

nature of the Federal-State relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. EPA*, 427 U.S. 246, 256-66 (1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rules that include a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate or to the private sector, of \$100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 15, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2) of the CAA).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: March 26, 1998.

Jack McGraw,

Acting Regional Administrator, Region VIII.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart TT—Utah

2. Section 52.2350 is amended by designating the existing text as paragraph (a) and by adding paragraph (b) to read as follows:

§ 52.2350 Emission inventories.

* * * * *

(b) On November 12, 1997, the Governor of Utah submitted the 1993 Carbon Monoxide Periodic Emission Inventories for Ogden City and Utah County as revisions to the Utah State Implementation Plan. These inventories address carbon monoxide emissions from stationary point, area, non-road, and on-road mobile sources.

[FR Doc. 98-9678 Filed 4-13-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 422

[HCFA-1027-IFC]

RIN 0938-A160

Medicare Program; Definition of Provider-Sponsored Organization and Related Requirements

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

ACTION: Interim final rule with comment period.

SUMMARY: The Balanced Budget Act of 1997 establishes a new Medicare+Choice program that significantly expands the health care options available to Medicare beneficiaries. Under this program, eligible individuals may elect to receive Medicare benefits through enrollment in one of an array of private health plans that contract with HCFA. Among the new options available to Medicare beneficiaries is enrollment in a provider-sponsored organization (PSO). This interim final rule with comment period defines the term "provider-sponsored organization" for purposes of the Medicare program and establishes requirements related to meeting this definition.

We believe that setting forth the definition of a PSO and the related requirements will facilitate the submission of applications to participate in the Medicare program as a PSO.

DATES: *Effective date:* This interim final rule is effective May 14, 1998. *Comment period:* Comments will be considered if received at the appropriate address, as provided below, no later than June 15, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1027-IFC, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) 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.

Comments may also be submitted electronically to the following e-mail address: hcfa1027ifc@hcfa.gov. E-mail comments must include the full name

and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1027-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).

FOR FURTHER INFORMATION CONTACT: Maureen Miller, (410) 786-1097; Phil Doerr, (410) 786-1059.

SUPPLEMENTARY INFORMATION:

I. Background

A. Medicare+Choice Program

Health care benefits covered under the Medicare program are divided into two parts: Hospital insurance, also known as "Part A," and supplementary medical insurance, also known as "Part B." Health care services covered under Part A include: inpatient hospital care, skilled nursing facility care, home health agency care, and hospice care. Part B coverage is optional and requires payment of a monthly premium. Part B covers physician services (in both hospital and nonhospital settings) and services furnished by certain nonphysician practitioners. It also covers certain other services, including: clinical laboratory tests, durable medical equipment, most supplies, diagnostic tests, ambulance services, prescription drugs that cannot be self-administered, certain self-administered anticancer drugs, some other therapy services, certain other health services, and blood not supplied by Part A.

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted August 5, 1997, adds sections 1851 through 1859 to the Social Security Act (the Act) to establish a new Part C of the Medicare program, known as "Medicare+Choice." (The existing Part C of the statute, which included provisions in section 1876 of the Act governing existing Medicare health maintenance organization (HMO) contracts, was redesignated as Part D.) Under the new Medicare+Choice program, every individual entitled to Medicare Part A and enrolled under Part B, except for individuals with end-stage renal disease, may elect to receive

benefits through either the existing Medicare fee-for-service program or a Part C Medicare+Choice plan.

B. Medicare+Choice Plan Options

The Medicare+Choice plan options include both the traditional managed care plans (such as HMOs) that have participated in Medicare on a capitated payment basis under section 1876 of the Act as well as a broader range of plans comparable to those now available through private insurance. Specifically, effective January 1, 1999, section 1851(a)(2) of the Act provides for three types of Medicare+Choice plans:

- Coordinated care plans, including HMO plans, provider sponsored organization (PSO) plans, and preferred provider organization (PPO) plans.
- Medical savings account (MSA) plans (that is, combinations of a high deductible, catastrophic insurance plan with a contribution to a Medicare+Choice MSA). This option is a demonstration.
- Private fee-for-service plans.

C. Statutory Requirements

Section 1856(b)(1) of the Act directs the Secretary to publish by June 1, 1998, regulations necessary for overall implementation of the Medicare+Choice program. These regulations will establish a new Part 422 in title 42 of the Code of Federal Regulations and will set forth the basic requirements for all Medicare+Choice plans.

Additionally, section 1856(a) of the Act provides that the Secretary establish through a negotiated rulemaking process, the solvency standards (as described in section 1855(c)(1) of the Act) that entities will be required to meet if they obtain a waiver of the otherwise applicable requirement that they be licensed by the State. (For more information on the negotiated rulemaking process see the HCFA notices published on September 23, 1997, and October 28, 1997, 62 FR 49649 and 62 FR 55773, respectively.)

As we worked on developing procedures to allow PSOs to sign Medicare+Choice contracts in 1998, we determined that interested health plans needed to know the fundamental organizational requirements they had to meet as soon as possible. In addition, in the course of the negotiated rulemaking process, it has become clear to HCFA and the negotiated rulemaking committee that a clear definition of PSO was needed to establish solvency standards. Therefore, in order to assist entities considering applying to become PSOs under the Medicare+Choice program we have developed the definition of a PSO and related

requirements for publication in this interim final rule with comment period.

II. Provider-Sponsored Organizations Under the Medicare+Choice Program

In recent years, the term "provider-sponsored organization" has been one of several terms applied to health care delivery systems that are owned or controlled and operated by a provider or group of providers within a community. Such systems, also referred to as integrated delivery systems, are most commonly formed by physicians and hospitals and can provide an array of health care services to patients under a variety of payment mechanisms, including risk-sharing arrangements through contracts with HMOs. A few States have passed laws specifically recognizing these types of new entities, and some PSOs have undertaken direct contracting with employers and other payors. Until implementation of the BBA, these types of entities are eligible to participate in the Medicare program only if they meet the requirements for a risk contract under section 1876 of the Act.

Section 4001 of the BBA established new sections 1851 through 1859 of the Act. Section 1851(a)(2) of the Act now explicitly provides for participation of a PSO plan in the Medicare+Choice program. For the most part, a PSO plan is required to meet the same requirements as other coordinated care plans that participate in the program. However, the statute establishes two special rules for PSOs.

First, a fundamental requirement of the Medicare+Choice program, as set forth under new section 1855(a)(1) of the Act, is that a Medicare+Choice 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 a Medicare+Choice plan." However, section 1855(a)(2) of the Act establishes an exception to this general rule by allowing a PSO to obtain a Federal waiver from the State licensure requirement if it meets one of three criteria specified in the Act. A PSO that files a request for a Federal waiver can qualify as a Medicare+Choice plan if the Secretary determines that any of the following criteria is met:

- The State failed to complete action on a licensing application within 90 days.
- The State denied the licensing application based on discriminatory treatment.
- The State denied the licensing application based on the organization's failure to meet solvency requirements,

and there is a difference between the State's solvency requirements and the Federal solvency requirements to be established through the negotiated rulemaking process mentioned above.

Application for a waiver of the licensure requirement may be made until November 1, 2002, and the approved waiver is effective for a nonrenewable 36-month period. We will discuss the waiver criteria and application process in a separate rulemaking document on PSO Solvency Standards and Waiver.

