

§ 422.154

42 CFR Ch. IV (10-1-00 Edition)

- (ii) High-volume services.
- (iii) High-risk services.
- (iv) Continuity and coordination of care.
- (5) The required nonclinical areas include:
 - (i) Appeals, grievances, and other complaints.
 - (ii) Access to, and availability of, services.
- (6) In addition to requiring that the organization initiate its own performance improvement projects, HCFA may require that the organization—
 - (i) Conduct particular performance improvement projects that are specific to the organization; and
 - (ii) Participate in national or statewide performance improvement projects.
- (7) For each project, the organization must assess performance under the plan using quality indicators that are—
 - (i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and
 - (ii) Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.
- (8) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.
- (9) Interventions must achieve improvement that is significant and sustained over time.
- (10) The organization must report the status and results of each project to HCFA as requested.

(e) *Requirements for M+C PPO plans, non-network MSA plans, and M+C private fee-for-service plans.* An organization offering an M+C plan, non-network MSA plan, or private fee-for-service plan must do the following:

- (1) Measure performance under the plan using standard measures required by HCFA and report its performance to HCFA. The standard measures may be specified in uniform data collection and reporting instruments required by HCFA and will relate to—
 - (i) Clinical areas including effectiveness of care, enrollee perception of care, and use of services; and
 - (ii) Nonclinical areas including access to and availability of services, ap-

peals and grievances, and organizational characteristics.

(2) Evaluate the continuity and coordination of care furnished to enrollees.

(3) If the organization uses written protocols for utilization review, the organization must—

(i) Base those protocols on current standards of medical practice; and

(ii) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans—*
(1) *Health information.* For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality assessment and performance improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to HCFA.

(2) *Program review.* For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality assessment and performance improvement program.

(3) *Remedial action.* For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000]

§ 422.154 External review.

(a) *Basic rule.* Except as provided in paragraph (c) of this section, each M+C organization must, for each M+C plan it operates, have an agreement with an independent quality review and improvement organization (review organization) approved by HCFA to perform functions of the type described in part 466 of this chapter.

(b) *Terms of the agreement.* The agreement must be consistent with HCFA guidelines and include the following provisions:

- (1) Require that the organization—

(i) Allocate adequate space for use of the review organization whenever it is conducting review activities; and

(ii) Provide all pertinent data, including patient care data, at the time the review organization needs the data to carry out the reviews and make its determinations.

(2) Except in the case of complaints about quality, exclude review activities that HCFA determines would duplicate review activities conducted as part of an approved accreditation process or as part of HCFA monitoring.

(c) *Exceptions.* The requirement of paragraph (a) of this section does not apply for an M+C private fee-for-service plan or a non-network M+C MSA plan if the organization does not carry out utilization review with respect to the plan.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000]

§ 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An M+C organization is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The M+C organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by HCFA; and

(2) The accreditation organization used the standards approved by HCFA for the purposes of assessing the M+C organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) Quality assurance.

(2) Antidiscrimination.

(3) Access to services.

(4) Confidentiality and accuracy of enrollee records.

(5) Information on advance directives.

(6) Provider participation rules.

(c) *Effective date of deemed status.* The date on which the organization is deemed to meet the applicable requirements is the later of the following:

(1) The date on which the accreditation organization is approved by HCFA.

(2) The date the M+C organization is accredited by the accreditation organization.

(d) *Obligations of deemed M+C organizations.* An M+C organization deemed to meet Medicare requirements must—

(1) Submit to surveys by HCFA to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to HCFA a copy of its most recent accreditation survey, together with any survey-related information that HCFA may require (including corrective action plans and summaries of unmet HCFA requirements).

(e) *Removal of deemed status.* HCFA removes part or all of an M+C organization's deemed status for any of the following reasons:

(1) HCFA determines, on the basis of its own survey or the results of the accreditation survey, that the M+C organization does not meet the Medicare requirements for which deemed status was granted.

(2) HCFA withdraws its approval of the accreditation organization that accredited the M+C organization.

(3) The M+C organization fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* HCFA retains the authority to initiate enforcement action against any M+C organization that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

[63 FR 35082, June 26, 1998, as amended at 65 FR 40323, June 29, 2000]

§ 422.157 Accreditation organizations.

(a) *Conditions for approval.* HCFA may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

(1) In accrediting M+C organizations, it applies and enforces standards that are at least as stringent as Medicare requirements with respect to the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 422.158.

(3) It ensures that: