs, and 37 PCCM systems. We believe that only a few of these entities qualify as small entities. Specifically, we believe that 16 MCOs, 14 PIHPs, 11 PAHPs, and most managed care entities in the 37 PCCM systems are likely to be small entities. We estimate that there are 4.8 million beneficiaries enrolled in these small entities. We believe that the remaining MCOs, PIHPs, and PAHPs have annual receipts from Medicaid contracts and other business interests in excess of \$8.5 million.

The primary impact on small entities will be through the requirements placed on PIHPs and PAHPs by §438.8. Under this rule, PIHPs will be subject to nearly all of the requirements for MCOs, including the requirements for quality assessment and improvement and grievances and appeals. PAHPs are not subject to the grievance and

appeals requirements, but will be subject to quality requirements like network adequacy and coverage and authorization of services where it is determined to be applicable. The impact on these entities from these provisions is discussed later in this section. However, we are identifying additional burden on the 14 PIHPs and 11 PAHPs, which we project to be small entities of 2,000 hours from the requirement for advance directives and 900 hours on information on solvency requirements, for a total burden of 2,900 hours. Using the mean hourly wage the average wage for the health care service sector of \$16.34 (Bureau of Labor Statistics, March 2001), this will result in a total cost to these small entities of \$47,386.

The most significant burden relates to providing information to enrollees. Specifically, MCOs, PIHPs, PAHPs, and PCCMs are required to make written materials available in languages that are prevalent in its service area (as determined by the State) and provide oral interpretation services when needed. The final rule requires MCOs, PIHPs, PAHPs, and PCCMs to make oral interpretation services available to each potential enrollee or enrollee requesting them. This requirement is actually derived from the provisions of Title VI of the Civil Rights Act of 1964 and Executive Order 13166, and not created by this rule. We estimate that less than 1% of the enrollees of these entities (or 48,000 individuals) will require this service an average of 2 times per year. Using the baseline commercial language line charges of \$2.20 per minute with a one hour minimum, we estimate the cost of providing oral interpretation services to be \$12.7 million annually. We believe that this estimate may overstate the impact of this requirement, because: (1) many providers are bilingual or have staff that are bilingual (particularly in areas with relatively a large percentage of non-English speaking

individuals); (2) there are less costly alternatives than the example we have used to provide oral interpretation; (3) many enrollees in need of oral interpretation will prefer to use a friend or relative; and (4) these specific costs should be mitigated by the costs of complying with current civil rights requirements to provide translation services.

We do not believe that there is significant burden as a result of the remainder of this section. PCCMs or PAHPs do not normally provide much written material directly to enrollees since, in the final rule, we place the responsibility on States, rather than PCCMs and PAHPs. We believe that States will usually prepare this information so that the only burden on PCCMs and PAHPs will be to distribute the information when it is requested by an enrollee. For the small entities who must perform this function themselves, including those MCOs and PIHPs identified as such we have projected a burden of 36,000 hours for compliance with the requirements in the information section. This results in an additional burden of \$588,240.

The final rule also imposes requirements for quality assessment and improvement in Subpart D on all MCOs and PIHPs and those PAHPs designated by the State. Based on the estimates in the Collection of Information section of this preamble, we project a burden of 3,800 hours or \$62,092.

In addition, Subpart F of this rule requires the 16 MCOs and 14 PIHPs that are small entities to develop and implement a grievance system as described in that section. While most of these entities would have had a system in place already, they will, at a minimum, need to modify the current system to comply with the requirements of this section. We project the burden for these modifications and operation of the grievance systems by these entities to be a total of 8 hours per entity for the development and

modification of the current system and an average of 4 hours each for the resolution of the expected 1440 grievances and appeals filed by the enrollees of these entities (based on the estimates contained in section IV of this preamble on Information Collection Requirements). This results in a total burden of 6,000 hours at the mean hourly wage of \$16.34, for a total cost of \$98,040.

We do not believe that the remaining impact of the provisions of this final rule are great on the small entities that we have identified. These small entities must meet certain contract requirements, however, these are consistent with the nature of their business in contracting with the State for the provision of services to Medicaid enrollees. They, likewise, must meet requirements related to disenrollment of enrollees for cause, including receipt and initial processing of disenrollment requests if the State delegates this function to the entity. However, all enrollees have an annual opportunity to disenroll, and historically the number of disenrollment requests for cause are small. In addition, these entities must submit marketing material to the State for review and approval, and those MCOs, PIHPs, and PAHPs which are at risk for emergency services must cover and pay for emergency services based on the prudent layperson standard. However, the provisions governing marketing materials and emergency services have already been implemented through State Medicaid Director Letters.

We have clarified that PAHP enrollees have the right to a State fair hearing under subpart E of part 431, although this is not a new requirement. Additionally, PAHPs may not discriminate against providers seeking to participate in the plan. This requirement imposes no burden as it would reflect their usual and customary business operations.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds.

We do not anticipate that the provisions in this final rule will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on States, MCOs, and PIHPs, but no new direct requirements on individual hospitals. However, the prudent layperson standard for emergency services should benefit these hospitals by providing a uniform standard on which to determine the potential for coverage of these services across all MCOs. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs and PIHPs, but any additional burden on small rural hospitals should be negligible.