The other special rule for PSOs involves the minimum enrollment requirements set forth under new section 1857(b) of the Act. Section 1857(b)(1) specifies that participating Medicare+Choice organizations must have at least 5,000 individuals receiving health benefits through the organization, or at least 1,500 if the organization primarily serves a rural area. For PSOs, though, these minimum enrollment requirements are set at 1,500 for urban areas and 500 for rural areas. These lower minimum enrollment requirements apply to entities that meet the Medicare definition and related requirements for a PSO, including State-licensed PSOs, in addition to PSOs that participate in the Medicare+Choice program under a Federal waiver of the State licensure requirement.

III. Provisions of the Interim Final Rule With Comment Period

A. Overview

The requirements contained in this interim final rule represent the first set of published regulations applicable to the Medicare+Choice program. To accommodate the new regulations needed to implement this program, we are establishing a new Part 422—Medicare+Choice Program, in Title 42 of the Code of Federal Regulations. We intend to set forth the overall framework of part 422 in the comprehensive interim final rule scheduled to be published by June 1, 1998. At this time, we are establishing only Subpart H, the subpart necessary to address Provider-Sponsored Organizations issues.

B. Discussion of PSO Definition and Related Requirements

We are establishing a new § 422.350 Basis, scope and definitions.

Paragraph (a) states that the regulations set forth in subpart H are based on sections 1851 and 1855 of the Act. It also specifies that the scope of the subpart is to (1) authorize PSOs to contract with HCFA as a Medicare+Choice plan; (2) require that a PSO meet certain qualifying

requirements; and (3) provide for waiver of State licensure for PSOs under specified conditions.

Paragraph (b) of § 422.350 sets forth the meaning of terms as they are used for purposes of subpart H. The terms defined here are discussed in logical order below; note that they appear in alphabetical order in the regulations text.

Provider-Sponsored Organization

We define in regulations a PSO as it is defined in section 1855(d)(1) of the Act. That is, a PSO is a public or private entity that—

(1) Is established or organized, and operated, by a health care provider or group of affiliated (as defined in § 422.354(a)) health care providers.

(2) Provides a "substantial proportion" (as defined in § 422.352(b)) of the health care items and services under its Medicare+Choice contract directly through the provider or affiliated group of providers. "Substantial proportion" is discussed below.

(3) In the case of a group of affiliated providers, the providers share, directly or indirectly, substantial financial risk (as defined under § 422.356(a)) for the provisions of items and services under its contract and have at least a majority financial interest (as defined under § 422.356(b)) in the PSO.

This definition focuses on the unique, provider-based nature of this type of entity and lays the groundwork for the requirements that follow. As set out in legislation, providers are the core of a PSO, and must establish, organize, and control the health plan. Further, the definition clearly establishes that providers must have a stake in the PSO enterprise by sharing in the financial risk passed to the health plan by HCFA.

Control—As discussed below, section 1855(d)(4) of the Act sets forth a specific meaning of "control" for purposes of determining whether a provider is affiliated with another provider. For all other purposes related to PSOs, however, we define in § 422.350(b) that control exists if an individual, group of individuals, or organization, has the power, directly or indirectly, "to direct or influence significantly" the actions or policies of an organization or institution.

This definition is essentially the same as the long-standing definition of control that is used for purposes of providers in the Medicare fee-for-service programs (see 42 CFR 413.17.) The term "control" is used in several contexts in relation to PSOs (aside from its specific meaning for purposes of determining affiliation under section 1855(d)(3)), and

we believe that this general definition, which results in case-by-case determinations, is appropriate for all these uses.

New section 1855(d)(5) defines the term "health care provider" for purposes of PSO requirements. This definition is much broader than the definition of "provider of service" found in section 1861(u) of the Act and the definition of "provider" found in § 400.202 of our regulations (definitions specific to Medicare). Here, the term can apply to both individuals (such as physicians, nurse practitioners, physician assistants, etc.) and the entities commonly considered to be providers, as well as other types of health care entities.

Pursuant to section 1855(d)(5) of the Act, we are defining "health care provider" as:

- Any individual who is engaged in the delivery of health care services in a State and who is licensed or certified by that State to engage in the delivery of such services in the State; and
- Any entity that is engaged in the delivery of health care services in a State provided, if required by the State, the entity is licensed or certified to engage in the delivery of such services in the State.

To meet the terms of this definition, an individual health care practitioner must be licensed or certified by the State to be considered a provider for purposes of the PSO requirements. We believe this complies with the intent of section 1855(d)(5)(A) of the statute. Consistent with section 1855(d)(5)(B) of the Act, all entities that require licensure or certification must be in compliance with these State requirements. As contemplated by the statute, health care entities that are not required to be licensed or certified may meet this definition of "health care provider", although individual components of the entity may be required to be licensed or certified. An example, or hypothetical situation of this, is a health care system where, through merger or acquisition, a licensed hospital, a certified home health agency, a licensed rehabilitation facility, and a medical group consisting of individually licensed physicians have formed a corporate entity that provides a wide range of health care services. In this example, each of the component entities would be licensed, as are the individual physicians, but not the health care system as a whole. Thus, the corporate entity could be considered a "health care provider" even though it itself is not licensed.

Given the evolving nature of the industry, we recognize that other types

of health care entities may exist that are not addressed by this regulatory definition. We welcome comments or suggestions on these types of arrangements, and will consider whether they would necessitate changes in the definition.

We anticipate that the current requirement for Medicare-contracting HMOs and competitive medical plans to furnish services through providers that comply with conditions of participation and certification, as required by § 417.416 of the regulations, will be incorporated (in the same or similar manner) into the Medicare+Choice standards to be issued June 1.

Engaged in the Delivery of Health Care Services

This phrase is used in both contexts of the statutory definition of a health care provider, that is, both for individual providers and entities. Section 422.350(b) specifies that for an individual, "engaged in the delivery of health care services" means that the individual directly furnishes health care services. For an entity, it means that the entity is organized and operated primarily for the purpose of furnishing health care services directly or through its provider members or entities.

We are clarifying the meaning of this phrase in the definitions section of the regulations largely because of the new types of health care organizations that are continuing to be formed. For example, a number of provider entities or institutions that had been organized and operated to furnish health care services have added other types of non-clinical health-related services, such as management services, utilization review services, electronic information services, etc. On the other hand, some health-related companies have ventured into areas associated with direct health care delivery. We believe that PSOs are intended to be established and operated by providers actively furnishing patient care. Thus, in this definition, we clarify the role and importance of furnishing health care services—for both individuals and entities—in order to be considered engaged in the delivery of health care services. If it is necessary for HCFA to make a determination whether an entity can be considered engaged in the delivery of health care services, we will consider the entity's organizational structure, (including lines of business), mission, bylaws and control to determine the predominant nature of the entity. Thus, for example, the extent to which physician members provide services and control an independent practice association (IPA) could be determining factors whether the IPA

group is considered to be engaged in the delivery of health care services.

C. Basic Requirements for PSOs (§ 422.352)

New § 422.352 specifies that to be considered a PSO for purposes of the Medicare+Choice program, an organization must comply with the following general requirements.

In paragraph (a) we require the organization to—

- Be licensed by the State or obtain a waiver of licensure as provided for under section 1855(a)(2) of the Act.
- Meet the definition of a PSO set forth in § 422.350 and other applicable requirements of 42 CFR Part 422, subpart H.
- Be controlled by a health care provider or, in the case of a group, by one or more of the affiliated providers that established and operate the PSO.

