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42 CFR Part 422

Medicare Program: Waiver Requirements and Solvency Standards for Provider-Sponsored Organizations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 422

[HCFA–1011–IFC]

RIN 0938–AI83

Medicare Program; Waiver Requirements and Solvency Standards for Provider-Sponsored Organizations

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with a request for comments implements authority to waive, in the case of provider-sponsored organizations (PSOs) that meet certain criteria, the requirement that Medicare+Choice organizations be licensed by a State as risk-bearing entities. The waivers will be approved only under certain conditions where the State has denied or failed to act on an application for licensure.

This rule also establishes solvency standards that certain entities must meet to contract as PSOs under the new Medicare+Choice program. These standards apply to PSOs that have received a waiver of the requirement that Medicare+Choice organizations be licensed by a State as risk-bearing entities.

DATES: *Effective date:* These regulations are effective on June 8, 1998.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, by 5 p.m. on July 6, 1998.

ADDRESSES: Mail an original and 3 copies of written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, *Attention:* HCFA–1011–IFC, P.O. Box 26688, Baltimore, MD 21207–5187.

If you prefer, you may deliver an original and 3 copies of your written comments to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1011–IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

If you wish to submit comments on the information collection requirements contained in this interim final rule, you may submit comments to:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, *Attn:* John Burke, HCFA–1011–IFC

Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attn:* Allison Herron Eydt, HCFA Desk Officer

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

A. Current Medicare Contracting Program

Sections 1876 (g)(1) and (h)(1) of the Social Security Act (the Act) authorize the Secretary to enter into risk-sharing and cost contracts with eligible organizations to provide certain health benefits to members. Section 1876(b) of the Act requires an eligible organization, that may be a health maintenance organization (HMO) or a competitive medical plan (CMP), to be organized under the laws of a State. Additionally, section 1876(b) requires that such entities assume full financial risk on a prospective basis for the provision of health care services, and make adequate provisions against the risk of insolvency.

B. Current Regulations

Regulations at title 42 of the Code of Federal Regulations (CFR), Part 417, reflect the above requirement that Medicare contracting organizations be organized under State law, and make adequate provision against the risk of insolvency. Specifically, regulations at 42 CFR 417.120 require that Medicare contracting HMOs and CMPs have a fiscally sound operation as demonstrated by the following:

- Total assets greater than total unsubordinated liabilities.
- Sufficient cash flow and adequate liquidity to meet obligations as they become due.
- A net operating surplus or a financial plan.
- An insolvency protection plan.
- A fidelity bond or bonds, procured and maintained by the HMO, in an amount fixed by its policy-making body but not less than $100,000 per individual, covering each officer and employee entrusted with handling of its funds. The bond may have reasonable deductibles based upon the financial strength of the HMO.
- Insurance policies or other arrangements, secured and maintained by the HMO and approved by HCFA to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement and other casualty risks.

Since section 1876 of the Act requires that Medicare contracting HMOs and CMPs be organized under the laws of any State, these entities are subject to State laws regarding financial solvency. Many States follow the financial solvency provisions of the HMO Model Act of the National Association of Insurance Commissioners (NAIC). The financial requirements of the Model HMO Act are distinct from those of the Health Care Financing Administration (HCFA).

C. Balanced Budget Act of 1997

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Public Law 105–33), enacted August 5, 1997, added new sections 1851 through 1859 to the Act. Those sections establish a new Medicare+Choice (M+C) program under part C of title XVIII of the Act. Part C is designed to give beneficiaries access to health plan choices that go beyond the original Medicare fee-for-service program and existing Medicare HMOs. Once the M+C program is implemented, an individual entitled to Medicare Part A and Part B will be able to elect benefits either through original Medicare or an M+C plan, depending on availability in their area. Under Part C, the M+C plans that may be offered are coordinated care plans (e.g., HMOs, provider-sponsored organizations (PSOs), and preferred provider organizations (referred to as PPOs)), private-fee-for service plans, and demonstration medical savings account (MSA) plans (that is, a combination of a high deductible, catastrophic insurance plan with a contribution to a Medicare+Choice account).

Regulations for the overall implementation of the M+C program are required by the BBA to be published by June 1, 1998. Those regulations will be incorporated into Part 422 of title 42 of the CFR. Provisions enacted by the BBA and the forthcoming M+C regulations establish broad and comprehensive requirements for contracting as an M+C plan, including basic benefits, payment, access to service, quality assurance, beneficiary hold harmless, continuation of benefits, appeals mechanisms, marketing and enrollment processes. Those overall M+C regulations will apply to PSOs as well.

Section 1851(a)(2) of the Act explicitly provides for participation of a PSO in the M+C program as a coordinated care plan. 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 such items and services and have at least a majority financial interest in the entity.

We recently published an interim final rule with an opportunity for public comment setting out this definition, clarifying certain terms, and establishing related requirements. (This PSO definitions rule established 42 CFR Part 422 and, more specifically, Subpart H, which is designated for the PSO provisions.) The terms and requirements related to the definition of a PSO are now found at §§ 422.350 through 422.356. Here, in this interim final rule with opportunity for public comment, we focus on two more portions of the law established specifically for PSOs and the M+C program: the Federal waiver of State licensure and the solvency standards that will apply to PSOs that have obtained such a waiver.

Section 1855(a)(2) of the Act establishes a special exception for PSOs to the otherwise applicable requirement for State licensure if certain conditions occur. This interim final rule implements the PSO waiver provisions specified in the BBA, and makes clarifications. In order to assist organizations that are considering applying to become PSOs under the M+C program, we determined that the waiver provisions should not be delayed until the June 1, 1998 regulation is published. As with the PSO definitions rule mentioned above, early publication of these PSO provisions is desirable because of requirements that must be met before contract application.

Section 1856(a) of the Act 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. We note here that based on §§ 422.352(a) and 422.380, State-licensed organizations that meet the PSO definition (see §§ 422.350 through 356) may qualify for the minimum enrollment standards established under Section 1857(b) of the Act but are not subject to these solvency standards.

The solvency standards in this interim final rule with comment period are a product of the negotiated rule making process. This rule does not necessarily conclude the negotiated rulemaking process because the Committee may be reconvened to consider public comments that are received.

II. Waiver of State Licensure Requirement

A. Background

1. Statutory Basis

A fundamental requirement of the M+C program, as set forth under new section 1855(a)(1) of the Act, is that an M+C organization must be ''organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers an M+C plan.'' However, section 1855(a)(2) of the Act establishes an exception to this requirement by allowing certain organizations established or operated and controlled by providers, and known in the BBA as PSOs, to obtain from the Secretary a Federal waiver of the State licensure requirement under certain circumstances. This interim final rule with comment sets forth regulations for implementing that waiver.

Unlike the regulations contained in this rule relating to PSO solvency and capital adequacy, the waiver provisions were not developed through the negotiated rulemaking process. The regulations described in this section were developed by HCFA under its rulemaking authority.

2. State Licensure and the Medicare Program

Under section 1876(b) of the Act and implementing regulations at 42 CFR Part 417, Medicare contracting HMOs and CMPs must be organized under the laws of a State. As used in section 1876 of the Act, the term ''HMO'' means a Federally qualified HMO and the term ''CMP'' means a prepaid health plan that is likely regulated by the State as an HMO, but is not Federally qualified. Thus a provider sponsored health plan could apply to contract with HCFA as an HMO or a CMP if it became Federally qualified or met the definition of CMP, and satisfied other section 1876 requirements. In recent years, several States have adopted licensure laws for PSOs (sometimes known as integrated or organized delivery systems), thereby creating another licensure vehicle and avenue for contracting with Medicare. (Some State PSO laws, however, are limited in scope and licensed entities would not meet the CMP requirements).

3. Federal Waivers and PSO Applications

As indicated above, section 1855(a)(1) requires that M+C organizations be licensed as risk-bearing entities under the laws of the State. Section 1855(a)(2) of the Act provides an exception to this requirement for PSOs. PSOs are the only organization eligible to participate in M+C without State licensure. It is clear from the statute, however, that all organizations, including those established by providers, must seek State licensure as the initial step toward an M+C contract. Only under specific conditions, as described below, will the organization be permitted to forego the preliminary and fundamental requirement to be State-licensed as a risk-bearing entity.

If an organization believes that the circumstances of its State application comply with one of the conditions for a waiver, it must submit to HCFA a completed waiver request form. The request form, that the Office of Management and Budget approved on April 2, 1998, (form #0938–0722) is available through HCFA, and is posted on the HCFA web site at http://www.hcfa.gov/Medicare/mplusc.htm. HCFA will make a determination to approve or disapprove a waiver within 60 days of receipt of a substantially complete request. If the waiver request is approved, the organization will be considered eligible for a waiver, and then may submit its contract application to HCFA. (The PSO application form will be posted at the aforementioned Internet address in the near future.) It is through the application process that the organization must demonstrate to HCFA's satisfaction that it meets the PSO definitions and requirements as set forth in 42 CFR 422.350 through 422.356, as well as the solvency standards established later in this interim final rule. If it meets the

definition, the organization will be considered a PSO and remains eligible for a waiver.

Given the 60-day time period permitted HCFA to approve a waiver request under section 1855(a)(2)(F) of the Act, we felt it would be impossible in many cases to simultaneously process the waiver request and determine whether an organization is a PSO as defined under § 422.350 through § 422.356. This determination may require an extensive review and verification of the organization's structure, ownership or partnership arrangements, contracts and payment arrangements. Therefore, as described above, the 60-day maximum time period will apply to determining whether the organization is eligible for a waiver, as required by law. The determination that the organization is in fact a PSO will occur once it is eligible for a waiver and has submitted an application for an M+C contract.

B. Waiver Provisions

In this interim final rule, we are establishing new provisions at § 422.370 through § 422.378 for purposes of implementing section 1855(a)(2) of the Act. Because entities applying for a waiver as yet will not have been determined to meet the PSO definition and requirements of subpart H, the regulation text refers to these entities as ''organizations.''

Section 422.370 implements the authority under section 1855(a)(2)(A) of the Act to waive the State licensure requirement for M+C organizations contained in section 1855(a)(1) and restates the two basic conditions for doing this. First, the rule requires organizations interested in a waiver to file a request by no later than November 1, 2002, a time limit specified by the statute. Second, HCFA must determine whether the organization meets one of the grounds for a waiver listed in § 422.372.

Section 422.372 of the rule establishes the basis for a waiver as set forth in sections 1855(a)(2)(B), (C), and (D) of the Act. These three conditions and a fourth condition identified by HCFA are described below. In order for three of the conditions to be effectuated, the organization must have applied for a State license before requesting a waiver. By requiring that the organization apply for ''the most closely appropriate'' license (or authority), we are clarifying that the type of license must relate to the nature of M+C coordinated care plans; that is, health plans providing coordinated, comprehensive benefits through a health care delivery net work on a fixed, prepayment basis. We are requiring this to ensure that organizations requesting and obtaining waivers will likely meet the PSO definition and M+C requirements during the application stage. We expect that for most States the most appropriate license available will be an HMO license, although this may change as States adopt PSO or modify current licensure laws. It is very unlikely that we will approve a PSO waiver based on an application for an indemnity insurance license, a PPO license, any license or authority to provide limited health services, or a limited license to bear risk for an HMO as a downstream contractor.

Section 422.372(a) sets out the first basis on which an organization may establish waiver eligibility, that is, the State failed to complete action on the licensing application within 90 days of the date the State received a substantially complete application. (See section 1855(a)(2)(B).) The 90-day period may begin any time after enactment of the BBA. It is counted from the date the State received a ''substantially complete application.'' In order to clarify the term ''substantially complete application,'' we consulted several parties for technical assistance, and intend to make determinations as follows:

(1) If the State has notified the organization, in writing, that the organization has submitted a substantially complete application, the date of that notification will be considered the date the State received a substantially complete application.

(2) If the State has not notified the organization, in writing, as to the completeness of its application within 60 days of the date of submission of an application, we will consider the date the organization submitted its initial application to be the date the State received a substantially complete application.

(3) If the organization can demonstrate to HCFA that it has submitted all of the information requested in an incompleteness notification from the State and the State still regards the application as incomplete or fails to notify the organization as to the status of its application within 30 days from the date it receives the organization's submission of the additional information requested, then HCFA will consider the date the State received the additional information requested to be the date the State received a substantially complete application.

(4) In a dispute between an organization and the State over whether the organization has submitted a substantially complete application or over the date the State received a substantially complete application, HCFA will make the final determination based on consultation with the organization and the State.

We believe that this process for determining the date the State received a substantially complete application is consistent with Congressional intent that an organization must make an earnest attempt to become State licensed before requesting a waiver. This earnest attempt includes working with the State in good faith to submit all of the information necessary to have a license either approved or denied. At the same time, however, we also believe that State licensing agencies should be working in good faith with the organization to either approve or deny an application in a timely manner.