We have determined that we are not preparing analysis for either the RFA or section 1102(b) of the Act because we have determined, and we certify that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals in comparison to total revenues of these entities.

B. Anticipated Effects

This final rule implements the Medicaid provisions as directed by the BBA. The primary objectives of these provisions are to provide greater beneficiary protections and quality assurance standards and to allow for greater flexibility for State agencies to participate in Medicaid managed care programs. The final rule addresses pertinent areas of concern between States and MCOs, PIHPs, PAHPs and PCCMs.

Specific provisions of the regulation include the following:

- Permitting States to require in their State plan that Medicaid beneficiaries be enrolled in managed care. (This provision was implemented through a State Medicaid Director (SMD) Letter dated December 17, 1997, but this rule adds requirements for public involvement in the process.)
- Eliminating the requirement that no more than 75 percent of enrollees in an MCO or PHP be Medicaid or Medicare enrollees. (This provision was implemented through an SMD Letter dated January 14, 1998.)
- Specifying a grievance and appeal procedure for MCO and PIHP enrollees.
- Providing for the types of information that must be given to enrollees and potential enrollees, including requirements related to language and format.
- Requiring that MCOs, PIHPs and PAHPs document for the States that they have adequate capacity to serve their enrollees and that States certify this to us.
- Specifying quality standards for States, MCOs, and PIHPs.
- Increasing program integrity protections and requiring certification of data by MCOs and PIHPs.
- Increasing the threshold for prior approval of MCO contracts. (This provision was implemented through an SMD Letter dated January 14, 1998.)

- Permitting cost sharing for managed care enrollees under the same circumstances as permitted in fee-for-service. (This provision was implemented through an SMD Letter dated December 30, 1997.)

- Expanding the managed care population for which States can provide 6 months of guaranteed eligibility. (This provision was implemented through an SMD Letter dated March 23, 1998.)

- Revising the rules for setting capitation rates.

It is extremely difficult to accurately quantify the overall impact of this regulation on States, MCOs, PIHPs, PAHPs, and PCCMs because there is enormous variation among States and these entities regarding their current regulatory and contract requirements, as well as organizational structure and capacity. Any generalization would mask important variations in the impact by State or managed care program type. The Lewin Group, under a contract with the Center for Health Care Strategies, released a study of the cost impact of the earlier proposed regulation published on September 29, 1998 the **Federal Register** (63 FR 52022). Because this new final rule addresses the same areas as the September 29, 1998 proposed rule and includes many similar provisions, the Lewin study remains the best information we have available on the potential incremental impact of this final rule. However, the provisions discussed in the study were more prescriptive, and thus more costly to implement, than the provisions contained in this final rule. Consequently, we believe that these estimates are higher than the actual costs will be to implement these requirements.

The Lewin study did not analyze the original proposed regulation in total, but

focused on four areas within the original proposed regulation: individual treatment plans, initial health assessments, quality improvement programs, and grievance systems/State fair hearings. These areas are discussed in more detail in the specific section of the Impact Analysis addressing that provision. While the study's focus is limited to selected provisions of the previous regulation, and some of the details of the provisions in this final rule differ from the earlier proposed rule, nevertheless, we believe that the overall cost conclusions are relevant to this final rule. In addition to examining the four regulatory requirements, the Lewin study cited the need to evaluate both the incremental and aggregate effects of the rule; the affect on different managed care environments (for example, overall enrollment; the Medicare, commercial, and Medicaid mix; geographic location); and differing regulatory requirements of the State (for example, State patient rights laws, regulation of noninsurance entities). The Lewin report also points out that many of the BBA provisions were implemented through previous guidance to the States, so the regulatory impact only captures a subset of the actual impact of the totality of BBA requirements.

In summary, according to the Lewin Study, States and their contracting managed care plans have already implemented many provisions of the BBA. While there are incremental costs associated with these regulatory requirements, they will vary widely based on characteristics of individual managed care plans and States. Finally, the BBA requirements are being implemented in an increasingly regulatory environment at the State level. Therefore, States, MCOs, and PIHPs will likely face additional costs not related to these regulatory requirements absent these new regulations. Thus, the

incremental impact of these requirements on costs to be incurred would be difficult if not impossible to project.

We believe that the overall impact of this final rule will be beneficial to Medicaid beneficiaries, MCOs, PIHPs, PAHPs, PCCMs, States, and CMS. Many of the BBA Medicaid managed care requirements merely codify the Federal statute standards widely in place in State law or in the managed care industry. Some of the BBA provisions represent new requirements for States, MCOs, PIHPs, PAHPs, and PCCMs, but also provide expanded opportunities for participation in Medicaid managed care.

It is clear that all State agencies will be affected by this final Medicaid rule but in varying degrees. Much of the burden will be on MCOs, PIHPs, PAHPs, and PCCMs contracting with States, but this will also vary by existing and continuing relationships between State agencies and MCOs, PIHPs, PAHPs, and PCCMs. This regulation is intended to provide important beneficiary protections while giving States flexibility and minimizing the compliance cost to States, MCOs, PIHPs, PAHPs, and PCCMs to the extent possible consistent with the detailed BBA requirements. We believe the final rule provisions will result in improved patient care outcomes and satisfaction over the long term.

