Medicare
Managed Care Manual

Department of Health and Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

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CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
11		10 - 140	---

NEW/REVISED MATERIAL--EFFECTIVE/IMPLEMENTATION DATE: Not Applicable

This is the initial issuance of Chapter 11 of the Medicare Managed Care Manual, Medicare Plus Choice Contract Requirements. Chapter 11 addresses Medicare+Choice contract requirements only, and does not address Medicare cost-based managed care contract requirements. It covers contract provisions, renewal, nonrenewal, terminations, contract provisions, and relationships with entities under contract to the M+C Organization.

These instructions should be implemented within your current operating budget.

NOTE: Normally red italicized font identifies new material. However, because this is a new chapter, normal text font is used for the initial release.

Medicare Managed Care Manual

Chapter 11 - Medicare Plus Choice Contract Requirements

NOTE: This chapter addresses Medicare+Choice contract requirements only, and does not address Medicare cost-based managed care contract requirements. Information on Medicare cost-based contract requirements can be found in Chapter 17.

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10 - Definitions Applicable to Understanding Medicare + Choice (M+C) Organization Contracting Requirements.

(Rev. 8, 03-20-02)

The term **Business transaction** means any of the following kinds of transactions:

1. Sale, exchange, or lease of property;

2. Loan of money or extension of credit;

3. Goods, services, or facilities furnished for a monetary consideration, including management services, but not including:

    - Salaries paid to employees for services performed in the normal course of their employment; or

    - Health services furnished to the M+C organization's enrollees by hospitals and other providers, and by M+C organization staff, medical groups, or independent practice associations, or by any combination of those entities.

The term **clean claim** means a claim that has no defect, impropriety, lack of any required substantiating documentation - including the substantiating documentation needed to meet the requirements for encounter data - or particular circumstance requiring special treatment that prevents timely payment; and a claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

The term **downstream entity** means any party that enters into an acceptable written arrangement below the level of the arrangement between an M+C organization (and contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of health and/or administrative services.

The term **first tier entity** means any party that enters into a written arrangement with an M+C organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

The term **party in interest** includes the following:

1. Any director, officer, partner, or employee responsible for management or administration of an M+C organization.

2. Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

3. In the case of an M+C organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law.

4. Any entity in which a person described in paragraph (1), (2), or (3) of this definition:

    - Is an officer, director, or partner; or

    - Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

5. Any person that directly or indirectly controls, is controlled by, or is under common control with, the M+C organization.

6. Any spouse, child, or parent of an individual described in paragraph (1), (2), or (3) of this definition.

The term **related entity** means any entity that is related to the M+C organization by common ownership or control and:

1. Performs some of the M+C organization's management functions under contract or delegation;

2. Furnishes services to Medicare enrollees under an oral or written agreement; or

3. Leases real property or sells materials to the M+C organization at a cost of more than $2,500 during a contract period.

The term **significant business transaction** means any business transaction or series of transactions of the kind specified in the above definition of "business transaction" that, during any fiscal year of the M+C organization, have a total value that exceeds $25,000 or 5 percent of the M+C organization's total operating expenses, whichever is less.

20 - General M+C Contract Provisions

(Rev. 8, 03-20-02)

CMS may enter into contracts with organizations without regard to provisions of law or regulations that the Secretary of Department of Health and Human Services (DHHS) determines to be inconsistent with the furtherance of the purpose of Title XVIII of the Act. Based on this authority, CMS may enter into contracts with M+C applicant organizations without regard to the Federal and Departmental acquisition regulations set forth in Title 48 of the CFR.

Medicare+Choice Organizations may agree to operate coordinated care plans (as defined in 42 CFR §422.2 (a)(1)) so long as they do so in compliance with the requirements of their contract and applicable Federal statutes, regulations, and policies. The M+C contract is deemed to incorporate any changes that are required by statute to be implemented during the term of the contract, and any regulations or policies implementing or interpreting such statutory provisions. However, any regulations or policy statements issued by CMS after the date on which final adjusted community rate proposals (ACRs) must be submitted for a calendar year, and which create significant new operational costs of which the M+C organization did not have reasonable notice prior to such date, shall not become effective before the next contract year for which these requirements can be taken into account in making ACR submissions, unless earlier implementation is required by statute or in connection with litigation challenging CMS policies.

20.1 - Conditions for Entering an M+C Contract

(Rev. 8, 03-20-02)

Organizations that seek to operate as an M+C organization must enter into a contract with CMS. A single M+C contract may cover more than one M+C plan offered by the contracting M+C organization. An applicant entity, however, must meet certain requirements before CMS can consider entering into a contract with the organization.

- The applicant must document that it is authorized under State law in the requested service area (SA) to operate as a risk bearing entity that may offer health benefits. If the applicant offers a continuation area in another (host) State, then the applicant must show that it is authorized by the (host) State to offer health benefits. As such, before an applicant entity may apply to become a Medicare+Choice organization, it must first submit a completed Certification Form to CMS. Existing §1876 cost contractors do not have to complete this form. Please note that the revised HMO, PPO, and State Licensed Provide Sponsored Organization (PSO) application includes this form.

- The applicant entity must be licensed (or if the state does not license such entities, hold a certificate of authority/operation) as a risk-bearing entity in the State in which it wishes to operate as an M+C organization. The law does, however, allow for a waiver of this requirement for Federally-waivered PSOs under certain circumstances.

- The applicant must meet certain minimum enrollment requirements. The applicant entity must have at least 5,000 (or 1,500 if it is a Federally-waivered PSO) individuals receiving health benefits from the organization or at least 1,500 (or 500 if it is a PSO) individuals receiving benefits in a rural area. CMS has the authority to waive the minimum enrollment requirements for the first 3 contract years.

- An M+C organization must demonstrate certain administrative and managerial capabilities. They include:

    - A policy making body that exercises oversight and control over the M+C organizations policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees;

    - Personnel and systems sufficient for the M+C organization to organize, plan, control, and evaluate financial and marketing activities, the furnishing of services, the quality assurance program, and the administrative and management aspects of the organization;

    - At a minimum, an executive manager whose appointment and removal are under the control of the policy making body;

    - A fidelity bond or bonds procured and maintained by the M+C organization, in an amount fixed by its policy making body but not less than $100,000 per individual, covering each officer and employee entrusted with the handling of its funds (the bond may have reasonable deductibles, based upon the financial strength of the M+C organization);

    - Insurance policies or other arrangements, secured and maintained by the M+C organization and approved by CMS to insure the M+C organization against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks; and

    - A compliance plan that consists of the following:

        - Written policies, procedures, and standards of conduct that articulate the organizations commitment to comply with all applicable Federal and State standards;

        - The designation of a compliance officer and compliance committee that are accountable to senior management;

- Effective training and education between the compliance officer and organization employees;

- Effective lines of communication between the compliance officer and the organization's employees;

- Enforcement of standards through well-publicized disciplinary guidelines;

- Provision for internal monitoring and auditing; and

- Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's M+C contract.

20.2 - Monitoring and Promoting Staff and Affiliated Provider Compliance With Policies

(Rev. 8, 03-20-02)

The organization should monitor compliance through analysis of complaints or grievances, requests to change providers, enrollee satisfaction surveys, rapid disenrollment surveys, and other sources of enrollee input. Issues in compliance should be addressed through education or counseling of the staff or providers or other corrective action, and information on compliance with the policies should be considered during the recredentialing and staff evaluation process and within the Quality Assurance and Project Improvement (QAPI) program.

The organization ensures compliance with Federal and State laws affecting the rights of enrollees.

Applicable Federal laws include, but are not limited to:

1. Title VI of the Civil Rights Act;

2. Section 504 of the Rehabilitation Act of 1973;

3. The Age Discrimination Act of 1975;

4. Titles II and III of the Americans with Disabilities Act;

5. Section 542 of the Public Health Service Act (pertaining to nondiscrimination against substance abusers); and

6. Title 45, Part 46 of the Code of Federal Regulations, pertaining to research involving human subjects.

In general, agencies other than CMS or the State Medicaid Agency enforces these laws, and reviews conducted under these standards will not include detailed assessment of an

organization’s compliance. However, CMS or States will report any observed violations and refer any enrollee complaints to the appropriate agency for resolution.