We believe the process outlined above balances the concerns of the States and of the organization. However, given the complexity of implementing this provision, we invite comment on this approach.

Paragraph (b) of § 422.372 establishes the second basis for a waiver. Here, waiver eligibility results from the organization experiencing discriminatory treatment in the State's denial of its application. As provided in the statute, discriminatory treatment can occur in two ways, as follows:

- The State has denied the licensure application on the basis of any material requirements, procedures or standards (other than solvency requirements) that the State does not generally apply to other entities engaged in a substantially similar business.
- The State required, as a condition of licensure, that the organization offer any product or plan other than an M+C plan.

Thus, an organization will be eligible for a waiver under this provision if the State imposes different requirements, and these different requirements are the basis of a license denial. In addition, the organization must demonstrate what requirement, procedure, or standard it failed to meet, and how this differs from what is generally applied to other similar plans. In order to demonstrate that the State does not ''generally apply'' the requirement on which the denial was made, the organization must show that the requirement is more of an exception and not usually applied to similar health plans. For example, if a pattern exists where most HMOs within a State are not held to a requirement, the PSO will be eligible for a waiver based on discriminatory treatment.

By ''substantially similar business'' we mean entities that provide and manage a comprehensive set of health

care services, and are prepaid a fixed amount in advance and without regard to the frequency or cost of services when utilized. Such entities are likely to include HMOs, and may include certain PPOs and State-licensed PSOs. We do not anticipate considering indemnity insurers, PPOs reimbursed on a discounted fee-for-service basis, or ''single-service'' managed care plans as being engaged in a ''substantially similar business'' to the waiver-requesting organization.

We considered a broader use of the term ''engaged in a substantially similar business'', but believe our interpretation is consistent with the PSO provisions in section 1855 of the Act. We believe an expanded interpretation, which includes all risk-bearing entities (for example, indemnity insurers) does not comply with the language of the statute. In processing waiver requests under this provision at this time, we anticipate looking to the requirements, procedures and standards that a State places on HMOs.

The second criterion for discriminatory treatment, set forth in § 422.372(b)(2), is that the State requires the organization to offer its health plan to other than the Medicare population. Here, an organization would have to demonstrate only that it was denied a license because the health plan would serve only Medicare beneficiaries. We believe this provision permits the establishment of Medicare-only PSOs, and establishes a Federal preemption over any State laws that would prevent it.

Paragraph (c) of § 422.372, the third basis for approving a waiver of the State licensure requirement, pertains to a State imposing different requirements related to financial solvency. Two conditions, or criteria are specifically addressed in this paragraph. (See 1855(a)(2)(D)(i) and (ii).) Under § 422.372(c)(1), a waiver may be granted if the State has denied the licensure application, in whole or in part, based on the organization's failure to meet solvency requirements that are different from those set forth in §§ 422.380 through 422.390. This provision incorporates the new regulatory citation for PSO solvency standards developed through negotiated rulemaking as established in this rule.

An issue arose regarding waiver eligibility when a State has adopted the Medicare PSO solvency standards and denies a license based solely on a provision of the solvency standards that give the regulator discretion. For example, it is likely that while using the same solvency standards, HCFA and States could reach different decisions regarding the acceptance of administrative infrastructure to reduce the minimum net worth amount requirement. If a State does not permit such a reduction, the issue arose whether HCFA would consider this a basis for a waiver. We have decided to permit requests for waivers in these situations. As documentation, we will require organizations to submit all information relevant to the specific solvency requirement in question, including any State correspondence. As part of our review, we will likely seek input from the State. If we concur with the State's determination regarding the specific discretionary issue, the waiver request will be denied. However, if we make a decision, that differs from the State's, then the waiver will be approved and the organization may submit an M+C application. We considered acceding to States' decisions where a regulator's discretion is warranted under the PSO solvency rules, but concluded that this might overly restrict the availability of waivers.

The second condition, for a waiver under § 422.372(c) is that the State has imposed documentation or information requirements, or other requirements, procedures or standards related to solvency or other material requirements that are different from those imposed by HCFA in carrying out §§ 422.380 through 422.390. As with the previous condition, we believe that a PSO may seek a waiver if a State denies a license based on its exercise of discretion in requiring different information or documentation than HCFA. Therefore, documentation, information, and other requirements which may stem from such discretion can be the sole basis for granting a waiver under this particular provision. Our position on this issue is based upon the intent of the Congress, as reflected in the Conference Report accompanying the BBA, that the State not impose documentation or information requirements ''that are dilatory or unduly burdensome and that are not generally applied to other entities engaged in a substantially similar business.'' (H.R. Rep. No.105–217, 105th Congress, Session 632 (1997))

The fourth basis for approving a waiver of the State licensure requirement, paragraph (d) of § 422.372, is that the appropriate State licensing authority has notified the organization in writing that it will not accept their licensure application. While this grounds for approval is not in the Act, we are using our authority under section 1856(b)(1) to establish standards to add this provision based on concerns that the Act allows for a waiver only if the PSO submits an application to the State. We have identified a concern that some State agencies may refuse to accept licensing applications from PSO-like organizations, thus preventing these organizations from requesting a waiver until 90 days have transpired.

We believe this provision facilitates the waiver process and conforms with the intent of section 1855(a)(2) of the Act. If it is clear that a State licensing agency will not act on an application as described here, both the State and the organization can save time and resources by permitting the organization to go directly to HCFA for a waiver.

In § 422.374 we clarify certain conditions and provisions related to the waiver request and approval process. Paragraph (a) clarifies section 1855(a)(2)(f) of the Act, which requires organizations seeking a waiver to submit a substantially complete waiver request. Section 422.374(a) specifies that to be substantially complete, a request must clearly demonstrate and document the organization's eligibility for a waiver. HCFA will notify the organization if the request is not complete, and will work with the organization to determine the information necessary to make a decision on the request. HCFA will have final discretion in determining whether a waiver request is substantially complete.

Paragraphs (b) and (c) of § 422.374 provide that HCFA will act promptly (within 60 days) to grant or deny a substantially complete waiver request and allow organizations that have been denied a waiver request to submit subsequent requests until November 1, 2002. (See section 1855(a)(2)(F).)

Paragraph (d) of § 422.374 establishes that the waiver will take effect upon the effective date of the M+C contract. We have added this provision to clarify that a waiver is linked to the contract and is not active, or operable, without an effective M+C contract. This provision helps organizations seeking a waiver, because the waiver is limited to a one-time, three-year period. If the waiver is made effective immediately upon approval of a waiver request and the approval of the M+C contract takes longer than anticipated, the three-year waiver period would be running and the organization could lose a significant amount of time that it is eligible to operate without a State license. If the contract application is denied, an even greater amount of time may elapse by the time the organization can develop, submit and gain approval of a revised contract application.

Paragraph (e) of § 422.374 gives HCFA the right to revoke a waiver if we

subsequently find that the organization's M+C application is significantly different from the application submitted to the State. Because Congress intended for organizations to make an earnest attempt to obtain a State license before applying for a Federal waiver, we believe that significant changes from the State application to the M+C waiver application could undermine this policy. We believe that requiring that the M+C contract application be very similar to the application submitted for a State license addresses two possible situations. First, it prevents organizations from circumventing the intent for them to achieve State licensure if possible. It also assures States the right to license an organization that has evolved or reorganized from the time of its first application; that is, the organization has undergone some significant changes and the application for all intent and purposes is ''new.''

Organizations that reapply for an M+C contract because they were not successful M+C applicants do not have to reapply to the State or re-submit a waiver request as long as the revised application does not invoke paragraph (e) of § 422.374.

Section 422.376 is added to establish parameters of the waiver. Paragraph (a) of this section restates section 1855(a)(2)(E)(i) of the Act, the waiver is effective only for the particular State for which it is granted and does not apply to any other State. It also clarifies that an organization must be licensed or request and gain waiver approval for each State where it wishes to operate an M+C plan.

Paragraph (b) of § 422.376 incorporates section 1855(a)(2)(E)(ii) of the Act by limiting the waiver to a 36-month period. We have modified this provision, however, to extend the period through the end of the calendar year in which the 36-month period ends unless the waiver is revoked based on paragraph (c) of this section. We made this modification because we were concerned about terminating the waiver and the M+C contract during the middle of a contract year. Such mid-year terminations are unreasonable, disruptive, costly, and could unnecessarily jeopardize the health care of beneficiaries enrolled in a PSO. By waiting until the end of the contract year to end a waiver (and thus the M+C contract), beneficiaries will be able to transition into other M+C plans through the annual enrollment process.

Paragraph (c) of § 422.376, mid-period revocation, was added to clarify that the waiver will cease before the end of the 36 month period if the organization's M+C contract is terminated or if the organization becomes State licensed. This provision emphasizes again the relationship between the waiver and the contract; namely that the waiver is not effective without a contract in effect, and the contract cannot be effective without the waiver. It also restates the Act by conditioning the waiver upon the organization's compliance with State consumer protection and quality standards as discussed further below.

The last section of the waiver provisions, § 422.378, addresses the relationship between State law and waivered organizations, or PSOs. These provisions are a codification of sections 1855(a)(2)(E)(iii) and (iv), and 1855(a)(2)(G) of the Act. Section 422.378(a) establishes a general Federal preemption of any State law related to licensing the organization that interferes with contracting under the M+C program. Section 422.378(b), on the other hand, establishes the State's right to require waivered organizations to comply with consumer protection and quality standards applicable to all other M+C plans in the State, as long as the standards are consistent with Medicare requirements. Paragraphs (c) and (d) of § 422.378 establish processes for ensuring compliance with § 422.378(b). We are developing a memorandum of understanding with the NAIC to implement §§ 422.378 (b), (c) and (d).

III. PSO Solvency Standards

A. Background

1. Negotiated Rulemaking Act

The Negotiated Rulemaking Act (Pub. L. 101–648), establishes a framework for the conduct of negotiated rulemaking. Negotiated rulemaking is a process whereby a rule (generally a proposed rule) is developed by a committee of representatives of interests that are likely to be significantly affected under the rule and includes a Federal government representative. The goal of the process is to reach consensus on the text or content of the rule and then publish that text for public comment. Consensus is defined in the Negotiated Rulemaking Act as unanimous concurrence among the interests represented. However, the committee could agree on another specified definition. The committee is assisted by a neutral facilitator.

The agency responsible for the rule may use the services of an impartial convener to identify potential participants in the negotiation, determine whether they are willing to participate, inform them about the process, discuss issues with potential participants, and make recommendations regarding how to make the process work. The committee must be chartered under the Federal Advisory Committee Act (FACA) (5 U.S.C. App.2).

2. Establishing the Process

To expedite the development of PSO solvency standards, Congress modified the negotiated rulemaking process by requiring that this rule be published as an interim final rule with comment, shortening the period for forming the committee, establishing a shortened period for committee negotiations, and setting a target date for publication of the interim final rule for April 1, 1998. (See section 1856(a) of the Act.)

We selected the Department of Health and Human Services Departmental Appeals Board (DAB) to serve as the convener and facilitator for these negotiations because of their reputation for impartiality, as well as their experience and availability. The DAB has familiarity with HHS programs and experience convening and facilitating negotiated rulemaking on Medicare issues such as the Medicare Hospice Wage Index and the Shared-risk Exemption to Federal Health Care Anti-Kickback Provisions. Further, a poll of parties interested in the development of PSO solvency standards indicated unanimous support for using the DAB to facilitate the negotiated rulemaking.

During the convening process, the DAB interviewed over 50 individuals from outside the Federal government, representing over 25 different associations, coalitions or companies. On September 8, 1997, the DAB issued a convening report recommending participants for the negotiated rulemaking committee (the Committee). This recommendation was based on an evaluation of the potential effects of the rule on groups that indicated a desire to serve on the Committee. When any differences among groups were identified, the convener sought information about how these differences were relevant with respect to solvency standards, whether those differences could be adequately represented by other groups, and whether there had been demonstrated concern about solvency standards during the legislative debate. The report also identified issues to be negotiated and potential barriers to consensus.

On September 23, 1997, we published in the **Federal Register** (62 FR 49649) a notice of intent to form a negotiated rulemaking committee and notice of meetings. Based on the recommendations contained in the convener's report, the notice appointed

representatives of interests likely to be affected by PSO solvency standards to the negotiated rulemaking Committee. Committee members included the—

American Association of Health Plans,
American Association of Retired Persons,
American Hospital Association,
American Medical Association,
American Medical Group Association,
Blue Cross/Blue Shield Association,
Consortium on Citizens with Disabilities,
Federation of American Health Systems,
Health Insurance Association of America,
National Association of Insurance Commissioners,
National Rural Health Association
Coalition of the Catholic Hospital Association and Premier Health Care
Coalition of the American Association of Homes and Services for the Aging, the American Health Care Association, the Home Health Services and Staffing Association, and the National Association for Home Care; and
Coalition of the Independent Practice Association of America and the National Independent Practice Association.

