

§ 422.354

(2) Enroll Medicare beneficiaries, the majority of which reside in the rural area the PSO serves.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998; 65 FR 40327, June 29, 2000]

§ 422.354 Requirements for affiliated providers.

A PSO that consists of two or more 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, 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 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 for the furnishing of services the PSO is obligated to provide under the contract.

(c) Affiliated providers, as a whole or in part, have at least a majority financial interest 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.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 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 M+C contract to each affiliated provider. The PSO must demonstrate that the fi-

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ancial 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 provider to accept capitation payment for each Medicare enrollee.

(2) Agreement by a 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) Affiliated providers agree 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.

[63 FR 18134, Apr. 14, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.370 Waiver of State licensure.

For an organization that seeks to contract to offer an M+C plan under this subpart, HCFA may waive the

State licensure requirement of section 1855(a)(1) of the Act if—

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

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

[63 FR 25376, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 422.372 Basis for waiver of State licensure.

(a) *General rule.* Subject to this section and to paragraphs (a) and (e) of § 422.374, HCFA may waive the State licensure requirement if the organization has applied (except as provided in paragraph (b)(4) of this section) for the most closely appropriate State license or authority to conduct business as an M+C plan.

(b) *Basis for waiver of State licensure.* Any of the following may constitute a basis for HCFA's waiver of State licensure.

(1) *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.

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

(i) Denied the license 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

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

(3) *Denial of application based on different solvency requirements.* (i) The State has denied the 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

(ii) HCFA determines that the State has imposed, as a condition of licensure, any documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, or standards set forth by HCFA to implement, mon-

itor, and enforce §§ 422.380 through 422.390.

(4) *State declines to accept licensure application.* The appropriate State licensing authority has given the organization written notice that it will not accept its licensure application.

[63 FR 35098, June 26, 1998]

§ 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) HCFA gives the organization written notice of granting or denial of waiver within 60 days of receipt of a substantially complete waiver request.

(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.

[63 FR 25377, May 7, 1998, as amended at 63 FR 35098, June 26, 1998]

§ 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