rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 8, 1999.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. In § 180.443, by amending the table in paragraph (b), by revising the following entries to read as follows:

§ 180.443 Myclobutanil; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
* * * * *		
Caneberries	1.0	12/31/00
* * * * *		
Hop cones, dried ..	5.0	12/31/01
* * * * *		
Peppermint	2.5	12/31/00
* * * * *		
Spearmint	2.5	12/31/00
* * * * *		

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[FR Doc. 99–33158 Filed 12-21-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 422

[HCFA–1011–F]

RIN 0938–AI83

Medicare Program; Solvency Standards for Provider-Sponsored Organizations

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: The Balanced Budget Act of 1997 established a new Medicare+Choice (M+C) program that offers eligible individuals Medicare benefits through enrollment in one of an array of private health plans that contract with us. Among the new options available to Medicare beneficiaries is enrollment in a provider-sponsored organization (PSO). This final rule revises and responds to comments on solvency standards that certain entities must meet to contract as PSOs under the new M+C program. These standards, originally established in an interim final rule published on May 7, 1998, apply to PSOs that have received a waiver of the requirement that M+C organizations must be licensed by a State as risk-bearing entities.

DATES: *Effective date:* These regulations are effective on January 21, 2000.

FOR FURTHER INFORMATION CONTACT: Marty Abeln, (410) 786–1032.

SUPPLEMENTARY INFORMATION:

I. Background—Balanced Budget Act of 1997 and the Medicare+Choice Program

Section 4001 of the Balanced Budget Act (BBA) (Public Law 105–33), enacted August 5, 1997, added a new Part C (sections 1851 through 1859) to title XVIII of the Social Security Act (the Act), establishing the ''Medicare+Choice'' (M+C) program. Under Part C, M+C eligible individuals (generally individuals with both Part A and Part B coverage who do not have End Stage Renal Disease (ESRD) may elect to receive their Medicare benefits through private health plans (M+C organizations) that choose to contract with HCFA. M+C organizations may offer one or more M+C plans of one of three types. Under ''coordinated care plans,'' beneficiaries receive benefits through a network of providers, as in the case of an health maintenance organization (HMO) or preferred provider organization (P.O.). A ''provider sponsored organization'' (PSO), which is owned by providers through which it provides benefits, and which is the subject of this final rule, necessarily offers a coordinated care plan. (See section 1851(a)(2)(A) of the Act). Other M+C plan options provided for in Part C, but not yet offered by any M+C organization, are private-fee-for service plans and medical savings account (MSA) plans (that is, a combination of a high deductible, catastrophic insurance plan with a contribution to an M+C MSA account). Interim final regulations for the overall implementation of the M+C program were published in the **Federal Register** on June 26, 1998 (63 FR 34968) and are set forth in part 422 of title 42 of the Code of Federal Regulations (CFR). Provisions enacted by the BBA and implemented in the interim final M+C regulations establish broad and comprehensive requirements for contracting as an M+C organization, including basic benefits, payment, access to service, quality assurance, beneficiary hold harmless, continuation of benefits, appeals mechanisms, marketing, and enrollment processes. These overall M+C regulations apply to M+C organizations that are PSOs.

A PSO is described in section 1855(d) of the Act as a public or private entity—

- That is established or organized, and operated, by a health care provider or group of affiliated health care providers;
- That provides a substantial proportion of the health care items and services directly through the provider or affiliated group of providers; and
- With respect to which the affiliated providers share, directly or indirectly, substantial financial risk for the provision of these items and services and have at least a majority financial interest in the entity.

On April 14, 1998, we published an interim final rule in the **Federal Register** at 63 FR 18124, titled ''Definition of Provider-Sponsored Organization and Related Requirements'' with an opportunity for public comment setting out the PSO definition, clarifying certain terms, and establishing related requirements. This PSO definitions rule established 42 CFR part 422 and subpart H of that part, dealing with PSOs. The terms and requirements related to the definition of a PSO are now found at §§ 422.350 through 422.356. On May 7, 1998, we published an interim final rule in the **Federal Register** at 63 FR 25360 titled ''Waiver Requirements and Solvency Standards for Provider Sponsored Organizations,'' establishing solvency requirements that apply to PSOs that obtain a waiver of the M+C State licensure requirement and setting forth procedures and standards that apply to requests for the waivers. The solvency portion of the interim final PSO regulation was based on the work of the PSO negotiated rulemaking committee, as required at section 1856(a) of the Act, which provides that the Secretary establish through a negotiated rulemaking process the solvency standards that entities will be required to meet if they obtain a waiver of the otherwise applicable requirement that

they be licensed by a State. The results of the PSO solvency negotiated rulemaking committee are described in the preamble to the interim final regulation published on May 7, 1998 (63 FR 25360).

