Medicare Managed Care Manual
Chapter 4 - Benefits and Beneficiary Protections

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(Rev. 87, 06-08-07)

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1 - Introduction

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These guidelines reflect CMS's current interpretation of the provisions of the Medicare Advantage statute and regulations (Chapter 42 of the Code of Federal Regulations, Parts 422 and 423) pertaining to benefits and beneficiary protections. These guidelines were developed after careful evaluation by CMS of current technology, coverage rules, and industry practices with respect to plan design, in light of recent changes to the Medicare Advantage program enacted in the Medicare Modernization Act, in particular the addition of several new health plan options. The guidance set forth in this document may be subject to change as technology and industry practices in plan design and administration continue to evolve, and as CMS gains more experience administering the Medicare Advantage program and its new health plan options.

The contents of this chapter are governed by regulations set forth in 42 CFR 422, Subpart C. Although MA plans in certain circumstances, may, and in other circumstances, are required, to offer Part D benefits, the discussion in this chapter is generally limited to the benefits offered under Medicare Part C of the Social Security Act. Guidance on cost plans may be found in Subpart F of Chapter 17 of this manual. *Guidance on Part D plans may be found in the Prescription Drug Benefit manual located at http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage. Further important information on Part D benefits may also be found in the following sections of this chapter: Section 20.26, "Part D Vaccines", the subsection of section 10.3*

entitled "Part D Rules for MA Plans", section 20.25, "OTC (Over-the-Counter) Benefits", and section 20.21 "Diabetic Supplies."

10 - General Requirements

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

10.1 - Basic Rule

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

An MA organization offering an MA plan must provide enrollees in that plan with all original Medicare-covered services (that is, Part A and Part B services), except hospice, by furnishing the benefit directly or through arrangements, or by paying on behalf of enrollees for the benefit. In addition, to the extent applicable, the organization will also furnish, arrange, or pay for supplemental benefits. CMS reviews and approves an MA organization's coverage of benefits by ensuring compliance with requirements described in this manual, including this chapter, *Chapter 7, "Bids, Premiums and Related information," Chapter 8, "Bidding Methodology for Medicare Advantage Organizations,"* and other CMS instructions, such as the guidance contained in the Call Letter.

10.2 - Services of Non-contracting Providers and Suppliers

(Rev. 23, 06-06-03)

An MA 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 MA organization to provide services covered by the MA plan:

- Ambulance services dispatched through 911 or its local equivalent where other means of transportation would endanger the beneficiary's health, as provided in §140 of this chapter;

- Emergency and urgently needed services under the circumstances described in §140 of this chapter;

- Maintenance and post-stabilization care services under the circumstances described in §140 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 MA plan cannot require prior authorization or notification. However, an enrollee may voluntarily advise the MA plan if they will temporarily be out of the plan's service area. The MA plan may provide medical advice and recommend that the enrollee use a qualified dialysis provider. The MA plan must clearly inform the beneficiary that the plan will pay for care from any qualified dialysis provider the beneficiary may independently select; and

- Services for which coverage has been denied by the MA 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 MA organization.

Payments to Non-contracting Providers and Suppliers

An MA plan (and an MA MSA plan, after the annual deductible has been met) offered by an MA organization generally satisfies its requirements of providing basic benefits with respect to benefits for services furnished by a non-contracting provider if that MA 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. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

An MA plan includes, at a minimum, basic benefits and may also include mandatory supplemental benefits and optional supplemental benefits as described in 42 CFR 422.102.

- **Basic benefits** are all Medicare-covered services, except hospice services.

- **Mandatory supplemental benefits** *are MA non-drug plan benefits, not covered by original Medicare, but are covered by the MA plan, for every person that has enrolled in the MA plan.* Mandatory supplemental benefits are paid for either in full, directly by, or on behalf of, MA enrollees by premiums and cost sharing, or through application of rebate dollars. An MA MSA plan may not provide mandatory supplemental benefits.

- **Optional supplemental benefits** are similar to mandatory supplemental benefits in that they are non-drug benefits that are not covered by original Medicare. However, plan enrollees may choose whether to elect and pay for optional supplemental benefits. MA organizations may offer individual items or groups of items and services as optional supplemental benefits. Rebate dollars may not be applied toward optional supplemental benefits.

  MA MSA plans are permitted to offer optional supplemental benefits, except that they may not offer optional supplemental benefits that cover expenses that count towards the annual MSA deductible.

General Guidelines for Benefits

MA Plans have a great deal of flexibility in the benefits they may offer. However, all benefits that are part of the MA plan must satisfy the following guidelines:

- All benefits must be directly health-related, that is, health care services or items whose primary purpose is to prevent, cure or diminish, actual or future, illness or injury for which the MA plan incurs a bid-priced cost that is not solely administrative. *For a complete definition of benefit see section 10.10 of this chapter;*

- All benefits must be offered uniformly to all enrollees;

- All benefits must be priced in the bid, and

- *All benefits must be specified in the appropriate marketing vehicles as indicated in the Medicare Marketing Guidelines located at url http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf*

Complementary Benefits (42 CFR 422.106(a)(2))

Plans may offer their enrollees, through associations, employers or through a State Medicaid agency the right to purchase complementary benefits – that is, benefits that are in addition to the benefits that are part of the MA plan. These complementary benefits are not regulated by CMS. Therefore the MA plan must comply with all state regulations governing such benefits. See §70.1 of this chapter for further guidance on complementary benefits.

Part D Rules for MA Plans

Section 42 CFR 423.104 (f)(3) provides that an MA organization can offer an MA coordinated care plan in a service area – either local coordinated care or regional PPO – only if that plan, or another MA plan offered by the same organization in the same service area, includes required prescription drug coverage under Part D. This rule applies only to coordinated care plans. By law, all regional plans are PPOs and therefore are also by definition coordinated care plans. See 42 CFR 423.104(f)(4) and 42 CFR 417.440(b)(2) for rules related to cost plans offering Part D.

All Special Needs Plans, which are a type of MA coordinated care plan, are required to provide Part D prescription drug coverage. See the definition of Special Needs Plan in CFR 422.2. This is an important beneficiary protection because special needs individuals must have access to prescription drugs to manage and control their special health care needs.

The MMA specifies that MSA plans may not offer Part D coverage. The MMA also specifies that PFFS plans and cost plans have the option of offering Part D coverage. If a beneficiary enrolls in an MSA plan, a PFFS plan, or a cost plan that either does not offer Part D coverage (or, in the case of a cost plan, if the member also does not select the Part D offering of a cost plan), s/he may also enroll in a Prescription Drug Plan (PDP). Otherwise, if the beneficiary enrolls in an MA coordinated care plan, and even if that MA

coordinated care plan does not offer Part D coverage, s/he cannot enroll in a PDP. Note that since cost plans must offer Part D coverage only as an optional supplemental benefit, this means that for a cost plan enrollee in a plan that offers Part D, as long as the cost member does not elect Part D from the cost plan, s/he may also enroll in a PDP at the same time s/he is enrolled in the cost plan.

*(**NOTE:** A beneficiary enrolled in both original Medicare and a stand-alone Prescription Drug Plan (PDP), who takes advantage of the limited open enrollment periods created by the Tax Relief and Health Care Act of 2006, TRHCA, in order to join an MA-PD plan, must be disenrolled from the PDP since a person cannot be simultaneously enrolled in both a PDP and MA-PD. For further information about enrollment see Chapter 2 of this manual, "Enrollment and Disenrollment.", located at http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/Chapter_2_+exhibits_Sept_8_2006_update_.pdf).*

The guidance of this section applies to the provision of Part D, prescription drug benefits. For guidance governing OTC (Over-the-Counter) drug benefits, see section 20.25 of this chapter.