Recognizing that a large number of entities, such as hospitals, State agencies, MCOs, PIHPs, PAHPs, and PCCMs will be affected by the implementation of these statutory provisions, and a substantial number of these entities may be required to make changes in their operations, we have prepared the following analysis. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by both the RFA and RIA.

1. State Options to Use Managed Care

Under this provision, a State agency may amend its State plan to require all Medicaid beneficiaries in the State to enroll in either an MCO or PCCM without the need to apply for a waiver of "freedom of choice" requirements under either section 1915(b) or 1115 of the Act. However, waivers will still be required to include certain exempted populations in mandatory managed care programs, notably dual Medicare-Medicaid eligibles, Indians, and groups of children with special needs. Federal review will be limited to a one-time State plan amendment approval, while States will no longer need to request waiver renewals every 2 years for section 1915(b) of the Act and 3-5 years for section 1115 of the Act waivers. State agencies may include "exempted" populations as voluntary enrollees in the State plan managed care programs or as mandatory enrollees in State waiver programs. Currently, ten States use State plan amendments to require beneficiary enrollment in MCOs and PCCMs. In short, the new State plan option provides State agencies with a new choice of method to require participation in managed care. The ability of States to require enrollment in managed care through their State plans rather than through a waiver will not alter the standards of care practiced by MCOs and health care providers and, therefore, will not change the cost of providing care to managed care enrollees.

Pursuing the State plan amendment option rather than a waiver under section 1915(b) or 1115 of the Act waiver may reduce State administrative costs because it will eliminate the need for States to go through the waiver renewal process. Likewise, we will benefit from a reduced administrative burden if fewer waiver applications and renewals are requested. However, we believe the overall reduction in administrative

burden to both the States and Federal government of approximately 40 hours annually per State will be offset by an additional burden of approximately 40 hours annually to develop and maintain the public process required by this rule

2. Elimination of 75/25 Rule

Before the passage of the BBA, nearly all MCOs, and PHPs contracting with Medicaid were required to limit combined Medicare and Medicaid participation to 75 percent of their enrollment, and State agencies had to verify enrollment composition as a contract requirement. Elimination of this rule allows MCOs, PIHPs, and PAHPs to participate without meeting this requirement and eliminates the need for States to monitor enrollment composition in contracting MCOs, PIHPs, and PAHPs. This will broaden the number of MCOs, PIHPs, and PAHPs available to States for contracting, leading to more choice for beneficiaries. This provision results in no additional burden on States since it merely eliminates a previous statutory requirement and has already been implemented through the BBA amendment and the State Medicaid Director Letter in 1998.

3. Increased Beneficiary Protection - Grievance Procedures

The BBA requires MCOs to establish internal grievance procedures that permit an eligible enrollee, or a provider on behalf of an enrollee, to challenge the denials of medical assistance or denials of payment. Prior to the enactment of the BBA, the regulations at 42 CFR 434.59, required MCOs and PHPs to have an internal grievance procedure. While the regulations do not specify a procedure for MCOs or PIHPs to follow for their grievance process, we believe that these entities have grievance systems that are similar in their processes to the requirements of this final regulation. This belief is supported by surveys of State Medicaid agencies, such as the survey of 10 States

conducted by the National Academy for State Health Policy in 1999, and the survey of 13 States conducted by the American Public Human Services Association in 1997.

Therefore, while this regulation will require uniform procedures across MCOs and PIHPs, and will require MCOs and PIHPs to change their procedures to conform to the regulation, the requirements of the final rule will not impose significant additional requirements on MCOs and PIHPs, beyond the 8 hours per entity we estimated in the Collection of Information section of this preamble (and included in the totals below) to make current systems conform with the provisions of this rule. For States, we estimate an additional burden for the development of an expedited process for State fair hearings of 20 hours per State for the 40 States that contract with MCOs and/or PIHPs for a total burden of 800 hours and a cost of \$13,640.

In the Collection of Information section of this preamble, we assigned 9,875 burden hours to MCOs and PIHPs for the notice requirements of the grievance system, and 1,583 hours for the record keeping requirements and summary reports to be prepared by MCOs and PIHPs and submitted to the States. This results in 11,458 total burden hours. Using the mean hourly wage for the health care service sector (the Bureau of Labor Statistics, March 2001) of \$16.34, this would result in a total cost to MCOs and PIHPs of \$187,224.

4. Provision of Information

In mandatory managed care programs, we require that beneficiaries be informed of the choices available to them when enrolling with MCOs, PIHPs, PAHPs, and PCCMs. Section 1932(a)(5) of the Act, enacted in section 4701(a)(5) of the BBA, describes the kind of information that must be made available to Medicaid enrollees and

potential enrollees. It also requires that this information, and all enrollment notices and instructional materials related to enrollment in MCOs, PIHPs, PAHPs, and PCCMs be in a format that can be easily understood by the individuals to whom it is directed. We do not believe that these requirements deviate substantially from current practice, including the new mechanism requirement. Programs operated under section 1915(b) and 1115 authority have always had more stringent beneficiary protections. Furthermore, there is no way to quantify the degree of burden on State agencies, MCOs, PIHPs, PAHPs, and PCCMs for several reasons. We do not have State-specific data on what information States currently provide, or the manner in which they provide it. Variability among States indicates that implementing or continuing enrollee information requirements will represent different degrees of difficulty and expense.