In this final rule, we focus solely on the solvency standards that will apply to PSOs that have obtained a waiver. Other PSO provisions will be addressed in the upcoming overall final M+C regulation. We note that based on §§ 422.352(a) and 422.380, State-licensed organizations that meet the PSO definition (see §§ 422.350 through 422.356) may qualify for the minimum enrollment standards established under section 1857(b) of the Act but are not subject to these solvency standards.

II. Response to Comments

The PSO solvency standards are the result of a negotiated rulemaking process. The participants in the negotiated rulemaking described their agreement on the PSO solvency standards in a Committee Statement titled ''Negotiated Rulemaking Committee on PSO Solvency Standards'' dated March 5, 1998. Based on these agreed upon PSO solvency standards, we published an interim final PSO solvency regulation on May 7, 1998 (63 FR 25360). The participants in the negotiated rulemaking process agreed not to submit negative comments on the interim final rule unless they determined that any provision of the interim rule incorrectly reflects the Committee solvency agreement. Section 1856(a)(9) of the Act, as amended by the BBA, requires that we publish final solvency standards within 1 year of the interim final regulations. Accordingly, this final regulation will address only the solvency standards for PSOs. Other comments on PSOs (for example, on the waiver process and definitions) will be addressed in the final M+C regulation due to be published in the fall of 1999.

We received eight public comments. Seven of the letters were from major organizations, and one letter was from a State. The comments we received are summarized below along with our responses.

Comment: We received several comments regarding whether unique solvency standards should be established for PSOs operating in rural areas. Several commenters discouraged establishing separate solvency standards for rural PSOs. One commenter noted that no State has separate solvency standards for entities that operate in distinct geographic areas. Another commenter stated that developing a successful Medicare managed care program is more difficult in a rural area than in an urban area in part because enrollment growth is smaller in rural areas, making it more difficult to cover fixed administrative costs. The commenter was also concerned that it would be difficult to track ''rural'' and ''nonrural'' PSOs within a State. According to the commenter, regulators would have the additional burden of monitoring the rural PSOs to determine whether, through growth or other reasons, it no longer met the definition of a rural PSO. If the PSO was no longer considered rural, there could be a possible disruption of services since the PSO would have to recapitalize in order to meet the higher solvency requirements for non-rural PSOs. The commenters also pointed out that rural PSOs, given less stringent solvency standards, would have a more difficult time making the transition from meeting the standards required for a Federal waiver to meeting the solvency requirements of a State once the 36-month waiver period expires.

Two commenters suggested that we consider allowing rural PSOs to ''aggregate'' specifically for purposes of meeting solvency standards (Regional PSOs). For example, we could permit rural providers or local rural PSOs that band into a regional PSO or rural PSOs that link to nonrural PSOs to be considered as one entity for the purpose of satisfying the PSO solvency standards. The commenter contended that such a regional approach to PSOs is likely to produce greater financial stability and greater access to care and would reduce unnecessary redundancy of solvency requirements as applied to individual entities that comprise the regional plan.

Another commenter recommended that solvency adjustments for rural PSOs be allowed in circumstances under which the commenter believes the solvency rules require more financial resources than might be necessary for smaller rural PSOs. The commenter suggested that certain solvency requirements could be reduced for rural PSOs without placing the PSO in financial jeopardy. Specifically, this commenter recommended that we have discretion to—(1) selectively allow for reductions in the minimum cash and liquidity requirements for rural PSOs; (2) allow for a reduction in the insolvency deposit for small and rural PSOs; (3) allow the use of irrevocable letters of credit for the insolvency deposit; and (4) allow for a reduction in the minimum cash portion of a rural PSO's net worth requirement.

Response: At this time, we will not establish separate solvency standards for rural PSOs. We believe that the lack of current rural PSO activity makes it difficult to realistically evaluate under what circumstances it would be feasible for us to reduce certain solvency standards for rural PSOs. We note that the States do not have different solvency requirements depending on whether an entity is operating in a rural area compared to an urban area. As a commenter noted, PSOs will be subject to State standards at the end of the 36-month waiver period. In addition, we are concerned about lessening solvency requirements and thereby putting beneficiaries at increased risk if the rural PSO becomes insolvent.