The organization must include provisions relating to compliance with Federal and State laws in subcontracts with providers. Assessment of compliance should be included in the organization’s credentialing procedures to the extent feasible and appropriate. For example, if site visits to individual providers’ offices are conducted, they should include a general assessment of physical accessibility. Compliance issues identified may be addressed through the organization’s QAPI program.

Each M+C contract is for a period of at least 12 months. The contract is effective on the date specified in the contract between the M+C organization and CMS.

An M+C organization's M+C contract with CMS will contain a provision specifying inspection and auditing rights, along with CMS's rights to inspect or evaluate the quality, appropriateness, and timeliness of services performed under the contract; CMS's rights to inspect or evaluate the facilities of the organization when evidence of the need to do so exists; and CMS's right to inspect books, contracts, and records of the M+C organization that pertain to the organization's ability to bear financial risk, perform services, and determine amounts payable.

An M+C organization's M+C contract will contain a severability provision that provides that upon CMS's request (1) The contract will be amended to exclude any M+C plan or State-licensed entity specified by CMS, and (2) A separate contract would be deemed to be in place for the plan removed from the M+C contract, when such a request is made.

An M+C organization’s M+C contract will contain a provision stating that any regulations or policy statements issued by CMS after the date on which final ACR proposals must be submitted for a calendar year, and which create significant new operational costs of which the M+C organization did not have reasonable notice prior to such date, will not become effective before the next contract year for which these requirements can be taken into account in making ACR submissions, unless earlier implementation is required by statute or in connection with litigation challenging CMS policies.

30 - Minimum Enrollment Requirements for M+C Organizations

(Rev. 8, 03-20-02)

Unless an organization has a minimum enrollment waiver as explained below, CMS does not enter into a contract with an entity unless it meets the following minimum enrollment requirements:

- At least 5,000 individuals (or 1,500 individuals if the organization is a PSO) are enrolled for the purpose of receiving health benefits from the organization; or

- At least 1,500 individuals (or 500 individuals if the organization is a PSO) are enrolled for purposes of receiving health benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in 42 CFR §412.62 (f) (or, in the case of a PSO, the PSO meets the requirements of 42 CFR §422.352(c)).

Except when an organization has a minimum enrollment waiver, the organization must maintain the minimum enrollment standards above for the duration of its contract.

30.1 - Minimum Enrollment Waiver

(Rev. 8, 03-20-02)

For an organization that does not meet the applicable enrollment requirements when it applies for an M+C contract or during the first 3 years of its M+C contract, CMS may waive the minimum enrollment requirement. To receive a waiver, an organization must demonstrate to CMS's satisfaction that it is capable of administering and managing an M+C contract and is able to manage the level of risk required under the contract.

CMS considers the following factors when making this evaluation:

- The organization management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity;

- The organization has the financial ability to bear financial risk under an M+C contract including experience managing an organization and stop-loss insurance that is adequate and acceptable to CMS; and

- The organization is able to establish a marketing and enrollment process that will allow it to meet the applicable enrollment requirement prior to completion of the third contract year.

If the M+C organization fails to meet the enrollment requirement in the first year, CMS may waive the minimum requirements for another year provided that the organization requests an additional minimum enrollment waiver no later than 120 days before the end of the first year, continues to demonstrate it is capable of administering and managing an M+C contract and is able to manage the level of risk, and demonstrates an acceptable marketing and enrollment process.

Enrollment projections for the second year of the waiver become the organization's transitional enrollment standard. If an organization fails to meet the enrollment requirement in the second year, CMS may waive the minimum requirements for the third year only if the organization has attained the transitional enrollment standard established based on its enrollment projections for the second year.

CMS may elect to not renew its contract with an M+C organization that fails to meet the applicable enrollment requirement.

40 - Term and Effective Date of an M+C Contract

(Rev. 8, 03-20-02)

An M+C contract is effective on the date specified in the contract between the M+C organization and CMS.

Each M+C contract is for a period of at least 12 months.

50 - Contracting Prohibitions Under the Medicare+Choice (M+C) Program

(Rev. 8, 03-20-02)

An M+C organization will be subject to a 2-year contracting prohibition when the organization leaves the M+C program entirely by non-renewing all of its M+C contracts. As long as an M+C organization continues to offer at least one M+C plan, the prohibition will not apply. If an M+C organization that non-renews all of its M+C contracts proposes to return to Medicare contracting within the two-year time period, the organization must provide a written request to CMS asking for an exemption to the prohibition based on special circumstances. The M+C organization will automatically be permitted to re-enter the program if, during the 6-month period beginning on the date the organization notified CMS of the intention to non-renew all of its M+C contracts, there was a change in the statute or regulations that had the effect of increasing M+C payments in the payment area or areas at issue. The M+C organization will also be permitted to re-enter the program if "circumstances . . .warrant special consideration." CMS will evaluate proposed special circumstance requests on a case-by-case basis. However, there are certain special circumstances under which CMS generally will grant an exemption to the 2-year contracting prohibition. These circumstances are:

1. The organization is proposing to introduce an M+C plan(s) in a geographic area(s) currently served by two or fewer M+C plans.

2. The organization is proposing to introduce M+C plans in counties other than the counties they had previously withdrawn from when they ended their earlier contract with the Medicare program.

3. The organization proposes to offer a different M+C plan type than they had previously offered. For example, an organization that had offered a health maintenance organization may want to reenter the program and offer a preferred provider organization.

4. The organization has undergone a significant change such as a merger or acquisition and could thereby demonstrate that the new entity is essentially a

different organization from the one that severed its contracting relationship with CMS. CMS reserves the right to make a determination whether the nature and extent of the organizational change is sufficient to consider the organization as a new entity, and therefore, no longer subjected to the 2-year contracting prohibition.

In addition, CMS may grant an exception based on other "special circumstances" than those above, at CMS's discretion.

60 - M+C Contract Renewal

(Rev. 8, 03-20-02)

M+C contracts are renewed annually only if:

- CMS informs the M+C organization that it authorizes a renewal; and
- The M+C organization has not provided CMS with a notice of intention not to renew.

CMS will notify each M+C organization of its decision whether to authorize the renewal of their M+C contract, along with applicable appeal rights, by May 1 of the current contract year.

70 - Contract Nonrenewal

(Rev. 8, 03-20-02)

70.1 - Nonrewal of M+C Contract: M+C Organization-Initiated

(Rev. 8, 03-20-02)

An M+C organization may elect not to renew its contract with CMS at the end of the contract for any reason provided it meets specified timeframes for doing so. If an M+C organization does not intend to renew its contract, it must notify:

- CMS in writing by July 1 of the year in which the contract would end, or a later date specified by CMS as described below;
- Each Medicare enrollee at least 90 days before the date on which the nonrenewal is effective. The CMS approved-notice to the enrollee must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative M+C plans, Medigap options, and Original Medicare; and

- The general public at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community located in the M+C organization's service area. This notice must be pre-approved by CMS.

CMS may accept a nonrenewal notice submitted after July 1 if:

- The M+C organization notifies its Medicare enrollees and the public as specified above; and

Acceptance of the delayed non-renewal notice would not be inconsistent with the effective and efficient administration of the Medicare program.

70.2 - Responsibilities of Non-renewing M+C Organizations

(Rev. 8, 03-20-02)

M+C organizations non-renewing their M+C contracts must continue to meet the following requirements through the remainder of their final contract year:

1. **Adjusted Community Rate (ACR) Audits** - CMS is required by statute to audit at least one-third of M+C organizations' ACR's each year. Therefore, those audits started for the current year must be completed. This will assure the public that payments to M+C organizations for the final contract year were correctly reflected in the adjusted community rate proposals submitted by M+C organizations, and that Medicare beneficiaries received appropriate benefits at proper price levels.

2. **Corrective Action Plans (CAP)** - M+C organizations operating under a corrective action plan must continue to fulfill the requirements of the plan through December 31 of the final contract year.

3. **Health Employer Data Information Set (HEDIS)** â **/ Consumer Assessment of Health Plans Study (CAHPS)** - Non-renewing M+C organizations will not be required to submit HEDIS® data results from their final M+C contract year. (For example, M+C organizations non-renewing their M+C contract January 1, 2001, would not be required to submit HEDIS® results from the year 2000 measurement year.) Non-renewing M+C organizations are similarly not required to participate in the CAHPS survey for the final year of their M+C contract by submitting names and telephones numbers for telephone follow-up on nonrespondents.