Plan Type	Regional or Local MA Plan?	Must offer Part D?	Can an enrollee elect a PDP?
MA Coordinated Care Plan (CCP)			
HMO	Local	Yes. 423.104(f)(3) Rule[1]	No
HMO-POS	Local	Yes. 423.104(f)(3) Rule[1]	No
PPO	Either	Yes. 423.104(f)(3) Rule[1]	No
Special Needs Plan (SNP)	Either	Yes, required	No
Provider-sponsored organization (PSO)	Local	Yes. 423.104(f)(3) Rule[1]	No
Part B-only CCP	Local	Yes[2]	No
MA Private Fee-for-Service (PFFS) Plan			
PFFS plan with Part D	Local	Option = yes	No
PFFS plan without Part D	Local	Option = no	Yes
MA Medical Savings Account (MSA) Plan	Local	Not allowed	Yes
Sec. 1876 Cost Plans			
Cost plan offering Part D qualified prescription drug coverage	NA	No. Can only be offered as optional supp. Benefit	Yes
Cost plan not offering qualified Part D coverage but offering some outpatient drug coverage[3]	NA	Can only be offered as optional supp. Benefit	Yes
Cost plan not offering any outpatient prescription drug coverage	NA	NA	Yes
Sec. 1833 HCPP	NA	*No*	Yes
Demonstration Plans			
Social HMO plans (SHMOs)	NA	Yes	No
MN Disability Health Options	NA	Yes	No
MN Senior Health Options	NA	Yes	No
MA Senior Care Organizations	NA	Yes	No
WI Partnership Program	NA	Yes	No
PACE Programs	NA	Yes[4]	No

Notes to table:

1. **423.104(f)(3) Rule.** An MA organization can offer an MA coordinated care plan (CCP) in a service area only if that plan, or another MA plan offered by the same organization in the same service area, includes required prescription drug coverage under Part D. This rule applies to regional plans because they are CCPs and must be offered as PPOs.

- "Required" prescription drug coverage means coverage of Part D drugs under an MA-PD plan that consists of either: (1) Basic prescription drug coverage; or (2) Enhanced alternative coverage, provided there is no MA monthly

supplemental beneficiary premium due to the application of a credit against the premium of a rebate.

- *Special guidance for MA Organizations offering a SNP: Every SNP offered by an MA Organization must offer part D.*

  Every MA Organization must offer at least one MA-PD plan that is accessible to all potential enrollees in the service area. An MAO cannot satisfy this requirement, of offering at least one MA-PD plan in a service area, by offering an MA-PD exclusive SNP plan.

2. *Part B-only* CCPs. To accommodate "grandfathered" Part B-only enrollees in CCPs, we will require MA organizations with such members to offer at least one MA-PD plan in which Part B-only members can enroll.

3. This option is unique to the Section 1876 cost plan program. This option of offering other than qualified Part D coverage is not available to MA plans.

4. PACE Providers offering PACE Programs, as defined in §1894 of the Act, will no longer receive payment for prescription drugs from Medicaid on behalf of dual eligible enrollees. As a result, we anticipate that these programs will elect to provide Part D coverage in order to receive payment for the prescription drug coverage that they are statutorily required to provide.

Guidance Regarding MA Special Needs plans (SNPs)

A SNP can be offered as any type of coordinated care plan. The primary difference between SNPs and other CCPs is that SNPs may restrict enrollment to a specific population of special needs individuals. For further guidance on SNPs please visit http://www.cms.hhs.gov/DualEligible/04_IntegratedMedicareandMedicaidModels.asp#TopOfPage

10.4 - General Requirements for all MA Plans

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Although there are many types of plan structures, the following items are uniformly required of all plans:

- An MA organization offering an MA plan must offer it to all Medicare beneficiaries with Parts A and B of Medicare residing in the service area of the MA plan;

- An MA organization offering an MA plan must offer it 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. (See Chapter 1

of this manual, “General Provisions,” for the definition of segment.) (Individuals with ESRD are generally excluded from enrollment. See 42 CFR 422.50(a)(2));

- Although an MA Organization plan may “tier” its cost sharing to beneficiaries for the same service based on provider, (with the exception of post-stabilization services for which the co-payment must be the same or lower for non-plan providers as for plan providers), nevertheless, all beneficiaries must be charged the same amount for the same service with the same provider. All beneficiaries must have reasonable access to network providers at the lowest tier of cost sharing;

- The uniform premium requirement prohibits plans from offering nominal discounts to those enrollees electing to pay premiums electronically. All plans must offer the option to enrollees of having their premiums deducted electronically from their Social Security payment; a plan may also offer the option of electronically paying for premiums from sources other than their Social Security payment, but may not charge or discount for this option. Furthermore, plans may not require electronic payment of premiums;

- An MA enrollee should never pay more than the plan required cost sharing - coinsurance, deductibles and copays:

    - This cap on beneficiary liability *applies* if a provider or delegated provider declares insolvency;

    - This cap on beneficiary liability applies even if a non-contracted provider *who* provided services to the enrollee, for emergency, ambulance, urgent care or dialysis, is entitled to balanced billing; and

    - This cap on beneficiary liability prohibits a plan from requiring a beneficiary to first pay a contracted provider, except for co-payments, and then receive reimbursement from the MA organization.

- *Enrollee indemnification. In the following two situations, an enrollee, who has correctly identified him/herself as a plan enrollee has no liability beyond plan cost-sharing:*

    Situation 1:

    - *The enrollees receives a plan-covered service or item from a plan provider which requires referral or preauthorization, but*

    - *The enrollee has not been advised of his/her obligation to obtain the referral or preauthorization.*

The plan must cover such services; the plan cannot retroactively overturn a plan physician's decision that a service is medically reasonable and necessary after the service is provided.

The plan may indemnify the enrollee by directly paying for the service or through contractual arrangements that obligate the contracted provider to hold the enrollee harmless from payments above the plan required cost-sharing.

Situation 2:

- *A plan provider refers the enrollee to a plan specialist for a plan-covered service, but*

- *The plan provider does not follow the required referral requirements such as completion of a properly filled out referral form.*

The lack of a proper referral form is a technicality and is a contractual issue between the provider and the plan. The plan must treat this enrollee's health care as if a proper referral had been made. The enrollee is only liable for plan cost-sharing.

- Provider Enrollee Relationships**:** Providers are frequently called upon to give advice and referrals. It is of the utmost importance that a provider who refers a patient to a provider for a non-covered service ensures that the enrollee is aware of his or her obligation to pay in full for such non-covered services;

- Non-contracting Assistant: The plan-covered services provided to an enrollee, who properly sought such services, from a contracted provider of the plan, are considered plan-provided services even if that contracted provider employs assistants who are not contracted in the delivery of such services.

10.5 - Terms of MA Plans
(Rev. 23, 06-06-03)

Terms of MA plans described in instructions to beneficiaries, as described in §120 of this chapter, must include basic and supplemental benefits and terms of coverage for those benefits.

10.6 - Annual Caps on Additional and Supplemental Benefits
(Rev. 36, 10-31-03)

An MA organization may offer more than one MA 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 MA program. Financial caps for a benefit can only be imposed at the MA plan level.

For example, if an MA organization offers two plans in the same service area, then an enrollee, who has exhausted the benefit of one plan, is entitled to the full benefit of the other plan, should the enrollee enroll in it.

10.7 - 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.

10.8 - *This section left intentionally blank – will be used in future revisions*
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

10.9 - Original Medicare Covered Benefits
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

As indicated in §30.1 of this chapter, MA organizations must provide coverage of, by furnishing, arranging for, or making payment *on behalf of an enrollee* for: 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 *– i.e., is a grandfathered "Part B only" enrollee*) 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. Specific health care services must fit into one of these benefit categories, and not be otherwise excluded *from* 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. Some benefit

categories are defined more broadly than others. 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 *interpretation* is presented in the Code of Federal Regulations and CMS guidance.

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 §30.1, at the discretion of local *Medicare Advantage Contractors, (MACs*). The guidance concerning the adoption of uniform local coverage *determinations* by MA local or regional plans is discussed in §30.1.

10.10 – Definition of Benefit

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

The basic definition: In order for an item or service to be identified as a benefit, the following three conditions must be met.

(1) Primarily health related: The item or service must be directly health related. That is the primary purpose of the item or service is to prevent, cure or diminish, an illness or injury that is actually present or expected to occur in the future. If the primary purpose of the item or service is comfort, cosmetic or daily maintenance then it may not be classified as a health benefit.

