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CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
4		1 - 160.8	

NEW/REVISED MATERIAL - EFFECTIVE DATE:

This is the initial issuance of Chapter 4 of the Medicare Managed Care Manual. This chapter describes the benefits that must be offered by Medicare + Choice organizations. It addresses basic benefits, mandatory supplemental benefits, and optional supplemental benefits.

In addition, this chapter describes Medicare + Choice organization rights and responsibilities with respect to coordination with programs where Medicare is secondary to the other program. It also provides instructions related to the prohibition of discrimination against beneficiaries, about disclosure of information, access and availability of care, and advance directives.

Medicare Managed Care Manual

Chapter 4 -Benefits and Beneficiary Protections

Table of Contents

1 - Introduction

(Rev. 23, 06-06-03)

The contents of this chapter are governed by regulations set forth in 42 CFR 422 Subpart C.

10 - General Requirements

(Rev. 23, 06-06-03)

10.1 - Basic Rule

(Rev. 23, 06-06-03)

An M+C organization offering an M+C plan must provide enrollees in that plan with coverage of basic benefits - defined as all Medicare-covered services, except hospice - and additional benefits, by furnishing the benefit directly or through arrangements, or by paying for the benefit. In addition, to the extent applicable, the organization will also furnish, arrange, or pay for supplemental benefits. The CMS reviews and approves an M+C organizations' coverage of benefits by ensuring compliance with requirements expressed in this manual, in particular Chapters 4 (this chapter) and 8, as well as other CMS instructions.

10.2 - Services of Noncontracting Providers and Suppliers

(Rev. 23, 06-06-03)

An M+C organization must make timely and reasonable payment to, or on behalf of, the plan enrollee, for the following services obtained from a provider, or supplier, that does not contract with the M+C organization to provide services covered by the M+C plan:

- Ambulance services dispatched through 911 or its local equivalent where other means of transportation would endanger the beneficiary's health, as provided in §130 of this chapter.

- Emergency and urgently needed services under the circumstances described in §130 of this chapter.

- Maintenance and post-stabilization care services under the circumstances described in §130 of this chapter.

- Medically necessary dialysis from any qualified provider selected by an enrollee when the enrollee is temporarily absent from the plan's service area and cannot reasonably access the plan's contracted dialysis providers**.** An M+C plan cannot require prior authorization or notification. However, an enrollee may voluntarily advise the M+C plan if they will temporarily be out of the plan's service area.

The M+C plan may provide medical advice and recommend that the enrollee use a qualified dialysis provider. The M+C plan must clearly inform the beneficiary that the plan will pay for care from any qualified dialysis provider the beneficiary may independently select.

- Services for which coverage has been denied by the M+C organization and found (upon appeal under subpart M of 42 CFR Part 422) to be services the enrollee was entitled to have furnished, or paid for, by the M+C organization.

Payments to Noncontracting Providers and Suppliers

An M+C plan (other than an M+C Medical Savings Account (MSA) plan) offered by an M+C organization generally satisfies its requirements of providing basic benefits with respect to benefits for services furnished by a non-contracting provider if that M+C plan provides payment in an amount the provider would have been entitled to collect under original Medicare (including balance billing permitted under Medicare Part A and Part B).

10.3 - Types of Benefits

(Rev. 23, 06-06-03)

An M+C plan includes, at a minimum, basic benefits and may also include mandatory supplemental benefits and optional supplemental benefits.

- **Basic benefits** are all Medicare-covered services, except hospice services, and additional benefits, as defined below and meeting the requirements specified in 42 CFR 422.312.

- **Additional benefits** are part of the package of basic benefits for which beneficiaries are not charged a premium, beyond any premium the M+C organization is permitted to charge for original Medicare benefits. The costs of additional benefits are funded by the difference between an organization's "adjusted community rate" (ACR) for the original Medicare benefit package and the amount of the M+C payment made to the organization by CMS, plus any approved enrollee cost sharing. A more detailed discussion on "additional benefits" is found in Chapter 8 of this manual, "Premiums and Cost Sharing."

- **Mandatory supplemental benefits** are M+C plan benefits not otherwise covered under original Medicare to which anyone who enrolls in an M+C plan, offering such benefits, is entitled. Thus, additional benefits (included in the basic benefit package) and mandatory supplemental benefits are similar in that they are not covered by original Medicare, and all M+C enrollees must receive them as part of their M+C plan. See Chapter 8 of this manual, "Premiums and Cost Sharing," for additional discussion.

- **Optional supplemental benefits** are similar to additional and mandatory supplemental benefits in that they are benefits that are not covered by original

Medicare. However, plan enrollees may choose whether to elect and pay for optional supplemental benefits. The M+C organizations may offer M+C plans that offer individual items or groups of items and services as optional supplemental benefits.

10.4 - Availability and Structure of Plans

(Rev. 23, 06-06-03)

An M+C organization offering an M+C plan must offer it:

- To all Medicare beneficiaries with Parts A and B of Medicare residing in the service area of the M+C plan; and

- At a uniform premium, with uniform benefits and cost-sharing throughout the plan's service area, or segment of service area when such segments have been approved. (Individuals with ESRD are generally excluded from enrollment. See 42 CFR 422.50(a)(2).)

10.5 - Terms of M+C Plans

(Rev. 23, 06-06-03)

Terms of M+C plans described in instructions to beneficiaries, as described in §110 of this chapter, must include basic and supplemental benefits and terms of coverage for those benefits.

10.6 - Multiple Plans in One Service Area

(Rev. 23, 06-06-03)

An M+C organization may offer more than one M+C plan in the same service area. However, each plan and its benefit package, is subject to the conditions and limitations that are established for the M+C program. Financial caps for a benefit can only be imposed at the M+C plan level. For example, if an M+C organization offers two plans in the same service area, then an enrollee, who has exhausted the Rx benefit of one plan, is entitled to the drug benefit of the other plan, should the enrollee join it.

10.7 - CMS Review and Approval of M+C Benefits

(Rev. 23, 06-06-03)

The CMS reviews and approves M+C benefits using written policy guidelines and requirements in this manual, managed care manual updates, and other CMS instructions to ensure that:

- Medicare-covered services meet CMS guidelines under original fee-for-service Medicare;

- M+C organizations are not designing benefits to discriminate against beneficiaries with higher health care costs; and

- Benefit design meets other M+C program requirements.

Benefits Affecting Screening Mammography, Influenza Vaccine, and Pneumococcal Vaccine

Enrollees of an M+C organization may directly access (through self-referral) screening mammography and influenza vaccine. The organization may not impose cost-sharing for influenza vaccine and pneumococcal vaccine on their M+C plan enrollees.

No Exclusions Related To Medicare Benefits That Are Not Present in Original Medicare Program

An M+C organization may not impose exclusions on Medicare-covered benefits that are not present in the original Medicare program. However, an M+C organization can deny coverage of Medicare-covered services when the services do not meet the standard of being medically necessary and appropriate. In addition, an M+C organization may impose limitations or exclusions on Medicare covered benefits to the extent that such limitations or exclusions are present in the original Medicare statute or regulations.

Inpatient Hospital Rehabilitation Services

Medically necessary inpatient hospital rehabilitation services cannot be limited to a greater extent than they are under the original Medicare program - 60 days, plus 30 coinsurance days, plus remaining lifetime reserve days per Medicare benefit period. For periods of M+C enrollment that begin or end during an inpatient stay in a Medicare certified rehabilitation hospital, the inpatient rehabilitation hospital bill must be split between the parties with financial liability.

Value-Added Items and Services

Value added items and services (VAIS) may not be part of an M+C plan's benefit package as either a basic or supplemental benefit. Value-added items and services are discussed more fully in Chapter 3 of this manual, "Marketing."

Waiting Periods

All beneficiaries must be provided all medically necessary benefits covered in the plan in which they enroll (including optional supplemental benefits) at the time of their initial enrollment. Waiting periods or exclusions from coverage due to pre-existing conditions are not permitted.

Annual Beneficiary Out-of-Pocket Cap

Each year CMS will announce a total annual beneficiary copay cap on member liability associated with Medicare-covered benefits. If an M+C plan does not propose a limit on

beneficiary liability at or below the published cap, CMS will conduct an intensified review of the benefit package in the submitted ACR to ensure that the proposed cost-sharing structure does not discriminate against "sicker" beneficiaries, inappropriately encourage disenrollment or discourage enrollment. With acceptable justification, CMS provides latitude to those plans with member out-of-pocket caps above the published limit as long as the cost-sharing is spread across widely used health care services. The CMS will not approve higher caps that concentrate cost-sharing on specific services, such as dialysis or chemotherapy drugs. Generally, CMS considers monthly premiums and broad-based deductibles as more equitable and potentially less discriminatory than copayments and coinsurance related to infrequently used services.