In addition the Committee included a representative from HCFA.

We requested public comment on whether we had identified the key solvency issues to be negotiated by the Committee; if we had identified the interests that will be affected by key issues listed; and whether the party we were proposing to serve as the neutral facilitator was acceptable. We also sought comments on several key definitions related to the negotiated rulemaking and the forthcoming rulemaking for Medicare+Choice organizations. In general, commenters supported the notice and as a result no changes were made to the Committee membership or issues to be discussed.

3. Summary of the Committee Process

The Committee met seven times from October 1997 to March 1998. Notices of meetings were published in the **Federal Register** on September 23, 1997 (62 FR 49649) and February 13, 1998 (63 FR 7359). Minutes for each of these meetings are posted on the M+C web page at http://www.hcfa.gov/Medicare/mplusc.htm. At the first meeting, held October 20, 21, and 22, 1997, business and health industry analysts made presentations that related to health plan solvency. Also the Committee discussed how to address the principle solvency issues and how to proceed in developing solvency standards. The Committee devoted the remaining series of 3-day meetings, and a final 1-day meeting, primarily to substantive discussion of solvency standards for Federally waived PSOs.

The Committee's deliberations focused on the following issues: the stages at which to evaluate a PSO's financial solvency, the amount, composition, and location of assets and liabilities that PSOs must maintain to be considered financially solvent; the planning and data collection necessary to track PSO solvency; and the mechanisms needed to protect beneficiaries if a PSO becomes insolvent.

On March 5, 1998, the Committee reached consensus on a PSO solvency standards proposal. All Committee members signed an agreement indicating unanimous concurrence with a written Committee statement of the Committee's recommendations for PSO solvency standards.

In the agreement, HCFA agreed that, to the maximum extent possible and consistent with legal obligations, it will draft an interim final rule consistent with the Committee statement. We believe that the PSO solvency provisions of the interim final rule published herein are fully consistent with the Committee's recommendations, with some additional clarifications. Committee members have agreed not to submit negative comments on the interim final rule. If, however, a member believes any provision of this rule incorrectly reflects the Committee statement, the member may comment on the matter. If necessary, the Committee will be reconvened at a later date.

4. Summary of the Committee's Deliberations

The Committee agreed that there are three stages at which to consider solvency standards: initially at start-up, as an ongoing business operation, and during insolvency. While these stages are only concepts that do not have exact starting or finishing points, the Committee felt that they are a useful framework for setting solvency standards at different stages of operation. These stages are translated in regulation to the application stage, the stage during which the M+C contract is in effect, and insolvency.

The initial stage represents the period of activity prior to the first day of actual operation as an M+C contracting PSO. It includes the periods when an organization will request a Federal waiver of State licensure and will apply for an M+C contract. In this preamble and the regulation, the term PSO is reserved for organizations that are: approved for a Federal waiver, determined to meet the definition and related requirements of a PSO, and awarded a Medicare+Choice contract.

The ongoing stage represents the period that begins when a PSO's M+C contract becomes effective. This is when a PSO will assume responsibility for providing services to Medicare beneficiaries for a fixed payment. During this stage, the appropriate solvency standards are affected by the number of Medicare enrollees for which a PSO is responsible. Lastly, the insolvent stage represents the period beginning when a PSO's total liabilities exceed its total assets.

Using this three stage framework, the Committee developed alternate proposals regarding the amount, composition, and status of assets and liabilities that PSOs must maintain in order to be considered fiscally sound and financially solvent. The alternate proposals reflected the various interests of the Committee members and their constituencies. These proposals formed the basis for negotiations and the subsequent Committee statement and consensus agreement.

To develop the solvency standards, the Committee considered what financial, capital and other factors must be present to assure that a PSO is fiscally sound. Specifically, the Committee considered requirements for net worth, financial plans, liquidity, financial indicators, and beneficiary protection.

B. Net Worth Amount Requirements

The Committee considered the net worth requirements for the initial and ongoing stages. In each stage, the Committee deliberated on the appropriate amount and composition of assets to be counted toward the net worth requirement. The Committee agreed that in the initial stage an organization should have an initial minimum net worth amount of $1,500,000. This is the same minimum net worth amount that is specified in the HMO Model Act, with a significant difference. The Committee agreed to allow HCFA to reduce the net worth requirement by up to $500,000 if the PSO has available to it an administrative infrastructure that HCFA considers appropriate to reduce, control or eliminate start-up costs associated with the administration of the organization. Such infrastructure would include office space and equipment, computer systems, software, management services contracts and personnel recruitment fees. In recognizing a reduction of up to $500,000 for these costs, the Committee acknowledged that the minimum net worth drops from $1,500,000 to $1,000,000 as soon as the PSO is approved and that the $500,000 difference was to account for start-up costs. HCFA has the discretion to approve the administrative costs that an organization offers to obtain a reduction of up to $500,000.

For the ongoing stage, the Committee agreed that the minimum net worth should be at least $1,000,000. This is the minimum specified in the HMO Model Act for the ongoing stage. The difference between the ongoing minimum net worth and the initial minimum net worth reflects the Committee belief that PSOs will incur administrative costs in the initial stage that will not be repeated in the ongoing stage. While the floor on the minimum net worth amount in the ongoing stage is $1,000,000, the Committee agreed to subject PSOs to a series of ''greater of'' tests to determine an appropriate minimum net worth. The ''greater of'' tests link the minimum net worth amount to the size of annual premium revenues, the amount of uncovered health care expenditures, and the amount of health care expenditures paid to non-capitated and non-affiliated providers. These factors are indirectly related to the size of the plan (that is, number of enrollees) and the amount of risk being assumed.

The Committee discussed whether to include, among the factors considered in setting the ongoing net worth amount for PSOs, the authorized control level (i.e., the point in a financial crisis where a State regulator is authorized to take control of an organization) capital requirement derived from the NAIC Health Care Organization Risk Based Capital (RBC) Formula. RBC is a new formula adopted by the NAIC to determine the minimum capital level that an organization should have before regulators become concerned about its solvency. The RBC level depends on the riskiness of the company's assets, investments, and products. RBC has several trigger points. As currently envisioned, if a company's actual net worth falls below the trigger point called the authorized control level, the State's insurance commissioner may take control of the company. The RBC for health organizations has not yet been adopted by States for setting minimum net worth requirements.

The RBC formula by design will be used by States to monitor the financial viability of State-regulated managed care plans. It has not yet been adopted by States in setting the minimum net worth amount requirements. The Committee agreed that HCFA should consider adding that RBC authorized control level factor to the ongoing net worth amount requirements after evaluating whether the RBC is a valid indicator of Medicare PSO solvency and after considering the manner in which States have regulated managed care plans using the RBC authorized control level. In 1999, after PSOs have begun to operate and report financial data, HCFA will issue a notice requesting comment on adding this factor to the net worth calculation for PSOs. As part of HCFA's normal data collection process for all M+C plans, HCFA expects to be collecting information necessary to perform the RBC calculations.

With regard to the composition of the minimum net worth amount, the Committee agreed upon the following requirements—

- At least $750,000 of the minimum net worth must be in cash or cash equivalents. After the effective date of the contract, however, the Committee agreed that $750,000 or 40 percent of the minimum net worth amount must be in cash or cash equivalents.
- Up to 10 percent of the minimum net worth amount can be comprised of intangible assets in the initial stage. However, in the initial stage, if a PSO keeps $1,000,000 in cash or cash equivalents and does not use the administrative reduction, then up to 20 percent of that PSO's minimum net worth can be comprised of intangible assets. In the ongoing stage, a PSO must keep the greater of $1,000,000 or 67 percent of the ongoing minimum net worth in cash or cash equivalents to qualify for the 20 percent level on intangibles.
- Subject to the above provisions, health care delivery assets (HCDAs) may be admitted at 100 percent of their value according to generally accepted accounting principles (GAAP).
- Subject to the above provisions, other assets may be admitted according to their value under Statutory Accounting Practices (SAP).
- Subordinated debts and subordinated liabilities can be excluded from the calculation of liabilities for the purposes of determining net worth.
- Deferred acquisition costs are excluded from the net worth calculation.

The Committee also agreed that HCFA will look at SAP codification upon its completion and will consider whether to adopt codification standards on the asset concentration and quality of HCDAs for waivered PSOs. SAP codification standards are currently being developed by the NAIC to make SAP more consistent among the States. HCFA will request public comment on whether to use any such standards in the notice on the NAIC RBC (see above). Meanwhile, HCFA may apply judgement in evaluating HCDAs for concentration and quality.

In the Committee's deliberations the concepts of net worth and liquidity were closely related. Some Committee members suggested that because PSOs have the potential to provide ''sweat equity,'' these organizations could operate under different solvency standards for net worth and liquidity than might be acceptable for other forms of integrated delivery systems. The term ''sweat equity'' was used to represent the value of health services that a PSO could provide directly. One premise presented to the Committee was that PSOs could continue to furnish services during financial crises because the ''owners'' actually provide health care services, whereas other managed care systems that contract for the delivery of care may not be able to continue to operate. In addition, PSOs could adopt contingent reimbursement arrangements with their providers. Under such arrangements, the affiliated providers' payments could be reduced until the PSO had weathered the financial crisis.

The consensus was not to explicitly recognize sweat equity in the solvency standards. This position evolved because of the difficulty in developing an administrable solvency standard based upon sweat equity. Further, the solvency standards implicitly recognize sweat equity in other areas (e.g., the financial plan).

C. Liquidity Requirements

In conjunction with a minimum net worth amount requirement, the Committee discussed a standard for meeting financial obligations on time. The Committee adopted, for both the initial and the ongoing stages, the liquidity standard that a PSO have sufficient cash flow to meet its obligations as they become due. Also, the Committee recommended that in the initial and ongoing stages HCFA should use the same factors to determine the ability of a PSO to meet the liquidity standard: (1) the timeliness of PSO payments of obligations, (2) the extent to which the current ratio is maintained at 1:1 or whether there is a change in the current ratio over a period of time, and (3) the availability to a PSO of outside financial resources to meet its obligations.

The current ratio focuses on a period that is up to one year long. It compares all assets that are convertible to cash within that period with all liabilities that will come due in that same period using the following formula:

$$\text{Current ratio} = \frac{\text{Current Assets}}{\text{Current Liabilities}}$$

The Committee agreed that PSOs should maintain a current ratio of at least 1:1. That is, current assets should be equal to or greater than current liabilities. The Committee also agreed that the current ratio is a target rather than an absolute standard. This position

recognizes that valid reasons may exist for a PSO's current ratio to go below 1:1 for short periods of time. However, there were also concerns by some Committee members that the current ratio is an important indicator of an organization's condition and a current ratio of under 1:1 should trigger some regulatory action. Therefore, the current ratio will be used to identify trends or sudden major shifts in a PSO's financial performance.

D. Financial Plan Requirements

Several presenters before the Committee identified poor planning and management control as the primary reasons for the early HMO failures. As a standard to encourage good planning and strong management, the Committee agreed that a financial plan is essential for PSOs. Further, such plans should be prospective, reasonable, and consistent. The Committee used the financial plan standard for contractors under section 1876 of the Act to develop the PSO standard, but specified certain provisions differently. The specific requirements of the financial plan are presented in the discussion of provisions, below.

The Committee believed that the financial plan standard they agreed to represents the minimum needed to monitor Federally waived PSOs. The Committee agreed that HCFA should have the discretion to modify the financial plan to require additional or different information as necessary to evaluate the financial position of a Federally waived PSO.

The Committee agreed that in the initial stage, at the time of application, organizations must submit financial plans covering the period from the most recent financial audit until 12 months after the effective date of an M+C contract. If, however, a financial plan projects losses, then the time horizon must extend further, to 12 months after the point that the financial plan projects two consecutive quarters of net operating surplus.

E. Pre-Funding of Projected Losses

One area of the financial plan that the Committee discussed considerably was a requirement that PSOs must identify all sources of funding for projected losses (and in certain circumstances actually have the cash available). A key issue in this discussion was if and how to recognize such financing methods as guarantees and letters of credit (LOC). Some Committee members expressed concern about quickly securing money that was pledged to a PSO in a guarantee or letter of credit during a financial crisis. For a PSO that is under financial strain, the timely availability of cash is crucial to both the PSO and HCFA in attempting to protect Medicare enrollees. A delay in securing needed cash—if, for example, the guarantor stalls or reneges on its obligation—could exacerbate a financial crisis and further threaten the quality and continuity of care for enrollees.