4. **Physician Incentive Plan (PIP) Reporting** - Non-renewing organizations must provide to CMS any outstanding PIP information that M+C organizations were required to submit for the final contract year. Non-renewing organizations have no reporting obligations for PIP information for the final contract year, which is due the year following the final contract year. Organizations with incentive

arrangements at substantial financial risk must maintain adequate stop-loss protection through December 31 of the final contract year.

5. **Quality Assurance and Performance Improvement Projects (QAPI)** - M+C organizations are required by regulation and contract to perform QAPI projects; QAPI projects generally run on a 3-year cycle. CMS will require non-renewing organizations to meet their QAPI requirements according to the following criteria:

    - For Projects in Their Third Year - During the M+C organization's final contract year, the M+C organizations must complete the project data collection and continue any quality improvement initiatives;

    - For Projects in Their Second Year, (unless the second year of a QAPI project is the project's completion year) - During the M+C organization's final contract year, the organization must continue its quality improvement initiatives but need not continue data collection; and

    - For Projects in Their First Year - During the M+C organization's final contract year, the organizations may discontinue the project altogether. However, if a health care intervention has been started designed to improve the health status of enrollees, the M+C organization must continue to provide that care until the actual end of the M+C contract.

The following are M+C requirements for which non-renewing organizations remain responsible beyond December 31 of the final contract year:

1. **Maintenance of Records** - M+C organizations are required to maintain and provide CMS access to books, records, and other documents related to the operation of an M+C contract. Under 42 CFR §422.502(d) and (e), M+C organizations are to maintain these records, and allow CMS access to them, for six years from the termination date of the contract or the date of the completion of any audit or in the case of service area reductions, the date from which service in a particular county was discontinued. This includes contract terminations that result from a decision by an M+C organization not to renew its M+C contract with CMS.

2. **Continuation of Care** - Terminating M+C organizations and those plans reducing their service areas may, in certain situations, be responsible for costs incurred for Medicare beneficiaries hospitalized beyond the last day of the contracts. If a Medicare beneficiary is hospitalized in a prospective payment (PPS) hospital, the M+C organization is responsible for all Part A inpatient hospital services until the beneficiary is discharged, as stated in 42 CFR §422.264(c). Original Medicare or the beneficiary's next Medicare-contracting managed care organization will assume payment for all services covered under Part B after the terminating M+C organization's M+C contract ends. If a Medicare beneficiary is in a non-PPS hospital, your organization is responsible for the covered charges through the last day of your contract or, for plans

reducing their service areas, the last day in which service in a particular county are discontinued.

With respect to enrollees receiving care in a skilled nursing facility (SNF) upon the termination of the M+C contract, terminating M+C organizations are financially liable for such care through December 31 of the final contract year. After that date, Medicare beneficiaries continuing a SNF stay may receive coverage through either fee-for-service Medicare or enrollment in another M+C plan. Assuming that the SNF stay is Medicare covered, the number of days of the beneficiary's SNF stay while enrolled in the M+C plan will be counted toward the 100-day Medicare limit. For example, if a beneficiary entered a SNF on December 1, 2000, and was disenrolled on December 31, 2000, 31 days of the stay would be covered by the M+C organization, leaving 69 days of fee-for-service coverage beginning January 1, 2001. Those beneficiaries who enroll in another M+C plan will receive SNF coverage beginning January 1, 2001, according to the CMS-approved benefit package offered by that plan. M+C organizations reducing their service areas must apply this SNF coverage policy to their enrollees who reside in the discontinued portion of the service area.

3. **Pending Appeals** - The M+C contract and the regulations at 42 CFR §422.502(a)(3) require M+C organizations to provide access to benefits for the duration of their contracts. Also the language in 42 CFR §422.618(b) requires M+C organizations to "pay for, authorize, or provide" the services that the Center for Health Dispute Resolution (CHDR) determines should have been covered by the organization. As such, M+C organizations are obligated to process any appeals for services which would have been provided or paid for while Medicare beneficiaries were enrolled in the plan. Reconsiderations and appeals decided in favor of the Medicare beneficiary after the date that the M+C organization's contract terminates are the obligation of the (former) M+C organization - regardless of when the decision is effectuated.

4. **Retroactive Payment Adjustments -** For terminating M+C organizations, once the M+C contract has been terminated and the M+C organization is no longer receiving payments from CMS, the organization will still be required to reimburse CMS for any overpayments. Also, the M+C organization will still have the right to seek reimbursement from CMS for any previously identified underpayments to the extent permitted by applicable law. M+C organizations seeking payment adjustments should report corrected information within 45 days from the date of the organization's last CMS reports to the Social Security Administration (for State/County code changes), the CMS Regional Office, or the CMS Central Office (for working aged adjustments). It is important to note that all working aged corrections should be entered into the McCoy system no later than December 31 of the final contract year, as the organization will no longer have access to that system once its contract terminates. The reporting of corrected information to the appropriate office will trigger the CMS retroactive payment adjustment process. The reported corrections will be verified and applied to your

(former) members' records. These corrections will be included as a part of your final payment reconciliation.

There is also a situation related to members that elected hospice coverage that may have resulted in inaccurate payments to M+C organizations. CMS's data systems maintain only one payment rate for hospice. Organizations that offered multiple plans during their final contract year will have to have their final year's hospice rates adjusted. CMS will conduct an annual reconciliation of hospice-related rates based on membership data submitted into Health Plan Management System (HPMS) until the Agency fully implements risk-adjusted rates for hospice. Operational Policy Letter #115 explains the details of this reconciliation process.

CMS will complete final reconciliation of its accounts with the M+C organization within approximately 9 months of the termination date of the M+C contract. However, it is important to note that completion of final reconciliation may be delayed in the event that the organization fails to comply with remaining encounter data submission requirements.

70.3 - Nonrenewal of M+C Contract: CMS-Initiated

(Rev. 8, 03-20-02)

CMS may elect not to authorize renewal of an M+C contract. Reasons for CMS non-renewing a contract include the following:

- The M+C organization has not fully implemented or shown discernable progress in implementing quality improvement projects;
- For any of the same reasons that CMS would terminate a contract; or
- The M+C organization has committed any of the acts that would support imposition of intermediate sanctions or civil money penalties.
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80 - Contract Terminations

(Rev. 8, 03-20-02)

80.1 - When CMS Terminates an M+C Contract

(Rev. 8, 03-20-02)

Medicare+Choice contract terminations differ from Medicare+Choice contract non-renewals in that the Secretary may initiate a contract termination at any time for reasons set forth in the Medicare statute. In contrast, Medicare+Choice contract non-renewals occur according to a prescribed time-schedule, whereby CMS must notify an M+C

organization of its intention to non-renew the M+C organization's M+C contract by May 1 of the final contract year.

CMS may terminate an M+C contract for any of the following reasons:

- The M+C organization fails substantially to carry out the terms of its contract with CMS;
- The M+C organization carries out its contract with CMS in a manner that is inconsistent with the effective and efficient implementation of the M+C program;
- The M+C organization no longer meets the requirements of this manual for being a contracting organization;
- The M+C organization commits or participates in fraudulent or abusive activities affecting the Medicare program including the submission of fraudulent data;
- The M+C organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists. When this occurs, CMS may immediately terminate its contract with an M+C organization;
- The M+C organization substantially fails to comply with the grievances and appeals requirements described in chapter 13 of this manual;
- The M+C organization fails to provide CMS with valid encounter data;
- The M+C organization fails to implement an acceptable quality assessment and performance improvement program;
- The M+C organization substantially fails to comply with the prompt payment requirements;
- The M+C organization fails to comply with the service access requirements;
- The M+C organization fails to comply with the requirements regarding physician incentive plans;
- The M+C organization substantially fails to comply with the marketing requirements.

In determining whether a failure is "substantial," CMS considers both the frequency and the seriousness of the noncompliance. In the case of a serious violation that could put the health of an enrollee at risk, even a single violation might be considered substantial. In the case of a less serious violation, the noncompliance would have to be more pervasive or systematic in order to be considered substantial.

80.2 - Termination Process When CMS Initiates Contract Termination

(Rev. 8, 03-20-02)

If CMS decides to terminate a contract for reasons other than the grounds precipitating immediate termination, it gives notice of the termination as follows:

- CMS notifies the M+C organization in writing at least 90 days before the intended date of the termination;

- CMS requires that the M+C organization notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination. CMS pre-approves such member notifications; and

- CMS requires that the M+C organization notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the M+C organization's service area. CMS pre-approves these notices to the general public.

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80.3 - Immediate M+C Contract Termination by CMS

(Rev. 8, 03-20-02)

In instances where the M+C organization experiences financial difficulties so severe that life and physical well being of beneficiaries is in jeopardy, or otherwise fails to make services available to the extent that such a risk to health exists, CMS can immediately sever its relationship with an M+C organization in order to protect beneficiaries and to safeguard taxpayer confidence in CMS's administration of the Medicare program.

When this occurs, CMS:

1. Notifies the M+C organization in writing that its contract has been terminated effective the date of the termination decision by CMS. If termination is effective in the middle of a month, CMS has the right to recover the prorated share of the capitation payments made to the M+C organization covering the period of the month following the contract termination.

2. Notifies the M+C organization's Medicare enrollees in writing of CMS's decision to immediately terminate the M+C organization's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the M+C contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining Medicare services, including alternative M+C organizations in a similar geographic area and original Medicare.

3. Notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the M+C contract. This notice is published in one or more newspapers of general circulation in each community or county located in the M+C organization's service area.

If a contract is immediately terminated by CMS, the M+C organization will not have the opportunity to submit a corrective action plan to correct the finding that precipitated CMS's contract termination action. However, affected M+C organizations do maintain appeal rights that become effective following the effective date of the termination. See Chapter 14 for a full discussion of the M+C contract appeal rights afforded M+C organizations.

80.4 - When an M+C Organization Terminates an M+C Contract

(Rev. 8, 03-20-02)

An M+C organization may terminate its M+C contract if CMS fails to substantially carry out the terms of the M+C contract.

80.5 - Termination Process When M+C Organization Initiates Contract Termination

(Rev. 8, 03-20-02)

- The organization must give CMS notice at least 90 days before the intended date of termination which specifies the reasons the M+C organization is requesting contract termination.

- The organization's Medicare enrollees must be given a CMS-approved notice at least 60 days before the proposed termination effective date and include a description of alternatives available for obtaining Medicare services within the service area, including alternative M+C plans, Medigap options, Original fee-for-service Medicare.

- The M+C organization must also notify the public at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the M+C organization's service area.

The effective date of the termination is determined solely by CMS and is at least 90 days after the date CMS receives the M+C organization's notice of its intent to terminate the contract. CMS's liability for payment to the M+C organization ends as of the first day of the month after the last month for which the contract was in effect. If termination occurs, CMS will not contract with the same organization for two years from the date of

termination of the previous contract unless the organization meets specified exceptions (see §50 of this chapter).

90 - Modification or Termination of an M+C Contract by Mutual Consent

(Rev. 8, 03-20-02)

There are circumstances under which an M+C organization may agree to a termination by mutual consent. Further, CMS may decide that it is in the best interests of tax payers, Medicare beneficiaries and the Medicare program to agree to let an M+C organization terminate its contract midyear.

An M+C contract may be modified or terminated by CMS or an M+C organization at any time by written mutual consent of both parties. M+C organizations must provide notice to their Medicare enrollees and the general public when mutually agreeing to terminate an M+C contract as follows:

- To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the services area, including alternative M+C plans, Medigap options, original Medicare, it and must receive CMS approval.

- To the general public, at least 60 days before the termination effective date by publishing a CMS-approved notice in one or more newspapers of general circulation in each community or county located in the M+C organization's geographic area.

The general exception to these notice requirements occurs when an M+C contract, that is terminated by mutual consent, is replaced the day following such termination by a new M+C contract covering the same population. If the new contract is effective during a calendar year, it must include benefits under the same terms as the old contract for this exception to apply.

100 - M+C Contract Provisions

(Rev. 8, 03-20-02)

100.1 - Material Provisions of an M+C Contract

(Rev. 8, 03-20-02)

The contract between the M+C organization and CMS will contain the following material requirements and conditions.

The M+C organization shall:

- Accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments as provided in Chapter 2 of this manual;
- Not discriminate in regards to beneficiary enrollment;
- Provide the basic benefits and to the extent applicable, supplemental benefits;
- Provide access to benefits in accordance with the QISMC standards;
- Provide health care services in a manner consistent with professionally recognized standards of health care;
- Disclose information to beneficiaries in the manner and the form prescribed by CMS;
- Operate a quality assurance and performance improvement program and have an agreement for external quality review in accordance with the QISMC standards;
- Comply with all applicable provider requirements and specific physician requirements ;
- Comply with all requirements governing coverage determinations, grievances, and appeals;
- Comply with all reporting requirements including the submission of encounter data;
- Accept payment;
- Develop and submit an annual ACRP and submit all the required information on premiums, benefits, and cost-sharing by the due date specified by CMS each year;
- Acknowledge that CMS may not renew or may terminate its M+C contract;
- Comply with all the requirements that are specific to a type of M+C plan;
- Comply with the confidentiality, privacy, and enrollee record accuracy requirements;
- Submit to CMS certified financial information demonstrating that the organization has a fiscally sound operation; and

- Submit to CMS information as CMS may require pertaining to the disclosure of ownership and control of the M+C organization.

An M+C organization's noncompliance with material requirements of its M+C contract are grounds for contract termination by CMS.

100.2 - Other Provisions of the M+C Contract

(Rev. 8, 03-20-02)

Provisions Necessary to Implement M+C Program - The M+C organization agrees that a provision will be included in its contract with CMS that specifies such other terms and conditions as CMS may find necessary and appropriate in order to implement requirements of the M+C program.

Severability of Contracts - The M+C contract will provide that, upon CMS's request:

- The contract will be amended to exclude any M+C plan or State-licensed entity specified by CMS; and

- A separate contract will be deemed to be in place for any such organization or entity that is removed from its former M+C contract when such a request is made.

Electronic Communication - An M+C organization must have the capacity to communicate with CMS electronically which includes notifying CMS of appropriate e-mail addresses for contact individuals within the organization (and receiving and sending e-mail), accessing the Internet to receive instructions and communications, and sending individual or batch information to CMS or its contractors such as encounter and enrollment/disenrollment information;

Prompt Payment - The M+C organization must comply with the following prompt payment of claims provisions for claims that have been submitted by providers for services and supplies rendered to Medicare enrollees when these services and supplies are furnished by non-contracted providers:

- The contract between CMS and the M+C organization must provide that the M+C organization will pay 95 percent of the "clean claims" within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an M+C private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider.

- The M+C organization must pay interest on clean claims that are not paid within 30 days.

- Non-clean claims must be paid or denied within 60 calendar days from the date of the request for payment.

If a Medicare+Choice organization chooses to use non-contracting providers to provide services “in lieu of” executing contracts with providers to provide such services, the Medicare+Choice organization must pay the provider the amount it would have received under original Medicare for the services.

In the case of "unforseen" services furnished by a provider that Medicare pays under a prospective payment system (PPS), e.g., emergency or urgently needed care or certain post-stabilization care service(s) - a Medicare + Choice must pay the lesser of the hospital’s billed charges or the PPS rate, but no more than would have been paid under original Medicare.

If CMS determines that the M+C organization fails to make payments promptly to non-contracting providers and suppliers, CMS may, following an opportunity for a hearing:

- Provide for direct payment of the sums owed to providers, or M+C private fee-for-service plan enrollees; and

- Provide for appropriate reduction in the amounts that would otherwise be paid to the organization, to reflect the amounts of the direct payments and the cost of making those payments.

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100.3 - Beneficiary Financial Protections

(Rev. 8, 03-20-02)

Each M+C organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the M+C organization. To meet this requirement, the M+C organization must:

- Ensure that all contractual or other written arrangements with providers prohibit the organization's providers from holding any beneficiary enrollee liable for payment of any such fees; and

- Indemnify the enrollee for any fees that are the legal obligation of the M+C organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the M+C organization, to provide services to the organization's beneficiary enrollees.

The M+C organization must provide for continuation of enrollee health care benefits for:

- All enrollees, for the duration of the contract period for which CMS payments have been made; and

- Enrollees who are hospitalized on the date its contract with CMS terminates, or, in the event of an insolvency, through discharge.

To meet this continuation of benefits requirements, an M+C organization may use:

- Contractual arrangements (see M+C contract requirements described at §20 and §§100.1 - 100.2);]
- Insurance acceptable to CMS;
- Financial reserves acceptable to CMS; or
- Any other arrangement acceptable to CMS.