(2) Cost requirement: The MA plan must incur a non-zero direct medical cost in providing the benefit. If the MA plan only incurs an administrative cost, this cost requirement is not met. Note: The MA Organization must properly price all items in its submitted bid including administrative and medical cost components.

(3) Classification: The proposed benefit must be correctly classified as an original Medicare or supplemental benefit.

In reviewing if this requirement is met it is important to emphasize that under Part A the statute covers any item or service that is considered medically necessary, as requested by a qualified Medicare provider for provision of care, in an institutional setting. Part B coverage is determined by the category to which the item or service belongs.

Further requirements: An item or service that meets the above three conditions may be called a benefit. CMS accepts a plan's benefits by accepting its submitted bid and PBP. However, CMS does not automatically accept all benefit packages. Additional requirements governing acceptance of a benefit package are presented in sections 20.1 and 20.13 of this chapter.

Non-standard Benefits: In limited circumstances, an item or service that is normally classified as cosmetic, comfort or maintenance may, in a specific context, be classified as a benefit, provided the provision of the item or service is based on an underlying medical need, or reason, consistent with the normal pattern of delivery of care for this illness. For example, as stated in section 20.24 of this chapter, meals are not classified as a benefit. However, if a nutritional service is based on an underlying medical need, or reason, consistent with the normal pattern of delivery of care for this illness then the nutritional service may be classified as primarily health related. Here, the specific context is the underlying medical need or the normal pattern of delivery of care, which justifies the classification of the nutritional service as primarily health related instead of maintenance.

The final determination of the status of all benefit designs is made by CMS during the annual review of benefit packages. The burden of proof of being primarily health related lies with the plan who should submit adequate documentation to justify its conclusions.

20 - CMS Approval of Proposed Plan MA Benefits

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

20.1 - General Guidelines on Benefit Approval

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

CMS reviews and approves MA benefits using *statutes, regulations, final rules*, policy guidelines and requirements in this manual, and other CMS instructions to ensure that:

- MA organizations provide Medicare-covered services that meet CMS guidelines under original fee-for-service Medicare;

- An MA organization does not offer a cost sharing structure for plans that:

    - Discriminates against beneficiaries;

    - Promotes discrimination;

- Discourages enrollment;
- Encourages disenrollment;
- Steers specific subsets of Medicare beneficiaries to particular MA plans (with the exception of specialized MA plans for special needs individuals (SNPs));
- Inhibits access to services; or
- Designs cost sharing differentials in such a way as to unduly limit choice by the beneficiary. (For example, an MA Organization cannot charge higher copays for all providers in the western portion of the county while charging lower co-payments for providers in the eastern portion of the county); and

- Benefit designs meet other MA program requirements.

20.2 - Screening Mammography, Influenza Vaccine, and Pneumococcal Vaccine

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

Enrollees of an MA organization may directly access (through self-referral to any plan participating provider) screening mammography and influenza vaccine. The organization may not impose cost sharing for influenza vaccine and pneumococcal vaccine on their MA plan enrollees.

20.3 - *Original Medicare Covered Services with Benefit Periods*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Several original Medicare covered services, such as, inpatient medical, surgical and psychiatric hospitalization are only covered for the duration of the benefit period. An MA plan in fulfilling its requirement of providing all original Medicare services cannot impose further limitations.

20.4 - Value-Added Items and Services *(VAIS)*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Value-Added Items and Services (VAIS) are items and services provided to an organization's enrollees by an organization that do not meet the definition of "benefits" but do meet the definition provided immediately below. VAIS may not be funded by Medicare program dollars. However, VAIS may be of value to some beneficiaries. We do not wish to deny Medicare enrollees access to items and services commonly available to commercial enrollees.

An item or service is classified as a VAIS if the cost, if any, incurred to the plan in providing the item or service, is solely administrative. A cost is not automatically classified as administrative simply because it is either minimal or non-medical. The cost, if any, must be intrinsically administrative: The cost must cover only such items as clerical or equipment and supplies related to communication (such as phone and postage), or database administration (such as verifying enrollment or tracking usage).

Examples:

(1) A plan offers a vision exam (for which it incurs a direct medical cost). The center providing the vision exam offers the plan a 10% discount on glasses. The plan does not incur a direct medical cost as a result of this discount. The plan may incur administrative costs related to negotiating the discount, notifying members and verifying eligibility.

Since the plan does not incur a direct medical cost in providing the discount on glasses the discount may not be classified as a benefit. The plan may offer the discount on glasses as a VAIS. Since the glasses is not a benefit it may not be advertised on the Medicare Options Compare Web site and the Medicare & You Handbook Other restrictions on advertising apply.

(2) A plan wishes to offer free groceries with vouchers to its enrollees. Such grocery vouchers could not be offered as VAIS if the plan pays costs for the vouchers provided. The cost is not "solely administrative" since it is paying for vouchers even if the cost is minimal.

A VAIS is not a benefit since no direct medical cost is incurred to the plan in providing the VAIS. Therefore a VAIS:

- *May not be priced in the bid;*
- *Is not reviewed during the annual review of plan benefit design; and*
- *May not appear in the PBP, SB ANOC or the EOC. (MA Organizations wishing to advertise VAIS must follow specific marketing guidelines. For details, see section 110.1.2 of the Medicare Marketing Guidelines at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf*

However:

- *CMS does review VAIS during site visits;*
- *CMS may initiate a special monitoring visit if it becomes aware of problems or complaints.*

Organizations offering VAIS must:

- *Offer it for the entire contract year*
- *Offer it uniformly to all plan members*
- *Maintain the privacy and confidentiality of enrollee records in accordance with all applicable statues and regulations*
- *Comply with all applicable HIPAA laws. For information on HIPAA visit url http://www.hhs.gov/ocr/hipaa/. In particular a Medicare Advantage Organization or sponsor may not directly contact Medicare beneficiaries if a VAIS item or service is not directly health related. This prohibition of contact includes the prohibition of distributing names, addresses, or information about the individual enrollees for commercial purposes. If the organization or sponsor uses a third party to administer VAIS that is not directly health related, the organization or sponsor is ultimately responsible for adhering to and complying with these confidentiality requirements.*

Comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries.

20.5 - *This section left intentionally blank – will be used in future revisions*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

20.6 - Waiting Periods and Exclusions That Are Not Present in Original Medicare

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

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. However, an MA 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 MA 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, *or in applicable local coverage decisions (See section 30.1 for guidance on selection of local coverage decisions).*

20.7 - *This section left intentionally blank – will be used in future revisions*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

20.8 - *Therapy Caps and Exceptions*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Effective, January 1, 2006, the therapy cost-sharing caps for most original-Medicare rehabilitation services, were reinstated. However, certain services are exempted from these caps. Complete details may be found in section 10.2 of chapter 5 of publication 100-04, the Medicare Claims Processing Manual, which can be found on the internet-only-manual page at http://www.cms.hhs.gov/Manuals/IOM/list.asp#TopOfPage.

20.9 - Drugs That Are Covered Under *Part B* Original Medicare

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

(For this subsection, the term "drug" means "drug or biological.") *The drugs that are covered under Medicare Part B are governed by the original Medicare regulations and local coverage decisions. The examples provided in this section are illustrative and not a comprehensive list.*

The following drugs are covered under Part B original Medicare:

- Injectable drugs that have been determined by *MACs* to be "not usually 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 MA enrollee takes through durable medical equipment (such as nebulizers) that were authorized by the enrollee's MA 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 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 MA enrollee wishes to receive a "not usually self-administered" drug in a physician's office, then the MA organization must cover the drug and the service of administering the drug. That is, MA 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. (MA 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.)

Injectable drugs that the applicable MAC has determined are not usually self-administered, but that members purchase at a pharmacy and administer at home may only be offered by MA Organizations as a Part D benefit, but cannot be a supplemental benefit. However, MA enrollees always have the option of receiving the Medicare-covered benefit, i.e., administration of the covered drug in a physician's office *from the physician's stock of drugs.*

20.10 - Mid-Year Benefit Enhancements (MYBE)

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

An MA Plan, other than a PACE plan, offered by an MA Organization, is allowed only one MYBE per plan under the following conditions:

- The MYBE can be effective only on September 1 of the contract year and will be in effect for the rest of the contract year;
- A MYBE can only be submitted between June 1 and June 30 of the contract year; and
- For plans with bids below the benchmark, 25% of the MYBE will be retained by the government.