The information requirements for MCOs and PCCMs in the final rule are required under the BBA. In this final rule, however, we extend requirements to PIHPs and PAHPs. In the Collection of Information section of this Preamble, we have estimated the total burden on States, MCOs, PIHPs, PAHPs, and PCCMs of 2,358,678 hours to comply with these requirements. Using a weighted average between the mean hourly wages for State employees and the health care service sector of \$16.70, this results in a total cost of \$39,389,923.

As a requirement under the provision of information section, State agencies opting to implement mandatory managed care programs under the State plan amendment option are required to provide comparative information on MCOs and PCCMs to potential enrollees. Currently only ten States have exercised the option to use a State plan amendment to require beneficiary enrollment in managed care. However, for States

that do select this option, we do not believe that providing the comparative data in itself represents an additional burden, as these are elements of information that most States currently provide. The regulation specifies that the information must be presented in a comparative or chart-like form that facilitates comparison among MCOs, and PCCMs. This may be perceived as a burden to States that have previously provided this information in some other manner; however, it is our belief that even in the absence of the regulation, the trend is for States, and many accreditation bodies such as the National Committee for Quality Assurance (NCQA), to use chart-like formats. Consequently, enrollees will benefit from having better information for selecting MCOs, and PCCMs. Only a few States have opted for State plan amendments so far, but it is anticipated that more States will participate over the long term. States that participate in the future will benefit from any comparative tools developed by other States. We state in the Collection of Information section of this preamble that ten States availed themselves of the State Plan option, and thereby will be required to display information on a comparative chart. We are assuming it will take 8 hours each to create the comparative chart, or 80 hours for 10 States. Using the mean hourly wage for State employees (the Bureau of Labor Statistics, March 2001) of \$17.05, this would result in total costs to States of \$1364. We estimate that there may be additional costs associated with the production of these charts of \$2,000 - \$5,000 per state that are not reflected in the Collection of Information requirements. This results in a total estimated cost from \$21,364 to \$51,364 to comply with this requirement

5. Demonstration of Adequate Capacity and Services

The BBA requires Medicaid MCOs to provide the State and the Secretary of HHS

with assurances of adequate capacity and services, including service coverage, within reasonable timeframes. States currently require assurances of adequate capacity and services as part of their existing contractual arrangements with MCOs, PIHPs and PAHPs. However, certification of adequacy has not been routinely provided to us in the past. Under this rule, each State retains its authority to establish standards for adequate capacity and services within MCO, PIHP and PAHP contracts. This may be perceived as a burden to MCOs, PIHPs and PAHPs, and for States that have not been required to formally certify that an MCO, PIHP or PAHP meets the States' capacity and service requirements. However, certification to us will ensure an important beneficiary protection while imposing only a minor burden on States to issue a certification to us of the information that should already be in their possession.

Each State agency has its own documentation requirements and its own procedures to assure adequate capacity and services. This regulation contemplates that States continue to have that flexibility.

Under this regulation, State agencies must determine and specify both the detail and type of documentation to be submitted by the MCO, PIHP or PAHP as applicable, to assure adequate capacity and services and the type of certification to be submitted to us. We believe the 24 PAHPs contracting as dental plans or transportation providers will need to meet this requirement. Accordingly, variability among State agencies implementing this regulation represents different degrees of detail and expense. Regardless of the level of additional burden on MCOs, PIHPs, PAHPs, State agencies, and us, Medicaid beneficiaries will receive continued protections in access to health care under both State and Federal statute. For purposes of the Collection of Information

section of this preamble, we assume that it would take 20 hours per MCO, PIHP, or PAHP to complete this requirement. For the 486 MCOs, PIHPs, and PAHPs, this requirement would take 9,720 hours to complete annually. Based on a mix of clerical and administrative salaries to produce, verify, and submit this information, we project a total cost of \$174,960 (9720 hours at \$18 per hour) to MCOs, PIHPs, and PAHPs to comply with this requirement.

6. New Quality Standards

The BBA requires that each State agency have an ongoing quality assessment and improvement strategy for its Medicaid managed care contracting program. The strategy, among other things, must include: (1) standards for access to care so that covered services are available within reasonable timeframes and in a manner that ensures continuity of care and adequate capacity of primary care and specialized services providers; (2) examination of other aspects of care and service directly related to quality of care, including grievance procedures and information standards; (3) procedures for monitoring and evaluating the quality and appropriateness of care and service to enrollees; and (4) periodic reviews to evaluate the effectiveness of the State's quality strategy.