Drug Benefits

M+C organizations frequently design M+C plans in which a beneficiary receives coverage for outpatient prescription drugs that would not normally be covered under the Medicare program. The CMS has approved non-Medicare prescription drug benefits that provide for annual, quarterly and monthly caps on the dollar amount of benefits available to enrolled members. An M+C organization may also pro-rate an annual drug benefit that has an annual cap. Pro-rating of the annual cap is permitted according to the member's enrollment date, since this would be similar to, but more generous than, a quarterly or monthly cap. However, marketing materials, both pre-and post-enrollment (Summary of Benefits, EOC) must clearly and accurately describe this limitation.

Drugs That Are Covered Under Original Medicare

For this subsection, the term "drug" means "drug or biological."

- Injectable drugs that have been determined by Medicare carriers (and in some cases Fiscal Intermediaries) to be "usually not self-administered" and that are administered incident to physician services. For further information, see PM AB-02-072 (May 15, 2002) and PM AB-02-139 (October 11, 2002), found at CMS 2002 Program Memos;

- Drugs that the M+C enrollee takes while using durable medical equipment (such as nebulizers) that were authorized by the enrollee's M+C plan;

- Clotting factors if the enrollee is diagnosed with specific clotting disorders;

- Immunosuppressive drugs, if the enrollee had an organ transplant that was covered by Medicare;

- Injectable osteoporosis drugs, if the enrollee is homebound, has a bone fracture that a doctor certifies was related to post-menopausal osteoporosis, and cannot self-administer the drug;

- Antigens;

- Certain oral anti-cancer drugs and anti-nausea drugs; and

- Erythropoietin by injection if the member has end-stage renal disease and needs this drug to treat anemia.

Effective August 1, 2002, if an M+C enrollee wishes to receive a "not usually self-administered" drug in a physician's office, the M+C organization must cover the drug and the service of administering the drug. That is, M+C organizations may not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered incident to physician services. (M+C organizations can continue to make determinations concerning the appropriateness of a drug to treat a patient's condition, and the appropriateness of the intravenous or injection form as opposed to the oral form of the drug.)

The M+C organizations can choose to cover, as an additional benefit, injectable drugs that the local carrier has determined are not usually self-administered, but that members purchase at a pharmacy and administer at home. However, M+C enrollees always have the option of receiving the Medicare-covered benefit, i.e., administration of the covered drug in a physician's office.

Multi-Year Benefits

These are services that are provided to a plan's Medicare enrollees over a period exceeding one year. For example, a plan may include coverage of one new pair of eyeglasses every two years. Details on marketing criteria for multi-year benefits are provided in the Must Use/Can't Use/Can Use chart located in Chapter 3 of this manual, "Marketing."

Mid-Year Benefit Enhancements (MYBE)

The CMS will continue to permit M+C organizations to enhance their benefit plans during a contract year. Pursuant to 42 CFR 422.300(b)(1), enhancements may include one or a combination of the following elements:

- Adding new benefits at no additional cost to the plan enrollee;
- Reducing premiums; or
- Reducing cost sharing (i.e., copayments, coinsurance, and deductibles).

Multi-Year Benefits

These are services that are provided to a plan's Medicare enrollees over a period exceeding one year. For example, a plan may include coverage of one new pair of eyeglasses every 2 years. Details on marketing criteria for multi-year benefits are provided in the Must Use/Can't Use/Can Use chart located in Chapter 3 of this manual, "Marketing."

10.8 - Requirements Relating to Medicare Conditions of Participation

(Rev. 23, 06-06-03)

Basic benefits must be furnished through providers meeting requirements that are specified in 42 CFR 422.204(b)(3) and discussed more fully in Chapter 6 of this manual, "Relationships With Providers." In the case of providers meeting the definition of "provider of services" (a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or other institutional providers), the provider must have a provider agreement with CMS. Supplemental benefits, which may be offered as an alternative to, but not instead of, Medicare benefits, do not need to be provided through Medicare providers.

10.9 - Provider Networks

(Rev. 23, 06-06-03)

The M+C plans offered by an M+C organization may share a provider network as long as each M+C plan independently meets the access and availability standards that are established by CMS.

20 - Requirements Relating to Benefits

(Rev. 23, 06-06-03)

20.1 - Basic Benefits

(Rev. 23, 06-06-03)

Except for entitlement that begins or ends during a hospital stay, and with respect to hospice care, each M+C organization must meet the following requirements relating to basic benefits:

- Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if the enrollee is entitled only to benefits under Part B) that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees, and the service delivery is consistent with patterns of care for original Medicare beneficiaries who reside in the same area.

- Comply with the following:

    - CMS' national coverage determinations (see §90, below);

- General coverage guidelines included in original Medicare manuals and instructions (unless superseded by written CMS instructions or regulations contained in Part C of the Medicare program); and

- Written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered under the M+C plan (except that an M+C organization that serves more than one local area may apply a single, consistent coverage policy where local carrier policies differ, as long as the single policy applied is the most beneficial to M+C enrollees).

The requirement that an M+C organization provide coverage for all Medicare-covered services is not intended to dictate care delivery approaches for a particular service. M+C organizations may also encourage patients to see more cost-effective provider types than would be the typical pattern in original Medicare (as long as those providers are working within the scope of care they are licensed to provide, and the M+C organization complies with the provider anti-discrimination rules set forth in 42 CFR 422.205).

An M+C organizations' flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the M+C program. If original Medicare covers a service only when certain conditions are met, these conditions must be met in order for the service to be considered part of the Medicare benefits component of an M+C plan. The M+C plans may cover the same service when the conditions are not met, but these benefits would then be defined as additional or supplemental.

20.2 - Additional Benefits

(Rev. 23, 06-06-03)

This section provides a brief discussion on payment for additional benefits. A more detailed discussion on additional benefits requirements can be found in Chapter 8 of this manual, "Premiums and Cost Sharing."

Additional Benefits are:

- Healthcare services not covered by Medicare;

- Reductions in premium or cost-sharing for Medicare covered services; and/or

- Reductions in the Medicare Beneficiaries standard Part B premium.

Additional benefits are funded by the "adjusted excess" as defined in the ACR.

Chapter 8 of this manual, "Premiums and Cost Sharing," presents detailed definitions of "adjusted excess" and related terms.

20.3 - Supplemental Benefits - Mandatory Supplemental and Optional Supplemental

(Rev. 23, 06-06-03)

Mandatory Supplemental Benefits

Subject to CMS' approval, an M+C organization may require Medicare enrollees of an M+C plan, other than an MSA plan, to accept and pay for services in addition to Medicare-covered services. If an M+C organization elects to require mandatory supplemental benefits for Medicare enrollees electing a specific plan, it must impose the requirement to purchase mandatory supplemental benefits uniformly on all Medicare beneficiaries electing that M+C plan. The CMS will approve mandatory supplemental benefits, if it determines that imposition of the mandatory benefits will not substantially discourage Medicare beneficiaries from enrolling in the M+C plan.

Optional Supplemental Benefits

Each M+C organization may offer (for election by the enrollee and without regard to health status) optional supplemental services or benefits - that is, services or benefits that are in addition to those included in the basic benefits and any mandatory supplemental benefits. All optional supplemental benefits must be offered for a period of at least 30 consecutive days to both new plan enrollees and to all current enrollees of a plan at least once a year.

Optional supplemental benefits (1) are paid for directly, by (or on behalf of) the enrollee; and (2) must be offered uniformly at the time of initial enrollment to all Medicare beneficiaries electing enrollment in the M+C plan. The M+C organization may then (1) continuously offer each optional supplemental benefit uniformly to all enrollees for the entire contract year, **OR** (2) choose to place a time limit, of not less than 30 consecutive days, during which a new enrollee can select any particular optional supplemental benefit offered by the M+C plan. After the enrollees' 30-day selection period ends the optional benefits may be closed to that enrollee for the rest of that contract year during which the beneficiary remains continuously enrolled. The 30-day optional supplemental selection period cannot end before an enrollee has been a member of an M+C plan for 30 consecutive days.

Although M+C organizations may limit the availability of optional supplemental benefits to current enrollees as described above, enrollees may voluntarily drop or discontinue optional supplemental benefits any time during the contract year upon proper advance notice to the M+C organization.