Other Committee members contended that guarantees and LOC are a common and accepted means of obtaining capital for integrated health delivery systems. Furthermore, many providers who are candidates to become Federally waived PSOs could not participate unless guarantees or LOC, or both, are allowed. Advocates of guarantees and LOC felt that they should be admitted for two purposes: meeting the net worth requirements and funding projected losses.

As a compromise, the Committee agreed to accept guarantees, but only for funding projected losses that are reported by a PSO in its financial plan. As previously mentioned, the solvency standards contained herein require PSOs to fund all projected losses in the financial plan from the effective date of their M+C contracts until they achieve two consecutive quarters of net operating surplus. The Committee agreed that guarantees are an acceptable means to fund projected losses provided certain conditions are met. Further, the Committee agreed that each PSO's guarantee would be subject to a trial period of one-year from the effective date of the PSO's M+C contract. During this period, guarantees would be accepted, but cash or cash equivalents equaling the obligations covered by the guarantee would have to be on a PSO's balance sheet six months prior to the date actually needed. After a year, assuming that the guarantee obligations are met timely, the Committee agreed that a PSO should be permitted to notify HCFA of its intent to reduce or eliminate the pre-funding period. The Committee further agreed that HCFA should have up to 60 days after the receipt of such notice to exercise its discretion and modify or reject the notice. However, if the guarantee obligations are not properly met on a timely basis, the Committee agreed that HCFA should have the discretion to require a PSO to fund projected losses through other methods or further in advance.

HCFA presented the Committee with draft standards on guarantees. The Committee generally supported the draft with some revisions, but did not officially adopt the standards as part of the Agreement before needing to vote on consensus.

The Committee agreed that it should recognize LOC as a means to fund projected losses. To be accepted, LOC must be irrevocable, clean, and unconditional. Additionally, LOCs must be capable of being promptly paid upon presentation of a sight draft under the LOC without further reference to any other agreement, document or entity. The Committee also agreed that beginning one year after the effective date of an M+C contract, a PSO should be allowed to use the following other means to fund projected losses: (1) lines of credit from regulated financial institutions, (2) legally binding capital contribution agreements, and (3) other legally binding contracts of similar reliability.

The Committee recognized that HCFA should have discretion regarding the acceptance of guarantees, LOCs and other means to fund projected losses. Accordingly, use of these vehicles is subject to an appropriateness standard. That is, guarantees, LOCs and other means of funding projected losses may only be used in a combination or sequence that HCFA determines is appropriate.

F. Reporting

The Committee agreed that PSOs must meet HCFA requirements for compiling, maintaining and reporting such financial information as the agency determine is necessary. HCFA should have the discretion to specify the contents, method of calculation, and the schedule for reporting such financial indicators. We believe that this discretion is necessary for proper oversight of Federally waived organizations as they evolve and as market conditions evolve. The Committee recommended that the general reporting format be the NAIC's Official Annual Statement Blank—HMO Edition (the Orange Blank). HCFA will modify data obtained from this form for application to PSOs. Use of this form will not prohibit HCFA from requesting additional information if the agency determines that such information is necessary to accurately assess a PSO's financial condition.

The Committee agreed that the common practice should be to require quarterly or annual reports. If a PSO has not achieved a net operating surplus, the Committee felt that HCFA could require financial reporting as frequently as monthly. Monthly reporting would be necessary to enable HCFA to maintain better oversight of PSOs that are at heightened financial risk.

G. Insolvency Protections

The Committee's deliberation in the area of insolvency focused upon protecting beneficiaries. The Committee considered five issues regarding insolvency: an insolvency deposit requirement, a hold harmless requirement, a continuation of coverage provision, reserves for uncovered expenditures, and termination of an M+C contract.

The Committee agreed that an insolvency deposit should be required. The insolvency deposit would be used to pay for the costs associated with receivership or liquidation. Committee discussions focused on the amount of the insolvency deposit rather than the need for a deposit. For the insolvency deposit requirement, the Committee considered a range between $100,000 and $300,000. Committee members supporting a $300,000 deposit contended that a lower deposit would be quickly exhausted and inadequate in a financial crisis. Committee members who supported the $100,000 deposit countered that a higher deposit would be too onerous when combined with the cash reserves required to meet the minimum net worth amount. The consensus position was to allow the lower insolvency deposit of $100,000, provided that the requirement for the cash portion of the minimum net worth amount be set at $750,000. Additionally, the Committee agreed that the insolvency deposit would be counted toward the minimum net worth requirement although not toward the $750,000 cash requirement.

With regard to uncovered expenditures, the Committee adopted the HMO Model Act standard. The Model Act requires that whenever uncovered expenditures exceed 10 percent of total health care expenditures, an entity must create a deposit equal to 120 percent of outstanding liabilities for uncovered expenditures. Rather than being available for a State insurance commissioner, the deposit would be restricted for HCFA's use in the event of an insolvency to pay claims and administration costs.

While the Committee discussed the issues of Federal bankruptcy/State receivership, hold harmless, and continuation of coverage, they concluded that these issues were beyond the scope of the negotiations. Further, Federal bankruptcy and State receivership matters are not within the purview of HCFA. The hold harmless and continuation of benefits provisions will be considered as part of the overall M+C regulation due to be published later this year.

H. Solvency Standards for Rural PSOs

In pre-consensus Committee discussion, there was vigorous discussion of separate solvency standards for rural PSOs. (See § 422.352(c) for a definition of rural PSO.) Some Committee members contended that rural providers would find it particularly difficult to meet the solvency standards, especially the cash requirements. Rural providers, as compared to their urban counterparts tend to have high portions of their assets concentrated in health care delivery assets and intangible assets. To rural PSOs, an excessive cash requirement may amount to an undue barrier to entry.

The Committee's consensus on this issue was to develop one solvency standard for all PSOs. The underlying premise was that the experience of an unexpected, major claim would harm rural PSOs more because rural PSOs tend to have smaller enrollments than urban PSOs, and therefore a smaller revenue base for absorbing sudden financial fluctuations. The Committee believed that financial instability in a rural PSO could be more easily triggered by lower solvency standards.

However, recognizing the unique needs of rural communities, the Committee directed HCFA to solicit public comment on the issue of separate solvency standards for rural PSOs. Thus, we are hereby seeking comments on this matter, particularly on the appropriateness of the net worth and liquidity requirements of this interim final rule for rural PSOs. HCFA is interested in the merit and appropriateness of separate standards, alternative proposals, relevant analysis, and administrative simplicity.

I. Credit for Reinsurance

As directed by the BBA, the Committee considered whether to allow a credit for reinsurance. Several Committee members advocated that reinsurance reduces the risk that PSOs will have to bear and would be particularly valuable during the initial stage where PSOs are likely to have fewer enrollees and claims are harder to predict. Committee members who opposed reinsurance argued that many HMO reinsurance contracts contain termination clauses that are triggered once an organization starts losing money. Underlying this contract issue is a broader problem; namely there would need to be provisions developed for Federal regulation and oversight of PSO reinsurers given the Federal waiver of State licensure. Without proper regulation and safeguards, reinsurance policies could not be relied upon to protect beneficiaries in the event of a financial crisis. Opponents also indicated that reinsurance is an essential part of a sound business plan. Therefore, it should not be treated as an optional credit against the minimum net worth amount. Lastly, to the extent that reinsurance will reduce a PSO's current and projected losses, reinsurance is implicitly recognized in the financial plan. The consensus was not to admit reinsurance as a credit against the minimum net worth amount. The Committee felt that to the extent that reinsurance reduces projected losses, it is implicitly recognized in the financial plan.

J. Financial Solvency Standards Provisions

The requirements of this interim final rule are found in 42 CFR Part 422, Subpart H, Provider-Sponsored Organizations. Here we set forth the solvency requirements for organizations that are applying for and are operating under an M+C contract.

Section § 422.350, *Basis, Scope and Definitions,* is amended to include definitions and terminology for new terms related to the solvency standards for PSOs.

Section § 422.380 sets forth the general requirement that a PSO must have a fiscally sound operation that meets the requirements of the following provisions.

Section 422.382 sets forth the minimum net worth amount requirements. There is a minimum net worth amount requirement for organizations that are in the process of applying for a PSO M+C contract, and another for organizations that are operating as a PSO under an M+C contract.

Paragraph (a) of § 422.382 sets forth the requirements that must be met at the time of application. An organization must have a $1,500,000 minimum net worth amount. This is the same amount that is specified in the HMO Model Act, except that under this regulation, HCFA has the discretion to reduce this amount by up to $500,000 for organizations that at the time of application have available administrative infrastructure that will reduce, control or eliminate administrative costs.

Paragraph (b) of § 422.382 sets forth the requirements that must be met after the effective date of an M+C contract. A PSO must have a minimum net worth amount of at least $1,000,000. The minimum net worth amount is determined by a ''greater of'' test. The

''greater of test'' requires a PSO to have a minimum net worth amount equal to the greater of—

- $1,000,000;
- Two percent of annual premium revenues up to and including the first $150,000,000 of annual premiums and 1 percent of annual premium revenues on premiums in excess of $150,000,000;
- An amount health care expenditures; or
- An amount equal to the sum of 8 percent of annual health care expenditures paid on a non-capitated basis to non-affiliated providers, and 4 percent of annual health care expenditures paid on a capitated basis to non-affiliated providers plus annual health care expenditures paid on a non-capitated basis to affiliated providers. Annual health care expenditures that are paid on a capitated basis to affiliated providers are not included in this calculation. In essence, the ''greater of'' test establishes a minimum net worth requirement above $1,000,000 that varies in proportion to the size of the PSO's operation.

Section 422.382(c) establishes the composition of assets that are needed to meet the minimum net worth requirement. The objective of the minimum net worth requirement is to enable PSOs to avoid a financial crisis or to mitigate the effects of a crisis. To achieve this, organizations applying to become PSOs are required to have on their balance sheets a minimum level of cash or cash equivalents. In paragraph (c)(1) of § 422.382, the minimum cash requirement is set at $750,000 at application, and at $750,000 or 40 percent of the minimum net worth amount after the effective date of the contract. After the effective date of an M+C contract the cash requirement above $750,000 is proportional to the minimum net worth amount. Lower cash requirements were proposed, but the Committee was unable to reach consensus on them. As discussed below, organizations that maintain a higher cash level are permitted to use a greater proportion of intangible assets to meet the minimum net worth requirement.

Other provisions of the paragraph address assets besides cash or cash equivalents that may be included in determining the minimum net worth, and limitations. Paragraph (c)(2) of § 422.382 establishes the proportion of the minimum net worth amount that may be comprised of intangible assets, depending on an organization's cash level. Intangible assets can comprise up to 10 percent of the minimum net worth amount, at the time of application for an organization with $750,000 (and less than $1,000,000) in cash or cash equivalents. However, an organization that has $1,000,000 in cash or cash equivalents at application can satisfy up to 20 percent of its minimum net worth amount requirement with intangible assets. After the effective date of the contract, an organization must maintain the greater of $1,000,000 or 67 percent of the minimum net worth amount in cash or cash equivalents to qualify for the admission of intangible assets up to 20 percent of the minimum net worth amount.

Under paragraph (c)(3) of § 422.382, HCDAs are admissible to satisfy the minimum net worth amount requirement, subject to the cash requirement. They are valued at 100 percent of their value according to GAAP. Section 1856(a) of the Act directed the Secretary to take into account ''the delivery system assets of [provider sponsored organizations].'' The recognition of HCDAs under GAAP, that often times is limited under SAP, was adopted to recognize that large portions of PSOs' assets are HCDAs. The Committee agreed that if the cash requirement were set at the appropriate level, then any perceived risk from recognizing HCDAs was reduced.

Under paragraph (c)(4) of § 422.382, other assets that are not used in the delivery of health care are admissible to satisfy the minimum net worth amount. However, they are admitted at their value according to State SAP which generally are more conservative than GAAP. Because SAP are determined at the State level, organizations will have to follow the accounting methodology approved by the insurance commissioner in the State in which they operate.

As set out in paragraph (c)(5) of § 422.382, an organization does not have to include subordinated debts or subordinated liabilities for the purpose of calculating the minimum net worth. (Subordinated liability is a new concept that the Committee defined to mean claims liablities otherwise due to providers that are retained by the PSO to meet the net worth requirements.) The Committee discussed this provision in the context of provider reimbursement arrangements that withhold a portion of payment contingent upon certain budget or utilization targets being met. The Committee agreed that if these payments are fully subordinated to all other creditors, then they should not be included in the calculation of a PSOs net worth for the purpose of meeting the minimum net worth amount requirement. We believe that this provision is another example how the concept of sweat equity is implicitly considered in these solvency standards.