The new MYBE may only take the form of:

- An enhancement without additional cost sharing for an existing supplemental mandatory non-drug benefit; or
- Offering a new mandatory supplemental non drug benefit without additional premium.

The MYBE may be introduced by plans for:

- Groups; or
- Individual markets.

(FR Volume 70, Number 18, Page 4640) PACE plans are allowed to offer multiple MYBEs, at any time during the contract year, except January, related to non-Part-D-drug benefits.

For guidance on MYBEs for Employer Group Health Plans see Chapter 9 of this manual, "Employer/Union-Sponsored Group Plans.")

20.11 - Multi-Year Benefits

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Multi-year benefits 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 *The Medicare Marketing Guidelines located at url http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf*

20.12 - Return to Home Skilled Nursing Facility (SNF)

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

An MA plan must provide coverage of post-hospital extended care services to Medicare enrollees through a home skilled nursing facility – *for example, a nursing facility capable of providing care where the enrollee was cared for prior to his/her hospital stay* - if the enrollee elects to receive the coverage through the home skilled nursing facility (42 CFR 422.133).

This requirement of providing post-hospital extended care through a home skilled nursing facility also applies if the MA organization elects to furnish SNF care in the absence of a prior qualifying hospital stay.

20.13 - Guidance on Acceptable Cost-Sharing and Deductibles

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

As indicated above in §20.1, Medicare Advantage regulatory requirements specify that organizations may not design benefit packages that discourage enrollment or encourage disenrollment of severely ill or chronically ill beneficiaries. Consequently, CMS will not approve a bid if CMS determines that either the plan's cost sharing or deductible structure discriminates based on health status. CMS will closely scrutinize the cost-sharing and deductible structures of all plans.

Each year, the Office of the Actuary, at CMS, will determine the appropriate maximum for aggregate out-of-pocket expenses for original Medicare covered services, excluding monthly basic premium. This maximum will generally be announced in the Call Letter. This recommended maximum applies*, in the manner indicated below*, to Coordinated Care plans including regional MA plans. *Plans whose aggregate out-of-pocket expenses for original Medicare covered services are above this maximum will be reviewed as indicated below:*

CMS offers the following guidance for <u>cost sharing</u>:

- For Plans at or below the recommended *maximum* level: These plans will be granted latitude in establishing cost-sharing amounts for individual items or services;

- For Plans above the recommended *maximum* level: These plans will be granted less latitude in establishing cost-sharing amounts for individual items or services;

- Specific services to be closely scrutinized: Independent of the cost-sharing level of the plan, CMS will especially closely scrutinize cost sharing for the list of items and services below. Historically these services are expensive and have lent themselves to high cost sharing, *that is, above the recommended maximum.* These are services that are typically used by sicker Medicare beneficiaries and consequently, high cost sharing for these services has the potential to be discriminatory:

  - Dialysis;

  - Chemotherapy drugs;

  - Inpatient acute/psych and SNF stays;

  - *Home Health services; and*

  - DME and supplies.

  With acceptable justification, CMS may accept plans with member out-of-pocket caps above the published limit if the cost sharing is spread across widely used health care services. Generally, CMS considers monthly premiums and broad-based cost-sharing as more equitable and potentially less discriminatory than cost-sharing related to infrequently used services. High deductibles are supported for MA MSA plans. However, CMS will closely scrutinize high deductibles in other plan types;

- Coinsurance and Co-payments: CMS, *in its review of plan cost sharing* will monitor both co-payments and coinsurance percentages;

- Part B drugs covered under original Medicare: No dollar limits can be placed on the provision of drugs covered under original Medicare unless this limit is stated in statute or specified by a national or applicable local coverage determination. (See section 30.1 of this chapter for more detailed guidance on the obligation of plans to follow local coverage determinations);

- Emergency and Post-stabilization cost sharing limits: The cost-sharing for emergency department services is the lesser of: a) $50, *or* b) the in-network cost sharing for that service. The cost-sharing for post-stabilization services cannot exceed the in-network cost-sharing for that service; and

- Regional MA Plans: *Detailed guidance on deductibles for MA regional plans is presented in section 30.2 of this chapter. In addition to the one-deductible requirement described in section 30.2 and the recommended cap on cost sharing described above,* regional MA plans must also have a system for tracking and reporting the deductibles (if any) and catastrophic limit accruals as they occur for members during the course of the contract year. Regional MA plans must also provide for a total catastrophic limit on beneficiary expenditures for in-network and out-of-network benefits under original Medicare. *See section 30.2 of this chapter for more details.*

Original Medicare Cost-Sharing Caps: CMS has determined that an MA plan may not impose, for an in-network, original Medicare benefit, a cost-sharing requirement that exceeds 50% of the total MA plan financial liability for this benefit.

RPPO Cost Sharing: Special rules apply to Regional Preferred Provider Organizations (RPPO). A PPO, like any other Coordinated Care Plan, must maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of all enrollees in its entire service area. (42 CFR 422.112(a)(1)(i)). However, a RPPO, can meet the requirement for having a comprehensive network of preferred providers in all parts of its service area (42 CFR 422.112(a)(1)(ii)) by demonstrating to CMS's satisfaction that there is adequate access, for provision of all plan-covered services, in all parts of its service area, through written contracts or other arrangements.

Enrollee cost sharing for services from a non-contracted provider in a specific geographic location

- *May be higher than the in-network cost-sharing if there is a contracted provider network established in that area;*

- *Must be the same as the in-network cost-sharing if there is no contracted provider network in that area.*

  An RPPO has the right, during its contract year, to increase the number of providers or add to its contracted provider network in a location that initially had no contracted network. Since, upon the inclusion of additional contracted network providers, the RPPO would have the right to charge higher cost-sharing for out-of-network provision of services in the affected portion of the service area, the RPPO must disclose the augmentation of its contracted network to the enrollees in the affected parts of its service area, at least 30 days prior to charging out-of-network cost-sharing in cases where such enrollees obtain services from non-contracted providers. Furthermore, the RPPO must provide continuity of care as described in section 120.3 of this chapter, for the enrollees in the affected parts of its service area.

20.14 - Homemaker Services

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Homemaker services are not primarily medical in nature and therefore cannot be offered by an MA plan as a supplemental benefit. Homemaker services include such items as laundry, meal preparation, shopping, or other home care services furnished mainly to assist people in meeting personal, family, or domestic needs. *Similarly, assistance with daily living activities (ADLs) and other comfort services may not be offered as a supplemental benefit (also see section 10.10 of this chapter).*

20.15 - *This section left intentionally blank – will be used in later revisions*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

20.16 - Electronic Monitoring

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

Electronic monitoring of beneficiaries, besides the electronic monitoring covered by original Medicare, is considered a health benefit, and may be offered by plans as a supplemental benefit, provided that the sole purpose of the electronic monitoring device is communication on health related issues. (Consequently, purchase of cell phones for beneficiaries would not be considered a health benefit since their primary purpose is general communication.)

20.17 - Dentures

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

A plan may offer dentures as a supplemental benefit.

20.18 - Chiropractic Services

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

Section 1861(r) of the Social Security Act provides the definition of a physician for Medicare coverage purposes, which includes a chiropractor for treatment of manual manipulation of the spine to correct a subluxation. (As a standard Medicare Part B benefit, manual manipulation of the spine to correct a subluxation must be made available to enrollees in all Medicare Advantage plans.) The statute specifically references manual manipulation of the spine to correct a subluxation as a physician service. Thus Medicare Advantage organizations must use physicians, including Chiropractors to perform this service. They may not use non-physician physical therapists for manual manipulation of the spine to correct a subluxation. Medicare Advantage organizations may continue to use physical therapists to treat enrollees for conditions not requiring physician services as defined in §1861(r) of the Social Security Act.

