

care services to be offered under the M+C contract; or

(ii) Federal waiver as described in subpart H of this part.

(2) The authorized individual must describe thoroughly how the entity and M+C plan meet, or will meet, the requirements described in this part.

(c) *Responsibility for making determinations.* HCFA is responsible for determining whether an entity qualifies as an M+C organization and whether proposed M+C plans meet the requirements of this part.

(d) *Resubmittal of application.* An application that has been denied by HCFA may not be resubmitted for 4 months after the date of the notice from HCFA denying the application.

(e) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), should label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR part 5.

#### § 422.8 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) HCFA evaluates an application for an M+C contract on the basis of information contained in the application itself and any additional information that HCFA obtains through on-site visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, HCFA notifies the entity and allows 60 days from the date of the notice for the entity to furnish the missing information.

(3) After evaluating all relevant information, HCFA determines whether the entity's application meets the applicable requirements of § 422.6.

(b) *Use of information from a prior contracting period.* If an entity has failed to comply with the terms of a previous year's contract with HCFA under title XVIII of the Act as an HMO, competitive medical plan, health care prepayment plan, or M+C organization or an

entity has failed to complete a corrective action plan during the term of the contract, HCFA may deny an application based on the entity's failure to comply with that prior contract with HCFA even if the entity meets all of the current requirements.

(c) *Notice of determination.* HCFA notifies each entity that applies for an M+C contract under this part of its determination and the basis for the determination. The determination may be approval, intent to deny, or denial.

(d) *Approval of application.* If HCFA approves the application, it gives written notice to the M+C organization, indicating that it meets the requirements for an M+C contract.

(e) *Intent to deny.* (1) If HCFA finds that the entity does not appear to meet the requirements of an M+C organization and appears to be able to meet those requirements within 60 days, HCFA gives the entity notice of intent to deny qualification and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the entity may respond in writing to the issues or other matters that were the basis for HCFA's preliminary finding and may revise its application to remedy any defects HCFA identified.

(f) *Denial of application.* If HCFA denies the application, it gives written notice to the M+C organization indicating—

(1) That the M+C organization does not meet the contract requirements under part C of title XVIII of the Act;

(2) The reasons why the M+C organization does not meet the contract requirements; and

(3) The M+C organization's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(g) *Oversight of continuing compliance.*

(1) HCFA oversees an entity's continued compliance with the requirements for an M+C organization.

(2) If an entity no longer meets those requirements, HCFA terminates the contract in accordance with § 422.510.

#### § 422.10 Cost-sharing in enrollment-related costs.

(a) *Basis and scope.* This section implements that portion of section 1857 of