The requirement that an entity either be licensed by the State or have obtained a Federal waiver, basically restates the two ways in which a PSO can participate in the Medicare+Choice program, as spelled out under section 1855(a) of the Act. The general requirement concerning control explicitly incorporates into the regulations the underlying statutory intent that in PSOs, health care providers must have controlling authority over the organization. The joint conference committee report states: "A PSO is a term generally used to describe a cooperative venture of a group of providers who *control* its health service delivery and financial arrangements." (emphasis added) (H.R. Report 105-217, Conference Report to accompany H.R. 2015, 630). As discussed above, control is defined in the same way as it is used in other Medicare settings, and we intend to make decisions about whether control exists on an individual case basis. In general, we believe that control implies that the providers or groups of affiliated providers that furnish health care services through a PSO must exercise control, not only over clinical decision-making and quality assurance, but also govern the PSO, e.g., direct the administration of the enterprise, maintain control of the governing body, and remain fully accountable for the organization. (See also the discussion of majority financial interest.)

In paragraph (b) we include requirements concerning provision of services. We incorporate the general requirement that a PSO must demonstrate that it is capable of delivering to Medicare enrollees the range of services required under a contract with HCFA. This requirement

currently applies to all managed care plans that contract with HCFA under section 1876 of the Act. We intend to establish a similar requirement for network-based organizations that enter into contracts under the Medicare+Choice program, in accordance with the general requirement for provision of services under section 1852(a)(1) of the Act. Thus, this requirement for PSOs will supplement the overall Medicare+Choice requirement that participating health plans (where applicable) be capable of providing all contracted services directly or through arrangement. (These organizations also are responsible for payment of out-of-plan emergency and urgently needed services, as well as care furnished in connection with point-of-service options.)

Another key component of § 422.352(b) involves the requirement that a PSO deliver a substantial proportion of the health care items and services through the provider or affiliated group of providers responsible for operating the PSO, as required under section 1855(d)(1) of the Act. Section 1855(d)(2)(A) of the Act then specifies that in defining what constitutes a "substantial proportion," the Secretary is to take into account the need for a PSO to be responsible for providing "significantly more than the majority" of items and services under its contract through its own affiliated providers, with most of the remaining items and services to be furnished through agreements between the PSO and other nonaffiliated providers. The statute clarifies that the intent of the substantial proportion provisions is " * * * to assure financial stability and to address practical considerations involved in integrating the delivery of a wide range of service providers."

In establishing the appropriate level for the substantial proportion requirement, our goal was to identify a threshold high enough to comply with the intent of the statute but not so high as to discourage participation in the program. A simple majority being 51 percent, we determined that a PSO must directly provide significantly more than 51 percent of the items and services committed to under its contract in order to meet this requirement. We also recognize that some portion of services will be provided by nonplan providers on an emergency or urgently needed basis. In addition, we did not want to preclude the possibility of a PSO offering a point-of-service option. Therefore, we evaluated and modeled substantial proportion options between

60 and 80 percent of contractually required Medicare services.

We considered both aggregate models, that is, comparisons of total services furnished by affiliated providers with total services furnished by the PSO, as well as hybrid models that compared services in various categories (for example, setting separate substantial proportion requirements for different types of care such as inpatient hospital services or physician services.) However, we determined that the hybrid models were unnecessarily complicated and administratively burdensome for both PSOs and HCFA, without contributing to the objective of assuring the financial stability of the organization. Based on our analysis, and consultation with health care industry and beneficiary representatives, we concluded that setting the substantial proportion requirement at 70 percent appropriately balances two key interests: (1) that we not set the proportion of services so high as to prevent participation by all but the most sophisticated provider organizations and (2) that the substantial proportion threshold be sufficient to ensure that a PSO have a well-developed capacity to deliver services, thus meeting the financial stability objective explicit in the statute and increasing the prospects for successful development and solvent operation of a PSO. Therefore, we are specifying under § 422.352(b)(1) that in general a substantial proportion constitutes not less than 70 percent of Medicare items and services covered under a PSO's contract.

Section 1855(d)(2)(C) of the Act provides that the Secretary may allow for variation in the definition of substantial proportion for rural PSOs. Consistent with this provision, and based upon consultations with rural health care industry representatives and beneficiary representatives, we have established under § 422.352(b)(2), a substantial proportion threshold of 60 percent of Medicare items and services required under contract for rural PSOs. We believe that this requirement reflects the lower proportion of specialty and other medical services that are likely to be available in some rural areas and is necessary to foster the likelihood of PSO development and success in rural areas.

Finally, along with the decision of how to define substantial proportion, we also needed to identify the best method for comparing the proportion of items and services furnished by a PSO's affiliated providers with the overall amount of items and services furnished through the PSO. The two possible approaches involved either the use of Medicare encounter data or Medicare

expenditure data. During discussions with health care industry representatives, we learned that using expenditure data generally would not be burdensome for PSOs because it is commonly collected for internal financial management purposes. Furthermore, expenditure data may also produce a measurement more in line with the intent of the substantial proportion requirement. For example, the expenditures associated with an acute hospital visit would reflect a higher draw upon the PSO's resources than a physician office visit. Likewise, with expenditure data, the dollar amounts associated with each physician office visit, home care visit, etc., will reflect resource use and the ability of PSO providers to manage medical utilization. Therefore, based upon its immediate availability and superior meaningfulness, we concluded that use of expenditure data is the better approach at this time for determining compliance with the substantial proportion requirement. We intend to provide guidance on the calculation of substantial proportion in future documents concerning application and compliance procedures.

Paragraph (c) discusses characteristics a PSO must have to be considered rural. For purposes of the substantial proportion requirement, we are adopting the language of current § 412.62(f). This section references a widely accepted Office of Management and Budget methodology for identifying rural areas that is currently in use in the majority of HCFA programs. We considered several alternatives for defining rural areas including one that utilizes census tract data and another that utilizes a United States Department of Agriculture methodology whereby multiple levels of urban and rural definitions can be established through criteria. We concluded that the definitions set forth under § 412.62(f) would appropriately identify those areas that may be eligible for the rural standard for substantial proportion and that this definition would provide consistency in the application of rural definitions among the majority of Medicare programs.

Section 422.352(c) sets forth the standards for qualifying as a rural PSO, and allows non-rural providers to take part in the PSO as an affiliate or a subcontractor. The substantial proportion standards for rural PSOs recognize that non-rural providers are often an important source of care for residents of rural areas. Hence, the percentage of services that must be provided through affiliated providers of a rural PSO is less than the percentage

required of a non-rural PSO. The exception for rural PSOs is intended to foster the development of capitated plans that can be available to residents of rural areas, and to permit rural providers to participate in the formation of such plans. Non-rural providers may be components of a PSO eligible for the rural exception to the substantial proportion standard, but we wish to ensure that such a PSO is primarily a rural-based plan, and that the arrangements such a plan makes for the provision of services is consistent with the patterns of care for the rural community. Beneficiaries who enroll in a rural PSO should enjoy the same level of accessibility and availability of care through local providers as non-enrollees residing in the same area. Hence, we are requiring that the PSO must demonstrate that it can render, through affiliated providers located in the rural area, medical services commonly provided to beneficiaries by providers in the rural community. Services provided by providers located in the rural area generally should include primary care, emergency care, and commonly used types of specialty care available in the area, in order to ensure that a basic level of care is available to enrollees of the PSO at the local level. Patients may be referred to non-rural providers for more complex (e.g., tertiary-level) hospital care and for certain types of specialty care, and for other care, to the extent that the PSO can demonstrate that the use of non-rural providers is consistent with referral patterns in the service area. As far as is practicable, services provided outside the rural area should be provided by affiliated providers or by providers that have contracts with the PSO, except for unusual or infrequently used health services.

Another test as to whether the PSO qualifies as rural relates to the Medicare beneficiaries enrolling in the organization. A majority of the PSO's Medicare enrollees must reside within the rural area or areas served by the PSO. We considered higher thresholds for this standard, but, after consultation with rural health care and beneficiary representatives, determined that this was the most workable approach.

We believe that this approach to rural PSOs is balanced. That is, the two standards (in conjunction with the 60 percent threshold for substantial proportion) validate that the PSO is indeed a rural-based health plan yet is flexible enough to promote the development of rural PSOs.

D. Requirements for Affiliated Providers
(§ 422.354)

The concept of affiliation is central to the organization of PSOs. Section 1855(d)(3) of the Act sets forth four criteria under which a provider can demonstrate affiliation with another provider for PSO purposes. In this interim final rule, we are incorporating the statutory provisions into § 422.354 by specifying that a provider is affiliated with another provider if, through contract, ownership, or otherwise, any of the following criteria is met:

- One provider, directly or indirectly controls, is controlled by, or is under common control with the other.
- Each provider is a participant in a lawful combination under which each provider shares substantial financial risk (as set forth under § 422.356 of this part) in connection with the PSO's operations.
- Both providers are part of a controlled group of corporations under section 1563 of the Internal Revenue Code (IRC) of 1986.
- Both providers are part of an affiliated service group under section 414 of the IRC.

As specified under section 1855(d)(4) of the Act, control is presumed to exist for purposes of the first criterion if one party, directly or indirectly, owns, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance rights of another. The second criterion (§ 422.354(a)(2)) contains a two-pronged test. It requires that providers affiliate in a lawful combination, which we will interpret as meeting antitrust and other Federal guidelines, as well as applicable Federal and State statutes. However, HCFA's determination that providers are affiliated for purposes of the Medicare+Choice program does not constitute a determination that the arrangement among the affiliated providers is lawful under Federal or State antitrust law. (HCFA does not have authority to make such determinations, and will consult the Federal Trade Commission as necessary.) In addition, each affiliated provider must share substantial financial risk in the operations of the PSO. Our policy with respect to what constitutes substantial financial risk is discussed in detail below.

The last two criteria are based on provisions of the Internal Revenue Code of 1986. We do not intend to make determinations as to whether or not a PSO meets either of these criteria, since this is outside our authority, but will look to evidence provided by the PSO as to its standing under the tax code.

(When necessary, we will consult with appropriate officials within the Department of Treasury, as we have done in the development of this interim final rule.)

In general, under these criteria, we believe that an affiliated provider could be, for example, a medical group, an IPA, a hospital, a nursing home, or a home health agency. (We note that an individual provider who is not part of a larger entity also could be considered an affiliated provider of the PSO if the individual provider meets all applicable requirements.) The purpose of these affiliation tests is to distinguish the PSO as an entity made up of separate providers who have combined in an acceptable manner and are bound together in order to contract with the Medicare program. These rules are not intended to limit the structuring, or even the payment arrangements, of individuals, facilities, or other providers who are components of the entity that is the affiliated provider. For example, these rules do not limit an IPA's flexibility in bringing together individual physicians, or its payment arrangements with those physicians. Likewise, if a hospital has purchased a medical practice and a nursing home, the hospital (now a health care system) is considered one affiliated provider of the affiliated model PSO. The concerns addressed in this portion of the regulation are with how the hospital or health care system in this example affiliates with other provider entities outside of its corporate structure for purposes of establishing and operating a PSO, not the individuals or component provider entities within the corporate structure.

In addition to the organizational tests of affiliation under paragraph (a) of § 422.354, paragraph (b) then specifies that a PSO must demonstrate that each of its affiliated providers share, directly or indirectly, substantial financial risk for the provision of items and services under the Medicare contract that are the obligation of the organization. Similarly, we include under § 422.354(c) the requirement that affiliated providers, as a whole or in part, have at least a majority financial interest in the PSO. These requirements stem from section 1855(d)(1)(C) of the statutory PSO definition, and are included in § 422.356 of the regulations, as discussed below.

E. Determining Substantial Financial Risk and Majority Financial Interest
(§ 422.356)

The term "substantial financial risk" is used twice in section 1855(d) of the Act. First, section 1855(d)(1)(C)

stipulates that, where affiliated providers have established the PSO, they must share substantial financial risk for the items and services provided under the contract. The term is used again in section 1855(d)(3)(C), which sets forth one of the four ways in which providers may demonstrate affiliation, i.e. providers must be in a lawful combination and share substantial financial risk in the operation of the PSO.

In recent years, other legislation amending the Social Security Act has used the term "substantial financial risk" for purposes which differ from how the term is used here. Section 216 of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) requires the Secretary to establish, through a negotiated rulemaking process, a new safe harbor from the anti-kickback statute (section 1128B of the Act, 142 U.S.C. 1320a-7b(b)) for certain risk-sharing arrangements that place an individual or entity at "substantial financial risk for the cost or utilization" of items or services furnished by those providers. Section 4204 of the Omnibus Reconciliation Act of 1990 (Pub. L. 101-508) and the physician incentive plan under our regulations at 42 CFR 417.479 require managed care organizations that place physicians or physician groups at "substantial financial risk" to assure that stop loss coverage is in place and to conduct beneficiary satisfaction surveys. Physicians are deemed to be at substantial financial risk if their risk for referral services exceeds 25 percent of the maximum potential payments under the contract (unless the entity serves more than 25,000 patients and certain pooling criteria are met). In addition, financial risk sharing as an indicator of integration among otherwise competing health care providers was addressed by the Federal Trade Commission (FTC) and the Department of Justice (DoJ) in antitrust guidelines issued in August, 1996. Thus a regulatory clarification of this requirement as used for affiliated providers of PSOs is necessary.

In both uses of "substantial financial risk" in section 1855(d) of the Act, a provider entity—such as a hospital or medical group—is required to be at financial risk for more than the provider's own items and services. That is, each affiliated provider must have a stake in the PSO. We considered defining a specific level of risk, such as a percentage, or categories of risk, but determined that this would not be workable given the numerous types of providers (ranging from large facilities to small speciality practices), varying capacities of the providers, and various

financial concerns. Establishing categories or levels of risk was too arbitrary given the extent of potential affiliates, and administratively burdensome for us and the health plans. Because each PSO will be unique, we decided that a case-by-case determination would be needed. Thus, in this interim final rule, we establish that HCFA will determine whether the affiliated providers demonstrate substantial financial risk for purposes of section 1855(d)(1)(C) of the Act and for purposes of affiliation in section 1855(d)(3)(C).