20.19 - Cash

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

An MA Organization may not provide cash to an MA plan enrollee as an inducement for enrollment or for any other purpose. As indicated in section 10.4 of this chapter, except for cost-sharing, a plan may not require a beneficiary to pay a contracted provider and then get reimbursed.

20.20 - Beauty Parlor

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Hair care and salon benefits - *for example, pedicures* - may not be offered as a supplemental benefit because they are not primarily health related.

20.21 - *Diabetic Supplies*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Diabetic supplies associated with the injection of insulin -- specifically syringes and needles -- are now covered under Part D. MA Organizations offering these supplies as benefits may not offer them as either an original Medicare or supplemental benefit but, must offer them as a Part D benefit. An MA Organization cannot offer diabetic supplies as a Part C Over-the-Counter (OTC) benefit. (See section 20.25 of this chapter for further guidance on OTC benefits).

20.22 - Safety Items

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

Items such as shower safety bars may be offered as supplemental benefits since their exclusive goal is to prevent immediate injury.

20.23 - Transportation Benefits

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

There are situations when transportation may be a covered benefit. The following examples are illustrative:

Covered by original Medicare: *When original Medicare covers transportation the Medicare Advantage plan must also cover it, for example, ambulance transportation in a medical emergency. (Original Medicare covers ambulance transportation if a reasonable person would consider the enrollee to be in an emergency situation even if a later medical review found no emergency present).*

Not covered by original Medicare: *An MA plan may create supplemental benefits – either mandatory or optional - of transportation.*

A typical example is transportation for bariatric surgery. Bariatric surgery is typically not available in every county. Original Medicare does not cover transportation related to bariatric surgery. A Medicare Advantage plan can provide this transportation as a

supplemental benefit.

If the MA Organization covers transportation as a supplemental benefit it must be priced in the bid and advertised in appropriate plan disclosure statements.

Mandatory MA Coverage:

If a Medicare Advantage plan:

- *Offers transplant services; however,*
- *The Plan provides this transplant service at a distant location, (further than the normal community patterns of care).*

Then the MA plan must

- *Provide reasonable transportation for the member and a companion to the distant facility; and*
- *Provide reasonable accommodations for the member and a companion while present in the distant location for medical care.*

20.24 - Meals

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

All benefits must be health care services (42 CFR 422.2). While nutritional counseling is a desired aspect of case and/or disease management, the provision of "meals", "meal vouchers" or grocery vouchers to individuals, without an underlying health care need, cannot be classified as a health care benefit, because it is not primarily health-care related in nature (See §10.10 of this chapter).

Therefore, to be classified as a benefit under the MA program the nutritional service must be based on an underlying medical need, or reason - *consistent with the normal pattern of delivery of care for this illness,* - that requires either home delivery of meals, a special diet, or special diet foods. *For example, meals, immediately post-hospitalization for a specific limited number of days, to continue the required caloric or dietary needs of the patient, may be offered as a supplemental benefit.*

Social factors by themselves, such as limited income, or an inability to pick up meals cannot justify a classification of a nutritional service as an MA benefit.

Finally, note that all MA coordinated care plans are required to "coordinate MA benefits with community and social services generally available in the area served by the MA plan" (422.112(b)(3)). However, such community services are not benefits of the MA plan.

20.25 – OTC (Over-the-Counter) Benefits

(Rev. 87; Issued: 06-08-07; Effecitve/Implementation: 06-08-07

The subsection entitled "Part D Rules for MA Plans," of Section 10.3 of this chapter, provides detailed guidance on which plan types are required, permitted or prohibited from providing a prescription drug benefit.

However, for purposes of benefits, Over-the-Counter (OTC) items are not classified as drugs. Examples of OTC items include:

- *OTC non-prescription drugs (such as Prilosec and Claritin); and*
- *Health-related items (such as bandages).*

An MA organization that provides an OTC item as a benefit may:

- *Offer the OTC item as a Part C supplemental benefit (mandatory or optional), or,*
- *Offer the OTC item under Utilization Management in a Part D plan provided such an offering is consistent with the principles of UM as outlined in section 60.1 of Chapter 7 of the Part D manual located at http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage*

An MA organization may use a combined approach, offering some OTC items under Part C and others as UM under Part D.

An OTC item offered under Part C as a supplemental benefit must be classified in the bid as a direct medical cost. By contrast, an OTC item offered under UM Part D, must be classified in the bid as an administrative cost.

Example: Suppose the MA Organization wishes to offer bandages, Prilosec and Claritin as benefits. Note, that the guidance provided at section 60.1, Chapter 7 of the Part D manual does not allow bandages to be classified as Utilization Management. The MAO could:

- *Offer the bandages as a Part C supplemental benefit and offer the Prilosec and Claritin as UM Part D;*
- *Offer the bandages and Claritin as Part C supplemental benefits but offer the Prilosec as UM Part D;*
- *Offer the bandages and Prilosec as Part C supplemental benefits and the Claritin as UM Part D; or*
- *Offer all 3 items as Part C supplemental benefits.*

20.26 – Part D Vaccines
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Section 202(b) of the Tax Relief and Health Care Act of 2006 (TRHCA) established that, effective January 1, 2008, the administration of a vaccine covered under Medicare Part D is included in the definition of a "covered Part D drug" under the Part D statute, and thus covered under Part D.

For 2007 only, section 202(a) of TRHCA established a transition policy, which provides for Part B coverage of the administration of a vaccine covered under Part D.

In 2007:

- *For Medicare beneficiaries who are enrolled in a MA-PD plan, the plan is responsible for covering both the cost of the Part D vaccine and its administration (professional charge component);*

For Medicare beneficiaries who are enrolled in a MA-only plan and a "free standing" Part D PDP (for example, PFFS plan enrollees), the PDP is responsible for covering the cost of the Part D vaccine and the MA-only plan is responsible for covering the cost of its administration.

30 - Requirements Relating to Benefits
(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

30.1 - Basic Benefits
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Except for *enrollment* that *takes effect or ends* during a hospital stay, and with respect to hospice care, each MA organization must meet the following requirements relating to basic benefits:

- Provide coverage of, by furnishing, arranging for, or making payments, *on behalf of the enrollee*, 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. For coordinated care plans, 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 MACs with jurisdiction for claims in the geographic area in which services are covered under the MA plan, *as described below*.

When there are multiple MACs in an MA plan's service area with conflicting policies, the following alternatives and requirements apply:

Alternative 1: Both local MA plans and Regional MA plans may cover in *each county* according to what *the MACs* covers *to Fee For Service eligibles* in that county;

Alternative 2: Both local MA plans and Regional MA plans may adopt *a uniform coverage policy. The rules and requirements for adopting a uniform coverage policy differ for local and regional plans.*

- *For Regional Plans: A regional plan, if it wishes to adopt a uniform coverage policy, must select a single MAC group in the service area of the plan whose local coverage determinations or policies will apply to all members of the regional plan. Regional plans may not select local coverage policies from more than one MAC;*

- *For local plans: Local plans*

  - *must select the uniform coverage policy that is most beneficial to its enrollees;*

  - *must notify CMS 60 days before the date bids are due, if they elect to adopt a uniform local coverage policy for any plan or plans in the subsequent year (42 CFR 422.101(b)(3)(i)); and*

  - *Adopt a uniform coverage policy subject to CMS pre-approval.*

    CMS will consider a local plan to have met the "most beneficial" requirement if the MA organization offering the local plan elects to

    - *adopt the coverage policies of one FFS carrier in its service area whose local coverage policies and determinations will uniformly apply to all enrollees in the area, and CMS determines, that the carrier's policies, viewed in totality, are the most favorable to beneficiaries; or*

- *adopt any individual carrier coverage policy or policies to uniformly apply to all enrollees in the service area, and CMS determines that each such individual policy is most favorable to beneficiaries.*

In either case, the MA organization must comply with the notification requirements as indicated above.