Chapter 2 of this manual, "Enrollment," presents the requirements for an involuntary disenrollment of an enrollee from an M+C organization when that enrollee fails to make timely payments of premium for optional supplemental benefits.

Payment for Supplemental Services

All supplemental benefits are paid for in full, directly by (or on behalf of) the enrollee of the M+C plan.

Marketing of Supplemental Benefits

M+C organizations may offer enrollees a group of services as one optional supplemental benefit, offer services individually, or offer a combination of group and individual services.

20.4 - Basic Versus Supplemental Benefits

(Rev. 23, 06-06-03)

To properly classify a benefit as basic, mandatory supplemental or optional supplemental, three tests must be applied:

- Is this benefit covered by original Medicare?
- Is this benefit funded by the "adjusted excess?"
- Are all enrollees required to purchase this benefit?

The following table summarizes the types of benefits:

Type of benefit		**Questions to Determine Type of Benefit**		
Name	**Basic or Supplemental**	**Is the Benefit Covered by Original Medicare?**	**Does the Adjusted Excess Cover the Cost of the Benefit?**	**Are All Enrollees Required to Buy the Benefit?** [1]
Medicare	Basic[3]	Yes	NA	Yes
Additional	Basic[3]	No	Yes[2]	Yes
Mandatory	Supplemental[4]	No	No	es
Optional	Supplemental[4]	No	No	No

NOTES:

1. The M+C organization however, is required to offer all types of benefits in its benefit package to all enrollees in its service area (see §10.4 of this chapter).

2. The plan is required by statute to use the adjusted excess to either reduce premiums or cost sharing for Medicare-covered services or to offer health care services not

covered by Medicare. (A plan may also use the adjusted excess to contribute to a stabilization fund. See Chapter 8 of this manual - "Premiums and Cost Sharing.")

3. The cost to the beneficiary for basic benefits can never exceed the maximum charge. The cost of basic benefits is defined equal to the sum of premium and the actuarial value of the cost sharing. The CMS publishes the value of the maximum charge each year. The maximum charge equals the actuarial value of deductibles and coinsurance to the typical Medicare beneficiary in original Medicare.

4. The sum of the premium and the actuarial value of the cost sharing for a supplemental benefit cannot exceed the ACR value of the benefit.

30 - Medicare Covered Benefits

(Rev. 23, 06-06-03)

As indicated in §20.1 of this chapter, M+C organizations must generally provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if the enrollee is entitled only to benefits under Part B) that are available to beneficiaries residing in the plan's service area.

Administration of the Medicare program is governed by title XVIII of the Social Security Act (the Act). Under the Medicare program, the scope of benefits available to eligible beneficiaries is prescribed by law and divided into several main parts. Part A is the hospital insurance program and Part B is the voluntary supplementary medical insurance program.

The scope of the benefits under Part A and Part B is defined in the Act. The scopes of Part A and Part B are discussed in §§1812 and 1832 of the Act respectively, while §1861 of the Act lays out the definition of medical and other health services. Part C, known as the Medicare+Choice program includes at a minimum all of the items and services (other than hospice care) available under part A and part B to individuals residing in the area served by the plan. Some benefit categories are defined more broadly than others. Specific health care services must fit into one of these benefit categories, and not be otherwise excluded for coverage under the Medicare program.

The Act does not contain a comprehensive list of specific items or services eligible for Medicare coverage. Rather, it lists categories of items and services, and vests in the Secretary the authority to make determinations about which specific items and services within these categories can be covered under the Medicare program. That is, the Act allows Medicare to cover medical devices, surgical procedures and diagnostic services, but generally does not identify specific covered or excluded items or services. Further guidance is presented in the Code of Federal Regulations and CMS interpretations.

Medicare payment is contingent upon a determination that:

- A service meets a benefit category;

- Is not specifically excluded from coverage; and
- The item or service is "reasonable and necessary."

Section 1862(a)(1)(A) of the Act states that, subject to certain limited exceptions, no payment may be made for any expenses incurred for items or services that are not "reasonable and necessary" for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member. These authorities are exercised to make coverage determinations regarding whether a specific item or service meets one of the broadly defined benefit categories and can be covered under the Medicare program. National coverage decisions are published on the National Coverage Web site - for further information please see §90 of this chapter.

In the absence of a specific National Coverage Decision, coverage decisions are made, as indicated in §20.1, at the discretion of local contractors. In addition, we note that §1852(a)(2)(C) of the Act provides that in the case of a Medicare+Choice organization that offers a Medicare+Choice plan in an area in which more than one local coverage policy is applied with respect to different parts of the area, the organization may elect to have the local coverage policy for the part of the area that is most beneficial to Medicare+Choice enrollees apply with respect to all Medicare+Choice enrollees enrolled in the plan.

40 - M+C Medical Savings Account Plan Benefits

(Rev. 23, 06-06-03)

40.1 - General Rule

(Rev. 23, 06-06-03)

An M+C organization offering an M+C Medical Savings Account (MSA) plan must make available to an enrollee, or provide reimbursement for, at least the Basic Medicare benefits (as defined in §20 of this chapter) after the enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

M+C MSA plans must cover all Medicare Part A and Part B services, with the exception of hospice services and certain inpatient hospital services (see 42 CFR 422.264), once the enrollee's countable expenses reach the plan's annual deductible.

40.2 - Countable expenses

(Rev. 23, 06-06-03)

An M+C organization offering an M+C MSA plan must count toward the annual deductible at least all amounts that would be paid for the particular service under original Medicare, including amounts that would be paid by the enrollee as deductibles or coinsurance.

The MSA insurer does have the discretion to cover supplemental services and to increase payment amounts over and above the minimum services and payment amounts required by legislation.

40.3 - Services After the Deductible

(Rev. 23, 06-06-03)

For services received by the enrollee after the annual deductible is satisfied, an M+C organization offering an M+C MSA plan must pay, at a minimum, the lesser of the following amounts:

- 100 percent of the expense of the services; or
- 100 percent of the amounts that would have been paid for the services under original Medicare, including amounts that would be paid by the enrollee as deductibles and coinsurance.

40.4 - Balance Billing

(Rev. 23, 06-06-03)

Medicare balance billing protections for beneficiaries do not apply for M+C MSA plans. The only limitations on amounts billed by providers are those contained in contractual agreements between the plan and the providers.

40.5 - The Annual Deductible

(Rev. 23, 06-06-03)

The annual deductible for an M+C MSA plan is:

- For contract year 1999, the annual deductible for an M+C MSA plan, could not exceed $ 6,000;
- For subsequent contract years, the annual deductible may not exceed the deductible for the preceding contract year, increased by the national per capita growth percentage, determined under 42 CFR 422.252(b), rounded to the nearest multiple of $50;
- For partial year enrollees, apportionment of the deductible or year-to-year carry-over of claims is at the discretion of the MSA plan; and
- There is no required **minimum** deductible.

40.6 - Special Rules on Supplemental Benefits for M+C Medical Savings Account Plans

(Rev. 23, 06-06-03)

The purpose of establishing the Medical Savings Accounts account is to provide beneficiaries with funds to help them meet expenses under the deductible. Therefore, individuals with first dollar coverage such as those eligible for Medicaid, VA benefits, and FEHBP, or those with employer retirement benefits or Medigap policies, which would cover expenses under the deductible, are precluded from enrolling in an MSA plan.

An M+C organization offering an M+C Medical Savings Account plan may not provide supplemental benefits that cover expenses that count towards the deductible specified in §40.5 of this chapter. The Act (as amended by the Balanced Budget Act of 1997) forbids the sale of most freestanding supplemental health insurance policies, which cover expenses under the deductible for beneficiaries enrolled in an M+C Medical Savings Account. The exceptions to this prohibition are as follows:

Individuals may simultaneously possess both a Medical Savings Account, and

- Policies that provide coverage for:
    - Accidents;
    - Disability;
    - Dental care;
    - Vision care; or
    - Long-term care.
- Policies in which substantially all coverage relates to liabilities incurred under:
    - Workers' compensation laws;
    - Tort liabilities;
    - Liabilities relating to use of ownership of property; or
    - Any other similar liabilities that CMS may specify by regulation.
- Policies that:
    - Provide coverage for specified disease or illness, or
    - Pay a fixed amount per day (or other period) for hospitalization.

For an M+C Medical Savings Account plan, **mandatory** supplemental benefits are prohibited, but **optional** supplemental benefits are permitted subject to certain restrictions.

Once the M+C Medical Savings Account deductible has been met, there are no restrictions on supplemental coverage, either as optional supplemental benefits or as a separate policy, as long as the basic Medicare Part A and Part B services are covered.