To help us provide regulatory clarification on risk-sharing, we looked to the health care provider antitrust guidelines mentioned above for guidance. The antitrust guidelines and the requirement for substantial financial risk in the BBA have different purposes: The antitrust guidelines are concerned with the extent of economic integration among otherwise independently competing health care providers, while the BBA's requirement addresses the extent of the affiliated providers' stake in, and commitment to, the successful operation of the PSO. Because of the different contexts and purposes of the two provisions, we have not adopted the risk-sharing mechanisms outlined in the antitrust guidelines in total for this interim final rule with comment. We adopted with modifications three of the four examples of mechanisms identified by the FTC and DoJ. Through our analysis, we determined that the fourth, global payment rates for certain complex cases, or for case management, was not evidence of an affiliated provider's risk in the overall enterprise of the PSO.

One mechanism that may be acceptable for demonstrating financial risk is capitation; i.e., agreement by an affiliated provider (such as a medical group or IPA) to provide services at a capitated rate of payment from the PSO. A capitated rate is a preset, fixed payment per enrollee in exchange for the provision of a set of services without regard to frequency of use, intensity, or cost of such services for a specified time period. In these regulations, we are not concerned with the capitation or other payments to individual providers within the provider entity, but only the capitation arrangement between the PSO and the affiliated provider. The capitation arrangement must demonstrate that the affiliated providers share significant risk for the PSO enterprise. For example, we may consider a comprehensive, capitated payment rate that covers hospital and physician services as demonstrating substantial financial risk. In this case, a

capitated health care system that is providing the bulk of commonly used services to a significant portion of PSO's enrollment would be viewed as sharing in the financial risk of the PSO enterprise. However, more typical capitation arrangements (e.g. whereby an IPA is capitated for the primary and specialty care of its associated physicians) usually will not be adequate to demonstrate that an affiliated provider shares substantial financial risk in the PSO. In the latter case, another mechanism that links the affiliate financially to the overall health plan will likely be necessary because the capitated affiliated provider (such as an IPA or medical group) must demonstrate that it holds risk in the PSO, and is not at risk just for its own services. An example of what may be permissible here is the withholding of a significant amount of an affiliated provider's capitation, to be used to cover the losses of the PSO, if such occur, or to distribute back to the affiliated provider(s) if cost-containment and utilization management goals are met. Another example could be a significant capital investment in the PSO on the part of the capitated affiliate. The amount or level of financial risk borne by each affiliated provider may vary based on factors such as the size or capacity of the provider, the nature of services provided, and financial strength. For example, a well-capitalized hospital affiliate will bear more risk than a nursing home, home health agency, or federally qualified health center affiliates.

In addition to capitation, other possible risk-sharing mechanisms drawn from the antitrust guidelines include agreement by an affiliated provider to provide services for a predetermined percent of the PSO's premium (or revenue), and certain financial incentives considered to be significant, e.g., withholds and preestablished, fixed budgets or utilization targets for the affiliated provider. Again, the PSO must demonstrate that the affiliated provider shares risk in the PSO enterprise through these risk-sharing mechanisms.

We have included also a provision that allows HCFA to consider other means of demonstrating "substantial financial risk" in the PSO. This approach allows us the flexibility to consider other financial commitments that could be submitted for consideration, such as significant ownership in a for-profit PSO, significant investments from the affiliated provider, or a guarantee by an affiliated provider to cover the debt or operating expenses of the PSO.

We believe that the approach chosen for this regulation, a determination by HCFA as to the demonstration of substantial financial risk sharing and the outline of mechanisms that will be considered in the assessment, is appropriate at this early stage in the PSO program. We also believe that this approach will work for both provisions regarding the substantial financial risk in section 1855(d). As our experience evaluating risk-sharing arrangements, contractual agreements, and organizational structures for PSOs increases, we may provide further guidance through program issuances.

Paragraph (b) of § 422.356 reflects the requirements of section 1855(d)(1)(C) of the Act that the affiliated providers in a PSO have a majority financial interest in the organization. We considered requiring that all affiliated providers have an ownership interest, membership interest, or voting rights in the PSO. We rejected this alternative because we believed it would unnecessarily restrict the formation and development of PSOs. In addition, such a requirement could result in a nominal ownership interest, such as a \$1 stake in the PSO, rendering the requirement meaningless. We also considered establishing thresholds of financial interest, but determined this method to be too arbitrary. We believe, that by nature of the requirement that PSOs must be effectively controlled by the affiliated providers, the affiliated providers must have a majority financial interest in the PSO. Even where one or a portion of the affiliated providers control the PSO (this is permissible under the regulations), we believe that the requirement that all affiliated providers share substantially in the risk borne by the health plan—taken together with the requirements for affiliation—provides the appropriate incentives for provider "buy-in" to the PSO as envisioned by the statute. Therefore, § 422.356(b) simply states that majority financial interest means maintaining effective control of the PSO.

Following are two examples of how this requirement may be met:

Example 1. In a for-profit PSO, the affiliated providers (either all or some portion of the affiliated providers) both own(s) not less than 51 percent of the organization and maintain(s) control, including a majority position, in the governance of the PSO (such as control of the board of directors).

Example 2. In a not-for-profit, member-model PSO, the affiliated providers (either all or some portion of the affiliated providers) both control(s) not less than 51 percent of the membership and maintain(s) control,

including a majority position, in the governance of the PSO.

The requirement concerning majority financial interest does not preclude either providers not affiliated with the PSO (but who could have another arrangement to provide services) or nonproviders from ownership, membership, or other formal position in the PSO's organizational structure. However, any restrictions are intended to ensure that effective controlling authority rests with the affiliated providers.

IV. Applicability of These Rules

As noted above, the definition and requirements set forth in this interim final rule pertain only to PSOs and do not apply to any other type of coordinated care plan. However, in order to contract with the Medicare program, a PSO also must meet the general Medicare+Choice program requirements that will be established under Part 422. Until these requirements are established, we suggest that interested parties consult the current Medicare risk contract requirements under Part 417, in the managed care section on HCFA's Homepage on the Internet, in combination with the statutory requirements under the BBA, for guidance. An organization interested in entering into a contract with Medicare as a PSO must first apply to its State for licensure. Only a PSO that is denied licensure by the State based on any of the three criteria set forth under section 1855(a)(2) of the Act may obtain a waiver from HCFA. Following either State licensure or approval of a Federal waiver, the organization then applies to HCFA to participate in the Medicare+Choice program as a PSO. We will review the application first to determine whether the organization meets the PSO definition and related requirements set forth in this interim final rule. We then will determine whether the organization meets the general Medicare+Choice requirements.

An organization that applies under the Federal waiver provision also needs to meet the solvency standards established in regulations in compliance with new section 1856 of the Act. Again, this entire process will be discussed in greater detail in another interim final rule with comment period. This rule also will be used for entities that are licensed by the State but wish to avail themselves of the lower minimum enrollment standards for PSOs. In this situation, no waiver request and only that portion of the PSO application related to this interim final rule will be applied.

V. Regulatory Impact Statement

A. Introduction

Section 804(2) of Title 5, United States Code (as added by section 251 of Pub. L. 104-121), specifies that a "major rule" is any rule that the Office of Management and Budget finds is likely to result in—

- An annual effect on the economy of \$100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

As discussed throughout this interim final rule, the establishment of PSOs should promote competition in the managed care industry and thus will not produce cost or price increases. Although the definitions being established through this rule do not lend themselves to a quantitative impact estimate, we do not believe that they are likely to produce an annual effect on the economy of \$100 million or more.