The provisions of this final rule impose requirements for State quality strategies and requirements for MCOs and PIHPs that States are to incorporate as part of their quality strategy. These MCO and PIHP requirements address: (1) MCO and PIHP structure and operations; (2) Medicaid enrollees' access to care; and (3) MCO and PIHP responsibilities for measuring and improving quality. While these new Medicaid requirements are a significant increase in Medicaid regulatory requirements in

comparison to the regulatory requirements that existed before the BBA, we believe the increases are appropriate because many of the requirements are either identical to or consistent with quality requirements placed on MCOs by private sector purchasers, the Medicare program, State licensing agencies, and private sector accreditation organizations. While these new requirements also will have implications for State Medicaid agencies that are responsible for monitoring ~~for~~ compliance with the new requirements, we believe that a number of recent statutory, regulatory, and private sector developments will enable State Medicaid agencies to more easily monitor ~~for~~ compliance than in the past at potentially less cost to the State.

Prior to issuance of that proposed rule, we worked closely with State Technical Advisory Groups (TAGs) in developing the managed care quality regulations and standards. Requirements under this final regulation build on a variety of initiatives of State Medicaid agencies and us to promote the assessment and improvement of quality in plans contracting with Medicaid, including:

The Quality Improvement System for Managed Care (QISMC), an initiative with State and Federal officials, beneficiary advocates, and the managed care industry to develop a coordinated quality oversight system for Medicare and Medicaid that reduces duplicate or conflicting efforts and emphasizes demonstrable and measurable improvement.

QARI, serving as a foundation to the development of QISMC, highlights the key elements in the Health Care Quality Improvement System (HCQIS), including internal quality assurance programs, State agency monitoring, and Federal oversight. This guidance emphasizes quality standards developed in conjunction with all system

participants, such as managed care contractors, State regulators, Medicaid beneficiaries or their representatives, and external review organizations.

Further, we have built on efforts in other sectors in developing these quality requirements in order to capitalize on current activities and trends in the health care industry. For example, many employers and cooperative purchasing groups and some State agencies already require that organizations be accredited by the National Committee on Quality Assurance (NCQA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Accreditation Healthcare Commission (AAHC), or other independent bodies. Many also require that organizations report their performance using Health Plan Employer Data & Information Set (HEDIS), Foundation for Accountability (FACCT), or other measures and conduct enrollee surveys using the Consumer Assessment of Health Plans Study (CAHPS) or other instruments. NCQA estimates that more than 90 percent of plans are collecting some or all of HEDIS data for their commercial population. Also, States have heightened their regulatory efforts through insurance or licensing requirements, and the National Association of Insurance Commissioners (NAIC) has developed model acts on network adequacy, quality assessment and improvement, and utilization review.

While we anticipate that many organizations will need to invest in new staff and information systems in order to perform these new quality improvement activities, it is difficult to quantify these financial and operational "investments," as State agencies, MCOs, and PIHPs across the country exhibit varying capabilities in meeting these standards. These new quality requirements may present administrative challenges for some State agencies, MCOs, and PIHPs. However, States have significant latitude in

how these requirements are implemented. Acknowledging that there likely will be some degree of burden on States, MCOs, and PIHPs, we also believe that the long-term benefits of greater accountability and improved quality in care delivery outweigh the costs of implementing and maintaining these processes over time.

According to the MCOs included in the Lewin study, many of the quality provisions in the September 1998 proposed rule (as well as those in this final rule) are not expected to have large incremental costs. The study mainly focused on the assessment and treatment management components of the regulation, as well as the quality improvement projects. For example, they estimate the cost of an initial assessment (called “screening” in this final regulation) as ranging from \$0.17 to \$0.26 per member per month (PMPM), but for an MCO that currently performs an initial assessment, the incremental cost is estimated as \$0.03 to \$0.06 PMPM. Extrapolating these estimates to the population of Medicaid managed care enrollees, if all enrollees were enrolled in plans doing initial assessments, the total cost would range from \$6.8 million to \$13.5 million. If all enrollees were enrolled in plans that did not perform initial assessments, the total cost would be \$38 million to \$58 million.

Similarly, the costs of quality improvement projects can vary from \$60,000 to \$100,000 per project in the first year (start-up), \$80,000 to \$100,000 in the second and third years (the intervention and improvement measurement cycle), and \$40,000 to \$50,000 for the fourth and subsequent years (ongoing performance measurement). If we assume that each of the approximately 339 MCOs and 123 PIHPs were to have one quality improvement project in each year, these costs will range from \$180,000 to \$230,000 per MCO or PIHP for a total cost of between \$83 and \$106 million.

7. Administration

a. Certifications and Program Integrity Protections

Sections 1902(a)(4) and (19) of BBA require that States conduct appropriate processes and methods to ensure the efficient operation of the health plans. This includes mechanisms to not only safeguard against fraud and abuse but also to ensure accurate reporting of data among health plans, States, and us.

Section 438.602 of the final rule addresses the importance of reliable data that are submitted to States and requires MCOs and PIHPs to certify the accuracy of these data to the State. These data include enrollment information, encounter data, or other information that is used for payment determination. Even if States do not use encounter data to set capitation rates for MCOs and PIHPs, these data, along with provider and enrollment data, are useful for States in measuring quality performance and other monitoring of health plans. The provision of the final rule that requires plans to attest to the validity of data presents an additional step in the process of data submission. MCOs and PHPs have historically worked closely with States when reporting Medicaid data in order to affirm that the data are accurate and complete. Submitting a certification of validity of data submitted does not represent a significant burden to health plans.