50 - Point of Service Option

(Rev. 23, 06-06-03)

50.1 - General Rule

(Rev. 23, 06-06-03)

A point of service (POS) benefit is an option that an M+C organization may offer under an M+C coordinated care plan, or network M+C MSA plan, to provide enrollees in such plans with additional choice in obtaining specified health care services. A non-MSA coordinated care plan may include a POS option as an additional benefit, a mandatory supplemental benefit or an optional supplemental benefit. A network MSA plan may only offer a POS benefit as an optional supplemental benefit. An M+C organization may not implement a POS benefit until it has been approved by CMS.

Under a POS option, the M+C organization generally permits enrollees to obtain specified items and services outside of the M+C plan's normal prior authorization rules, but generally requires that enrollees will incur higher financial liability for such services. The enrollee may be required to pay a premium for the benefit unless the benefit is offered as an additional benefit. The M+C organizations can establish what services are available under a POS benefit and the amount of member cost sharing subject to ACR limits. The M+C organizations may also place other limits on the benefit. For example, a plan could offer a POS benefit as a travel benefit allowing members to access specified services only when members are traveling outside of the plan's service area.

50.2 - Accessing Plan Contracting Providers

(Rev. 23, 06-06-03)

Plans have the option of offering a POS benefit that can be used by plan members to receive services from plan contracting providers. Plans which allow a POS benefit to be used by enrollees to access plan contracting providers must separately track and report in-network POS utilization. An M+C network that includes a POS benefit must continue to provide all benefits and ensure access as required by the requirements specified in this chapter and set forth at 42 CFR Part 422 Subpart C.

50.3 - Financial Cap

(Rev. 23, 06-06-03)

Plans offering a POS benefit must establish an annual maximum dollar cap on enrollees' financial liability for POS benefits, and must calculate and disclose the maximum out-of-pocket expense an enrollee could incur. The reason for requiring a cap on enrollee financial liability is to ensure that beneficiaries understand in advance what the plan's and member's maximum financial risk is for POS benefits.

For example, suppose a plan offers a POS benefit, imposes a $5,000 annual maximum on its own obligations, and requires a 20 percent coinsurance from the beneficiary using the POS benefit. In this example, the member's annual maximum financial liability under POS is $1,000 (20 percent of $5,000). Once the $5,000 overall POS annual maximum is reached, the beneficiary has paid the out-of-pocket maximum of $1,000 and the plan has contributed $4,000 of the $5,000 total annual maximum for the POS benefit. At this point, the plan has no further obligation to cover services for the beneficiary under the POS benefit.

50.4 - Enrollee Information and Disclosure

(Rev. 23, 06-06-03)

Organizations offering a POS benefit must be able to provide enrollees with timely information on the POS financial limits, coverage rules, and enrollee cost-sharing for a given service, including the capacity to provide enrollees with advance coverage information over the phone. For example, enrollees should be able to phone the organization offering the POS benefit, and be informed how close they are to reaching the financial cap on the benefit. In addition, the plan should be able to advise an enrollee whether a particular service will be paid for under a POS benefit, how much the member will pay out-of-pocket, and how much the plan will contribute under the POS benefit.

Furthermore, M+C organizations must maintain written rules on how to obtain health benefits through the POS benefit. The M+C organization must provide to beneficiaries enrolling in a plan with a POS benefit an "evidence of coverage" document, or otherwise provide written documentation that specifies all costs and possible financial risks to the enrollee including :

- Any premiums and cost-sharing for which the enrollee is responsible;
- Annual limits on benefits and out-of-pocket expenditures;
- Potential financial responsibility for services for which the plan denies payment because they were not covered under the POS benefit, or exceeded the dollar limit for the benefit; and
- The annual maximum out-of-pocket expense an enrollee could incur.

50.5 - Prompt Payment

(Rev. 23, 06-06-03)

Health benefits payable under the POS benefit are subject to the prompt payment requirements described at 42 CFR 422.520.

50.6 - POS-Related Data

(Rev. 23, 06-06-03)

An M+C organization that offers a POS benefit through an M+C plan must report enrollee utilization data at the plan level by both plan contracting providers (in-network), and by non-contracting providers (out-of-network) including enrollee use of the POS benefit, in the form and manner prescribed by CMS.

60 - Service Area

(Rev. 23, 06-06-03)

60.1 - Definition

(Rev. 23, 06-06-03)

A service area is a geographical area approved by CMS within which an M+C eligible individual may enroll in a particular M+C plan offered by an M+C organization. An M+C plan's service area does not need to be contiguous.

The basic requirement of service area is that each M+C plan offered by an M+C organization must be offered to all beneficiaries in an M+C plan's service area with a uniform benefit package and uniform cost-sharing arrangements.

The designation of an M+C plan's service area affects the following five items:

- **Payment Rate:** The service area designation determines CMS' payment rate to the M+C organization based on the counties included in the service area;
- **Required Benefits:** The designation affects which benefits will be provided under the M+C plan, because benefits and premiums must be uniform for all Medicare beneficiaries residing in the plan's service area;
- **Eligibility:** The designation determines which Medicare beneficiaries are able to elect the plan. The M+C organizations are obligated to enroll any M+C eligible resident in the service area who elects the plan during "open" enrollment periods (provided an approved capacity limit has not yet been reached (see Chapter 2 of this manual, "Enrollment and Disenrollment"));

- **Access Requirements:** For coordinated care plans, the designation identifies the geographical area within which the plan's covered services must be "available and accessible;" and

- **Urgent Care Requirement:** For coordination care plans, the designation defines the boundaries beyond which the organization must always assume financial liability for urgently needed care.

60.2 - Factors That Influence Service Area Approvals

(Rev. 23, 06-06-03)

In deciding whether to approve an M+C plan's service area, CMS considers the following:

- Whether each M+C plan (except for Employer Only plans - see Chapter 8 of this manual, "Premiums and Cost Sharing") will be made available to all M+C eligible individuals within the plan's service area;

- Whether the plan will offer a uniform premium, benefit package and cost-sharing arrangement to all beneficiaries in the service area, or segment of a service area;

- Whether the service area meets the "county integrity rule" described below;

- Whether, for coordinated care plans and network MSA plans, the contracting provider network meets the CMS access and availability standards for the service area, as explained in §120 of this chapter, even if some of the contracting providers are physically located outside of the service area; and

- Whether there is any evidence that the service area is being manipulated to avoid areas with "sicker" people or that it would be discriminatory in some other way. In this regard, CMS also considers the extent to which the proposed service area mirrors service areas of existing commercial or M+C plans offered by the M+C organization. However, CMS may approve single county non-network M+C MSA plans even if the M+C organization's commercial plans have multiple county service areas.

60.3 - The "County Integrity Rule"

(Rev. 23, 06-06-03)

The CMS will generally approve only full counties in a service area, in order to prevent the establishment of boundaries that could "game" the countywide M+C payment system by excluding an area of the county where beneficiaries with expected higher health care utilization might reside. However, the counties do not need to be contiguous, and under limited circumstances described below, CMS may approve the inclusion of "partial" counties in a service area.

Approval of A "Partial" County in A Service Area

The CMS will consider approving a service area that includes a partial county, if it determines that the inclusion of a partial county is (1) Necessary, (2) Non-discriminatory, and (3) In the best interest of the beneficiaries. All three of these factors must be present in order for CMS to approve an exception to the county integrity rule.

1. **For CMS to determine that a partial county is necessary, an M+C organization must be able to demonstrate at least one of the following:**

   - The M+C organization cannot establish a provider network to make health care services available and accessible to beneficiaries residing in the excluded portion of the county.

     Examples include the following:

     a. A Provider Sponsored Organization or other type of M+C plan may have a health care network that is limited to one part of a county and cannot be readily extended to encompass an entire county.

     b. A section of a county may have an insufficient number of providers (or insufficient capacity among existing providers) to ensure access and availability to covered services.

     c. Geographic features, such as mountains, water barriers, and exceptionally large counties may create situations where the pattern of care in the county justifies less than a complete county because covered services are not available and accessible throughout the entire county.

   - The M+C organization demonstrates that it cannot establish economically viable contracts with sufficient providers to serve an entire county. The M+C organization can demonstrate this by furnishing documentation describing why the M+C organization was unable to establish viable contracts with providers in order to serve the proposed excluded portion of the county. As an example, supporting documentation can show what provider groups are in the portion of the county the M+C organization is proposing to exclude from its service area. Among those provider groups (in the proposed excluded county area) the M+C organization can document its unsuccessful efforts to establish contracts in order to serve the area.