Therefore, we have determined that this interim final rule does not constitute a major rule as defined in Title 5, United States Code, section 804(2).

We have examined the impacts of this interim final rule under Executive Order 12866, the Unfunded Mandates Act of 1995, 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, select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses and other small entities. For purposes of the RFA, most hospitals, and most other providers, physicians, and health care suppliers are small entities, either by nonprofit status or by having revenues of less than \$5 million annually. Most coordinated care plans are not considered to be small entities within the meaning of the RFA.

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million.

This rule has no consequential effect on State, local, or tribal governments. We believe that the private sector costs of this rule also fall below the \$100 million threshold.

Also, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102 of the Act, we define a small rural hospital as a hospital with fewer than 100 beds that is located outside a Metropolitan Statistical Area.

Although we do not believe the aggregate impact of the PSO definitions and requirements set forth in this interim final rule will approach \$100 million annually, it is clear that they may have a significant economic impact on certain hospitals, physicians, health plans and other providers. Thus, we have prepared the following analysis that, in combination with the rest of this interim final rule with comment period, constitutes a combined regulatory impact analysis and regulatory flexibility analysis.

B. Background

As discussed in section I of this preamble, we believe that issuing these definitions as an interim final rule at this time is a necessary precursor to the establishment of solvency standards for PSOs through a negotiated rulemaking process, as required under section 1856(a)(1). In addition, publishing the definitional requirements at this time will allow time for interested entities to meet the requirements before submission of a PSO waiver and application in the spring of 1998. This sequence of events is necessary to ensure that all administrative systems will be in place to allow PSOs to begin health care operations by January 1, 1999.

The PSO definition and requirements set forth in this interim final rule incorporate all statutory requirements set forth in section 1855(d) of the Act. In those areas where further clarification of the statute is necessary, we have established requirements consistent with the statutory intent, that is, in a manner that will foster the development of PSOs as a distinct health care option for Medicare beneficiaries without inappropriately limiting competition among the various organizations that can offer Medicare+Choice plans. We have attempted to achieve a balance between these two goals in choosing the best alternative for several of the key issues discussed below.

C. Major Issues

As discussed in section II of this preamble, the statute establishes two exceptions for PSOs to the requirements that apply to other Medicare+Choice organizations. Clearly, the primary benefit to an organization that can meet the definition of a PSO is that for 3 years, a PSO can qualify for a Federal waiver from State licensure requirements. In addition, PSOs are subject to lower minimum enrollment requirements than other Medicare+Choice organizations. We believe that the purpose of these exceptions is to encourage the development of a significantly different health care option for Medicare beneficiaries. Under the PSO option, providers are intended to bear a more direct responsibility for the delivery, management, and associated financial risks of a patient's health care than that borne by providers in other coordinated care plans. Establishing requirements in this interim final rule that allow health plans that are not significantly different from other Medicare+Choice options to contract as PSOs would undermine the intent of the statute by allowing organizations to receive the competitive advantage afforded by a waiver of state licensure and lower minimum enrollments without increasing options for beneficiaries.

1. Definition of a PSO

Section 422.350(b) sets forth the statutory definition of a PSO, including the requirement that a PSO be established or organized, and operated, by a health care provider or group of affiliated providers. We are also including under § 422.350(b) the statutory definition (from section 1855(d)(5) of the Act) of a health care provider, which specifies that a health care provider must be "engaged in the delivery of health care services." We are clarifying in this section that for an individual, "engaged in the delivery of health care services" means that the individual directly furnishes health care services. For an entity, it means that the entity is organized and operated primarily for the purpose of directly furnishing health care services.

We believe that this requirement will ensure that PSOs consist of providers that are actively delivering patient care, without arbitrarily prohibiting participation of entities that combined direct patient care services with other nonclinical health-related services. Under this definition, organized groups of providers, such as individual practice associations, physician practice management companies, or multi-

specialty medical groups could fall within the definition of a provider, if they meet related requirements concerning affiliation, substantial risk, etc.

2. Substantial Proportion

Section 1855(d)(1)(B) of the Act states that a PSO must provide a "substantial proportion" of health care services directly through the provider or affiliated group of providers. Section 1855(d)(2) then provides specific further direction on what the Secretary should take into account in order to define "substantial proportion" so as " * * * to assure financial stability and to address the practical considerations involved in integrating the delivery of a wide range of service providers." In particular, the statute directs that a PSO provide "significantly more than the majority" of the items and services required under the contract through its own affiliated providers.

In defining the level of services that should constitute a substantial proportion of items and services under section 1855(d) of the Act, we attempted to identify a proportion that would achieve a balance between two competing interests. First, we did not want to set a proportion so high as to preclude participation by all but the most integrated provider organizations. At the same time, we wanted to set a requirement that would ensure that a PSO had a sufficiently well-developed capacity to deliver services so as to meet the intent of the BBA both in terms of (a) providing a distinct and viable health care option for individual beneficiaries and (b) increasing the prospects for successful development and solvent operations of PSOs in general. Another consideration related to the establishment of the substantial proportion threshold percentage surfaced through our discussions with physician groups. They raised the possibility of establishing PSOs without hospitals as affiliates, and suggested that a 60 percent threshold might be low enough to allow such an organization. Finally, we had to take into account the fundamental requirement under section 1855(d)(2)(A)(I) that a substantial proportion consist of "significantly more than a majority" of items and services.

Given all these considerations, we evaluated substantial proportion options between 60 and 80 percent of contractually required services. As part of this evaluation, we modeled the various service mixes to attempt to identify the types of provider combinations that might be possible at these various substantial proportion

percentage levels. We came to the conclusion that it would be very difficult, if not impossible, to meet the substantial proportion percentage under any of these scenarios (that is, substantial proportion threshold of anywhere from 60–80 percent of services) without some combination of physician and hospital participation in the direct delivery of services as an affiliated provider of the PSO. Thus, under § 422.352(b)(1), we are establishing the substantial proportion threshold at 70 percent of all health care items and services. We believe that this percentage on its face constitutes significantly more than a majority and achieves an appropriate balance among the objectives discussed above, in particular the requirement that the definition of substantial proportion achieve the objective of assuring the financial stability of the PSO. As required by section 1855(d)(2)(A)(ii), the PSO must provide most of the remainder of items and services not provided by the PSO and its affiliates directly through contracts with other health care providers.

We also considered the possibility of specifying the composition of providers constituting the affiliated group of providers as a means of defining substantial proportion. Instead, we opted for the much more flexible approach of allowing PSO organizations to determine service mix within the constraint of meeting the overall substantial proportion requirement.

Section 1855(d)(2)(C) of the Act provides that the Secretary may allow for variation in the definition of substantial proportion for rural PSOs. Consistent with this provision, and based upon consultation with rural health care industry representatives, we have established under § 422.354(b)(2), a substantial proportion threshold of 60 percent of items and services required under contract. We believe that this requirement reflects the lower proportion of specialty and other medical services that are likely to be available in some rural areas and is necessary to promote the likelihood of PSO development and success in rural areas. Consistent with most other Medicare programs (and current § 417.1 of the regulations), we are adopting the widely accepted Office of Management and Budget definition of a rural area.