With respect to the proposal to allow rural PSOs to band together for the purpose of collectively meeting the solvency requirements, we are concerned that if more than one of these PSOs becomes insolvent, there will not be adequate funds available to protect beneficiaries. We believe the possibility of two PSOs becoming insolvent at the same time is significant because the PSOs will be operating in the same region. Accountability questions would also be raised if we allow organizations to combine for the purpose of meeting certain requirements in regulations. If several PSOs combine to meet the solvency standards, it is not clear whether these combined PSOs would be in noncompliance if one of the PSOs experienced financial difficulty. In regard to recommendations that we reduce or modify various solvency reserves, we believe these changes would be a significant departure from the solvency standards carefully worked out during the negotiated rulemaking process. For that reason and those cited above, we will not selectively reduce the solvency requirements for rural PSOs.

Comment: A commenter noted that with respect to affiliate guarantees, the Solvency Committee agreed that it was up to us to determine which entities could provide guarantees. Because of this agreement, the commenter believed that it is appropriate to comment on this part of the interim final regulation. The commenter recommended that the independently audited financial statement provided by a guarantor can only be acceptable to us if it consists of unqualified opinions from the auditor.

Response: We will not require that guarantee opinions in audited independent financial statements always be unqualified. There may be circumstances where a qualification of a financial opinion does not significantly affect the conclusions regarding the entity's ability to meet the financial solvency standards. Accordingly, we reserve the right to accept or reject a

financial statement depending on the nature and significance of the qualification of the opinion.

Comment: Several commenters requested that we clarify in this regulation whether Federal bankruptcy or State receivership law should take precedence if a PSO goes bankrupt.

Response: We recognize the importance of this question. Accordingly, we are researching the alternatives regarding the appropriate jurisdiction and venue in which to administer a financially insolvent PSO. However, resolving the precedence of Federal bankruptcy law versus State receivership law is beyond the scope of this regulation.

Comment: Several commenters stated that a current ratio of 1:1 should be a factor we will use in evaluating the ongoing solvency of a PSO but not an absolute requirement as indicated at § 422.386 of the interim final rule. Section 422.386(d) of the interim final regulations states that if a PSO fails to maintain a current ratio requirement of 1:1, we will require the PSO to initiate corrective action. The commenters pointed out that the Liquidity section of the PSO Solvency Committee Statement states that we *may* require a PSO to initiate corrective action if either of the following is evident—(1) the current ratio declines significantly, or (2) there is a continued downward trend in the current ratio.

The corrective action may include change in the distribution of assets, a reduction of liabilities, or alternative arrangements to secure additional funding requirements to restore the current ratio to 1:1.

Response: We agree that the Committee Statement indicates that a PSO current ratio of 1:1 should be a factor we will use in evaluating the solvency of a PSO but not an absolute requirement that will always result in corrective action when violated. Accordingly, we will change § 422.386(d) in the final regulation to read as follows:

> (d) If HCFA determines that a PSO fails to meet the requirement of paragraph (b)(2) of this section, HCFA may require the PSO to initiate corrective action to* * *

Comment: A commenter noted that § 422.382(a) requires that the initial net worth requirement be met at ''* * * the time an organization applies to contract with us as a PSO.'' The commenter recommended that this requirement be changed to require that the initial net worth requirement be met at the time the application is approved or the contract entered into, rather than on the date the application is first submitted. The commenter expressed concern that since the application process can take a number of months, the PSO might have drawn down its net worth in the intervening months after the initial application and may have an inadequate net worth by the time the PSO actually enters into the contract with us.

Response: The Committee Statement on the PSO solvency standards specifies that the PSO minimum net worth amount must be met when the PSO submits the initial application. The interim final PSO regulations at § 422.382 reflect this Committee Statement. We believe it is necessary that the net worth requirement be met at the start of the application process to ensure that the applicant is financially able to enter into a contract with us. We also believe that the ongoing net worth requirement will ensure that PSOs have adequate net worth on the effective date of the contract.