In paragraph (c)(6) of § 422.382, deferred acquisition costs are not permitted to be included in the calculation of the minimum net worth amount. The Committee believed that in an insolvency situation, these would have little or no value.

Paragraphs (a) (b) and (c) of § 422.384 sets forth the financial plan requirement. The same documents required of Medicare contracting HMOs and CMPs under section 417.120(a)(2) of the Medicare regulations are required here; namely marketing plans, statements of revenue and expense, statements of sources and uses of funds, balance sheets, detailed justifications and assumptions supporting the financial plan, and statements of the availability of financial resources to meet projected losses.

PSOs should anticipate the need to utilize the services of qualified actuaries (e.g., a member in good standing with the American Academy of Actuaries) in (a) the preparation of financial plans consistent with the PSO's business plan, (b) the development of claim costs for the benefits to be offered by the PSO and (c) the analysis of claim liabilities and the necessary liquid assets to meet obligations on a timely basis. Accordingly, the Committee agreed that the financial plan must be satisfactory to HCFA. HCFA expects and, at its discretion, will ascertain that the information contained in the financial plan has been certified by reputable and qualified actuaries.

Paragraph (d) of § 422.384 sets forth the requirement that organizations that are projecting a loss must have the resources to fund those projected losses. This section also defines the conditions under which HCFA will recognize various arrangements as acceptable funding of projected losses. The general rule is that organizations must have on their balance sheets assets that they identify to fund projected losses. Exceptions are made for guarantees, LOCs, and other means provided that certain conditions are met.

Paragraph (e) of § 422.384 sets forth the exception to the ''on the balance sheet'' requirement that applies when guarantees are used to fund projected losses. Guarantees are permitted, but they are subject to a trial period. For the first year after the effective date of an M+C contract any organization using a guarantee must have from the guarantor, in cash or cash equivalents, funds to cover projected losses six months in advance of when needed. For example, prior to the effective date of an M+C contract, a PSO must have funding from

the guarantor equal to the projected losses for the first two quarters (6 months) of the contract. Before the start of the second quarter, funding of projected losses through the third quarter must be added to the balance sheet of the PSO. Because of the time it takes to bring a new contractor onto the HCFA systems, the first two quarters funding will need to be in the PSO, that is, on its balance sheet at least 45 days before the effective date of the contract. Quarters, or 90-day periods, will be counted from the effective date of a PSO's M+C contract.

If guarantee funding is timely during the first year, a PSO may reduce or eliminate the period of pre-funding in future years by providing notice to HCFA. Upon receipt of such notice, HCFA will have up to 60 days in which to modify or reject any changes in the period of prefunding. If the guarantee funding is not timely, then HCFA may take appropriate action including requiring an organization to use other methods or timing to fund projected losses. Lastly, guarantors and guarantees must meet the requirements specified under § 422.390, discussed below.

Paragraph (f) of § 422.384 sets forth the exception to the ''on the balance sheet'' requirement that applies when LOCs are used to fund projected losses. LOCs are admissible to fund projected losses on the condition that they are provided by a high quality source and be irrevocable, unconditional and satisfactory to HCFA. Additionally, LOCs must be capable of being promptly paid upon presentation of a sight draft under the LOCs without further reference to any other agreement, document or entity. The Committee agreed that HCFA should have the discretion to accept or reject a letter of credit.

Paragraph (g) of § 422.384 sets forth the exception to the ''on the balance sheet'' requirement that applies when other means are used to fund projected losses. Other means of funding such as LOCs credit, legally binding capital contribution agreements, and other legally binding contracts of similar quality are admissible to fund projected losses. However, these methods are available only after an organization has had an M+C contract for at least one year.

Paragraph (h) of § 422.384 sets forth the general rule that HCFA will have the discretion to decide whether a PSO is using guarantees, LOCs or other means in a combination or sequence that HCFA deems appropriate. We note here that the BBA directed the Secretary to take into account alternative means of protecting against insolvency including guarantees, LOCs and other means. The Committee considered whether to admit guarantees, LOCs, and other means to reduce the minimum net worth amount, as well as to fund projected losses. However, the consensus was to recognize them only toward meeting the requirement to fund projected losses.

Section 422.386(a) sets forth the general liquidity requirement that a PSO must have sufficient cash flow to meet its financial obligations as they become due and payable. This requirement is consistent with the standard that is applied to Medicare contracting HMOs and CMPs under 42 CFR § 417.120.

Paragraph (b) of § 422.386 contains three tests to determine whether an organization is able to meet its financial obligations as they become due and payable: (a) history for timeliness in meeting current obligations, (b) the extent to which a PSO maintains a current ratio of 1:1, and (c) the availability of outside financial resources to the PSO. The Committee adopted (a) because such a history is a strong signal of management's commitment to maintaining a fiscally sound organization.

The second test requires more discussion. We define ''current ratio'' as total current assets divided by total current liabilities, where the word ''current'' means less than one year. A current ratio of 1:1 means that an organization's current assets are sufficient to meet its current liabilities. The possibility exists that in the course of normal business operations PSOs may miss the current ratio slightly for short, nonrecurring periods of time. In light of this, HCFA is using a 1:1 current ratio as a target rather than as an absolute standard. Accordingly, HCFA will monitor PSOs that drop below the 1:1 ratio and act where a PSO experiences a long-term, declining trend or a sudden, large decline in its current ratio.

The use of trends in the current ratio allows HCFA to recognize certain situations where current assets do not have to equal or exceed current liabilities. For HMOs and PSOs in their early years, the reported current ratio results will likely produce misleading trends. The amount of pre-funding of projected losses ''within'' versus ''outside'' the organization may change over time, distorting trends. Changing patterns of liabilities (for example, 30-day business expenses unpaid or estimates of unreported claims) can also distort the current ratio from one based on consistent underlying data. Consequently, the PSO has an obligation to monitor underlying true trends and to provide such information, together with a projection of continuing current liabilities consistent with its business plans. The information should be certified by a qualified actuary and presented to HCFA prior to the filing of a timely financial report with a current ratio below standard.

The third test for evaluating liquidity highlights in several ways the importance of having outside financial resources available to a PSO. First, such resources fill a practical role by providing a cushion in the event of a financial crisis. Second, if such resources are available from a parent or affiliate organization, it signals a continuing commitment to the PSO. Third, the availability of such resources from outside the corporation, either from a private or a commercial source, indicates continuing market confidence that the organization is a viable ongoing business concern.

Paragraph (c) of § 422.386 requires that if HCFA determines that an organization is not in compliance with the liquidity requirement, it will require the organization to initiate corrective action to pay all overdue obligations.

Paragraphs (d) and (e) of § 422.386 specifies that corrective action can include requiring the organization to change the distribution of its assets, reduce its liabilities, secure additional funding, or secure funding from new funding sources.

Section 422.388 sets forth the deposit requirements to provide protection in the event of an insolvency. Paragraph (a) of § 422.388 establishes an insolvency deposit that organizations are required to make at the time of application and maintain for the duration of the M+C contract. The insolvency deposit is $100,000. The deposit must be restricted to use in the event of insolvency to help assure continuation of services or pay costs associated with receivership or liquidation. At the time of application and thereafter, upon HCFA's request, the organization must provide HCFA with proof of the insolvency deposit, in a form that HCFA considers appropriate.

Paragraph (b) of § 422.388 establishes an uncovered expenditures deposit requirement. The amount of uncovered expenditures that a PSO experiences will vary, and this deposit is required any time that they exceed 10 percent of the PSO's total health care expenditures. The deposit must at all times have a fair market value of an amount that is 120 percent of the PSO's outstanding liability for uncovered expenditures for enrollees, including incurred, but not reported claims. The deposit must be calculated as of the first day of each month required and maintained for the remainder of each month required. If a

quarterly report is not otherwise required, a report must be filed within 45 days of the end of the calendar quarter to demonstrate compliance. The deposit must be restricted for HCFA's use to protect the interests of the PSO's Medicare enrollees and to pay the costs associated with administering the insolvency. The deposit is restricted and in trust and may be used only as provided in § 422.388.

Under paragraph (c) of § 422.388 the deposits may be used to satisfy the organization's minimum net worth requirement. Under paragraph (d) of § 422.388 all income from the deposits or trust accounts are considered assets of the organization. Upon HCFA's approval, the income from the deposits may be withdrawn.

Paragraph (e) of § 422.388 sets forth requirements that upon HCFA's written approval, the income from the deposits may be withdrawn if a substitute deposit of cash or securities of equal amount and value is made, the fair market value exceeds the amount of the required deposit, or the required deposit is reduced or eliminated.

The deposit requirement for uncovered expenditures is triggered by a historical trend analysis that indicates such expenditures are comprising an increasing portion of total health care expenditures. The Committee adopted the HMO Model Act language for the uncovered expenditures deposit.

Section 422.390 sets forth the requirements for guarantors and guarantees, which under § 422.384(e), above, can be used to fund projected losses. We are exercising caution in the use of guarantees because we will have to monitor the financial viability of the PSO and the guarantor as well. We believe we have selected a screening approach that recognizes financially strong guarantors and protects Medicare enrollees, yet permits affiliated providers or parent organizations to support the PSO with financial backing.

Paragraph (a) of § 422.390 vests HCFA with the discretion to approve or deny the use of a guarantor. Paragraph (b) of § 422.390 initiates the approval process with a request from the PSO, including financial information on the guarantor.

Paragraph (c) of § 422.390 sets forth the requirements that a guarantor must meet to be licensed and authorized to conduct business within a State or territory of the United States. The guarantor must be solvent and not be under any Federal bankruptcy or State proceedings, and have a net worth of at least three times the amount of the guarantee.

A distinction is made between guarantors that are and are not regulated by a State insurance commissioner. If regulated by a State insurance commissioner, the guarantor's net worth calculation need only exclude from its assets the value of all guarantees, investments in and loans to organizations covered by guarantees. But, if a guarantor is not regulated by a State insurance commissioner, then it must also exclude the value of guarantees, investments and loans to related parties (i.e., subsidiaries and affiliates) from its assets to calculate its net worth. We believe these requirements ensure the stability and financial strength of the guarantor without being overly restrictive.

Paragraph (d) of § 422.390 contains provisions for the guarantee document to be submitted to HCFA by the PSO, and signed by the guarantor. This document is the written commitment of the guarantor to unconditionally fulfill its financial obligation to the PSO on a timely basis.

In paragraph (e) of § 422.390, the PSO is required to routinely report financial information on the guarantor.

Paragraph (f) of § 422.390 sets forth the requirements for modification, substitution, and termination of the guarantee. A PSO must have HCFA's approval at least 90 days before the proposed effective date of the modification, substitution, or termination; demonstrate to HCFA that insolvency will not result; and demonstrate how the PSO will meet the requirements of this section within 15 days, and if required by HCFA, meet a portion of the applicable requirements in less than the time period granted.

Paragraph (g) of § 422.390 establishes conditions that must be met if the guarantee is nullified. If at any time the guarantor or the guarantee ceases to meet the requirements of § 422.390, HCFA will notify the PSO that it ceases to recognize the guarantee document. In the event of nullification, a PSO must meet the applicable requirements of this section within 15 business days and if required by HCFA, meet a portion of the applicable requirements in less than the above time period. These requirements and conditions are not only good business practices, but also protect Medicare enrollees by ensuring that a PSO's financial backing is sound.

IV. Applicability of These Rules

The provisions of this rule apply only to certain PSOs and do not apply to any other type of Medicare applicant or contracting entity.

Organizations that may be considered PSOs and that meet any of the criteria as set forth in § 422.372 may be eligible for a waiver of State licensure. As discussed earlier, an organization interested in entering into a contract with Medicare as a PSO must first contact the appropriate State agency and, in most cases, submit an application for a State license, or authority. A PSO that is denied licensure (and the denial is related to any of the criteria cited) or is denied the opportunity to apply for licensure, should submit a request for a waiver to HCFA. Organizations that have their waiver request approved by HCFA may then submit a PSO application. The PSO application contains provisions for demonstrating compliance with the PSO definitions and solvency requirements in addition to other contracting requirements (a supplemental application may be necessary after the June regulation is published). It is during the application process that an organization will be determined to qualify as a PSO for purposes of Medicare contracting under Part C of the Act. The waiver will take effect with signing of the M+C contract.

The solvency standards established in this rule apply to organizations which have had a waiver approved, as described above, and are applying for a Medicare PSO contract, as well as waivered PSOs with a Medicare contract in effect. These rules were developed through negotiated rulemaking specifically for risk-bearing entities that will enroll primarily beneficiaries of the Medicare program. Federal and State government agencies that may contemplate use of these solvency standards for other purposes or other populations should review them carefully, and consider the nature of the health plans and the populations they will serve.