Section 438.606 requires MCOs and PIHPs to have effective operational capabilities to guard against fraud and abuse. As a result, MCOs and PIHPs will uncover information about possible violations of law that they would be required to report to the State. We do not believe that these will be frequent or large in number and, therefore, will not result in burdens to the MCOs and PIHPs beyond what is usual in the course of business.

b. Change in Threshold from \$100,000 to \$1 Million

Before the passage of the BBA, the Secretary's prior approval was required for all HMO contracts involving expenditures of \$100,000 or more. Under the BBA, the threshold amount is increased to \$1 million. This change in threshold will have minimal impact on plans currently contracting with State agencies for Medicaid managed care. Currently, only one or two plans in the country have annual Medicaid expenditures of under \$1 million. Therefore, this final rule provision will not affect a significant number of plans or States.

8. Permitting Same Copayments in Managed Care as in FFP

Under section 4708(c) of the BBA, States may now allow copayments for services provided by MCOs to the same extent that they allow copayments under fee-for-service. Imposition of copayments in commercial markets typically results in lower utilization of medical services, depending on the magnitude of payments required of the enrollee. Thus, we normally expect State agencies that implement copayments for MCO enrollees to achieve some savings. However, applying copayments to Medicaid enrollees may cause States and MCOs to incur administrative costs that more than offset these savings. This is due to several factors. First, the amount of copayments allowed by statute are significantly lower than typical commercial copayments. Second, it is difficult to ensure compliance with these payments, especially given that the enrollees have limited income. Third, to achieve maximum compliance, collection efforts will be necessary on the part of MCOs or PHPs. It is also possible that, if State agencies take advantage of this option, Medicaid managed care enrollees may defer receipt of health care services, their health conditions may deteriorate, and the costs of medical treatment

may be greater over the long term. For these reasons, it is difficult to predict how many States will take advantage of this option or of the net costs or savings that would result.

9. Six-Month Guaranteed Eligibility

The legislation expanded the States' option to guarantee up to 6 months eligibility in two ways. First, it expands the types of MCOs whose members may have guaranteed eligibility, in that it now includes anyone who is enrolled with a Medicaid managed care organization as defined in section 1903(m)(1)(A) of the Act. Second, it expands the option to include those enrolled with a PCCM as defined in section 1905(t) of the Act. These changes were effective October 1, 1997. To the extent that State agencies choose this option, we expect MCOs, PIHPs, PAHPs, and PCCMs in those States to support the use of this provision since it affords health plans with assurance of membership for a specified period of time. Likewise, beneficiaries will gain from this coverage expansion, and continuity of care would be enhanced. The table below displays our estimates of the impact of the expanded option for 6 months of guaranteed eligibility under section 4709 of the BBA.

Cost of 6-Month Guaranteed Eligibility Option

(Dollars in millions rounded to the nearest \$5 million)

	FY 2002	FY 2003	FY 2004	FY 2005
Federal	80	115	165	230
State	60	90	125	175

Total	140	205	290	405
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Because this provision was effective shortly after enactment of the BBA, the estimates of Federal costs have been reflected in our Medicaid budget since FY 1998. The estimates assume that half of the current Medicaid population is enrolled in managed care and that this proportion would increase to about two-thirds by 2003. We also assume that 15 percent of managed care enrollees were covered by guaranteed eligibility under rules in effect prior to enactment of the BBA and that the effect of the expanded option under section 4709 of the BBA would be to increase this rate to 20 percent initially and to 30 percent by 2003. The guaranteed eligibility provision is assumed to increase average enrollment by 3 percent in populations covered by the option. This assumption is based on computer simulations of enrollment and turnover in the Medicaid program. Per capita costs used for the estimate were taken from the President's FY 1999 budget projections and the costs for children take into account the interaction of this provision with the State option for 12 months of continuous eligibility under section 4731 of the BBA. The distribution between Federal and State costs is based on the average Federal share representing 57 percent of the total costs.

In States electing the 6-month guaranteed eligibility option, Medicaid beneficiaries will have access to increased continuity of care, which should result in better health care management and improved clinical outcomes.

10. Financial Impact of Revised Rules for Setting Capitation Payments

This final rule replaces the current UPL requirement at \$447.361 with new rate-

setting rules incorporating an expanded requirement for actuarial soundness of capitation rates as described in detail in §438.6(c). In general, we do not expect a major budget impact from the use of these new rate setting rules. While the rate setting rules may provide some States additional flexibility in setting higher capitation rates than what would have been allowed under current rules, we believe that the requirements for actuarial certification of rates, along with budgetary considerations by State policy makers, would serve to limit increases to within reasonable amounts. Moreover, the Secretary retains the authority to look behind rates that appear questionable and disapprove any that do not comply with the rate setting requirements.

Because we cannot predict State behavior in these areas, we are unable to quantify the impact of potential rate increases that may be triggered by these new rules. However, as an illustration of the potential impact, we can compare states such as Oregon and Tennessee, which have had the upper payment limit requirement waived under their health care reform demonstrations to the other states providing managed care through contracts with MCOs. The capitation rates paid by these states do not vary significantly from most states operating under the UPL requirement.