Comment: Section 422.382(b) describes the ongoing net worth requirement as the greater of four amounts. The fourth amount, set forth in § 422.382(b)(4), begins with the statement ''Using the most recent annual financial statement filed with HCFA, an amount equal to the sum of * * *'' A commenter contended that this language was intended to be an adaptation of a similar provision set forth in Section 13.A.(2)(d) of the National Association of Insurance Commissioners (NAIC) HMO Model Act, requiring that the calculation be based ''* * * on the most recent financial statement filed with the commissioner * * *'' rather than the most recent annual financial statement.

The commenter noted that while the calculation results in an annualized number, the calculation should be based on the most recent HCFA filing, which could be a quarterly statement, not an annual statement. Accordingly, the commenter requested that the word ''annual'' be deleted from § 422.382(b)(4) in order to conform to the NAIC structure.

Response: We agree with the commenter that the word ''annual'' should be removed from § 422.382(b)(4). This is also consistent with the PSO Committee Agreement in which the ongoing minimum net worth requirements are specified and verification is through ''* * * the most recent financial statement filed with us.'' Accordingly, we will revise § 422.382(b)(4) to read as follows:

> Using the most recent financial statement filed with us, an amount equal to the sum of * * *

Comment: A commenter noted that § 422.384(b)(5) requires certification of reserves and actuarial liabilities by a ''qualified HMO actuary,'' which is not defined (the regulation does define ''qualified actuary''). The commenter requested clarification of what is meant by ''qualified HMO actuary.''

Response: We agree that the use of the phrase ''qualified HMO actuary'' at § 422.384(b)(5) is confusing. Accordingly, we will change the reference at § 422.384(b)(5) to read ''qualified actuary.'' We are not imposing any requirements on the qualifications of an actuary employed by a PSO beyond what is stated in the definition of qualified actuary under § 422.350(b).

Comment: Section 422.382(b)(4) describes the four-tiered minimum net worth test that will be applied to a PSO after the effective date of its M+C contract. Section 422.382(b)(4)(iii) states that the annual health care expenditures that are paid on a capitated basis to affiliated providers must not be included in the calculation of net worth under paragraphs (a) and (b)(4) of § 422.382. A commenter noted that the negotiated rulemaking committee specifically addressed this issue and was careful to note that the exclusion set forth in paragraph (b)(4)(iii) of § 422.382 would apply regardless of the downstream risk arrangements among providers. The commenter recommended that this nuance be noted in the text of the regulations.

Response: We agree as referenced in the Committee Statement that the exclusion from the net worth requirement calculation at § 422.382(b)(4)(iii) applies regardless of the downstream risk arrangements among providers. Accordingly, we will change the regulation at § 422.382(b)(4)(iii) by adding the following parenthetical clarification:

> Annual health care expenditures that are paid on a capitated basis to affiliated providers are not included in the calculation of the net worth requirement (regardless of downstream arrangements from the affiliated provider) under paragraphs (a) and (b)(4) of this section.

Comment: A commenter recommended that a statement be added to the preamble of the final solvency regulation clarifying (1) that funds accumulated by a PSO as subordinated liabilities may be disbursed to the affiliated providers if they are not needed to satisfy net worth requirements during the period for which the funds were held and (2) that the PSO has the flexibility to convert those funds to equity or debt to benefit the providers.

Response: As long as the minimum net worth requirement is maintained, any assets including those associated with subordinated liabilities may be disbursed as the PSO deems appropriate on the basis of sound business judgment. We do not believe any additional clarification in the preamble is necessary.

Comment: Under § 422.386(b)(3), in determining liquidity, we evaluate the level of outside financial resources to the PSO. A commenter recommended that we change § 422.386(e) to clarify that we will require a PSO to obtain funding from alternative financial resources under this provision only if there has been a change in the availability of outside financial resources available to the PSO. In support of its recommendation, the commenter pointed out that the language of the Solvency Standards Agreement (under the Part C Liquidity requirements) reads, ''If there is a change in the availability of the outside resources, we will require the PSO to obtain funding from alternative financial resources.''

Response: We agree with this comment. Section 422.386(b)(3) provides that, in monitoring liquidity, we will examine the ''availability of outside financial resources to the PSO.'' We will change § 422.386(e) to read as follows:

If HCFA determines that there has been a change in the availability of outside financial resources as required by paragraph (b)(3) of this section, HCFA requires the PSO to obtain funding from alternative financial resources.