2. **For CMS to determine if a partial county is non-discriminatory, an M+C organization must be able to demonstrate the following:**

   - The anticipated enrollee health care cost of the portion of the county it proposes to serve are similar to the area of the county that will be excluded from the service area. For example, if the M+C organization is requesting a service area reduction (creating a new partial county) the organization can demonstrate its anticipated cost of care (in the partial county area) by using data from the previous year of

M+C contracting comparing the health care costs of its enrollees in the excluded area to those in the area of the county it proposes to serve.

- The racial and economic composition of the population in the portion of the county it wants to serve is comparable to the excluded portion of the county. For example, the M+C organization can use U.S. census data to show the demographic make-up of the included portion of the county as compared to the excluded portion.

NOTE: The existence of other M+C organizations in the same county with adequate provider networks could contribute evidence that it would be discriminatory to approve a partial county service area.

3. **For CMS to determine if a partial county is in the best interest of beneficiaries, an M+C organization must provide reasonable documentation to support this premise.** Supporting documentation could include data obtained from:

    a. Enrollee satisfaction surveys;

    b. Grievance and appeal files; and

    c. Utilization files.

It is never acceptable for an M+C organization to devise an M+C plan service area that excludes portions of a county because it believes enrollees with anticipated higher health care costs or needs reside in the excluded portions of the county.

70 - Coordination of Benefits With Employer Group Health Plans and Medicaid

(Rev. 23, 06-06-03)

70.1 - General Rule

(Rev. 23, 06-06-03)

An M+C organization may contract with employers or State Medicaid Agencies to furnish benefits that **complement** those that an employee or retiree receives under an M+C plan. Some examples of **complementary benefits** are the following:

- The employer, or State Medicaid Agency, pays for some, or all, of the M+C plan's basic premiums, supplemental premiums, or cost sharing; and

- The employer (or State Medicaid Agency) provides other employer-sponsored (or state-sponsored) services that may require additional premium and cost sharing.

70.2 - Requirements, Rights and Beneficiary Protection

(Rev. 23, 06-06-03)

All requirements, rights, and protections that apply to the M+C program also apply to all M+C plan benefits - the basic, mandatory and optional supplemental benefits discussed in this chapter. By contrast, the employer (or State Medicaid) benefits that **complement** the M+C plan benefits are not considered M+C benefits and are therefore beyond the scope of M+C regulations. Marketing materials associated with the complement benefits are also not subject to CMS approval. (See Chapter 8 of this manual, "Premiums and Cost Sharing," for further discussion.)

80 - Medicare Secondary Payer (MSP) Procedures

(Rev. 23, 06-06-03)

80.1 - Basic Rule

(Rev. 23, 06-06-03)

The CMS does not pay for services to the extent that there is a third party that is required to be the primary payer. The principles on cost-sharing that are discussed below may not apply in circumstances where CMS has granted an employer group waiver. (See Chapter 8 of this manual, "Premiums and Cost Sharing," for further discussion.)

80.2 - Responsibilities of the M+C Organization

(Rev. 23, 06-06-03)

The M+C organization must, for each M+C plan:

- Identify payers that are primary to Medicare;
- Identify the amounts payable by those payers; and
- Coordinate its benefits to Medicare enrollees with the benefits of the primary payers.

80.3 - Medicare Benefits Secondary to Group Health Plans and Large Group Health Plans

(Rev. 23, 06-06-03)

Secondary status can arise both from **settlements** as well as **other insurance plans**.

In the case of **other insurance plans**, secondary payer status may, in certain circumstances depend on:

- Whether the entitlement to Medicare is because of age or disability;
- Who is the primary beneficiary of the other insurance plan; or
- The size (number of employees) of the sponsoring employer group.

Specifically, but not exclusively, an M+C organization is the secondary payer in the following situations:

- The M+C plan has an M+C enrollee who is 65 years or older, AND
    - Who is covered by a Group Health Plan (GHP) because of either:
        - Current employment, or
        - Current employment of a spouse of any age;

      and
    - The employer that sponsors or contributes to the GHP plan employs 20 or more employees.
- The M+C plan has an M+C enrollee who is disabled, AND
    - Who is covered by a Large Group Health Plan (LGHP) because of either:
        - Current employment, or
        - A family member's current employment,

      and
    - The employer that sponsors or contributes to the LGHP plan employs 100 or more employees.
- The first 30 months of eligibility or entitlement to Medicare for an M+C enrollee is entitled to Medicare solely on the basis of **end-stage renal disease** and group health plan coverage (including a retirement plan). This provision applies regardless of the number of employees and the enrollee's employment status.

Secondary payer status can also happen because of **settlements**. In this case, the M+C organization is the secondary payer for an M+C enrollee when:

- The proceeds from the enrollee's **workers' compensation settlement** are available; and
- The proceeds from the enrollee's **no-fault or liability settlement** are available.

Please note that Medicare does not coordinate with non-existent health insurance coverage, even when such health insurance is required by state law (i.e., auto-liability). In other words, in the absence of a reasonable expectation that another insurer will pay primary to Medicare, M+C organizations cannot withhold primary payment.

80.4 - Collecting From Other Entities

(Rev. 23, 06-06-03)

The M+C organization may bill, or authorize a provider to bill, other individuals or entities for covered Medicare services for which Medicare is not the primary payer, as specified in §§80.5 and 80.6 below.

80.5 - Collecting From Other Insurers or the Enrollee

(Rev. 23, 06-06-03)

If an M+C enrollee receives from an M+C organization covered services that are also covered under state or Federal workers' compensation, and no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the M+C organization may bill, or authorize a provider to bill any of the following:

- The insurance carrier, the employer, or any other entity that is liable for payment for the services under §1862(b) of the Act and §80 of this chapter; and

- The Medicare enrollee, to the extent that he or she has been paid by the carrier, employer, or entity for covered medical expenses.

80.6 - Collecting From GHPs and LGHPs

(Rev. 23, 06-06-03)

When an M+C organization is the secondary payer to an employer group health plan, the coordination of benefits occurs in the aggregate through the adjusted community rate (ACR) process. This process results in a copayment as part of the M+C plan benefit package for which every enrollee is liable. Therefore, there is no coordination of benefits on a beneficiary-specific basis that would relieve an M+C enrollee with employer group health plan coverage of his or her cost sharing obligation under the M+C plan. As a result, the M+C enrollee remains liable for payment of the M+C plan's cost sharing regardless of whether Medicare is primary or secondary. However, under 42 CFR 422.502(g), which addresses beneficiary financial protection contained in the contract between the M+C organization and CMS, the M+C organization is responsible for relieving the beneficiary of responsibility for payment of health care costs other than the M+C cost sharing, and therefore, the M+C organization must relieve the enrollee of his or her liability under the terms of the employer group health plan.

For example, if the employer group health plan (the primary payer) has a copayment of $20 and the M+C plan has a copayment of $10 for the service the beneficiary received,

the beneficiary cannot be liable to pay more than the M+C's copayment of $10. The M+C organization must absolve the beneficiary of the liability for any amount in excess of the M+C plan copayment of $10.

80.7 - MSP Rules and State Laws

(Rev. 23, 06-06-03)

Consistent with Federal preemption of state law that is addressed at 42 CFR 422.402, the rules established in this §80 and set forth at 42 CFR 422.108 supersede any state laws, regulations, contract requirements, or other standards that would otherwise apply to M+C plans only to the extent that those state laws are inconsistent with the standards established for the M+C program. Thus, M+C organizations could pursue their federally authorized claims under the remedies provided under state law as a state licensed insurer or health care plan. Federal preemption of state laws in the MSP context would occur only to the extent a state law would prohibit an M+C organization from complying with what the Federal rules authorize (that is, from billing and recovering from specified third parties, and from beneficiaries to the extent they have received third party payments that are primary to Medicare under MSP rules). However, nothing in §1852(a)(4) of the Act would prohibit a state from limiting the amount of the recovery. Therefore, state law could modify an M+C organization's rights in this regard, but could not deny them entirely.

(See Chapter 8 of this manual, "Premiums and Cost Sharing," for further discussion of how Medicare Secondary Payer and Coordination of Benefits affects the adjusted community rate filing.)

90 - National Coverage Determinations and Legislative Changes In Benefits

(Rev. 23, 06-06-03)

90.1 - Definitions

(Rev. 23, 06-06-03)

A **national coverage determination (NCD)** is a determination by CMS about whether or not a particular item or service is covered nationally under Medicare. The M+C organizations must comply with all NCDs (see §20.1).