For both local and regional plans adopting a uniform coverage policy:

- *Post-Review: CMS reserves the right to review the determination of any uniform coverage policy*

- *Beneficiary notification: Plans must make information on the selected local coverage policy determinations readily available, including through the Internet, to enrollees and health care providers.*

- *Uniformity: If choosing the option to apply a uniform set of local coverage policies, or in the case of a local plan, to uniformly apply individual policies, MA organizations must apply the policy or policies in question in all parts of the MA plan service area;*

NOTE: *If a local or regional plan adopts a uniform coverage policy, that uniform coverage policy only applies to its service area. Services for an enrollee outside the service area are reimbursed by the local coverage determinations of that area.*

In coverage situations where there is no National Coverage Decision, Local Coverage Decision, or Guidance on coverage in original-Medicare manuals:

- *a Medicare Advantage organization may use the coverage policies of other Medicare Advantage organizations in its service area; but*

- *if the Medicare Advantage organization decides not to use coverage policies of other MAOs in its service area, then the MAO*

  - *must make its own coverage determination;*

  - *must provide a rationale using an objective-evidence based process based on authoritative evidence such as*

    - *studies from government agencies (e.g. the FDA);*

    - *evaluations performed by independent technology assessment groups (e.g. BCBSA);*

- *well designed controlled clinical studies that have appeared in peer review journals;*

- *In providing justification the MAO may not use conclusory statements with no accompanying rationale (e.g., "It is our policy to deny coverage for this service.")*

The requirement that an MA organization provide coverage for all Medicare-covered services is not intended to dictate care delivery approaches for a particular service. MA organizations may 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 MA organization complies with the provider anti-discrimination rules set forth in 42 CFR 422.205).

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

30.2 - Cost-sharing Rules for MA Regional Plans

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

In addition to the requirements listed in §30.1, MA regional plans must provide for the following:

(A) Single deductible: If an MA Regional PPO (RPPO) wishes, in one of its plan packages, to offer a deductible for original Medicare services, either in-network or out-of-network, then the RPPO may:

- *Offer a single combined deductible for all original Medicare services, whether in-network or out-of-network;*

- *Offer separate deductibles for specific original Medicare in-network services, provided the RPPO also offers a single combined deductible for all original Medicare services, both in- and out-of-network, towards which the separate deductibles for specific in-network original Medicare services, count; and*

- *Not offer separate deductibles for out-of-network original Medicare services.*

- *May waive the deductible for specific items or services - that is, the RPPO may chose to always cover specific items or services at plan cost-sharing levels whether or not the deductible has been met.*

If the RPPO wishes to apply a deductible to supplemental services then the RPPO may either

- *include supplemental services in the single combined deductible;*
- *establish separate deductibles for supplemental benefits in addition to the single deductible for original Medicare services; or*
- *have a deductible for supplemental services but have no deductibles for any original Medicare services.*

The following examples illustrate the policies described above.

EXAMPLES:

- *Example 1: An RPPO has a single combined deductible of $1,000. The plan limits the amount of the deductible that will apply to in-network IP hospital services to $500, and the amount that will apply to in-network physician services to $100. It also waives application of the deductible to all preventive services (including immunizations) – whether they are received in- or out-of-network – and to all home health services (in- and out-of-network).*

  The example complies with the RPPO deductible guidance because it:

  - *Uses a single combined deductible;*
  - *Differentiates the applicability of this single deductible for two in-network services (IP Hospital and physician services);*
  - *Does not differentiate the single deductible for out-of-network services; and*
  - *Waives preventive and home-health services.*

- *Example 2a: An RPPO may not have both a $500 deductible for out-of-network physician services and a $1,000 deductible for in- and out-of network inpatient hospital services.*

  This example fails because:

  - *The RPPO does not have the right to establish a separate out-of-network deductible; and also*
  - *The RPPO failed to establish a single-combined deductible.*

- *Example 2b: An RPPO may have a single combined deductible of $1,500 that it applies to the aggregate costs of all in-network and out-of-network original Medicare services. The RPPO plan may specify that only $500 of the total deductible amount will be for in-network inpatient hospital services.*

  This example complies with the guidance because the RPPO met its requirement of a single deductible and exercised its right to differentiate for specific in-network services.

  In this case, a beneficiary could meet the deductible by spending $500 on an in-network hospital and the remaining $1,000 on an out-of-network SNF. The beneficiary could also meet the single deductible by spending $1,500 on an out-of-network inpatient hospital stay.

- *Example 3a: A RPPO plan may not have a single deductible of $3,000 with a $1,000 cap on Part A services (in- and out-of network).*

  This example fails because the RPPO created a differentiation in the deductible that applies to out-of-network services, since the $1,000 cap on Part A services applies to all Part A services, both in- and out-of network.

- *Example 3b: An RPPO plan may have a single deductible of $3,000 with a $1,000 cap on specific in-network Part A services.*

  In this case the RPPO met its requirement of a single deductible and differentiated for specific in-network services without affecting out-of-network services.

  In this case an enrollee can meet the deductible by spending $3,000 out-of-network. The enrollee can also meet the deductible by spending $1,000 in-network on Part A services and $2,000 on out-of-network services, or, by spending $1,000 on in-network Part A services, $1500 on in-network Part B services and $500 on out-of-network services.

(B) In-Network catastrophic limit: MA regional plans are required to provide for a catastrophic limit on beneficiary out-of-pocket expenditures for original Medicare in-network benefits;

(C) Total catastrophic limit: MA regional plans are required to provide an additional catastrophic limit on beneficiary out-of-pocket expenditures for original Medicare in-network and out-of-network benefits This second out-of-pocket catastrophic limit, which would apply to both original Medicare in-network and out-of-network benefits may be higher than the in-network catastrophic limit, but may not increase that limit;

Example:

- *A plan may not have a $1,000 limit on in-network out of pocket expenditures and a $2,000 limit on out-of-network out of pocket expenditures; however*

- *A plan may have a $1,000 limit in in-network out-of-pocket expenditures and a combined in-network/out-of network limit of $3,000.*

In this example the enrollee may meet the limit by spending $1,000 in-network and $2,000 out-of-network or by spending $3,000 out-of-network.

(D) Tracking of deductible and catastrophic limits and notification: MA regional plans are required:

- To track the deductible (if any) and catastrophic limits of incurred out-of-pocket beneficiary costs for original Medicare-covered services; and

- To notify members and health care providers when the deductible (if any) or a limit has been reached; and

- (E) Out of Network Reimbursement: MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within the network of contracted providers.

30.3 - Supplemental Benefits - Mandatory Supplemental and Optional Supplemental

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Mandatory Supplemental Benefits

Subject to CMS approval, an MA organization may require Medicare enrollees of an MA plan, other than an MSA plan, to accept and pay for services in addition to original Medicare-covered services. If an MA organization elects to require mandatory supplemental benefits for Medicare enrollees electing a specific plan, it must impose the requirement for mandatory supplemental benefits uniformly on all Medicare beneficiaries electing that MA plan. An MA organization electing to require mandatory supplemental benefits for Medicare enrollees electing a specific plan must have CMS approve those mandatory benefits. CMS will not approve mandatory supplemental benefits if it determines that *requiring enrollees to receive these benefits* violates the anti-discrimination requirements *described* in section 20.1 of this chapter.

An MA plan may chose to apply rebate dollars either towards a reduction in cost sharing below the actuarial value specified in §1854(e)(4)(B) of the Act, or towards mandatory supplemental benefits. However, rebate dollars may not be applied to optional supplemental benefits.

Optional Supplemental Benefits

Each MA organization may offer (for election by the enrollee and without regard to health status) optional supplemental services or benefits - that is, health care services or benefits that are in addition to those included in the basic benefits and any mandatory supplemental benefits. *Every new and current enrollee must be offered, for a period of at least 30 consecutive days, starting with the enrollment effective date, the right to purchase any optional supplemental benefits offered by the plan.*

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 MA plan. The MA 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 MA 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 MA plan for 30 consecutive days.

Although MA 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 MA organization.

Chapter 2 of this manual, "Enrollment and Disenrollment," *located at http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/Chapter_2_+exhibits_Sept_8_2006_update_.pdf),* presents the requirements for an involuntary disenrollment of an enrollee from an MA 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 MA plan. *As indicated in section 10.3 of this chapter mandatory supplemental benefits may also be paid for through application of rebate dollars.*

Marketing of Supplemental Benefits

MA 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.