Comment: Under § 422.390(d)(2)(ii), a guarantor must agree to not subordinate the PSO guarantee to any other claim on its resources. A commenter contended that in a typical PSO scenario, a tax-exempt hospital or health system may provide the guarantee to the PSO. In this case, the commenter believes it is likely that the hospital or health system has tax-exempt bonds in place that contain certain covenants with respect to the use and disposition of assets, including a pledge of revenues. Under most circumstances and bond documents, it would not be problematic in the commenter's view to satisfy the requirements at § 422.390(d)(2)(ii). However, the commenter believes that if a PSO were able to demonstrate that this requirement was unduly and substantially burdensome to the guarantor, we should have the authority to consider the specific facts and circumstances and sufficient discretion to modify this requirement.

Response: Section 422.390(a) of the Medicare+Choice regulations explicitly states that we have the discretion to approve or deny approval of the use of a guarantor. We believe this authority generally allows us to exercise discretion in the approval or modification of a guarantor agreement. We do not believe further clarification of this authority in the regulations is necessary.

Comment: One commenter expressed concerns that the requirement that the guarantor have a net worth of three times the amount of the guarantee may not always be adequate. The commenter noted that this amount may be adequate for some companies, but it may be a very slender margin. As an alternative approach, the commenter suggested that perhaps the net worth of a guarantor be determined as a percentage of assets or related to total liabilities in some fashion.

Response: While we agree with the commenter's concern that the guarantor having a net worth of three times the amount of the guarantee may not always be adequate, we do not believe it is necessary to change the regulation to address this concern. Section 422.390(a) explicitly states that we have the discretion to approve or deny approval of the use of a guarantor. We believe this authority generally allows us to exercise discretion in determining the net worth to be required of a particular guarantor that could be based on alternative approaches like those suggested by the commenter.

Comment: Section 422.384(e)(i) provides that guarantees will be an acceptable resource to fund projected losses of a PSO provided that, before the effective date of the PSO's M+C contract, the PSO obtains from the guarantor cash or cash equivalents to fund the amount of projected losses for the first two quarters. A commenter noted that the preamble to the interim final rule stated that funding for the first two quarters will need to be in the PSO ''at least (45) days before the effective date of the contract''. The commenter recommended that, rather than enforcing a uniform 45-day requirement, we exercise discretion consistent with the current language of § 422.384(e)(i). The commenter maintained that under certain circumstances the 45-day requirement could prove to be unduly burdensome and we have sufficient discretion to ensure that the guarantee amounts are sufficiently prefunded for the first quarter of operation under the contract.

Response: The preamble of the May 7, 1998 interim final rule (63 FR 25370) calls for organizations to have assets to fund the first two quarters of projected losses on their balance sheets 45 days before the effective date of the contract. However, this 45-day time period is a guideline to ensure that there is adequate time before the contract date for us to update necessary data systems. If a PSO is unable to have this funding in place 45 days before the contract effective date, this may result in a delay in the implementation of the contract.

III. Provisions of the Final Rule

We have agreed to the following changes in regulations text in response to comments on the interim final rule: Each change is based on a commenter establishing that the interim final regulation was not consistent with the agreement developed through the solvency negotiated rulemaking process.

- We have revised § 422.382(b)(4), which states that the ongoing net worth requirement be evaluated based on the most recent financial statement filed with us and not restricted to the most recent ''annual'' financial statement.
- We have accepted a comment to clarify in the final regulation that the exclusion from the net worth requirement calculation at § 422.382(b)(4)(iii) applies regardless of the downstream risk arrangements among providers.
- We have clarified that we are not imposing any requirement on the qualification of an actuary employed by a PSO beyond what is stated in the definition of a qualified actuary at § 422.384.
- We have changed § 422.386(d) to state that the PSO current ratio will be a factor we will use in evaluating the solvency of a PSO but not an absolute requirement that will always result in corrective action being imposed by us when violated.
- We have accepted a comment to change § 422.386(e) to make it clear that we will require a PSO to obtain funding from alternative financial resources if there is a change in the availability of outside financial resources available to the PSO.

IV. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this final rule as required by Executive Order 12866, the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), and the Regulatory Flexibility Act (RFA) (Public Law 96–354). 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 annually). The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief for small businesses, unless we certify that the regulation will not have a significant economic impact on a substantial number of small entities. Most hospitals, and most other providers, physicians, and health care suppliers, are small entities either by nonprofit status or by having revenues of less than $5 million annually. The impact of this regulation will be to create a new business opportunity for these small entities to form provider-sponsored organizations to contract with the Medicare program.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a final rule 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 50 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and we certify, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

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 one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. This final rule does not mandate any requirements for State, local, or tribal governments. Therefore, we have not prepared an assessment of anticipated costs and benefits of this final rule.