A **legislative change in benefits** refers to new Medicare coverage of an item or service mandated by the Congress.

The term **significant cost**, as it relates to a particular NCD or legislative change in benefits, means either of the following:

- The average cost of furnishing a single service exceeds a cost threshold that:

- For calendar years 1998 and 1999, is $100,000; and

- For calendar year 2000 and subsequent calendar years, is the preceding year's dollar threshold adjusted to reflect the national per capita growth percentage described at 42 CFR 422.254(b).

- The estimated cost of all Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national standardized annual capitation rate, as described at 42 CFR 422.254(f), multiplied by the total number of Medicare beneficiaries for the applicable calendar year.

90.2 - General Rules

(Rev. 23, 06-06-03)

Medicare coverage policies specify which benefits are provided under the Medicare program and under what circumstances (including the clinical criteria under which the item or service must be provided). Medicare coverage policies have several sources:

1. National coverage determinations made by CMS;

2. Other coverage guidelines and instructions issued by CMS (e.g., Program Memoranda and Program Transmittals);

3. Legislative changes in benefits; and

4. Local medical review policies established by Medicare contractors for local areas.

M+C organizations must provide all Medicare-covered benefits (see §20.1.). If CMS determines and announces that an NCD or legislative change in benefits **does not** meet a criterion for significant cost described in §90.1 above, then the M+C organization is required to assume risk for the costs of that service or benefit as of the effective date stated in the NCD or specified in the legislation.

However, if CMS determines and announces that an NCD or legislative change in benefits **does** meet a criterion for significant cost described in §90.1 above, then the M+C organization is not required to assume risk for the costs of that service or benefit until the contract year for which payments are appropriately adjusted to take into account the cost of the NCD service or legislative change in benefits.

Chapter 7, "Payment to M+C Organization," contains the detailed rules on payment for NCD or legislative change benefits that do meet the significant cost threshold, including a **list of exceptions** for which M+C organizations are responsible in the contract year before the payment adjustment becomes effective. During this period, M+C enrollees are responsible for the regular Medicare cost-sharing amounts associated with the benefit being paid for on a fee-for-service basis, with the exception of Part A and Part B deductibles.

After the Payment Adjustment Becomes Effective

For the contract year in which payment adjustments that take into account the significant cost of the NCD service or legislative change in benefits are in effect, the service or benefit is included in the M+C organization's contract with CMS.

Subject to all applicable rules under the M+C program, the M+C organization must furnish, arrange, or pay for the NCD service or legislative change in benefits. For these services or benefits, the Medicare enrollee will be responsible for M+C plan cost sharing, as approved by CMS.

90.3 - Sources for Obtaining Information

(Rev. 23, 06-06-03)

In an effort to make the coverage process more open, understandable, and predictable, CMS has redesigned its Medicare coverage process. Part of the redesign includes using the Internet to inform interested parties about how national coverage determinations are made and the progress of each issue under coverage review. The Web page on NCDs, found at http://www.cms.hhs.gov/coverage/8b3.asp, lists both pending and closed coverage determinations. For each coverage topic on the NCD web page, CMS provides a staff name and e-mail link so interested parties can use the Internet to send questions and to provide feedback.

The Coverage Issues Manual is the primary record of Medicare national coverage policies, and includes a discussion of the circumstances under which items and services are covered. Newly contracted M+C organizations are put on the distribution list to receive the Coverage Issuances Manual, CMS Publication 6. This distribution list includes regular updates. Alternatively, one may sign up to subscribe to the Coverage List by visiting the "Medicare Coverage Policy - Home Page" which may be found at http://www.cms.hhs.gov/coverage/.

Additional information on new coverage can be found in the Program Memoranda and Program Transmittals that transmit CMS' new policies and procedures. These may be found at http://www.cms.hhs.gov/manuals.

100 - Discrimination Against Beneficiaries Prohibited

(Rev. 23, 06-06-03)

100.1 - General Prohibition

(Rev. 23, 06-06-03)

Except for not enrolling most individuals who have been medically determined to have end-stage renal disease, an M+C organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an M+C plan offered

by the organization on the basis of any factor that is related to health status, including, but not limited to the following:

- Medical condition, including mental, as well as physical illness;
- Claims experience;
- Receipt of health care;
- Medical history;
- Genetic information;
- Evidence of insurability, including conditions arising out of acts of domestic violence; and
- Disability.

An M+C organization may not disenroll an M+C member just because they develop end-stage renal disease while **enrolled** in one of the organization's M+C plans. An individual who is an enrollee of a particular M+C organization, and resides in the M+C plan service area at the time he or she first becomes M+C eligible, is considered to be **enrolled** in the M+C organization for purposes of the preceding sentence.

100.2 - Additional Requirements

(Rev. 23, 06-06-03)

An M+C organization is also required to observe the provisions of the Civil Rights Act, Age Discrimination Act, Rehabilitation Act of 1973, and Americans with Disability Act.

100.3 - An M+C Organization's Responsibility

(Rev. 23, 06-06-03)

An M+C organization must ensure that their M+C plans have procedures in place to ensure that members are not discriminated against in the delivery of health care services consistent with the benefits covered in their policy based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

110 - Disclosure Requirements

(Rev. 23, 06-06-03)

110.1 - Introduction

(Rev. 23, 06-06-03)

This section, briefly addresses M+C Organization disclosure requirements. A more comprehensive discussion of disclosure requirements and CMS's methods for ensuring compliance with the disclosure requirements are found in Chapter 3 of this manual, "Marketing."

110.2 - Disclosure Requirements at Enrollment (and Annually Thereafter)

(Rev. 23, 06-06-03)

At the time of enrollment (and at least annually thereafter) an M+C organization must provide each enrollee electing an M+C plan it offers, the information listed below. The description must be presented in a clear, accurate, and standardized manner.

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

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

- The benefits offered under original Medicare, including covered services, beneficiary cost-sharing, and any beneficiary liability for balance billing; and
- The availability of the Medicare hospice option and any approved hospices in the service area, including those that the M+C organization owns, controls, or has financial interest in.

Access - The number, mix, and addresses of providers from whom enrollees may obtain services; any out-of network coverage; any POS option, including the supplemental premium for that option; and how the M+C organization meets the access to service requirements for access to services offered under the plan, which are discussed below in §120.

Out-of-area coverage - provided under the plan, including coverage provided to individuals eligible to enroll in the plan who may reside outside the service area of the M+C plan as provided under a provision set forth at 42 CFR 422.50(a)(3)(ii).

Emergency coverage - Coverage of emergency services, including:

- An explanation of what constitutes an emergency (M+C organizations must use the definitions of emergency services and emergency medical condition that are presented below in §130);

- The appropriate use of emergency services. The M+C organization must clearly state that prior authorization cannot be required for emergency services;

- The process and procedures for obtaining emergency services, including the 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.

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

Prior authorization and review rules - 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 non contracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit a bill directly to the M+C organization for processing and determination of enrollee liability, if any.

Grievance and appeals procedures - All grievance and appeal rights and procedures.

Quality Assurance program - A description of the quality assurance program that is required for all M+C organizations.

Disenrollment rights and responsibilities

110.3 - Disclosure Upon Request

(Rev. 23, 06-06-03)

Upon request by an individual who is eligible to enroll in an M+C plan, an M+C organization must provide the following information:

- Benefits covered under original Medicare, as described below in §110.5; and

- Utilization Control Mechanisms.

Aggregated number and disposition of disputes, categorized by (1) Grievances - as defined by CMS at 42 CFR 422.564; and (2) Appeals - as defined by CMS at 42 CFR 422.578.

- **Physician compensation methods -** A summary description of the method of compensation for physicians.

- **Financial Information -** Information on the 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.

110.4 - Information Pertaining to an M+C Organization Changing Their Rules or Provider Network

(Rev. 23, 06-06-03)

If an M+C organization intends to change its rules for one of their M+C plans, it must do the following:

- Submit the changes for a CMS review by following the procedures and time frames specified in Chapter 3 of this manual, "Marketing," and codified in regulation at 42 CFR 422.80;

- For changes that take affect on January 1, the M+C organization must notify all enrollees by the previous October 15; and

- For all other changes, the M+C organization must notify all enrollees at least 30 days before the intended effective date of the changes.