30.4 - *Classifying Basic and Supplemental Benefits*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

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

- Is this benefit covered by original Medicare?
- Are all enrollees required to purchase this benefit?

Supplemental benefits, whether mandatory or optional, are not covered by original Medicare. Mandatory supplemental benefits are non-drug plan benefits covered for every enrollee. However, each enrollee has the option to purchase, or not to purchase, optional supplemental benefits.

The MA organization 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).

40 - MA Medical Savings Account Plan Benefits
(Rev. 23, 06-06-03)

40.1 - General Rule
(Rev. 23, 06-06-03)

An MA organization offering an MA Medical Savings Account (MSA) plan must make available to an enrollee, or provide reimbursement for, at least the original Medicare benefits (as defined in section §30.1 of this chapter) after the enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

MA 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 422.318), once the enrollee's countable expenses reach the plan's annual deductible.

40.2 - The Annual Deductible
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

The maximum annual deductible for an MA MSA plan is determined as follows:

- For contract year 1999, the annual deductible for an MA MSA plan, could not exceed $6,000; and

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, rounded to the nearest multiple of $50; the maximum deductible amount is annually announced in the Announcement of MA Payment Rates.

40.3 - *Countable Expenses*
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

An MA organization offering an MA 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, *copays*, coinsurance, or *permitted balanced billing*.

- 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.

40.4 - *Services After the Deductible*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

For services received by the enrollee after the annual deductible is satisfied, an MA organization offering an MA 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*, copays,* coinsurance *or permitted balance billing.*

40.5 - *Balance Billing*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Medicare balance billing protections for beneficiaries also apply for MA MSA plans.

40.6 - Special Rules on Supplemental Benefits for MA Medical Savings Account Plans

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

The purpose of establishing the Medical Savings Accounts 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 or union retirement benefits or Medigap policies, which would cover expenses under the deductible, are precluded from enrolling in an MSA plan.

An MA organization offering an MA Medical Savings Account plan may not provide supplemental benefits that cover expenses that count towards the deductible specified in section §*40.2* of this chapter. The Act (as amended by the Balanced Budget Act of 1997) forbids the sale of most freestanding health insurance policies, which cover expenses under the deductible for beneficiaries enrolled in an MA Medical Savings Account. The exceptions to this prohibition are as follows:

Individuals may simultaneously possess both a Medical Savings Account, and any one, or any combination, of the following:

- 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 MA Medical Savings Account plan, **mandatory** supplemental benefits are prohibited, but **optional** supplemental benefits are permitted subject to certain restrictions.

Once the MA 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 *and the Visitor/Travel Program*

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

50 1- General Rule

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

A point of service (POS) option can be offered in a non-PPO MA coordinated care plan to provide enrollees in such plans with additional choice in obtaining specified health care services**.** A coordinated care plan may include a POS option as a mandatory or

optional supplemental benefit. Under a POS option, a non-PPO MA coordinated care plan permits enrollees to obtain specified items and services from non-network providers, with or without the plan's prior authorization rules, but may also require that enrollees *pay higher cost sharing for such services*. The MA organization might also establish a cap on the dollar amount of services that will be covered under the POS option. The MA organizations can limit the services that are available under a POS option. The MA organizations may also place other limits on the services available under the POS option. For example, an MA organization could offer a POS option as a travel benefit - allowing members to access specified services only when members are traveling outside of the plan's service area.

Since an MA Preferred Provider Organization, by definition, must allow members to obtain all covered services out-of-network without prior authorization, it follows that the term "POS option" would have misleading connotations when applied to either a local or regional PPO. However, a local or regional PPO may offer a POS-LIKE option. A POS-LIKE option refers to the right of an MA organization offering an MA PPO plan to charge lower cost-sharing for provision of covered benefits by out-of-network providers *when the enrollee complies with the special rules, if any, governing obtaining out-of-network benefits*. As with the POS option, the POS-LIKE option may apply only to certain services, may impose rules on usage including pre-authorization, and may impose a monetary cap on the value of services that will be available at the lower cost sharing. However, a PPO offering a POS-LIKE option must always provide reimbursement for all covered benefits, even if they are out of network without prior authorization. The examples immediately presented below clarify these guidelines:

> *Example 1*: An HMO plan that normally charges 20% coinsurance for in-network provider visits may elect to offer a POS option that charges 30% coinsurance for out-of-network provider visits.
>
> *Example 2*: A PPO plan that normally charges 20% coinsurance for out-of-network provider visits may elect to offer a POS-LIKE option that charges only 10% coinsurance for out-of-network provider visits if the member voluntarily complies with certain conditions. The PPO may place a monetary cap such as $5,000 on this POS-LIKE option. This would mean that the enrollee pays 10% for each out-of-network provider visit if s/he complies with the conditions and until the aggregate amount paid for out-of-network provider visits is $5,000. However, the enrollee retains the right, before or after the $5000 cap is exhausted, to receive plan services from out-of-network providers, without authorization, with the 20% coinsurance.

PFFS and PPO Out of area coverage: MA organizations offering a PFFS or PPO plan are required to provide reimbursement for covered services outside the plan's network; MA organizations must also provide reimbursement for covered services received from non-contracted providers outside the plan's service area.

For further information on referrals and pre-authorization see section §10.4 of this chapter.

50.2 - Accessing Plan Contracting Providers

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

HMOs 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 contract providers *without prior authorization or referral* must separately track and report in-network POS utilization. *Plan enrollees have the right to inquire from the plan how close they are to the monetary cap on POS services.* An MA plan that includes a POS benefit must continue to provide all benefits and ensure *adequate network* access as required by the requirements specified in this chapter and set forth at 42 CFR Part 422 Subpart C. Details on cost sharing requirements related to contracted providers are presented in §10.4.

50.3 - Financial Cap

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

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, a plan may offer a POS benefit with a $5,000 annual maximum on *aggregate costs*, and require 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 *aggregate* 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 *aggregate* 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. 72, Issued: 09-30-05, Effective Date:09-30-05)

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, MA organizations must maintain written rules on how to obtain health benefits through the POS benefit. The MA 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 MA organization that offers a POS benefit through an MA 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.

50.7 - The Visitor/Travel Program
(Rev. 36, 10-31-03)

An MA organization can offer extended "visitor" or "traveler" programs to members who have been out of the service area for up to 12 months, provided that the plan includes the full range of services available to other members. MA organizations offering these programs may limit their availability to certain areas and may impose restrictions on obtaining benefits, except for urgent, emergent, post-stabilization care, and renal dialysis. These organizations do not have to disenroll members in these extended programs who remain out of the service area for up to 12 months. However, those MA organizations without this program must continue to disenroll members once they have been out of the service area for more than 6 months.

60 - Service Area
(Rev. 23, 06-06-03)

60.1 - Definitions

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

A service area is a geographical area approved by CMS within which an MA eligible individual may enroll in a particular MA plan offered by an MA organization. A *local* MA plan's service area does not need to be contiguous. *A regional PPO's service area must be the entire MA region.*

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

The designation of an MA plan's service area affects the following five items:

- **Payment Rate:** The service area designation determines the benchmark applicable to the plan, and therefore, CMS' payment rate to the MA organization for the MA plan;

- **Required Benefits:** The designation affects which benefits will be provided under the MA 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 MA organizations -- *other than SNPs, which can limit enrollment based upon statutory and regulatory parameters* -- are obligated to enroll any MA eligible resident in the service area who elects the plan during an applicable enrollment period (provided an approved capacity limit has not yet been reached (see Chapter 2 of this manual, "Enrollment and Disenrollment" *located at http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/Chapter_2_+exhibits_Sept_8_2006_update_.pdf);*

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

- ***Urgently-needed Services*:** For coordinated care plans, the designation defines the boundaries beyond which the organization must cover *urgently-needed services.*

60.2 - Factors That Influence Service Area Approvals

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

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

- Whether each MA plan (except for Employer/*Union*-Only plans - see *Chapter 9 of this Manual,* "*Employer/Union-Sponsored Group Plans.*") will be made available to all MA 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, the contracting provider network meets CMS access and availability standards for the service area, as explained in §130 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 MA plans offered by the MA organization

For MA regional plans, the service area consists of the entire region.