As noted above, we recognize that the economic effects of the requirements set forth in this interim final rule concerning the substantial proportion threshold will be to require some combination of physician and hospital affiliation in most if not all PSOs. To the extent that this assumption is true, an

argument can be made that in setting the 70 percent substantial proportion threshold, we may be closing off market opportunities for physician groups by in-effect precluding them from establishing PSOs without hospital participation. However, we believe that, in most service areas, sufficient competition exists in the hospital industry to ensure hospital interest in engaging in a risk relationship with physician groups under a PSO; thus, physician groups should not be at an economic disadvantage. For rural areas, where such competition among hospitals is least likely to exist, we have established a lower substantial proportion threshold. We welcome comments on the economic effects of the substantial proportion threshold, particularly any data or statistical analysis relevant to this requirement.

3. Affiliation Status

As described in detail in section II.B.6 of this preamble, section 1855(d)(3) of the Act provides clear direction on the four possible meanings of the term "affiliation" as it applies to PSOs. We have adopted the statutory language under § 422.354 of the regulations, and do not believe there is any reasonable alternative to this approach. (See below for related discussions of the meaning of "substantial risk" and "majority financial interest.")

We considered whether providers would be required to affiliate individually with other providers of the PSO or whether they could affiliate as a group through organizations such as physician practice management companies or individual practice associations. We concluded that such group affiliation arrangements are acceptable where the group is controlled by providers and where all other requirements are met. Requiring individual affiliation would be overly burdensome and could have the effect of unnecessarily restricting the development of, and availability of care under, PSO plans. Thus, as noted above, we believe that an affiliated provider could be a medical group or an independent practice association, as well as a hospital, nursing home, or home health agency, as long as the affiliation tests are met.

In general, the affiliation rules are not intended to constrain the internal organizational structuring of the components of the entity that is the affiliated provider. For example, these rules do not limit an individual practice association's flexibility in bringing together individual physicians or its payment arrangements with those physicians. Similarly, if a hospital has

purchased a medical practice and a nursing home, the hospital (in effect, now a health care system) is considered one affiliate provider. The affiliation tests apply to how this hospital or health care system affiliates with other provider entities outside of its corporate structure.

4. Substantial Financial Risk

The term "substantial financial risk" is used in two contexts in section 1855(d) of the Act. First, section 1855(d)(1)(C) requires that all affiliated providers within a PSO share substantial financial risk in the provision of health care services. In addition, under section 1855(d)(3)(C), one basis for demonstrating provider affiliation is the sharing of substantial financial risk in connection with the organization's operations. In order to provide additional guidance to organizations considering applying for PSO status, we have clarified the meaning of these terms in this interim final rule. We believe that both of these provisions share the common statutory intent of ensuring that affiliated providers have a financial interest in seeing the PSO and its affiliated providers achieve operational and financial success. This could serve to differentiate PSOs from other coordinated care options because providers in PSOs would have a more direct economic incentive to improve the PSO's delivery of health care.

To satisfy this intent, we needed to determine both what type of financial arrangements were appropriate and whether the same set of arrangements should be considered substantial financial risk for both purposes. We considered allowing only those arrangements where affiliated provider income was based directly on the PSO's performance (for example, the ability of the PSO to "withhold" a significant amount of affiliated provider compensation to help pay other expenses). However, we determined that this option would unnecessarily restrict PSO development because a variety of arrangements may exist where affiliated providers have a financial interest in the PSO's performance. Therefore, we decided to consider a wide range of financial arrangements as constituting financial risk, as set forth under § 422.356(a). We believe that this approach can achieve the statutory objective that affiliated providers are financially motivated to improve and maintain PSO performance. At the same time, PSOs can retain sufficient flexibility to tailor their financial arrangements with affiliated providers

according to their particular circumstances.

We also considered using different interpretations of substantial financial risk for the two applications of the term. We concluded that the identical use of the term in the statute provides a clear indication that a similar meaning is called for in both applications.

We welcome comments on the potential effects of our interpretation of the term substantial financial risk.

5. Majority Financial Interest

Section 1855(d)(1)(C) of the Act concludes with the requirement that the affiliated providers in a PSO have at least a majority financial interest in the organization. As discussed in detail in section III.E of this preamble, we believe the intent of this requirement is to ensure that affiliated health care providers maintain effective control of the PSO. However, the statute does not specify whether the affiliated providers that are required to have at least a majority financial interest in the PSO must constitute the identical group of affiliated providers that is required to provide a substantial proportion of services as discussed above.

Thus, we considered two basic policy alternatives:

(a) All affiliated providers used for purposes of complying with the substantial proportion requirement must individually meet the majority financial interest requirement. That is, all affiliated providers must have a financial interest in the PSO.

(b) The majority financial interest requirement can be met under any combination of the affiliated providers. That is, at least one of the affiliated providers (or any combination of those providers) must maintain a majority financial interest in the PSO.

We believe that the first option creates unnecessary restrictions on the development of the PSO option and could inhibit the ability of PSOs to compete effectively with other Medicare+Choice plans. In addition, mandating that each affiliated provider maintain a financial interest in the PSO is not practical in view of the dynamic nature of affiliated provider group relationships. Therefore, we are implementing the second and less restrictive option through § 422.356(b), in combination with § 422.354(c). We believe this option meets the intent of the statute by ensuring that PSOs develop a key distinguishing characteristic, provider control, from other Medicare+Choice coordinated care plans, while allowing sufficient organizational flexibility to foster PSO development.

D. Conclusion

Overall, we believe that this interim final rule, as a complement to the statutory provisions regarding PSOs, can ensure that PSOs become a distinct and viable health care option under Medicare+Choice. Thus, this interim final rule should have beneficial effects in terms of providing additional coverage choices for Medicare beneficiaries. However, we are unable to quantify the economic effects of these provisions and recognize that not all of the potential effects can be anticipated. Therefore, we welcome comments on all aspects of this impact analysis, including the degree to which these definitions should promote availability of PSO plans, any effects of these definitions on the amount of interest among beneficiaries in joining these plans, and likely competitive effects (for example, whether the definitions set forth in this rule will promote competition or, alternatively, will unnecessarily created or close off opportunities in the health care market). Given the necessarily subjective nature of much of this impact analysis, we particularly solicit comments offering empirical data on the likely economic impact of the policies discussed here both on PSO health care plans and on competing Medicare+Choice plans.

In accordance with the provisions of Executive Order 12866, this interim final rule with comment period was reviewed by the Office of Management and Budget.

VI. 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. However, section 1871(b) of the Act provides that publication of a notice of proposed rulemaking is not required before issuing a final where "a statute specifically permits a regulation to be issued in interim final form." Section 1851(b)(1), as added by section 4001 of the BBA, expressly authorizes the Secretary to issue standards, other than the PSO solvency requirements, as necessary to carry out Part C and to accomplish this through interim final rulemaking with public comment. We are exercising this authority in issuing this interim final rule with comment on PSO definitions and related requirements.

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 in section I of this preamble, HCFA and the negotiated rulemaking committee developing the solvency standards believe that we needed to establish a clear definition of a PSO and the fundamental organizational requirements that a PSO must meet as a prerequisite to the development of appropriate solvency standards. The PSO solvency regulation has a statutory deadline for publication of April 1, 1998. Further, we determined that entities considering applying to become PSOs under the Medicare+Choice 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 Congress for implementation of the Medicare+Choice program, we believe that it is impractical and contrary to the public interest to publish a notice of proposed rulemaking before establishing the PSO definitions and related requirements set forth in this interim final rule. We are providing a 60-day period for public comment.