100.4 - Provider and Supplier Contract Requirements

(Rev. 8, 03-20-02)

Contracts or other written agreements between M+C organizations and providers and suppliers of health care or health care-related services must contain the following provisions:

- Contracting providers agree to safeguard beneficiary privacy and confidentiality and assure accuracy of beneficiary health records;
- Contracts must specify a prompt payment requirement, the terms and conditions of which are developed and agreed-to by the M+C organization and its contracted providers and suppliers;
- Contracts must hold Medicare members harmless for payment of fees that are the legal obligation of the M+C organization to fulfill. Such provision will apply, but will not be limited to insolvency of the M+C organization, contract breach, and provider billing;
- Contracts must contain accountability provisions specifying:
    - That first tier and downstream entities must comply with Medicare laws, regulations, and CMS instructions (422.502(i)(4)(v)), and agree to audits and inspection by CMS and/or its designees and to cooperate, assist, and provide information as requested, and maintain records a minimum of six years;
    - That the M+C organization oversees and is accountable to CMS for any functions and responsibilities described in the M+C regulations (422.502(i)(3)(ii)(A)); and
    - That M+C organizations that choose to delegate functions must adhere to the delegation requirements - including all provider contract requirements in these

delegation requirements - described in the M+C regulations (422.502(i)(3)(iii); 422.502(i)(4)).

- Contracts must specify that providers agree to comply with the M+C organization's policies and procedures.

In addition to the provisions mentioned above, M+C organizations must include certain M+C-related provisions in the policies and procedures that are distributed to providers and suppliers that constitute the organizations' health services delivery network. The following table summarizes these provisions:

Contract Requirements Through Policies, Standards & Manuals	Link to CFR 422
Safeguard privacy and maintain records accurately and timely	422.118
Permanent "out of area" members to receive benefits in continuation area	422.54(b)
Prohibition against discrimination based on health status	422.110(a)
Pay for emergency and urgently needed care according to	422.112(b); 422.100(b)
Pay for renal dialysis for those temporarily out of a service area	422.100(b)(1)(iii)
Direct access to mammography and influenza vaccinations	422.100(h)(1)
No copay for influenza and pneumoccocal vaccines	422.100(h)(2)
Agreements with providers to demonstrate "adequate" access	422.112(a)(1)
Direct access to women's specialists for routine and preventive services	422.112(a)(3)
Approved procedures to identify, assess and establish treatment plans for serious and complex conditions	422.112(a)(4)
Services available 24 hrs/day, 7 days/week	422.112(a)(8)
Adhere to CMS marketing provisions	422.80(a), (b), (c)
Ensure services are provided in a culturally competent manner	422.112(a)(9)
Maintain procedures to inform members of follow-up care or provide training in selfcare as necessary	422.112(b)(5)
Document in a prominent place in medial record if individual has executed Advance directive	422.128(b)(1)(ii)(E)
Provide services in a manner consistent with professionally recognized standards of care	422.502(a)(3)(iii)
Continuation of benefits provisions (may be met in several ways, including contract provision)	422.502(g)(2)(i); 422.502(g)(2)(ii); 422.502(g)(3)

Contract Requirements Through Policies, Standards & Manuals	Link to CFR 422
Payment and incentive arrangements specified	422.208
Subject to laws applicable to Federal funds	422.502(h)(2)
Disclose to CMS all information necessary to (1) Administer & evaluate the program (2) Establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services	422.64(a): 422.502(a)(4): 422.502(f)(2)
Must make good faith effort to notify all affected members of the termination of a provider contract within 15 days of notice of termination by plan or provider	422.111(e)
Submission of encounter data, medical records and certify completeness and truthfulness	422.502(a)(8); 422.502(1)(2) & (3)
Cooperate with quality review and improvement organization (review organization)	422.154(a)
Comply with medical policy, QM and MM	422.202(b); 422.502(a)(5)
Disclose to CMS quality & performance indicators for plan benefits re: disenrollment rates for beneficiaries enrolled in the plan for the previous two years	422.502(f)(2)(iv)(A)
Disclose to CMS quality & performance indicators for the benefits under the plan regarding enrollee satisfaction	422.502(f)(2)(iv)(B)
Disclose to CMS quality & performance indicators for the benefits under the plan regarding health outcomes	422.502(f)(2)(iv)(C)
Notify providers in writing for reason for denial, suspension & termination	422.204(c)(1)
Provide 60 days notice (terminating contract without cause)	422.204(c)(4)
Comply with Civil Rights Act, ADA, Age Discrimination Act, Federal funds laws	422.502(h)(1)
Prohibition of use of excluded practitioners	422.752(a)(8)
Adhere to appeals/grievance procedures	422.562(a)

100.5 - Administrative Contracting Requirements

(Rev. 8, 03-20-02)

The M+C administrative contracting requirements apply both to first tier contracts and to downstream contracts in the manner specified for provider contracts, as described above. At the same time, the responsibility of the M+C organization is to assure that its contractor and any downstream contractors have the information necessary to know how to comply with the requirements under the M+C program.

These requirements do not apply to administrative contracts that do not directly relate to the M+C organization's core functions under its contract with CMS. For example, a contract between the M+C organization and a clerical support firm would not need to contain these provisions. Similarly, a contract between the M+C organization and a real estate broker to identify rental properties for office space would not be required to address these areas. CMS would, however, view contracts for administration and management, marketing, utilization management, quality assurance, applications processing, enrollment and disenrollment functions, claims processing, adjudicating Medicare organization determinations, appeals and grievances, and credentialing to be administrative contracts subject to M+C requirements as articulated in the M+C regulation and this OPL.

The following provisions must be addressed in the administrative service contracts:

- The person or entity must agree to comply with all applicable Medicare laws, regulations, and CMS instructions.

- The person or entity must agree to comply with all State and Federal confidentiality requirements, including the requirements established by the M+C organization and the M+C program.

- The person or entity must agree to grant DHHS, the Comptroller General, or their designees the right to inspect any pertinent information related to the contract during the contract term, for up to six years from the final date of the contract period, and in certain instances described in the M+C regulation, periods in excess of six years, as appropriate.

- The contract must clearly state the responsibilities of the administrative services provider and its reporting arrangements.

- The contract must provide that the M+C organization and any first tier and downstream entities has/have the right to revoke the contract if M+C organizations do not perform the services satisfactorily, and if requisite reporting and disclosure requirements are not otherwise fully met in a timely manner.

- The contract must acknowledge that the responsibilities performed by an administrative service entity and/or any delegated administrative service entities

are monitored by the M+C organization on an ongoing basis, and that the M+C organization is ultimately responsible to CMS for the performance of all services.

- If the written arrangement provides for credentialing activities by a first-tier or downstream entity, the first-tier or downstream entity must meet all applicable M+C credentialing requirements.

- If the written arrangement provides for the selection of providers by a first-tier or downstream entity, written arrangements must state that the M+C organization retains the right to approve, suspend, or terminate any such arrangement.

    - Contracts between M+C organizations and first tier entities, and first tier entities and downstream entities must contain provisions specifying M+C delegation requirements specified at §422.502(i)(3)(iii) and §422.502(i)(4). A written agreement specifies the delegated activities and reporting responsibilities of the entity and provides for revocation of the delegation or other remedies for inadequate performance. Contracts must indicate what functions have been delegated and must require the entity to comply with the requirements of these standards and of applicable law and regulations. When a function is only partially delegated, contract provisions must clearly delineate which responsibilities have been delegated and which remain with the organization. In the QAPI area, for example, the organization might develop topics for projects in consultation with an affiliated medical group, but delegate the actual conduct of a specific project to the group. The agreement must specify how the delegate is to conduct QAPI activities, at what points in the process decisions by the delegate (for example, on data collection methodologies) are subject to the organization's review, and how the delegate's activities will be integrated into the organization's overall QAPI program (for example, through participation in an organization-wide committee).

100.6 - Implementation of Written Policies with Respect to the Enrollee Rights

(Rev. 8, 03-20-02)

The organization must articulate enrollees' rights, promote the exercise of those rights, ensure that its staff and affiliated providers are familiar with enrollee rights, and treat enrollees accordingly. While most of the standards in this domain address basic procedural protections for enrollees, they are closely related to quality of care. Interpersonal aspects of care are highly important to most patients. Enrollees' interactions with the organization and its providers can have an important bearing on their willingness and ability to understand and comply with recommended treatments, and hence, on outcomes and costs. For further technical assistance with this domain, readers are directed to the Consumer Bill of Rights and Responsibilities as promulgated

in November 1997, by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry.