Provider-sponsored managed care plans that obtain a State license should apply directly for an M+C contract by completing the application for HMO/PPOs/State-licensed PSOs (i.e., this is the same application as used by HMOs). These entities, whether licensed as a PSO or HMO or other managed care plan recognized by the State, will not have to demonstrate compliance with the PSO definitions in § 422.350 through 356, or with the PSO solvency standards. However, State-licensed PSOs or State-licensed managed care plans that wish to meet the lower minimum enrollment standard will have to meet the definitions criteria of the PSO application. These ''State-licensed PSOs'' must meet the solvency standards as required by their State, not the Medicare PSO solvency standards as established in this interim final rule.

V. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this interim final rule as required by Executive Order 12866 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, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental and public health and safety effects; distributive impacts and equity). The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief for small businesses, unless we certify that the regulation would 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 non-profit 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 such 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.

We prepared this impact analysis because of the probability that these waiver requirements and solvency standards may have an impact on certain hospitals, physicians, health plans and other providers. We are preparing to publish a regulation outlining the overall provisions of the M+C program. That regulation will consider the impacts of PSOs and other new provider types in greater detail than is provided in this regulation. The following analysis, in combination with the rest of this interim final rule with comment period, constitutes 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 meeting 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 42 CFR 422.350. Organizations that meet these definitional requirements can apply for a Federal waiver and a M+C contract. Having defined the term PSO in earlier regulation, this rule has two broad purposes: (1) To establish the requirements and process necessary for organizations to obtain Federal waiver of license requirements for risk-bearing entities; and (2) to establish standards for financial solvency to which such Federally waived organizations must adhere.

With regard to the impact of the waiver requirements and process, we emphasize three important underlying factors. First, waivers cannot exceed 36-months in duration and are not renewable. Second, the Secretary's authority to grant waivers ends November 1, 2002. Finally, the Secretary can grant waivers only to organizations that have first applied for a State license as a risk bearing entity, but were denied by virtue of three things: (1) States' failure to act timely on the license application; (2) States' denial of the application for ''discriminatory'' reasons; or (3) States'' denial for failure to meet different solvency standards than are promulgated here. The first two factors (i.e., the duration of the waiver and the waiver authority) are important to this impact analysis because they indicate that, under current law, no organization will operate under a Federal waiver after November 1, 2005. The third fact regarding eligibility for a Federal waiver may have an effect on the waiver application rate.

The solvency standards have an even narrower focus than the waiver requirements because the former only effect organizations that have received a Federal waiver and are either applying for or actually have received an M+C contract. Within this smaller population, organizations will be affected differently or not at all depending upon the status of the solvency standards in their respective States. 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

HCFA discussion with the industry as part of the negotiated rule making process suggests widespread interest in the benefits of becoming a PSO (i.e., waiver of State licensure and lower minimum enrollment standards). This regulation benefits certain health services providers that have been denied a State risk-bearing license by creating an opportunity for them to obtain a Federal waiver of the State license requirement and participate in the M+C program as contractors. As such, this regulation provides means for such providers to gain access to a market from which they otherwise would be excluded. While clearly not possible to predict how many organizations will attempt to take advantage of this new opportunity, we have seen estimates that the first year application rate will be between 25 and 150 organizations. For several reasons, we estimate between 25 and 50 organizations will apply. In the first year many organizations will be interested, but we expect that the ''learning curve'' necessary to gain familiarity with this new program will restrain the first year application rate. Second, the waiver process, which for this discussion includes the prerequisite State application process, and M+C application process, are time intensive steps. At a minimum, these steps could take up to 6 six months to complete. After the first year, however, the number of applicant organizations will increasingly be a function of PSOs' performance and their reception in the market place.

We do not expect that the waiver process will create a substantial additional burden for organizations. For one thing, the waiver process is not a mandatory burden. The waiver process affects only organizations that affirmatively choose to become Federally waived PSOs. For those organizations that apply, we estimate that the waiver application will require less than 20 hours to complete. However, we do believe that waiver applicants will face the additional task of documenting their denial of a State license.

Regarding the application for an M+C contract, there are existing application requirements for organizations that seek to contract with Medicare under section 1876 of the Act. We do not believe that the M+C application process, which will be essentially the same, will be any

more burdensome than an application under section 1876 of the Act. To the extent that organizations that previously have not contracted with the Medicare program choose to seek an M+C contract, the application will be a new task. Given the new provider focus of this initiative, it is plausible to expect that many applicants have not previously contracted directly with Medicare. However, we believe that the benefit to Medicare beneficiaries gained by screening potential contractors outweighs the burden associated with having a reasonable application process in place.

2. Effects on the Market Place

We expect that the advent of PSOs will increase market competition among health care service providers, albeit only slightly. The increase in competition is expected to be limited for four reasons. First, since Federally waived PSOs are limited to serving Medicare enrollees, any changes in competition will be primarily concentrated in the Medicare sector of the health services delivery market. We note that there may be crossover effects to the extent that service providers' success with Medicare may affect their success generally.

Second, we believe that this rule, primarily concerns the structure of entities that can participate in the market for Medicare enrollees. We expect transfer effects; that is, existing providers changing corporate form in order to avail themselves of PSO status. However, we do not anticipate a significant increase in the aggregate market place capacity of providers or health service delivery assets. The providers and hospitals that will form PSOs are coming from the same pool that are currently providing services. In addition, the principle effect on revenues will be a change in the source of payment from Medicare parts A and B to the new part C.

Third, to the extent that these solvency standards are similar to existing standards, the potential transfer effect will be limited. Since standards vary greatly by State, and State standards are evolving, it is difficult to assess the relative effect of the instant standards. We note, however, that with several key exceptions (e.g., different initial minimum net worth requirement and a lower insolvency deposit) the instant standards track the HMO Model Act. Therefore, we do not believe there will be a significant transfer 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 insure that PSOs have the financial resources to provide adequate quality care and to reduce the possibility of disrupting beneficiary care.

Finally, in the preamble to this regulation, HCFA agreed that it will consider the NAIC's Risk Based Capital formula as well as the codification of Statutory Accounting Practices when these methodologies become available. If one or both of these methodologies are adopted for the PSO solvency standards, it would help to narrow any existing differences between State-level and Federal solvency standards.

3. Effects on States

This regulation will affect States in several ways, some of which are offsetting. First, we expect that a few States may have to reduce their application turnaround times in order to avoid tolling the 90-day limit for State review of a waiver application. However, based upon conversations with State insurance commissioners, we believe in many States the application turnaround time is at or near the 90-day limit.

The second effect will be a reduction in States' oversight burden. For PSOs that obtain a Federal waiver, responsibility for monitoring their financial solvency will be transferred from the States to HCFA. This is 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. To minimize the chances of a gap in financial oversight, HCFA is negotiating with the State Insurance Commissioners via the NAIC to develop a Memorandum of Understanding regarding sharing information on the financial solvency of PSOs.

Lastly, it has been suggested that this interim final rule may pressure States to adopt solvency standards that mirror the Federal standards. Currently, we do not have a good measure of the extent to which this will occur. However, we emphasize that the negotiated rulemaking committee developed these solvency standards solely in the context of Federally waived PSOs that will provide services under an M+C contract. States are cautioned not to adopt these standards for general application without first considering their affect on the overall health services delivery market in their jurisdictions.

4. Effects on Beneficiaries

We expect that this regulation will have a positive effect on Medicare beneficiaries since it creates a new managed care option. We expect that the principle source for enrollees for newly formed PSOs will be current Medicare fee-for-service enrollees. 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. Conclusion

By enacting the BBA provisions related to PSOs, Congress has indicated its belief in the potential for provider controlled organizations to improve the delivery of services to Medicare beneficiaries. While expanding the options available to Medicare beneficiaries, we believe that this regulation provides an opportunity for providers to test their ability to manage the delivery of health care services. The negotiated rulemaking Committee, which included representatives from the entire range of interested parties, reached consensus on provisions that were acceptable when considered as a whole. It is safe to say that Committee members considered the impact of these provisions on their respective constituencies during the negotiating process.

We conclude that this regulation will have an undeterminable impact on small health service providers. However the provisions of this interim 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 proposed rule will not result in a significant economic impact on a substantial number of small entities and would 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.

VI. Collection of Information Requirements

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. The Agency cannot reasonably comply with the normal clearance procedures because of the statutory requirement, as set forth in section 1856 of Balanced Budget Act of 1997, to implement these requirements on June 1, 1998.

HCFA is requesting OMB review and approval of this collection within eleven working days, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below, within ten working days of publication of this notice in the **Federal Register**.

During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR. 1320.5.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements discussed below.

Section 422.374(a), requires an organization to submit a waiver request if it has been denied licensure as a risk-bearing entity by the State in which it operates or wishes to operate. To facilitate the implementation of the requirements of this section we developed a model waiver request form and submitted it to OMB for emergency clearance in compliance with section 3506(c)(2)(a) of Paperwork Reduction Act of 1995. OMB has concurred with the model request form, and the form and instructions are currently on view on the HCFA web site, the address of which is provided in section II.A.3 of this document. The OMB approval number is 0938–0722 and is referenced on the document.

A modification of this waiver request form is necessary to incorporate the fourth criterion for a waiver of State licensure as established in this interim final rule. The additional criterion allows a PSO-type organization to forego a lengthy application process with the State if the State informs the organization in writing that such an application will not be reviewed. As part of the waiver request, the organization will be required to submit a copy of the written communication from the State. This criterion is mentioned in the purpose section of the form, and, with publication of this rule, we can add it to the check list in section III, Waiver Eligibility. We intend to submit this modification to OMB in the near future.

Section 422.382(c) establishes the composition of assets the organization must have at the time it applies to contract with HCFA as a PSO. The organization must demonstrate that it has the required minimum net worth amount as determined under paragraph (c), demonstrate that it will maintain at least $750,000 of the minimum net worth amount in cash or cash equivalents, and demonstrate that after the effective date of a PSO's M+C contract, a PSO will maintain the necessary minimum net worth.

Section 422.384 requires that at the time of application, an organization must submit a financial plan acceptable to HCFA. The financial plan must include a detailed marketing plan; statements of revenue and expense on an accrual basis; a cash flow statement; balance sheets; the assumptions in support of the financial plan; and if applicable, statements of the availability of financial resources to meet projected losses. The financial plan must cover the first 12 months after the estimated effective date of a PSO's M+C contract; or if the PSO is projecting losses, cover 12 months beyond the period for which losses are projected. Except for the use of guarantees, LOC, and other means as provided in paragraphs (e), (f), (g) and (h) of § 422.384, an organization must demonstrate that it has the resources for meeting projected losses on its balance sheet in cash or a form that is convertible to cash in a timely manner, in accordance with the PSO's financial plan.

Guarantees will be an acceptable resource to fund projected losses, provided that the guarantor complies with the requirements in paragraph (e)(2) of this section, and the PSO, in the third quarter, notifies HCFA and requests a reduction in the period of advance funding of projected losses.

Section 422.386 sets forth the general liquidity requirement that at the time of application the PSO must demonstrate that it has sufficient cash flow to meet its financial obligations as they become due and payable. To meet this requirement HCFA will consider: the PSO's timeliness in meeting current obligations, the extent to which the PSO's current ratio of assets to liabilities is maintained at 1:1 and whether there is a decline in the current ratio over time, and the availability of outside financial resources to the PSO.

Section 422.388 sets forth the deposit requirements to provide protection in the event of an insolvency. At the time of application, an organization must demonstrate that they have deposited $100,000 in cash or securities (or any combination thereof) into an account in a manner that is acceptable to HCFA, and demonstrate that the deposit will be restricted only to use in the event of insolvency to help assure continuation of services or pay costs associated with receivership or liquidation.

At the time of the PSO's application for an M+C contract and, thereafter, upon HCFA's request, a PSO must provide HCFA with proof of the insolvency deposit, such proof to be in a form that HCFA considers appropriate.

If at any time uncovered expenditures exceed 10 percent of a PSO's total health care expenditures, then the PSO must demonstrate in a manner acceptable to HCFA that it has placed an uncovered expenditures deposit into an account with an organization or trustee.

The PSO must also demonstrate that, at all times the deposit will have a fair market value of an amount that is 120 percent of the PSO's outstanding liability for uncovered expenditures for enrollees, including incurred, but not reported claims; the deposit will be calculated as of the first day of each month required and maintained for the remainder of each month required; if a PSO is not otherwise required to file a quarterly report, it must file a report within 45 days of the end of the calendar quarter with information sufficient to demonstrate compliance with this section; the deposit required under this section will be restricted and in trust and may be used only as provided under this section.

As stated above, the burden associated with these provisions will be

captured as part of the M+C PSO application and/or quarterly financial reporting processes, similar to section 1876 HMO and CMP contractor applications and quarterly financial reporting processes. Based on section 1876 of the Act, we estimate the burden associated with the submission of the application to be 100 hours per application and 62 annual hours per organization to submit their quarterly financial report. Based upon the current volume of waiver reporting workload, we estimate that on an annual basis, we will receive 25 to 50 applications and 25 organizations will contract with us and will be required to submit quarterly financial reports.

Under § 422.388(d) PSOs may submit a written request to withdraw income from the solvency deposits. We anticipate that, on an annual basis, we will receive less than 10 requests. Therefore, these requirements are not subject to the Paperwork Reduction Act as defined in 5 CFR 1320.3(c).

Under § 422.388(e) a PSO may submit a written request to withdraw or substitute a deposit. We anticipate that, on an annual basis, we will receive less than 10 requests. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c).

Under § 422.390(b), in order to apply to use the financial resources of a guarantor, a PSO must submit to HCFA, documentation that the guarantor meets the requirements for a guarantor under paragraph (c) of this section; and the guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the guarantor's balance sheets, profit and loss statements, and cash flow statements. We believe that the initial burden associated with this activity is most likely incurred during the application process, for which we have previously estimated the aggregate burden. We expect that less than 10 PSOs per year will incur this burden in subsequent years. Therefore, these requirements are not subject to the Paperwork Reduction Act as defined in 5 CFR 1320.3(c).

Under § 422.390(d), if the guarantee request is approved, a PSO must submit to HCFA a written guarantee document signed by an appropriate authority of the guarantor. The guarantee document must state the financial obligation covered by the guarantee; agree to unconditionally fulfill the financial obligation covered by the guarantee and not subordinate the guarantee to any other claim on the resources of the guarantor; declare that the guarantor will act on a timely basis (that is, in not more than 5 business days) to satisfy the financial obligation covered by the guarantee; and meet other conditions as HCFA may establish from time to time. We believe that the initial burden associated with this activity is most likely incurred during the application process, for which we have previously estimated the aggregate burden. We expect that less than 10 PSOs per year will incur this burden in subsequent years. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c)

A PSO must submit to HCFA the current internal financial statements and annual audited financial statements of the guarantor according to the schedule, manner, and form that HCFA requests.

A PSO cannot modify, substitute or terminate a guarantee unless the PSO requests HCFA's approval at least 90 days before the proposed effective date of the modification, substitution, or termination; demonstrates to HCFA's satisfaction that the modification, substitution, or termination will not result in insolvency of the PSO; and demonstrates how the PSO will meet the requirements of this section.

The public will be afforded several subsequent comment periods in future publications of **Federal Register** notices announcing our intention to seek OMB approval for the application and quarterly reporting information collection requirements, including a modified version of the National Data Reporting Requirements (the Orange Blank), that will be submitted to OMB in the near future.

We have submitted a copy of this rule to OMB for its review of the information collection requirements above. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, E-mail your request, including your address, phone number and HCFA regulation identifier HCFA–1011, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

As noted above, comments on these information collection and record keeping requirements must be mailed and/or faxed to the designee referenced below, within ten working days of publication of this collection in the **Federal Register**:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850. *Attn:* John Burke HCFA–1011. *Fax Number:* (410) 786–1415, and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attn:* Allison Herron Eydt, HCFA Desk Officer. *Fax Number:* (202) 395–6974 or (202) 395–5167

VII. Waiver of Notice of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule are made final. Section 1871(b) of the Act, however, provides that publication of a notice of proposed rulemaking is not required before issuing a final rule where a statute specifically permits a regulation to be issued in interim final form. Section 1856(a)(1) of the Act, as added by section 4001 of the BBA, directs the Secretary to establish the solvency standards for PSOs on an expedited basis using a negotiated rulemaking process. Section 1856(a)(8) provides for the publication of solvency standards as an interim final rule, with an opportunity for comment to follow. Under section 1856(a)(3), the ''target date'' for publication of this rule was April 1, 1998. We are promulgating the solvency provisions in this rule according to the expressed interim final rule authority in section 1856(a)(8).

Section 1856(b)(1) also provides for the publication of other standards implementing the new M+C program in Part C on an interim final basis, with an opportunity for comment to follow. The PSO waiver provisions in this rule are being promulgated according to this latter expressed interim final rule authority. In addition, we may waive publication of a notice of proposed rulemaking if we find good cause that prior notice and comment are impractical, unnecessary, or contrary to public interest. As discussed earlier in this preamble, HCFA and the Committee believe that we need to establish the PSO waiver process early in order to allow the sequence of waiver request, application, and contract signing to occur, and to have PSOs initiate operations upon implementation of the M+C program. Further, we determined that entities considering applying to become PSOs under the M+C program need to know whether and how they can qualify to participate in the program in order to establish the complex organizational structures necessary under the law prior to application. Many of these entities also need to seek State licensure or a Federal waiver.

Given the time required for these events, and the clear impetus from the Congress for implementation of the M+C program, we believe that it is impractical and contrary to the public interest to publish a notice of proposed rulemaking before establishing the Federal waiver and solvency standards set forth in this interim final rule. We are providing a 60-day period for public comment.

VIII. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects in 42 CFR Part 422

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

42 CFR Part 422 is amended as set forth below:

PART 422—MEDICARE+CHOICE PROGRAM

Subpart H—Provider-Sponsored Organizations

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

Authority: Secs. 1851, 1855 and 1856 of the Social Security Act (42 U.S.C. 1302, 1395w–21 through 1395w–27, and 1395hh).

2. Section 422.350(b) is amended by adding the following definitions in alphabetical order:

§ 422.350 Basis, scope, and definitions.

* * * * *

(b) * * *

Capitated basis is a payment method under which a fixed per member, per month amount is paid for contracted services without regard to the type, cost or frequency of services provided.

Cash equivalent means those assets excluding accounts receivables, which can be exchanged on an equivalent basis as cash, or converted into cash within 90 days from their presentation for exchange.

* * * * *

Current ratio means total current assets divided by total current liabilities.

Deferred acquisition costs are those costs incurred in starting or purchasing a business. These costs are capitalized as intangible assets and carried on the balance sheet as deferred charges since they benefit the business for periods after the period in which the costs were incurred.

* * * * *

Generally accepted accounting principles (GAAP) means broad rules adopted by the accounting profession as guides in measuring, recording, and reporting the financial affairs and activities of a business to its owners, creditors and other interested parties.

Guarantor means an entity that—

(1) Has been approved by HCFA as meeting the requirements to be a guarantor; and

(2) Obligates its resources to a PSO to enable the PSO to meet the solvency requirements required to contract with HCFA as an M+C organization.

Health care delivery assets (HCDAs) means any tangible assets that are part of a PSO's operation, including hospitals and other medical facilities and their ancillary equipment, and such property as may be reasonably required for the PSO's principal office or for such other purposes as the PSO may need for transacting its business.

* * * * *

Insolvency means a condition where the liabilities of the debtor exceed the fair valuation of its assets.

M+C stands for Medicare+Choice.

Net Worth means the excess of total assets over total liabilities, excluding fully subordinated debt or subordinated liabilities.

* * * * *

Qualified Actuary means a member in good standing of the American Academy of Actuaries or a person recognized by the Academy as qualified for membership, or a person who has otherwise demonstrated competency in the field of actuarial determination and is satisfactory to HCFA.

Statutory accounting practices means those accounting principles or practices prescribed or permitted by the domiciliary State insurance department in the State that PSO operates.

Subordinated debt means an obligation that is owed by an organization, that the creditor of the obligation, by law, agreement, or otherwise, has a lower repayment rank in the hierarchy of creditors than another creditor. The creditor would be entitled to repayment only after all higher ranking creditors' claims have been satisfied. A debt is fully subordinated if it has a lower repayment rank than all other classes of creditors.

Subordinated liability means claims liabilities otherwise due to providers that are retained by the PSO to meet net worth requirements and are fully subordinated to all other creditors.

Uncovered expenditures means those expenditures for health care services that are the obligation of an organization, for which an enrollee may also be liable in the event of the organization's insolvency and for which no alternative arrangements have been made that are acceptable to HCFA. They include expenditures for health care services for which the organization is at risk, such as out-of-area services, referral services and hospital services. However, they do not include expenditures for services when a provider has agreed not to bill the enrollee.

3. A new § 422.370 is added to read as follows:

§ 422.370 Waiver of State licensure.

For an organization that seeks to contract as an M+C plan under this subpart, HCFA may waive the State licensure requirement of section 1855(a)(1) of the Act if—

(1) The organization requests a waiver no later than November 1, 2002; and

(2) HCFA determines there is a basis for a waiver under § 422.372.

4. A new § 422.372 is added to read as follows:

§ 422.372 Basis for waiver of State licensure.

In response to a request from an organization and subject to paragraphs (a) and (e) of § 422.374, HCFA may waive the State licensure requirement if the organization has applied (except as provided for in paragraph (d) of this section) for the most closely appropriate State license or authority to conduct business as an M+C plan as set forth in section 1851(a)(2)(A) of the Act and any of the following conditions are met:

(a) *Failure to act timely on application.* The State failed to complete action on the licensing application within 90 days of the date the State received a substantially complete application.

(b) *Denial of application based on discriminatory treatment.* The State has—

(1) Denied the licensure application on the basis of material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(2) Required, as a condition of licensure, that the organization offer any product or plan other than an M+C plan.

(c) *Denial of application based on different solvency requirements.* (1) The State has denied the licensure

application, in whole or in part, on the basis of the organization's failure to meet solvency requirements that are different from those set forth in §§ 422.380 through 422.390; or

(2) HCFA determines that the State has imposed, as a condition of licensure, any documentation or information requirements relating to solvency or other material requirements that are different from the requirements, procedures, or standards set forth by HCFA to implement, monitor and enforce §§ 422.380 through 422.390.

(d) The appropriate State licensing authority has notified the organization in writing that it will not accept their licensure application.

5. A new § 422.374 is added to read as follows:

§ 422.374 Waiver request and approval process.

(a) *Substantially complete waiver request.* The organization must submit a substantially complete waiver request that clearly demonstrates and documents its eligibility for a waiver under § 422.372.

(b) *Prompt action on waiver request.* The organization will be notified in writing within 60 days of having submitted to HCFA a substantially complete waiver request whether the waiver request has been granted or denied.

(c) *Subsequent waiver requests.* An organization that has had a waiver request denied, may submit subsequent waiver requests until November 1, 2002.

(d) *Effective date.* A waiver granted under § 422.370 will be effective on the effective date of the organization's M+C contract.

(e) *Consistency in application.* HCFA reserves the right to revoke waiver eligibility if it subsequently determines that the organization's M+C application is significantly different from the application submitted by the organization to the State licensing authority.

6. A new § 422.376 is added to read as follows:

§ 422.376 Conditions of the waiver.

A waiver granted under this section is subject to the following conditions:

(a) *Limitation to State.* The waiver is effective only for the particular State for which it is granted and does not apply to any other State. For each State in which the organization wishes to operate without a State license, it must submit a waiver request and receive a waiver.

(b) *Limitation to 36-month period.* The waiver is effective for 36 months or through the end of the calendar year in which the 36 month period ends unless it is revoked based on paragraph (c) of this section.

(c) *Mid-period revocation.* During the waiver period (set forth in paragraph (b) of this section), the waiver is automatically revoked upon—

(1) Termination of the M+C contract;

(2) The organization's compliance with the State licensure requirement of section 1855(a)(1) of the Act; or

(3) The organization's failure to comply with § 422.378.

7. A new § 422.378 is added to read as follows:

§ 422.378 Relationship to State law.

(a) *Preemption of State law.* Any provisions of State law that relate to the licensing of the organization and that prohibit the organization from providing coverage under a contract as specified in this subpart, are superseded.

(b) *Consumer protection and quality standards.* (1) A waiver of State licensure granted under this subpart is conditioned upon the organization's compliance with all State consumer protection and quality standards that—

(i) Would apply to the organization if it were licensed under State law;

(ii) Generally apply to other M+C organizations and plans in the State; and

(iii) Are consistent with the standards established under this part.

(2) The standards specified in paragraph (b)(1) of this section do not include any standard preempted under section 1856(b)(3)(B) of the Act.

(c) *Incorporation into contract.* In contracting with an organization that has a waiver of State licensure, HCFA incorporates into the contract the requirements specified in paragraph (b) of this section.

(d) *Enforcement.* HCFA may enter into an agreement with a State for the State to monitor and enforce compliance with the requirements specified in paragraph (b) of this section by an organization that has obtained a waiver under this subpart.

8. A new § 422.380 is added to read as follows:

§ 422.380 Solvency standards.