Because of the probability that these solvency standards may have an impact on certain hospitals, physicians, health plans, and other providers we prepared the following analysis which constitutes both a regulatory impact analysis and a regulatory flexibility analysis.

B. Background

While the term ''provider-sponsored organization'' has been used generally in reference to health care delivery systems that providers own or control and operate, the term has a more specific meaning for purposes of the M+C program. Accordingly, we defined, by regulation, the fundamental organizational requirements for entities seeking to be PSOs. These definitions are set forth at § 422.350. Organizations that meet these definitional requirements can apply for a Federal waiver and an M+C contract. Having defined the term PSO and the waiver process in earlier regulations, the purpose of this final rule is to finalize the interim standards for financial solvency to which these Federally waived organizations must adhere.

The solvency standards only affect organizations that have received a Federal waiver and are either applying for or actually have received an M+C contract. It is likely that waiver activity will be greater in States that have solvency standards that differ significantly from the standards developed in this regulation. Below we consider the anticipated impact of this rule.

C. Anticipated Effects

1. Effects on Providers

This final regulation establishes solvency standards for PSOs that have an approved waiver and are applying for a Medicare PSO contract. These solvency requirements are designed to ensure that provider groups have the necessary financial resources to participate in the M+C program. In addition, the regulations are intended to ensure the ongoing solvency of PSOs and to protect enrolled beneficiaries if an insolvency occurs. Through the negotiated rulemaking process and our own deliberations, we have carefully balanced the PSO solvency requirements to ensure that we are not imposing unreasonable financial barriers to the participation of provider groups in the M+C program. We believe that these solvency requirements will make it easier for provider groups to participate in the M+C program.

2. Effects on the Market Place

Since solvency standards vary by State, and State standards are evolving, it is difficult to assess the relative effect of these solvency standards. However, with several key exceptions (for example, a different initial minimum net worth requirement and a lower insolvency deposit), these solvency standards track the HMO Model Act. Therefore, we do not believe there will be a significant impact due to the existence of an unlevel playing field between PSOs and other entities. We believe that establishing standards of financial solvency is necessary to ensure that PSOs have the financial resources to provide adequate quality care and to reduce the possibility of disrupting beneficiary care.

3. Effects on States

For PSOs that obtain a Federal waiver, responsibility for monitoring their financial solvency will be transferred from the States to us. This a temporary reduction, since waivers last only 36 months and the Secretary's authority to grant waivers ends on November 1, 2002. By the end of a PSO's waiver, it will need a State license in order to continue its M+C contract. Therefore, to ease the transition from a Federal waiver to a State license, we encourage PSOs to establish a relationship with regulators in their respective States soon after receiving a waiver.

4. Effects on Beneficiaries

We expect that the advent of PSOs and M+C in general will have the effect of further mainstreaming managed care plans among Medicare enrollees. We do not anticipate an increase in the potential for service interruptions because these new PSOs will be subject to the same beneficiary hold-harmless provisions and continuation of benefits requirements as all M+C organizations. Lastly, section 1855(a)(2)(G) of the Act requires PSOs to comply with all existing State consumer protection and quality standards as if the PSO were licensed under State law.

D. Effects on the Medicare Program

We assume that PSOs will be more prone to favorable selection than other coordinated care plans since the providers in the PSO will, in many cases, know their patients. This may increase the level of favorable selection for the M+C program and could result in increased costs for the Medicare program. However, since PSOs are expected to make up a very small part of the M+C program, for the foreseeable future any PSO favorable selection will have a minimal dollar impact on the Medicare program.

We expect a greater insolvency rate from the PSOs than from the current coordinated care plans because PSOs generally have less business experience and they are smaller. Despite the insolvency rules including hold harmless, Medicare can lose money when there is an insolvency. This is particularly true when insolvency is imminent and providers therefore defer nonemergency procedures to the next month. Medicare may have to pick up the costs, especially if the beneficiary elects fee-or-service. However, as noted above, given the small number of PSOs participating in the M+C program, the

expected cost of insolvencies for the Medicare program is low.