Policies are communicated to enrollees in the enrollee statement furnished in accordance with Chapter 2 of this manual, and to the organization's staff and affiliated providers, at the time of initial employment or affiliation, and annually thereafter.

Material on enrollee rights must be included in provider contracts or provider manuals, and in staff handbooks or other training materials.

110 - M+C Organization Relationship with Related Entities, Contractors, Subcontractors, First-Tier and Downstream Entities

(Rev. 8, 03-20-02)

Organizations likely to apply for M+C contracts commonly enter into business relationships with entities that they place under contract to perform certain functions that otherwise would be the responsibility of the organization to perform, including management and provision of services.

110.1 - General Requirements

(Rev. 8, 03-20-02)

The M+C organization agrees to take ultimate responsibility for all services provided and terms of the contract and otherwise fulfilling all terms and conditions of its contract with CMS regardless of any relationships that the organization may have with entities, contractors, subcontractors, first-tier or downstream entities.

The M+C organization agrees to require all related entities, contractors, or subcontractors, first-tier and downstream entities to agree that:

- DHHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s), first-tier and downstream entities involving transactions related to the M+C contract as specified above under §110.4.4 of this chapter.

- DHHS's, the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period will exist through six years from the final date of the contract period or from the date of completion of any audit, whichever is later.

- All contracts or written arrangements between M+C organizations and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the contract language requirements described in §100 of this chapter.

110.2 - Delegation Requirements

(Rev. 8, 03-20-02)

The organization oversees and is accountable for any functions or responsibilities that are delegated to other entities.

With certain restrictions indicated below, an organization may, by written contract, delegate any activity required under or governed by these standards to another entity. However, an organization entering into a Medicare contract remains accountable to CMS or the State for performance of any such delegated function. It is the sole responsibility of the organization to ensure that the function is performed in accordance with applicable standards. (Note that this standard is not meant to imply that the organization is legally liable for the actions of its subcontractors. For example, in cases of malpractice any such liability is established by State or local law.)

Special note must be made of "carve-out" arrangements, under which a managed care organization contracts with an entity to assume entire responsibility for a given type or category of service and delegates to that entity a broad range of basic management functions. Such contracts are most common for mental health and substance abuse services, although some organizations use similar arrangements for prescription drugs, home health care, or other types of services. These arrangements are conceptually no different from those under which an organization capitates a single medical group to provide all physician and related ambulatory services and delegates management of those services to the group. Although the latter arrangements are never spoken of as "medical carve-outs," they are functionally comparable to "mental health/substance abuse carve-outs": the contractor assumes entire responsibility for management of a defined portion of the overall benefit package. Just as medical group contracts have never diminished the basic accountability of the organization directly contracting with Medicare or Medicaid, so with mental health or other carve-outs. The prime contractor remains wholly accountable for the activities of its subcontractors.

Because of the wide variety of organizational structures and contractual arrangements, it is difficult to develop simple guidelines for the review of delegated activities. In any given situation, the review methodology to be adopted should be that which is least burdensome for reviewers and for the organization, yet which provides positive assurance that the activity in question is being performed in compliance with these standards. For example, credentialing of providers might occur in several different ways:

1. The organization itself verifies the credentials of individual providers affiliated with its subcontractors. Review would focus directly on the organization's performance of this function.

2. An organization contracts with one or more independent physician groups, each of which is expected to verify the credentials of each affiliated provider. It would be impractical for a CMS or State reviewer to review compliance by the independent contractor(s). Instead, the organization itself must document that it has periodically reviewed the performance of each contractor, for example by verifying that all required credentialing information is present in a sample of each contractor's provider records.

3. An organization contracts with a single independent credentialing verification organization (CVO) to collect information about providers. The CVO, and not the organization, maintains documentation of verification of credentials from primary sources. If a single CVO provided services to multiple organizations in a State, a State Medicaid agency might review the CVO itself and deem in compliance all organizations that contracted with the CVO. Alternatively, the State might accept the findings of an independent body that accredits CVOs. For the purposes of Medicare, however, CMS does not at this time review CVOs or accept external accreditation of CVOs. It would, therefore, expect the organization to document that it has monitored the CVO's performance, again through a review of a sample of practitioner records. (Similarly, the organization would be required to review the credentialing performance of any "carve-out" contractor, such as a national managed behavioral health care organization.)

Again, as this illustrates, the variety and complexity of contracting arrangements makes it impractical to suggest a uniform method for review of delegated functions. As part of the advance preparation for on-site reviews, the reviewer and the organization should negotiate the most expeditious procedure. However, the burden of documenting a delegate's compliance with applicable standards ultimately rests with the organization.

It is especially important to identify instances in which a delegation has been made implicitly. For example, a contract with a medical group may hold the group responsible for providing or arranging for a wide range of ambulatory services in return for a fixed monthly capitation payment. The group is left to develop its own procedures for approving requests for referral services by its own primary care providers. If so, the utilization management function has been delegated, and the organization must ensure that the group complies with the standards for that function, including standards related to requests for expedited review.

The following specific requirements apply to all delegated functions:

- Written arrangements must specify delegated activities and reporting responsibilities.

- The organization evaluates the entity's ability to perform the delegated activities prior to delegation. The organization must document that it has approved the entity's policies and procedures with respect to the delegated function, and must verify that the contractor has devoted sufficient resources and appropriately qualified staff to performing the function**.**

- The performance of the entity is monitored on an ongoing basis and formally reviewed by the organization at least annually. The organization must have written procedures for monitoring and review of delegated activities. The nature of ongoing monitoring may vary according to the organization's past experience with the delegate and with the nature of the delegated activity. In the areas of grievance processing or utilization management, for example, monitoring may be more or less continuous, in as much as decisions by the delegate may be appealed to the organization. However, the organization must periodically verify that the delegate is in fact forwarding requests for reconsideration, and that its statistical or other reporting on these processes is accurate. In other areas, such as credentialing, annual review of the delegate's activities may be sufficient, particularly if the organization has ascertained in the past that the delegate is performing the activity properly.

The annual evaluation should be a comprehensive assessment of the delegate's performance, including both compliance with applicable standards and the extent to which the delegate's activities promote the organization's overall goals and objectives for the delegated function. If any problems or deficiencies are identified, the evaluation must specify any necessary corrective action and include procedures for assuring that the corrective action is implemented.

The organization must ensure that monitoring of delegates is carried out by staff of the organization who are qualified to assess the delegates' activities. For example, an organization that has delegated authorization of mental health and substance abuse services to an entity must use appropriately credentialed professionals to review the entity's authorization decisions.

The following requirements apply:

- Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where CMS or the M+C organization determine that such parties have not performed satisfactorily.

- Written arrangements must further specify that either:

    - The credentials of medical professionals affiliated with the party or parties will be either reviewed by the M+C organization;

    - The credentialing process will be reviewed and approved by the M+C organization and the M+C organization must audit the credentialing process on an ongoing basis; or

    - The policies and procedures that an M+C organization develops for its related entity, contractor, subcontractor, first-tier and downstream entities must state that these entities must comply with all applicable Medicare laws, regulations, and CMS instructions**.**

- If the organization delegates selection of providers to another entity, the organization retains the right to approve, suspend, or terminate any provider selected by that entity.

- Written arrangements must specify that the performance of the parties is monitored by the M+C organization on an ongoing basis.

110.3 - M+C Oversight and Beneficiary Protection Guidance

(Rev. 8, 03-20-02)

M+C organizations, provider groups, individual providers and CMS have a common interest in preventing delegated provider group financial difficulties that may negatively impact the well being of Medicare beneficiaries. Similarly, these parties share an interest in mitigating the impact that provider group failures might have upon Medicare beneficiaries enrolled in an M+C product.

The following is a list of M+C regulations that are relevant to M+C organizations that have relationships with delegated **entities**. These requirements hold M+C organizations responsible for providing care to Medicare beneficiaries,0 and for protecting Medicare beneficiaries in instances where delegated entities experience operational difficulties that may result in failure of the delegated entity to perform delegated functions.

- §422.100(a) - an M+C organization offering an M+C plan must provide enrollees in that plan with coverage of the (plan benefit package) by furnishing the services directly or through arrangements, or by paying for the benefits.