An M+C organization must make a "good faith" effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

110.5 - Other Information That Is Disclosable

(Rev. 23, 06-06-03)

This section contains a list of other disclosable information that must be disclosed upon request. Information for many (but not all) of the topics are found in the Evidence of Coverage (EOC). The EOC is annually published on the CMS Web site at http://www.cms.hhs.gov/. Information for other topic areas, such as comparative information, can be found in the "Medicare & You Handbook" that is published every year, as well as on the CMS Web site at http://www.medicare.gov/, under Medicare Personal Plan Finder. The M+C organizations are obligated to assist M+C plan enrollees in obtaining the information provided by CMS.

- **Benefits under original Medicare -** Including covered services, beneficiary cost-sharing (such as copayments and coinsurance), and any beneficiary liability for balance billing.

- **Enrollment procedure -** Information and instructions on how to exercise election options provided by the organization.

- **Rights -** The M+C organization must provide a general description of procedural rights (including grievance and appeal procedures) under original Medicare and the M+C program, and the right to be protected against discrimination based on the factors that are addressed in §100 of this chapter.

- **Medigap and Medicare Select -** The plan should provide a general description of the benefits, enrollment rights, and requirements applicable to Medicare supplemental policies under §1882 of the Act, and provisions relating to Medicare select policies under §1882(t) of the Act.

- **Potential for contract termination -** 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.

- **Comparative information -** A list of M+C plans that are (or will be) available to residents in the service area in the following calendar year, and, for each available plan, information on the aspects described below, in a manner that facilitates comparison among plans:

    - **Benefits**:

        - Covered services that are beyond those provided under original Medicare;

        - Any beneficiary cost-sharing;

        - Any maximum limitation on out-of-pocket expenses that may apply;

        - In the case of an M+C private fee-for-service plan, differences in cost sharing, enrollee premiums, and balance billing, as compared to M+C plans;

        - 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.

    - **Premiums -** The M+C monthly basic beneficiary premiums and the M+C monthly supplemental beneficiary premium;

    - **The plan's service area;**

- **Quality and performance indicators** for benefits under a plan to the extent they are available, (and how they compare with indicators under original Medicare), as follows:
    - 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 M+C requirements; and
    - Other performance indicators.
- **Supplemental benefits -** Whether the plan offers mandatory supplemental benefits or offers optional supplemental benefits and premiums and other terms and conditions for those benefits.

120 - Access to (and Availability of) Services

(Rev. 23, 06-06-03)

120.1 - Introduction

(Rev. 23, 06-06-03)

This section contains requirements for access, availability, and continuity of care.

120.2 - Access and Availability Rules for Coordinated Care Plans

(Rev. 23, 06-06-03)

An M+C organization may specify the providers through whom enrollees may obtain services if it ensures that all covered services, including additional or supplemental services contracted for, by, or on behalf of Medicare enrollees, are available and accessible under the coordinated care. To accomplish this, the organization must meet the following requirements:

- Maintain and monitor a network of appropriate providers, supported by written arrangements, that is sufficient to provide adequate access to covered services to meet the needs of the population served. This involves ensuring that services are geographically accessible and consistent with local community patterns of care. In other words, the M+C organization must ensure that providers are distributed so that no member residing in the service area must travel an unreasonable

distance to obtain covered services. For example, a commonly used service must be available within 30 minutes driving time. Of course, longer travel times are permissible as long as they are based on location (such as a rural area) and/or are established and based on the routine patterns of care that are available in the geographic area.

- Establish and maintain provider network standards that:
    - Define the types of providers to be used when more than one type of provider can furnish a particular item or service;
    - Identify the types of mental health and substance abuse providers in their network;
    - Specify the types of providers who may serve as a member's primary care physician; and
    - Assess other means of transportation that members rely on such as public transportation.
- Employ written standards for timeliness of access to care and member services that meet or exceed such standards as may be established by CMS, make these standards known to all first tier and downstream providers, continuously monitor its provider networks' compliance with these standards, and take corrective action as necessary. These standards must ensure that the hours of operation of the M+C organization's providers are convenient to, and do not discriminate against, members. The M+C organization must also ensure that, when medically necessary, services are available 24 hours a day, 7 days a week. The standards should consider the member's need and common waiting times for comparable services in the community. (Examples of reasonable standards for primary care services are: (1) Urgent but non-emergent - within 24 hours; (2) Non-urgent, but in need of attention - within one week; and (3) Routine and preventive care - within 30 days.)
- Establish, maintain, and monitor a panel of primary care providers from which the member may select a personal primary care provider. All M+C plan members may select and/or change their primary care provider within the plan without interference. The M+C organizations that require members to obtain a referral before receiving specialist services must ensure that their M+C plans have a mechanism for assigning primary care providers to members who do not select a primary care provider.
- Provide or arrange for necessary specialist care, and in particular give women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services. The M+C organization must arrange for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet a member's medical needs.

- Ensure that all services, both clinical and non-clinical, are provided in a culturally competent manner and are accessible to all members, including those with limited English proficiency or reading skills, and those with diverse cultural and ethnic backgrounds.

- Establish and maintain written standards, including coverage rules, practice guidelines, payment policies and utilization management that allow for individual medical necessity determinations.

- Provide coverage for ambulance services, emergency and urgently needed services, and post-stabilization care services in accordance with the requirements that are discussed below in §130.

- Ensure that for each M+C plan, the M+C organization has in effect procedures that:

    - Identify individuals with complex or serious medical conditions;

    - Assess those conditions, and use medical procedures to diagnose and monitor them on an ongoing basis; and

    - Establish and implement a treatment plan that:

        - Is appropriate;

        - Includes an adequate number of direct access visits to specialists;

        - Is time specific and updated periodically;

        - Ensure coordination among providers; and

        - Considers the beneficiary's input.

120.3 - Rules for All M+C Organizations to Ensure Continuity of Care

(Rev. 23, 06-06-03)

The M+C organization must ensure continuity of services through arrangements that include, but are not limited to the following:

- Implementing policies that specify under what circumstances services are coordinated and the methods for coordination. The policies should specify whether the services are coordinated by the enrollee's primary care provider or through some other means.

- Offering to provide each enrollee with an ongoing source of primary care and providing a primary care source to each enrollee who accepts the offer.

- Establishing coordination of plan services that integrate services through arrangements with community and social service programs generally available through contracting or non-contracting providers in the area served by the M+C plan, including nursing home and community-based services.

- Developing and implementing procedures to ensure that the M+C organization and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that:

    - The M+C organization makes a good faith effort to conduct an initial health assessment of all new members within 90 days of the effective date of enrollment;

    - Each provider, supplier, and practitioner furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the M+C organization, taking into account professional standards; and

    - There is appropriate and confidential exchange of information among provider network components.

- Utilizing procedures to ensure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health; and

- Employing systems to address barriers to enrollee compliance with prescribed treatments or regimens.

130 - Ambulance, Emergency and Urgently Needed, and Post-Stabilization Care Services

(Rev. 23, 06-06-03)

130.1 - Ambulance

(Rev. 23, 06-06-03)

The M+C organization is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, where other means of transportation would endanger the beneficiary's health. Medicare rules on coverage for ambulance services are set forth at 42 CFR 410.40.

130.2 Emergency and Urgently Needed Services

(Rev. 23, 06-06-03)

Definitions

An **emergency medical condition** is a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

- Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;
- Serious impairment to bodily functions; or
- Serious dysfunction of any bodily organ or part.

Emergency services are covered inpatient and outpatient services that are:

- Furnished by a provider qualified to furnish emergency services; and
- Needed to evaluate or stabilize an emergency medical condition.

Urgently needed services are covered services that are not emergency services as defined in this section, provided when an enrollee is temporarily absent from the M+C plan's service (or, if applicable, continuation) area when the services are medically necessary and immediately required:

- As a result of an unforeseen illness, injury, or condition; and
- It was not reasonable given the circumstances to obtain the services through the organization offering the M+C plan.

Note that under unusual and extraordinary circumstances, services may be considered urgently needed services when the enrollee is in the service or continuation area, but the organization's provider network is temporarily unavailable or inaccessible.

M+C organization responsibility. The M+C organization is financially responsible for emergency services and urgently needed services:

- Regardless of whether services are obtained within or outside the M+C organization;
- Regardless of whether there is prior authorization for the services. In addition:
    - No materials furnished to enrollees (including wallet card instructions) may contain instructions to seek prior authorization for emergency or

urgently needed services, and enrollees must be informed of their right to call 911;

- No materials furnished to providers, including contracts, may contain instructions to providers to seek prior authorization before the enrollee has been stabilized.