Another example to consider is pediatric dental care, where low payment rates have frequently been cited as a barrier to access. Using Medicaid statistical and financial data, we estimate that the average Medicaid payment for dental services to children, on a per member per month (PMPM) basis, is about \$10. A recent study by the Milbank Memorial Fund recommended a model pediatric dental program that is estimated to cost \$14.50 PMPM, or 45 percent higher than the current average.

If these new rules induced 10 percent of States (on a dollar volume basis) to adopt the Millbank program or its monetary equivalent, annual Federal and State premium costs for children would rise by about 0.3 percent, or approximately \$50 million. As indicated above, such increases in spending could be achieved under current rules, so it is difficult to predict the extent to which the proposed changes to rate setting requirements would precipitate these or any other additional costs to the Medicaid program.

As discussed in the Collection of Information section of this Preamble, we expect a net reduction in administrative burden on states of 11,904 hours through this change, resulting in a projected savings of \$202,963.

11. Costs to States and Providers of Provisions Assigned Burden Hours

The Collection of Information Requirements section of this preamble includes estimates of the number of hours it will take States, providers, and enrollees to provide information required under this regulation. For States, the total hours are estimated to be 2,481,076. To estimate the cost impact of these requirements on States, we assume the total cost of these requirements to be the sum of the estimated hours times the mean hourly wage for State employees of \$17.05 (the Bureau of Labor Statistics, March, 2001), or \$42,302,346. Because the Federal government shares the general administrative costs of the Medicaid program with the States, we estimate the total cost of these requirements to States to be approximately \$21 million dollars annually.

For MCOs, PIHPs, PAHPs, and PCCMs, we estimate that the Collection and Information Requirements will take 1,264,461.5 hours annually to complete. To estimate the cost impact of these requirements on providers, we multiplied these hours by the mean hourly wage for health care service workers of \$16.34 (the Bureau of Labor

Statistics, March, 2001) to estimate the cost of these requirements to be approximately \$20.7 million.

12. Contract Monitoring

This final rule requires States to include certain specifications in their contracts with MCOs, PIHPs, PAHPs, and PCCMs and to monitor compliance with those contract provisions. It also requires States to take a proactive role in monitoring the quality of their managed care program. These requirements add some administrative burden and costs to States. The amount of additional administrative cost will vary by State depending on how inclusive current practice is of the new requirements. In addition, for those States not using like requirements at present, we believe that most will be adopting similar requirements on their own in the future absent this final rule.

The final rule also increases Federal responsibilities for monitoring State performance in managing their managed care programs. However, no new Federal costs are expected as we plan to use existing staff to monitor these new requirements.

C. Alternatives Considered

In publishing this final rule implementing the BBA Medicaid managed care provisions, we considered two main alternatives. The first alternative was to allow the January 19, 2001 final rule with comment to become effective as published. The second alternative was to implement the BBA statute as written and not regulate beyond the statutory language. We believe that this final rule as now written maintains an appropriate balance between these two alternatives.

We realized that allowing the more prescriptive January 2001 rule to become effective would cost states and health plans more to implement and could potentially restrict access

if states and health plans became unwilling to participate in Medicaid managed care. We heard from several key stakeholders that the January 2001 final rule with comment was overly burdensome and did not allow sufficient State flexibility. In addition, others stated that the January 2001 final rule was a micro-managing approach to Medicaid managed care and would make it increasingly difficult for State Medicaid agencies to provide access to quality health care through managed care, since MCOs and other providers would not be willing to participate. Many felt that the requirements would be administratively burdensome to implement, particularly for small entities, and created significant business risks for MCOs. The rules would have resulted in an increase in health plan compliance costs and a significant additional burden on small entities without meaningfully improving patient care. Particular examples of provisions, which would increase costs significantly, were the requirements for specific timeframes for conducting initial health screenings, performing comprehensive health assessments and the detailed requirements under the notice of action provisions. Based on these concerns we decided that we needed more time to understand the impact of the January 2001 final rule. In the interim we believed the best approach was to streamline the January 2001 provisions and republish as a proposed rule. The removal of the highly prescriptive requirements will enhance States' abilities to continue innovations with their managed care programs leading to improved efficiencies and reduced costs. Further the new rate setting provisions will result in rates that more appropriately reflect the cost of health services.

On the other hand, implementing the BBA statutory language as written would not have provided adequate patient protections and may have resulted in lower overall quality of care. In addition to the broad patient protection and quality provisions in the

BBA statute, this final rule provides consumers with comprehensive, easy-to-understand information about their health plan, establishes timeframes for review of grievance and appeals, requires adequate provider networks sufficient to meet the needs of enrolled individuals, requires identification of individuals with special health care needs, specifies timeframes for service authorization decisions and requires continuity and coordination of care. In addition, States must have an overall strategy to ensure the delivery of quality health care by its MCOs, PIHPs and PAHPs. Further, MCOs and PIHPs are required to conduct performance improvement projects that must be designed to achieve significant improvement in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction. We believe that all of these provisions, while consistent with the BBA's intent will work to improve overall quality of care for Medicaid beneficiaries enrolled in Medicaid managed care. Through enhanced care coordination and quality monitoring, the final rule's provisions will enable the earlier identification of serious medical conditions and the effective management of individuals with special health care needs. States will be able to highlight quality of care, which will result in decreased costs for health plans and States. All of these requirements will work together to improve patient outcomes and possibly reduce health complications and costly procedures.