- §422.112(b) - The M+C organization must ensure continuity of care and integration of services.

- §422.502(g)(1) - Each M+C organization must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the M+C organization.

- §422.502(i)(1) - Notwithstanding any relationship(s) that the M+C organization may have with related entities, contractors, or subcontractors, the M+C organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS.

- §422.502(i)(4) - If any of the M+C organization's activities or responsibilities under its contract with CMS are delegated to other parties, written arrangements must specify that the performance of the parties is monitored by the M+C organization on an ongoing basis, and either provide for revocation of the delegated activities or specify other remedies where CMS or the M+C organization determines such parties have not performed satisfactorily.

The policies and procedures described in §110.4 are recommended but not required for M+C Organizations to ensure the operational integrity of delegated entities, and to protect beneficiaries in the event of a delegated provider group(s) insolvency and/or termination. This additional guidance may prove helpful to M+C organizations in their attempt to meet the aforementioned M+C regulatory requirements.

110.4 - Policies and Procedures for Assessing Contracting Provider Groups' Administrative and Fiscal Capacity to Manage Financial Risk

(Rev. 8, 03-20-02)

Before an M+C organization contracts with an entity to perform functions that are otherwise the responsibility of the M+C organization under its contract with CMS, the M+C organization should develop, implement, and maintain policies and procedures for assessing contracting provider groups' administrative and fiscal capacity to manage financial risk prior to delegating M+C-related risk to these groups. Suggested policies and procedures include:

- Establish minimum net worth, adequate liquidity and reserve requirements that the delegated entity must meet before the M+C organization contracts with a group.

- Conduct on-site audits to assess the delegated entity's administrative capabilities. Audit activities would include, but are not limited to: assessment of claims processing capabilities; financial planning and oversight capabilities; assessing a group's capacity to measure and accurately report Incurred But Not Reported (IBNR) claims estimates.

After an M+C organization has entered a contract with an entity to perform delegated functions it must develop policies and procedures for monitoring the fiscal soundness of at-risk delegated entities on an ongoing basis. These policies and procedures should specify thresholds that trigger M+C organization intervention. Suggested policies and procedures include:

- Periodic collection of at-risk entity's financial statements and claims timeliness reports;

- Periodic auditing of claims payment timeliness and accuracy;

- Periodic administrative performance assessments;

- Listing of interventions that the M+C organization will take and corrective actions it will require when an at-risk delegated entity falls below minimum standards or other thresholds; and

- Develop, maintain, and implement contingency plans to enable the M+C organization to quickly respond to delegated entity financial failures. Particular emphasis should be placed on assessing the availability, accessibility, and continuity of care for Medicare beneficiaries enrolled in an M+C plan, and for preventing inappropriate beneficiary billing for services that are the legal obligation of the M+C organization. See §110.4.1 for suggested elements of a contingency plan.

110.4.1 - Access to and Continuity of Care

(Rev. 8, 03-20-02)

- Honoring all open authorizations for care;

- Placing outbound calls to affected Medicare beneficiaries scheduled for services and undergoing treatment plans to coordinate continuation of care;

- Maintaining "network crossover reports", so Medicare beneficiaries can be quickly reassigned to other plan-contracted providers or groups within the approved service area; and

- Providing an opportunity for members undergoing a treatment plan to continue to see providers that are no longer in the network due to the group insolvency.

110.4.2 - Prevention of Member Billing

(Rev. 8, 03-20-02)

The following procedures may help prevent member billing.

- Initiate internal audits of hold-harmless provisions in downstream provider contracts.

- Provide written notification to all Medicare beneficiaries assigned to or receiving care through insolvent provider groups instructing them not to pay bills (except applicable copayments and or deductibles) for provider group obligations and to forward any bills to the M+C organization.

- Provide written notification to an insolvent group's downstream contractors informing them that billing Medicare members for an insolvent group's obligations is prohibited.

- Develop and implement specific policies and procedures to prevent non-contracting providers from billing Medicare beneficiaries for insolvent provider group obligations.

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110.4.3 - Maintenance of and Access to M+C-Related Record Requirements

(Rev. 8, 03-20-02)

DHHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the M+C organization or relating to the M+C organization's M+C contract. DHHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the related entity, contractor, subcontractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the M+C contract.

The M+C organization agrees to make available its premises, physical facilities and equipment, records relating to its Medicare enrollees, and any additional relevant information that CMS may require. Pursuant to these requirements, the M+C organization further agrees that it must maintain the following types of books, records, documents, and other evidence of accounting procedures and practices for six years from the end date of an M+C contract or the completion date of an audit, whichever is later.

- Records sufficient to accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, encounter data, and computation of the adjusted community rate proposal (ACRP));

- Records sufficient to enable CMS to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract and the facilities of the organization;

- Records sufficient to enable CMS to audit and inspect any books and records of the M+C organization that pertain to the ability of the organization to bear the risk of potential financial losses, to services performed, or determinations of amounts payable under the contract;

- Records sufficient to properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the ACRP;

- Records sufficient to establish component rates of the ACRP for determining additional and supplementary benefits;

- Records sufficient to determine the rates utilized in setting premiums for State insurance agency purposes, and for other government and private purchasers;
- Records relating to ownership and operation of the M+C organization's financial, medical, and other record keeping systems;
- Financial statements for the current contract period and six prior periods;
- Federal income tax or informational returns for the current contract period and six prior periods;
- Asset acquisition, lease, sale, or other ownership issues;
- Agreements, contracts, and subcontracts;
- Franchise, marketing, and management agreements;
- Schedules of charges for the M+C organization's fee-for-service patients;
- Documentation of matters pertaining to costs of operations;
- Documentation of amounts of income received by source and payment;
- Cash Flow statements; and
- Any financial reports filed with other Federal programs or State authorities.

This requirement includes allowing DHHS, the Comptroller General, or their designee to have access to facilities and records to evaluate through inspection or other means:

- The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;
- The facilities of the M+C organization; and
- The enrollment and disenrollment records for the current contract period and six prior contract periods.

DHHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through six years from the final date of the contract period or completion of audit, whichever is later unless:

- CMS determines there is a special need to retain a particular record or group of records for a longer period. CMS notifies the M+C organization at least 30 days before the normal disposition date;
- There has been a termination, dispute, or fraud or similar fault by the M+C organization, in which case the retention may be extended to six years from the

date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

- CMS determines that there is a reasonable possibility of fraud, in which case it may inspect, evaluate, and audit the M+C organization at any time.

110.4.4 - Disclosure Requirements

(Rev. 8, 03-20-02)

The M+C organization agrees to disclose the following to CMS:

- Certified financial information that must include the following:
    - Such information as CMS may require demonstrating that the organization has a fiscally sound operation; and
    - Such information as CMS may require pertaining to the disclosure of ownership and control of the M+C organization.
- All information that is necessary for CMS to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:
    - The benefits covered under an M+C plan;
    - The M+C monthly basic beneficiary premium and M+C monthly supplemental beneficiary premium, if any, for the plan or in the case of an MSA plan, the M+C monthly MSA premium;
    - The service area and continuation area, if any, of each plan and the enrollment capacity of each plan; and
    - Plan quality and performance indicators for the benefits under the plan including:
        - Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous two years;
        - Information on Medicare enrollee satisfaction;
        - Information on health outcomes;
        - The recent record regarding compliance of the plan with requirements of this part, as determined by CMS; and

- Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among M+C plans and traditional Medicare.

- Information about beneficiary appeals and their disposition;

- Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization; and

- Any other information deemed necessary by CMS for the administration or evaluation of the Medicare program.

- M+C organizations must disclose to existing enrollees and to each new enrollee electing an M+C plan it offers in clear, accurate, and standardized form; and at the time of enrollment and at least annually thereafter, information relating to the M+C organization's M+C plans, including:

  - The M+C plan's service area and any enrollment continuation area;

  - The benefits offered under the plan, including applicable conditions and limitations, premiums, and cost sharing (such as copayments, deductibles, and coinsurance, and any other conditions associated with receipt or use of benefits; and for the purposes of comparison;

  - The benefits offered under original Medicare;

  - For an M+C Medical Savings Account (MSA) plan, the benefits under other types of M+C plans; and

  - The availability of the Medicare hospice option and any approved hospices in the service area, including those the M+C organization owns, controls, or has a financial interest in.

- The number, mix, and distribution of providers from whom enrollees may obtain services; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the M+C organization meets M+C access to service requirements.

- Out-of-area coverage provided by the plan.

- Coverage of emergency services, including:

  - Explanation of what constitutes an emergency, referencing the definitions of emergency services and emergency medical condition at 42 CFR §422.113.

  - The appropriate use of emergency services, stating that prior authorization cannot be required;

- The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent; and

- The locations where emergency care can be obtained and other locations at which contracting physicians and hospitals provide emergency services and post-stabilization care included in the M+C plan.

- Any mandatory or optional supplemental benefits and the premium for those benefits.

- Prior authorization rules and other review requirements that must be met in order to ensure payment for the services. The M+C organization must instruct enrollees that, in cases where noncontracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the M+C organization for processing and determination of enrollee liability, if any.

- All grievance and appeals rights and procedures.

- A description of the M+C organization's quality assurance program.

- Enrollees' disenrollment rights and responsibilities.

Upon request of an individual eligible to elect an M+C plan, an M+C organization must provide to the individual the following information:

- Benefits under original Medicare, including covered services, beneficiary cost sharing, such as deductibles, coinsurance, copayment amounts and any beneficiary liability for balance billing;

- Information and instructions on how to exercise election options under this subpart;

- A general description of procedural rights (including grievance and appeals procedures) under original Medicare and the M+C program and the right to be protected against discrimination based on factors related to health status;

- A general description of the benefits, enrollment rights, and requirements applicable to Medicare supplemental policies under §1882 of the Social Security Act, and provisions relating to Medicare Select policies under §1882(t) of the Social Security Act;

- The fact that an M+C organization may terminate or refuse to renew its contract, or reduce the service area included in its contract, and the effect that any of those actions may have on individuals enrolled in that organization's M+C plan;

- A list of M+C plans that are or will be available to residents of the service area in the following calendar year, and, for each available plan, information on benefits,

premiums, service areas, and aspects of the M+C plan(s), presented in a manner that facilitates comparison among the plans;

- Benefits, including covered services beyond those provided under original Medicare, any beneficiary cost sharing, and any maximum limitations on out-of-pocket expenses, the extent to which an enrollee may obtain benefits through out-of-network health care providers, the types of providers that participate in the plan's network and the extent to which an enrollee may select among those providers, and the coverage of emergency and urgently needed services. In the case of an M+C MSA plan, the amount of the annual MSA deposit and the differences in cost-sharing, enrollee premiums, and balance billing, as compared to M+C plans. In the case of a M+C private fee-for-service plan, differences in cost sharing, enrollee premiums, and balance billing, as compared to M+C plans;

- The M+C monthly basic beneficiary premium and the M+C monthly supplemental beneficiary premium (if any);

- The plan's service area;

- Quality and performance indicators for benefits under a plan to the extent they are available as follows (and how they compare with indicators under original Medicare):

    - Disenrollment rates for Medicare enrollees for the two previous years, excluding disenrollment due to death or moving outside the plan's service area, calculated according to CMS guidelines;

    - Medicare enrollee satisfaction;

    - Health outcomes;

    - Plan-level appeal data;

    - The recent record of plan compliance with the requirements of this part, as determined by the Secretary; and

    - Other performance indicators.

- Whether the plan offers mandatory supplemental benefits or offers optional supplemental benefits and the premiums and other terms and conditions for those benefits.

- The procedures the organization uses to control utilization of services and expenditures.

- The number of disputes, and the disposition in the aggregate, in a manner and form described by the Secretary. Such disputes shall be categorized as:

- Grievances according to subpart M of 42 CFR §422 and chapter 13 of this manual.

- Appeals according to subpart M of 42 CFR §422 and chapter 13 of this manual. A summary description of the method of compensation for physicians.

- Financial condition of the M+C organization, including the most recently audited information regarding, at least, a description of the financial condition of the M+C organization offering the plan. Other M+C organizational financial information that must be disclosed:

  - The cost of its operations;

  - The patterns of utilization of its services;

  - The availability, accessibility, and acceptability of its services;

  - To the extent practical, developments in the health status of its enrollees;

  - Information demonstrating that the M+C organization has a fiscally sound operation; and

  - Other matters that CMS may require.

110.4.5 - Additional M+C Reporting Requirements

(Rev. 8, 03-20-02)

Each M+C organization must have a Management Information System to compile, evaluate, and produce reports for CMS, its enrollees, and the public as needed. This system must insure the confidentiality of the doctor-patient relationship and the privacy of individual's records. The system must be able to produce statistics and other information with respect to:

- The cost of the M+C organization's operations;

- The patterns of utilization of its services;

- The availability, accessibility, and acceptability of its services;

- To the extent practical, developments in the health status of its enrollees;

- Information demonstrating that the M+C organization has a fiscally sound operation; and

- And any other information required by CMS when it gives advance notice before the beginning of the contract year.

In addition, each M+C organization, through its Management Information System, must report to CMS:

- With respect to Business Transactions as defined above, M+C organizations must provide either:
    - A showing that the costs of the transactions listed do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest or
    - If they do exceed the limit of $25,000 or five percent of the M+C organization's total operating expenses, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements; and
- A combined financial statement for the M+C organization and a party in interest if either 35 percent or more of the costs of operation of the M+C organization go to a party in interest or 35 percent or more of the revenue of a party in interest is from the M+C organization.

110.4.6 - Reporting Requirements for Combined Financial Statements

(Rev. 8, 03-20-02)

The combined financial statements described at 42 CFR 422.516(c)(3) must display in separate columns the financial information for the M+C organization and each of the parties in interest. Inter-entity transactions must be eliminated in the consolidated column, the statements must have been examined by an independent auditor in accordance with generally accepted accounting principles, and must include appropriate opinions and notes. Upon written request from an M+C organization showing good cause that is determined at the discretion of CMS, CMS may waive the requirement that the organization's combined financial statement include the information required regarding combined financial statements.

110.4.7 - Reporting and Disclosure Requirements Under Employment Retirement Income Security Act of 1974 (ERISA)

(Rev. 8, 03-20-02)

For any employees' health benefits plan that includes an M+C plan in its offerings, the M+C organization must furnish, upon request, the information the organization needs to fulfill its reporting and disclosure obligations (with respect to the particular M+C

organization) under the ERISA. The organization must furnish the information to the employer or the employer's designee, or the plan administrator as defined under ERISA.

Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors, and related entities, and must make information reported to CMS regarding benefits, beneficiary cost sharing, service area and continuation area if any, plan quality and performance indicators, beneficiary appeals and grievances, MSA demonstration project information, and all formal actions taken by regulatory/ licensing/accrediting bodies available to its enrollees upon request.

120 - Compliance with Other Laws and Regulations

(Rev. 8, 03-20-02)

M+C organizations are obligated to comply with other laws, specifically Title VI of the Civil Rights Act of 1964 (and pertinent regulations at 45 CFR §84), 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975 (and pertinent regulations at 45 CFR §91), the Americans With Disabilities Act, other laws applicable to recipients of Federal funds, and all other applicable laws and rules.

M+C organizations receiving Federal payments under M+C contracts, and related entities, contractors, and subcontractors paid by an M+C organization to fulfill its obligations under its M+C contract are subject to certain laws that are applicable to individuals and entities receiving Federal funds. M+C organizations must inform all related entities, contractors and subcontractors, first tier and downstream entities that payments they receive are, in whole or in part, from Federal funds.

130 - Certification of Data that Determine Payment Requirements

(Rev. 8, 03-20-02)

As a condition for receiving a M+C related monthly payment from CMS, the M+C organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data include specified enrollment information, encounter data, and other information that CMS may specify.

The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an M+C plan offered

by the organization, and the information relied upon by CMS in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.

The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the encounter data it submits are accurate, complete, and truthful. If such encounter data are generated by a related entity, contractor, or subcontractor of an M+C organization, such entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data.

The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in its ACR submission is accurate, complete, and truthful and fully conforms to the ACRP requirements.

140 - Special Rules for Request for Bids (RFB) Societies

(Rev. 8, 03-20-02)

In order to participate as an M+C organization, an RFB society may not impose any limitation on membership based on any factor related to health status and must offer in addition to the M+C RFB plan, health coverage to individuals who are members of the church or convention or group of churches with which the society is affiliated, but who are not entitled to receive benefits from the Medicare program.