- In accordance with a prudent layperson's definition of "emergency medical condition" regardless of the final medical diagnosis; and

- Whenever a plan provider or other M+C organization representative instructs an enrollee to seek emergency services within or outside the plan.

Stabilization of an Emergency Medical Condition

The physician treating the enrollee must decide when the enrollee may be considered stabilized for transfer or discharge, and that decision is binding on the M+C organization.

Chapter 13 of this manual, "Appeals," addresses the enrollee's right to request a Quality Improvement Organization review for hospital discharges to a lower level of care. For transfers from one inpatient setting to another inpatient setting, an enrollee (or person authorized to act on his or her behalf) who disagrees with the decision and believes the enrollee cannot safely be transferred, can request that the organization pay for continued out-of-network services. If the M+C organization declines to pay for the services, appeal rights are available to the enrollee.

Limit on Charges for Emergency Services

Enrollees' charges for emergency services, i.e., outpatient and inpatient services until stabilized (as defined above), cannot exceed the lesser of :

- $50; or

- What the enrollee would be charged if he or she obtained the services through the M+C organization.

130.3 - Post-Stabilization Care Services

(Rev. 23, 06-06-03)

Post-stabilization care services means covered services that are:

- Related to an emergency medical condition;

- Provided after an enrollee is stabilized; and

- Provided either to **maintain** the stabilized condition, or under certain circumstances (see below), to **improve** or **resolve** the enrollee's condition.

M+C Organization Financial Responsibility

The M+C organization is financially responsible for post-stabilization care services obtained within, or outside, the M+C organization that :

- **Are pre-approved** by a plan provider or other M+C organization representative;
- **Are not pre-approved** by a plan provider or other M+C organization representative, but are administered to **maintain** the enrollee's stabilized condition **within one hour** of a request to the M+C organization for pre-approval of further post-stabilization care;
- **Are not pre-approved** by a plan provider or other M+C organization representative, but administered to **maintain, improve, or resolve** the enrollee's stabilized condition if:
    - The M+C organization does not respond to a request for pre-approval within one hour;
    - The M+C organization cannot be contacted; or
    - The M+C organization representative and the treating physician cannot reach an agreement concerning the enrollee's care, and a plan physician is not available for consultation. (In this situation, the M+C organization must give the treating physician the opportunity to consult with a plan physician. The treating physician may continue with care of the patient until a plan physician is reached or one of the criteria below is met.)

The M+C organization's financial responsibility for post-stabilization care services **it has not pre-approved ends** when:

- A plan physician with privileges at the treating hospital assumes responsibility for the enrollee's care;
- A plan physician assumes responsibility for the enrollee's care through transfer;
- An M+C organization representative and the treating physician reach an agreement concerning the enrollee's care; or
- The enrollee is discharged.

Limit on Charges for Post-Stabilization Care

Enrollees' charges for post-stabilization care services may not be greater than what the organization would charge the enrollee if he or she had obtained the services through the organization.

140 - Confidentiality and Accuracy of Enrollee Records

(Rev. 23, 06-06-03)

140.1 - General Rule

(Rev. 23, 06-06-03)

For any medical records or other health and enrollment information it maintains with respect to enrollees, an M+C organization must establish procedures to do the following:

- Abide by all Federal and state laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The M+C organization must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify:
    - For what purposes the information will be used within the organization; and
    - To whom and for what purposes it will disclose the information outside the organization.
- Ensure that medical information is released only in accordance with applicable Federal or state law, or pursuant to court orders or subpoenas;
- Maintain the records and information in an accurate and timely manner; and
- Ensure timely access by enrollees to the records and information that pertain to them.

150 - Private Fee-For-Service Plans

(Rev. 23, 06-06-03)

Enrollees in a Medicare+Choice Private-Fee-For-Service (PFFS) plan can obtain plan covered health care services from any entity that is authorized to provide services under Part A and Part B and who is willing to furnish services to a PFFS enrollee under the plan's terms and conditions of payment. To be eligible to furnish care to a PFFS enrollee:

- Physicians must be state licensed, and either have a Medicare billing number or be eligible to obtain one; and
- Institutional providers, such as hospitals and skilled nursing facilities, must be certified to treat Medicare beneficiaries.

The CMS will find that a PFFS plan meets Medicare access requirements if it establishes payment rates that are not less then the rates that apply under Original Medicare (see 42 CFR 422.114(a)(2)(i)). However, if a PFFS plan establishes provider payment rates

that are less then original Medicare payment rates then the plan must demonstrate to CMS that it has a contracted network of providers that meet Medicare access and availability standards (see 42 CFR 422.114(a)(2)(ii)).

In the event that the PFFS plan pays some categories of providers less than the original Medicare payment rate, then the PFFS plan must have direct contracts with those categories of providers in order to meet Medicare's access and availability standards. For example, a PFFS plan may choose to establish hospital payment rates that are less than original Medicare. However, in that circumstance to ensure member access to hospital services the PFFS plan must establish direct contracts with sufficient numbers of hospitals to meet Medicare's access and availability standards.

160 - Information on Advance Directives

(Rev. 23, 06-06-03)

160.1 - Definition

(Rev. 23, 06-06-03)

Advance directives are written instructions, such as living wills or durable powers of attorney for health care, recognized under state law and signed by a patient, that explain the patient's wishes concerning the provision of health care if the patient becomes incapacitated and is unable to make those wishes known.

160.2 - Basic Rule

(Rev. 23, 06-06-03)

The M+C organization must:

- Maintain written policies and procedures that meet the requirements for advance directives that are set forth in this section; and.

- Provide to its adult enrollees, at the time of initial enrollment, written information on their rights under the law of the state in which the M+C organization furnishes services to make decisions concerning their medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives.

The M+C organization is permitted to contract with other entities to furnish information concerning advance directive requirements. However, the organization remains legally responsible for ensuring that the requirements of this section are met.

The details of what written information must be given to the enrollee as well as other obligations of the M+C organization are outlined below in §160.4.

160.3 - State Law Primary

(Rev. 23, 06-06-03)

The M+C program's advance directive requirements, which fee-for-service providers have been following for some years, are guidelines which refer to state law, whether statutory or recognized by the courts of the state. Therefore, M+C organizations must comply with the advance directive requirements of the states in which they provide services. The CMS cannot give detailed guidelines as to what constitutes best efforts in each state. Medicare regulations give M+C organizations and states a great deal of flexibility, and CMS is prepared to work with the M+C organization (and the state, if needed) to ensure that advance directive requirements conform to Federal law.

Changes in state law must be reflected in the information M+C organizations provide their enrollees as soon as possible, but no later than 90 days after the effective date of the state law or the date of the court order.

160.4 - Content of Enrollee Information and Other M+C Obligations

(Rev. 23, 06-06-03)

The written information provided to enrollees must, at a minimum, include a description of the M+C organization's written policies on advance directives including an explanation of the following:

- That the organization cannot refuse care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;
- The right to file a complaint about an organization's noncompliance with advance directive requirements, and where to file the complaint;
- That the plan must document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive;
- That the M+C organization is required to comply with state law (See §160.3 for details);
- That the M+C organization must educate its staff about its policies and procedures for advance directives; and
- That the M+C organization must provide for community education regarding advance directives.

If the M+C organization cannot implement an advance directive as a matter of conscience, it must issue a clear and precise written statement of this limitation. The statement must include information that:

- Explains the differences between institution-wide objections based on conscience and those that may be raised by individual physicians;
- Identifies the state legal authority permitting such objection; and
- Describes the range of medical conditions or procedures affected by the conscience objection.

160.5 - Incapacitated Enrollees

(Rev. 23, 06-06-03)

If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information due to an incapacitating condition, the M+C organization may give advance directive information to the enrollee's family or surrogate.

The M+C organization is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

160.6 - Community Education Requirements

(Rev. 23, 06-06-03)

The M+C organization must provide for community education regarding advance directives either directly or in concert with other providers or entities. Separate community education materials may be developed and used, at the discretion of the M+C organization, for separate parts of the community. Although the same written materials are not required for all settings, the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable state law concerning advance directives. An M+C organization must be able to document its community education efforts.

160.7 - M+C Organization Rights

(Rev. 23, 06-06-03)

The M+C organization is not required to provide care that conflicts with an advance directive.

The M+C is not required to implement an advance directive if, as a matter of conscience, the M+C organization cannot implement an advance directive and state law allows any health care provider or any agent of the provider to conscientiously object.

160.8 - Appeal and Anti-Discrimination Rights

(Rev. 23, 06-06-03)

An M+C organization may not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive.

Furthermore, the M+C organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State Survey and Certification agency.