These new rules appropriately balance the necessary protections for all beneficiaries enrolled in MMC and state flexibility to manage their programs. They create a framework for States to design managed care programs that will permit innovation and support program growth. This final rule is written to recognize the responsibilities of States and the need to employ different approaches to achieving the

same goal of strong, viable Medicaid managed care programs that deliver high quality health care within State marketplaces and health care delivery systems.

D. Conclusion

This BBA managed care final rule will affect States, MCOs, PIHPs, PAHPs, PCCMs, providers, and beneficiaries ~~and us~~ in different ways. The initial investments that are needed by State agencies and MCOs, PIHPs, PAHPs, and PCCMs will result in improved and more consistent standards for the delivery of health care to Medicaid beneficiaries. Greater consumer safeguards will result from new quality improvement and protection provisions, which meet or exceed those in other public or private health care plans. In addition, this rule provides a degree of flexibility in how these new requirements are met, so that necessary changes can be phased in by states and health plans in ways that work best in a particular state's Medicaid program. Further, the new rules on payments under risk contracts remove the limitation on payment rates at historical fee-for-service costs, giving states some added flexibility in establishing payment systems that maintain or expand their current managed care programs, thus enhancing choice for Medicaid consumers and their ability to find a medical home. Consequently, long term savings will be derived from more consistent standards across States, MCOs, PIHPs, PAHPs, and PCCMs and increased opportunities for provider and beneficiary involvement in improved access, outcomes, and satisfaction.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

E. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$110 million or more (adjusted annually for inflation). We have determined that this final rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of \$110 million or more.

F. Federalism

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. We have determined that this final rule would not significantly affect States rights, roles, and responsibilities. This regulation supersedes existing State laws regulating managed care, unless State laws are more restrictive.

The BBA requires States that contract with organizations under section 1903(m) of the Act to have certain beneficiary protections in place when mandating managed care enrollment. This rule implements those BBA provisions in accordance with the Administrative Procedure Act. This rule also eliminates certain requirements viewed by States as impediments to the growth of managed care programs, such as disenrollment without cause at any time and the inability to require enrollment in managed care without a waiver. We also apply many of these requirements to prepaid health plans that provide for inpatient hospital and institutional services. We believe this is consistent with the intent of the Congress in enacting the quality and beneficiary protection provisions of the

BBA. We worked with States in developing this final regulation. In 1997-1998, when we were developing the original proposed rule, published in September 1998, we consulted with State Medicaid agency representatives in order to understand the potential impacts of the provisions of the regulations then being considered. In November 1997 we met with the Executive Board of the National Association of State Medicaid Directors (NASMD) and discussed the process for providing initial guidance to States about the Medicaid provisions of the BBA. We provided this guidance in a series of over 50 letters to State Medicaid Directors. Much of the policy included in this final regulation relating to the State plan option provision was included in these letters. In May 1998, we briefed the Executive Committee of NASMD on the general content of the proposed 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 agency staff with notable expertise in the subject area and our regional office staff and are staffed by the American Public Human Services Association. The Managed Care TAG devoted much of its agenda for several monthly meetings to BBA issues. The Quality TAG participated in two conference calls exclusively devoted to discussion of BBA quality issues. Through these contacts, we explored with State agencies their preferences regarding policy issues and the feasibility and practicality of implementing policy under consideration. We also invited public comments as part of the rulemaking process and received comments from over 380 individuals and organizations. Most of the commenters had substantial comments that addressed many provisions of the regulation.

Following publication of the final rule with comment on January 19, 2001, the new Administration delayed the effective date of the January 2001 rule three times to provide it an opportunity to conduct its own review of the regulation. During this additional review period, we heard from key stakeholders in the Medicaid managed care program, including States, provider organizations, and advocates for beneficiaries. Some of these parties expressed serious concerns about the regulation. After further consideration of the regulations and the issues raised, in August 2001 we published an interim final rule with comment period to further delay the effective date of the January 2001 final rule with comment. Immediately following the further delay, on August 20, 2001 we published a new Medicaid managed care proposed rule to implement the Medicaid managed care provisions of the BBA and to give consideration to all the concerns that were communicated to us.

We received comments from over 300 parties (States, managed care organizations, providers, provider organizations and advocates for beneficiaries) on the August 2001 proposed rule. Many of the recommendations made by commenters have been incorporated into this final rule. For recommendations not accepted, a response has been included in this preamble. Moreover, we discussed technical issues with State experts through the TAGS to make certain that the final rule could be practically applied.

List of Subjects**42 CFR Part 400**

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 430

Administrative practice and procedure, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 434

Grant programs-health, Health maintenance organizations (HMO), Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 435

Aid to Families with Dependent Children, Grant programs-health, Medicaid, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Wages.

42 CFR Part 438

Grant programs-health, Managed care entities, Medicaid, Quality assurance, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.