VII. Response to Comments

Because of the large number of comments 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 will respond to them in a forthcoming rulemaking document.

List of Subjects in 42 CFR Part 422

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

For the reasons set forth in the preamble, 42 CFR chapter IV is amended as set forth below:

A new Part 422 is added to read as follows:

PART 422—MEDICARE+CHOICE PROGRAM

Subparts A—G [Reserved]

Subpart H—Provider-Sponsored Organizations

Sec.

422.350 Basis, scope, and definitions.

422.352 Basic requirements.

422.354 Requirements for affiliated providers.

422.356 Determining substantial financial risk and majority financial interest.

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

Subparts A—G—[Reserved]

Subpart H—Provider-Sponsored Organizations

§ 422.350 Basis, scope, and definitions.

(a) *Basis and scope.* This subpart is based on sections 1851 and 1855 of the Act which, in part,—

(1) Authorize provider sponsored organizations, hereinafter referred to as PSOs, to contract as a Medicare+Choice plan;

(2) Require that a PSO meet certain qualifying requirements; and

(3) Provide for waiver of State licensure for PSOs under specified conditions.

(b) *Definitions.* As used in this subpart (unless otherwise specified)—

Control means that an individual, group of individuals, or entity has the power, directly or indirectly, to direct or influence significantly the actions or policies of an organization or institution.

Engaged in the delivery of health care services means—

(1) For an individual, that the individual directly furnishes health care services, or

(2) For an entity, that the entity is organized and operated primarily for the purpose of furnishing health care services directly or through its provider members or entities.

Health care provider means—

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation.

Provider-sponsored organization (PSO) means, for purposes of Medicare Part C, a public or private entity—

(1) That is established or organized, and operated, by

(i) A health care provider, or
(ii) Group of affiliated health care providers;

(2) That provides a substantial proportion (as defined in § 422.352(b)) of the health care items and services under the Medicare+Choice contract directly through the provider or affiliated group of providers; and

(3) In the case of paragraph (1)(ii) of this definition, the affiliated providers

(i) Share, directly or indirectly, substantial financial risk (as defined in § 422.356(a)) for the provision of items and services that are the obligation of the PSO under the Medicare+Choice contract, and

(ii) Have at least a majority financial interest in the PSO.

§ 422.352 Basic requirements.

(a) *General rule.* An organization is considered a PSO for purposes of a Medicare+Choice contract if the organization—

(1) Is licensed by the State or has obtained a waiver of such licensure as provided for under section 1855(a)(2) of the Act;

(2) Meets the definition of a PSO set forth in § 422.350 and other applicable requirements of this subpart; and

(3) Is effectively controlled by the health care provider or, in the case of a group, by one or more of the affiliated providers that established and operate the PSO.

(b) *Provision of services.* A PSO must demonstrate to HCFA's satisfaction that it is capable of delivering to Medicare enrollees the range of services required under a contract with HCFA. Each PSO must deliver a substantial proportion of those services directly through the health care provider or the affiliated providers responsible for operating the PSO. Substantial proportion means—

(1) For a non-rural PSO, not less than 70% of Medicare items and services covered under the contract.

(2) For a rural PSO as defined in § 422.354, not less than 60% of Medicare items and services covered under the contract.

(c) *Rural PSO.* To qualify as a rural PSO, a PSO must demonstrate to HCFA that—

(1) It has available in the rural area (as defined in § 412.62(f) of this chapter) routine services, including but not limited to primary care, routine specialty care, and emergency services, and that the level of use of providers outside the rural area is consistent with referral patterns; and

(2) As the PSO enrolls Medicare beneficiaries, a majority of these enrollees reside within the rural area served by the PSO.

§ 422.354 Requirements for affiliated providers.

A PSO that consists of by two or more health care providers must demonstrate to HCFA'S satisfaction that it meets the following requirements:

(a) The providers are affiliated. For purposes of this subpart, providers are affiliated if, through contract, ownership, or otherwise—

(1) One provider, directly or indirectly, controls (as defined in paragraph (d) of this section), is controlled by, or is under common control with another;

(2) Each provider is part of a lawful combination under which each shares substantial financial risk (as defined in § 422.356(a)) in connection with the PSO's operations;

(3) Both, or all, providers are part of a controlled group of corporations under section 1563 of the Internal Revenue Code of 1986; or

(4) Both, or all, providers are part of an affiliated service group under section 414 of that Code.

(b) Each affiliated provider of the PSO shares, directly or indirectly, substantial financial risk (as defined in § 422.356(a)) for the provision of items and services under the Medicare contract that are the obligation of the PSO.

(c) Affiliated providers, as a whole or in part, have at least a majority financial interest (as defined in § 422.356(b)) in the PSO.

(d) For purposes of paragraph(a)(1) of this section, control is presumed to exist if one party, directly or indirectly, owns, controls, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance right of another.

§ 422.356 Determining substantial financial risk and majority financial interest.

(a) *Determining substantial financial risk.* The PSO must demonstrate to HCFA's satisfaction that it apportions a significant part of the financial risk of the PSO enterprise under the Medicare+Choice contract to each affiliated provider. The PSO must demonstrate that the financial arrangements among its affiliated providers constitute "substantial" risk in the PSO for each affiliated provider. The following mechanisms may constitute risk-sharing arrangements, and may have to be used in combination to demonstrate substantial financial risk in the PSO enterprise.

(1) Agreement by a health care provider to accept capitation payment for each Medicare enrollee.

(2) Agreement by a health care provider to accept as payment a predetermined percentage of the PSO premium or the PSO's revenue.

(3) The PSO's use of significant financial incentives for its affiliated providers, with the aim of achieving utilization management and cost containment goals. Permissible methods include the following:

(i) Affiliated providers agree to a withholding of a significant amount of

the compensation due them, to be used for any of the following:

(A) To cover losses of the PSO.

(B) To cover losses of other affiliated providers.

(C) To be returned to the affiliated provider if the PSO meets its utilization management or cost containment goals for the specified time period.

(D) To be distributed among affiliated providers if the PSO meets its utilization management or cost-containment goals for the specified time period.

(ii) Agreement by the affiliated provider to preestablished cost or utilization targets for the PSO and to subsequent significant financial rewards and penalties (which may include a reduction in payments to the provider) based on the PSO's performance in meeting the targets.

(4) Other mechanisms that demonstrate significant shared financial risk.

(b) *Determining majority financial interest.* Majority financial interest means maintaining effective control of the PSO.

(Catalog of Federal Domestic Assistance Program Nos. 93.778, Medical Assistance Program; Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 25, 1998.

Nancy-Ann Min DeParle,
Administrator, Health Care Financing Administration.

Dated: March 27, 1998.

Donna E. Shalala,
Secretary.

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CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

45 CFR Parts 2510, 2516, 2517, 2519, 2521, and 2540

Administrative Costs for Learn and Serve America and AmeriCorps Grants Programs

AGENCY: Corporation for National and Community Service.

ACTION: Interim final rule.

SUMMARY: The Corporation issues this interim final rule to amend provisions relating to administrative costs in parts 2510, 2516, 2517, 2519, 2521, and 2540. For national service programs assisted by the Corporation that are subject to a statutory limit on the percentage of assistance that may be used to pay for administrative costs, the interim final