General rule. A PSO or the legal entity of which the PSO is a component that has been granted a waiver under § 422.370 must have a fiscally sound operation that meets the requirements of §§ 422.382 through 422.390.

9. A new § 422.382 is added to read as follows:

§ 422.382 Minimum net worth amount.

(a) At the time an organization applies to contract with HCFA as a PSO under this part, the organization must have a minimum net worth amount, as determined under paragraph (c) of this section, of:

(1) At least $1,500,000, except as provided in paragraph (a)(2) of this section.

(2) No less than $1,000,000 based on evidence from the organization's financial plan (under § 422.384) demonstrating to HCFA's satisfaction that the organization has available to it an administrative infrastructure that HCFA considers appropriate to reduce, control or eliminate start-up administrative costs.

(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—

(1) One million dollars;

(2) Two percent of annual premium revenues as reported on the most recent annual financial statement filed with HCFA for up to and including the first $150,000,000 of annual premiums and 1 percent of annual premium revenues on premiums in excess of $150,000,000;

(3) An amount equal to the sum of three months of uncovered health care expenditures as reported on the most recent financial statement filed with HCFA; or

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

(i) Eight percent of annual health care expenditures paid on a non-capitated basis to non-affiliated providers; and

(ii) Four percent of annual health care expenditures paid on a capitated basis to non-affiliated providers plus annual health care expenditures paid on a non-capitated basis to affiliated providers.

(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 under paragraphs (a) and (b)(4) of this section.

(c) *Calculation of the minimum net worth amount*—(1) *Cash requirement.* (i) At the time of application; the organization must maintain at least $750,000 of the minimum net worth amount in cash or cash equivalents.

(ii) After the effective date of a PSO's M+C contract, a PSO must maintain the greater of $750,000 or 40 percent of the minimum net worth amount in cash or cash equivalents.

(2) *Intangible Assets.* An organization may include intangible assets, the value of which is based on Generally Accepted Accounting Principles (GAAP), in the minimum net worth amount calculation subject to the following limitations—

(i) *At the time of application.* (A) Up to 20 percent of the minimum net worth amount, provided at least $1,000,000 of the minimum net worth amount is met through cash or cash equivalents; or

(B) Up to 10 percent of the minimum net worth amount, if less than $1,000,000 of the minimum net worth amount is met through cash or cash equivalents, or if HCFA has used its discretion under paragraph (a)(2) of this section.

(ii) *From the effective date of the contract.* (A) Up to 20 percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is met by cash or cash equivalents; or

(B) Up to ten percent of the minimum net worth amount if the greater of $1,000,000 or 67 percent of the minimum net worth amount is not met by cash or cash equivalents.

(3) *Health Care Delivery Assets.* Subject to the other provisions of this section, a PSO may apply 100 percent of the GAAP depreciated value of health care delivery assets (HCDAs) to satisfy the minimum net worth amount.

(4) *Other assets.* A PSO may apply other assets not used in the delivery of health care provided that those assets are valued according to statutory accounting practices (SAP) as defined by the State.

(5) *Subordinated debts and subordinated liabilities.* Fully subordinated debt and subordinated liabilities are excluded from the minimum net worth amount calculation.

(6) *Deferred acquisition costs.* Deferred acquisition costs are excluded from the calculation of the minimum net worth amount.

10. A new § 422.384 is added to read as follows:

§ 422.384 Financial plan requirement.

(a) *General rule.* At the time of application, an organization must submit a financial plan acceptable to HCFA.

(b) *Content of plan.* A financial plan must include—

(1) A detailed marketing plan;

(2) Statements of revenue and expense on an accrual basis;

(3) Statements of sources and uses of funds;

(4) Balance sheets;

(5) Detailed justifications and assumptions in support of the financial plan including, where appropriate, certification of reserves and actuarial liabilities by a qualified health maintenance organization actuary; and

(6) If applicable, statements of the availability of financial resources to meet projected losses.

(c) *Period covered by the plan.* A financial plan must—

(1) Cover the first 12 months after the estimated effective date of a PSO's M+C contract; or

(2) If the PSO is projecting losses, cover 12 months beyond the end of the period for which losses are projected.

(d) *Funding for projected losses.* Except for the use of guarantees, LOC, and other means as provided in § 422.384(e), (f) and (g), an organization must have the resources for meeting projected losses on its balance sheet in cash or a form that is convertible to cash in a timely manner, in accordance with the PSO's financial plan.

(e) *Guarantees and projected losses.* Guarantees will be an acceptable resource to fund projected losses, provided that a PSO—

(1) Meets HCFA's requirements for guarantors and guarantee documents as specified in § 422.390; and

(2) Obtains from the guarantor cash or cash equivalents to fund the projected losses timely, as follows—

(i) Prior to the effective date of a PSO's M+C contract, the amount of the projected losses for the first two quarters;

(ii) During the first quarter and prior to the beginning of the second quarter of a PSO's M+C contract, the amount of projected losses through the end of the third quarter; and

(iii) During the second quarter and prior to the beginning of the third quarter of a PSO's M+C contract, the amount of projected losses through the end of the fourth quarter.

(3) If the guarantor complies with the requirements in paragraph (e)(2) of this section, the PSO, in the third quarter, may notify HCFA of its intent to reduce the period of advance funding of projected losses. HCFA will notify the PSO within 60 days of receiving the PSO's request if the requested reduction in the period of advance funding will not be accepted.

(4) If the guarantee requirements in paragraph (e)(2) of this section are not met, HCFA may take appropriate action, such as requiring funding of projected losses through means other than a guarantee. HCFA retains discretion to require other methods or timing of funding, considering factors such as the financial condition of the guarantor and the accuracy of the financial plan.

(f) *Letters of credit.* Letters of credit are an acceptable resource to fund projected losses, provided they are irrevocable, unconditional, and satisfactory to HCFA. They must be capable of being promptly paid upon presentation of a sight draft under the letters of credt without further reference to any other agreement, document, or entity.

(g) *Other means.* If satisfactory to HCFA, and for periods beginning one year after the effective date of a PSO's M+C contract, a PSO may use the following to fund projected losses—

(1) Lines of credit from regulated financial institutions;

(2) Legally binding agreements for capital contributions; or

(3) Legally binding agreements of a similar quality and reliability as permitted in paragraphs (g)(1) and (2) of this section.

(h) *Application of guarantees, Letters of credit or other means of funding projected losses.* Notwithstanding any other provision of this section, a PSO may use guarantees, letters of credit and, beginning one year after the effective date of a PSO's M+C contract, other means of funding projected losses, but only in a combination or sequence that HCFA considers appropriate.

11. A new § 422.386 is added to read as follows:

§ 422.386 Liquidity.

(a) A PSO must have sufficient cash flow to meet its financial obligations as they become due and payable.

(b) To determine whether the PSO meets the requirement in paragraph (a) of this section, HCFA will examine the following—

(1) The PSO's timeliness in meeting current obligations;

(2) The extent to which the PSO's current ratio of assets to liabilities is maintained at 1:1 including whether there is a declining trend in the current ratio over time; and

(3) The availability of outside financial resources to the PSO.

(c) If HCFA determines that a PSO fails to meet the requirement in paragraph (b)(1) of this section, HCFA will require the PSO to initiate corrective action and pay all overdue obligations.

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

(1) Change the distribution of its assets;

(2) Reduce its liabilities; or

(3) Make alternative arrangements to secure additional funding to restore the PSO's current ratio to 1:1.

(e) If HCFA determines that a PSO fails to meet the requirement of paragraph (b)(3) of this section, HCFA will require the PSO to obtain funding from alternative financial resources.

12. A new § 422.388 is added to read as follows:

§ 422.388 Deposits.

(a) *Insolvency deposit.* (1) At the time of application, an organization must deposit $100,000 in cash or securities (or any combination thereof) into an account in a manner that is acceptable to HCFA.

(2) The deposit must be restricted to use in the event of insolvency to help assure continuation of services or pay costs associated with receivership or liquidation.

(3) At the time of the PSO's application for an M+C contract and, thereafter, upon HCFA's request, a PSO must provide HCFA with proof of the insolvency deposit, such proof to be in a form that HCFA considers appropriate.

(b) *Uncovered expenditures deposit.* (1) If at any time uncovered expenditures exceed 10 percent of a PSO's total health care expenditures, then the PSO must place an uncovered expenditures deposit into an account with any organization or trustee that is acceptable to HCFA.

(2) The deposit must at all times have a fair market value of an amount that is 120 percent of the PSO's outstanding liability for uncovered expenditures for enrollees, including incurred, but not reported claims.

(3) The deposit must be calculated as of the first day of each month required and maintained for the remainder of each month required.

(4) If a PSO is not otherwise required to file a quarterly report, it must file a report within 45 days of the end of the calendar quarter with information sufficient to demonstrate compliance with this section.

(5) The deposit required under this section is restricted and in trust for HCFA's use to protect the interests of the PSO's Medicare enrollees and to pay the costs associated with administering the insolvency. It may be used only as provided under this section.

(c) A PSO may use the deposits required under paragraphs (a) and (b) of this section to satisfy the PSO's minimum net worth amount required under § 422.382(a) and (b).

(d) All income from the deposits or trust accounts required under paragraphs (a) and (b) of this section, are considered assets of the PSO. Upon HCFA's approval, the income from the deposits may be withdrawn.

(e) On prior written approval from HCFA, a PSO that has made a deposit under paragraphs (a) or (b) of this section, may withdraw that deposit or any part thereof if—

(1) A substitute deposit of cash or securities of equal amount and value is made;

(2) The fair market value exceeds the amount of the required deposit; or

(3) The required deposit under paragraphs (a) or (b) of this section is reduced or eliminated.

13. A new § 422.390 is added to read as follows:

§ 422.390 Guarantees.

(a) *General policy.* A PSO, or the legal entity of which the PSO is a component, may apply to HCFA to use the financial resources of a guarantor for the purpose of meeting the requirements in § 422.384. HCFA has the discretion to approve or deny approval of the use of a guarantor.

(b) *Request to use a guarantor.* To apply to use the financial resources of a guarantor, a PSO must submit to HCFA—

(1) Documentation that the guarantor meets the requirements for a guarantor under paragraph (c) of this section; and

(2) The guarantor's independently audited financial statements for the current year-to-date and for the two most recent fiscal years. The financial statements must include the guarantor's balance sheets, profit and loss statements, and cash flow statements.

(c) *Requirements for guarantor.* To serve as a guarantor, an organization must meet the following requirements:

(1) Be a legal entity authorized to conduct business within a State of the United States.

(2) Not be under Federal or State bankruptcy or rehabilitation proceedings.

(3) Have a net worth (not including other guarantees, intangibles and restricted reserves) equal to three times the amount of the PSO guarantee.

(4) If the guarantor is regulated by a State insurance commissioner, or other State official with authority for risk-bearing entities, it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by guarantees excluded from its assets.

(5) If the guarantor is not regulated by a State insurance commissioner, or other similar State official it must meet the net worth requirement in § 422.390(c)(3) with all guarantees and all investments in and loans to organizations covered by a guarantee and to related parties (subsidiaries and affiliates) excluded from its assets.

(d) *Guarantee document.* If the guarantee request is approved, a PSO must submit to HCFA a written guarantee document signed by an appropriate authority of the guarantor. The guarantee document must—

(1) State the financial obligation covered by the guarantee;

(2) Agree to—

(i) Unconditionally fulfill the financial obligation covered by the guarantee; and

(ii) Not subordinate the guarantee to any other claim on the resources of the guarantor;

(3) Declare that the guarantor must act on a timely basis, in any case not more than 5 business days, to satisfy the financial obligation covered by the guarantee; and

(4) Meet other conditions as HCFA may establish from time to time.

(e) *Reporting requirement.* A PSO must submit to HCFA the current internal financial statements and annual audited financial statements of the guarantor according to the schedule, manner, and form that HCFA requests.

(f) *Modification, substitution, and termination of a guarantee.* A PSO cannot modify, substitute or terminate a guarantee unless the PSO—

(1) Requests HCFA's approval at least 90 days before the proposed effective date of the modification, substitution, or termination;

(2) Demonstrates to HCFA's satisfaction that the modification, substitution, or termination will not result in insolvency of the PSO; and

(3) Demonstrates how the PSO will meet the requirements of this section.

(g) *Nullification.* If at any time the guarantor or the guarantee ceases to meet the requirements of this section, HCFA will notify the PSO that it ceases to recognize the guarantee document. In the event of this nullification, a PSO must—

(1) Meet the applicable requirements of this section within 15 business days; and

(2) If required by HCFA, meet a portion of the applicable requirements in less than the time period granted in paragraph (g)(1) of this section.

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

Dated: April 20, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: April 28, 1998.

Donna E. Shalala,

Secretary.

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