E. Alternatives Considered

As previously discussed, the PSO solvency standards were developed through a formal negotiated rulemaking process. During the negotiated rulemaking, a number of alternatives were considered in the process of developing a consensus regarding the PSO solvency regulations. Please refer to the interim final PSO solvency regulation published in the **Federal Register** on May 7, 1998 for details on the negotiated rulemaking process including the solvency alternatives considered.

F. Conclusion

We conclude that this regulation will have an indeterminable impact on small health service providers. The provisions of this final rule are expected to be favorable for the managed care community as a whole, as well as for the beneficiaries that they serve. We have also determined, and the Secretary certifies, that this final rule will not result in a significant economic impact on a substantial number of small entities and will not have a significant impact on the operations of a substantial number of rural hospitals.

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

G. Federalism

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates regulations that impose substantial direct compliance costs on State and local governments, preempt State law, or otherwise have Federalism implications.

In this final rule, we focus solely on the solvency standards that apply to PSOs that have obtained a waiver from State licensure requirements. The PSO waiver provisions that describe the process by which a PSO obtains a waiver from HCFA of State licensure requirements will be addressed in the final M+C regulation expected to be published in the first quarter of 2000.

The solvency portion of the PSO regulation in this final regulation is based on the work of the PSO negotiated rulemaking committee, as required at section 1856(a) of the Act, which provides that we establish through a negotiated rulemaking the solvency standards that entities will be required to meet if they obtain a waiver of the otherwise applicable requirement that they be licensed by a State. The negotiated rulemaking process and participants are discussed in the preamble to the interim final waiver and solvency regulations published in the **Federal Register** on May 7, 1998 (63 FR 25364). Among the participants in the negotiated rulemaking were the National Association of Insurance Commissioners, which is the organization of the chief insurance regulators from the 50 States, the District of Columbia, and four U.S. territories. This final solvency regulation is consistent with the solvency standards agreed upon by all participants in the negotiated rulemaking process, which, as noted, included the NAIC. We received no comments on the interim final waiver and solvency regulation and made no determinations that materially altered the PSO solvency standards agreed upon in the negotiated rulemaking. It is also notable that with limited exceptions these solvency standards track those in the HMO model act which are the model solvency standards developed by all of the States through the NAIC. Accordingly, we believe this final regulation meets Federalism requirements because we have consulted with the appropriate State officials who are in agreement with these solvency standards.

List of Subjects in 42 CFR Part 422

Health maintenance organizations (HMO), Medicare+Choice, Provider sponsored organizations (PSO).

For the reasons set forth in the preamble, 42 CFR Chapter IV, part 422, is amended as follows:

PART 422—MEDICARE—CHOICE PROGRAM

1. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1851 and 1855 of the Social Security Act.

Subpart H—Provider-Sponsored Organization

2. In § 422.382, the introductory text to paragraph (b) is republished, and the introductory text to paragraph (b)(4) and paragraph (b)(4)(iii) are revised to read as follows:

§ 422.382 Minimum net worth amount.

* * * * *

(b) After the effective date of a PSO's M+C contract, a PSO must maintain a minimum net worth amount equal to the greater of—

* * * * *

(4) Using the most recent financial statement filed with HCFA, an amount equal to the sum of—

* * * * *

(iii) Annual health care expenditures that are paid on a capitated basis to affiliated providers are not included in the calculation of the net worth requirement (regardless of downstream arrangements from the affiliated provider) under paragraphs (a) and (b)(4) of this section.

* * * * *

§ 422.384 [Amended]

3. In § 422.384, in paragraph (b)(5), the phrase ''qualified health maintenance organization actuary'' is removed and the phrase ''qualified actuary'' is added in its place.

4. In § 422.386, the introductory text to paragraph (d) and paragraph (e) are revised to read as follows:

§ 422.386 Liquidity.

* * * * *

(d) If HCFA determines that a PSO fails to meet the requirement of paragraph (b)(2) of this section, HCFA may require the PSO to initiate corrective action to—

* * * * *

(e) If HCFA determines that there has been a change in the availability of outside financial resources as required by paragraph (b)(3) of this section, HCFA requires the PSO to obtain funding from alternative financial resources.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 3, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

Approved: August 16, 1999.

Donna E. Shalala,

Secretary.

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA–7721]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Final rule.

SUMMARY: We, FEMA, are suspending one community on the effective date of