60.3 - The "County Integrity Rule"

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

The principles presented in this subsection only apply to local MA plans.

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 MA 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. The CMS may also consider the extent to which the proposed service area mirrors the service area of existing commercial health care plans or MA plans offered by the organization.

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

- The MA 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 MA 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 MA organization demonstrates that it cannot establish economically viable contracts with sufficient providers to serve an entire county. The MA organization can demonstrate this by furnishing documentation describing why the MA 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 MA organization is proposing to exclude from its service area. Among those provider groups (in the proposed excluded county area) the MA 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 MA organization must be able to demonstrate the following:

- The anticipated enrollee health care cost of the portion of the county it proposes to serve is similar to the area of the county that will be excluded from the service area. For example, if the MA 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 MA 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; and

- 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 MA 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 MA 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 MA 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 MA organization to devise an MA 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/*Union* Group Health Plans and Medicaid

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

70.1 - General Rule

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

(42 CFR 422.106(a)(2)) An MA organization may contract with employers or State Medicaid Agencies to furnish benefits that **complement** those that an employee or retiree receives under an MA plan. Some examples of **complementary benefits** are the following:

- The employer, State Medicaid Agency or an association pays, or is financially responsible, for some, or all, of the MA plan's basic premiums, supplemental premiums, or cost sharing;

- The employer, State Medicaid Agency or an association provides other employer-sponsored (or State-sponsored) services that may require additional premium and cost sharing; and

- The employer, the State Medicaid Agency or an association purchases a non-Part D drug benefit from the MA Organization. As pointed out in §10.3 these complementary benefits are not within CMS jurisdiction.

70.2 - Requirements, Rights, and Beneficiary Protection

(Rev. 36, 10-31-03)

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

70.3 – Employer*/Union* Plans

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

For more details on employer/union coverage see Chapter 9 of this manual, "Employer/Union-Sponsored Group Plans."

80 - Medicare Secondary Payer (MSP) Procedures

(Rev. 23, 06-06-03)

80.1 - Basic Rule

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

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 the chapter of this manual entitled, "Premiums and Cost Sharing," for further discussion.) Special rules apply to the collection of cost sharing related to Part D benefits offered in an MA-PD plan. This §80, only discusses collections related to Part C benefits.

80.2 - Responsibilities of the MA Organization

(Rev. 23, 06-06-03)

The MA organization must, for each MA 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 (GHP) and Large Group Health Plans (LGHP)

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

Secondary payer 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 MA organization is the secondary payer in the following situations:

- The MA plan has an MA 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 MA plan has an MA 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 MA 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 MA organization is the secondary payer for an MA 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** is available.

Please note that Medicare does not coordinate with health insurance coverage, that is not currently owned, 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, MA organizations cannot withhold primary payment.

80.4 - Collecting From Other Entities
(Rev. 23, 06-06-03)

The MA 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. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

If an MA enrollee receives from an MA 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 MA organization may bill, or authorize a provider to bill any of the following:

- The insurance carrier, the employer/*union*, or any other entity that is liable for payment for the services under §1862(b) of the Act and §90 of this chapter; and

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

80.6 - Collecting From GHPs and LGHPs
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

When an MA organization is the secondary payer to an employer/*union* group health plan, the coordination of benefits occurs in the aggregate through the bid process. This process results in a co-payment as part of the MA 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 MA enrollee with employer/*union* group health plan coverage of his or her cost sharing obligation under the MA plan. As a result, the MA enrollee remains liable for payment of the MA plan's cost sharing regardless of whether Medicare is primary or secondary. However, under 42 CFR 422.504(g), which addresses beneficiary financial protection contained in the contract between the MA organization and CMS, the MA organization is responsible for relieving the beneficiary of responsibility for payment of health care costs other than the MA cost sharing, and

therefore, the MA organization must relieve the enrollee of his or her liability under the terms of the employer/*union* group health plan.

For example, if the employer/*union* group health plan (the primary payer) has a co-payment of $20 and the MA plan has a co-payment of $10 for the service the beneficiary received, the beneficiary cannot be liable to pay more than the MA's co-payment of $10. The MA organization must absolve the beneficiary of the liability for any amount in excess of the MA plan co-payment of $10.

80.7 - MSP Rules and State Laws

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

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 MA plans. A State cannot take away an MA organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. The MA organization may exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations as they apply to Medicare Advantage Plans.

(See the chapter of this manual entitled, "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. 72, Issued: 09-30-05, Effective Date:09-30-05)

The contents of this subsection are governed by regulations set forth at 42 CFR 422.109.

A **national coverage determination (NCD)** is a national policy determination made by CMS regarding the coverage status of a particular service under Medicare. An NCD does not include a determination of what code, if any, is assigned to a service or a determination about the payment amount for the service.

A **legislative change in benefits** is a coverage requirement adopted by the Congress and mandated by statute.

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

A. 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 422.308(a); or

B. The estimated cost of Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national average per capita costs.

90.2 - General Rules

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

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. All local medical review policies will be converted to local coverage determinations by the end of 2005.

MA organizations must provide all Medicare-covered benefits (see §30.1).

- When the significant – cost criterion is met

    - Prior to the adjustment of the annual MA capitation rate:

        If CMS determines and announces that an individual NCD service or legislative change in benefits **does** meet a criterion for significant cost described in §100.1 above, then the MA 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 significant cost of the service or benefit. However a plan must pay for the following:

            - Diagnostic services related to the NCD service or legislative change in benefits and most follow-up services related to the NCD service or legislative change (42 CFR 422.109(c)(2)(i),(ii)); and

- ❖ NCD services or legislative change in benefits which are already included in the plan's benefit package either as original Medicare benefits or supplemental benefits (or, prior to January 1, 2006, as additional benefits) (42 CFR 422.109(c)(2)(iii),(iv)).

Although the service or benefit may not be included in the services MA organizations must cover under their contract in exchange for monthly capitation payment, the MA organization must still provide coverage of the NCD service or legislative change in benefits by furnishing or arranging for the service.

The FFS contractors are responsible for reimbursements for NCD services or legislative changes that are not the legal obligation of the MA organization.

The chapter of this manual entitled, "Payments to MA Organizations," contains the detailed rules on payment for NCD services or legislative changes in benefits that meet the significant cost threshold. Included is a **description of services** for which MA organizations are responsible to pay for in the contract year prior to the adjustment of the annual MA capitation to account for the significant cost NCD service or legislative change in benefits. During this period, MA enrollees are responsible for any applicable coinsurance amounts under original Medicare.

- o After adjustment of the annual MA capitation rate is made:

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 MA organization's contract with CMS and is a covered benefit under the contract. Subject to all applicable rules under the MA program, the MA organization must furnish, arrange, or pay for the NCD service or legislative change in benefits. MA organizations may establish separate plan rules for these services and benefits, subject to CMS review and approval. CMS may, at its discretion, issue overriding instructions limiting or revising the MA plan rules, depending on the specific NCD or legislative change in benefits.

For these services or benefits, the Medicare enrollee is responsible for any MA plan cost sharing, as approved by CMS or unless otherwise instructed by CMS.

- When the significant-cost criterion is not met:

If CMS determines that an NCD or legislative change in benefits **does not** meet a criterion for significant cost described in §100.1 above, the MA

organization is required to provide coverage for the NCD or legislative change in benefits and assume risk for the costs of that service or benefit as of the effective date stated in the NCD or specified in the legislation.

90.3 - Sources for Obtaining Information

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

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 following Internet resources provide valuable information:

- MEDICARE COVERAGE HOMEPAGE

  The Medicare Coverage Homepage, located at *http://cms.hhs.gov/coverage* has links that:

  - Provide a listing of all **National Coverage Determinations; and**
  - Enable you to **Search the Database.**

  Both pending and closed coverage determinations are listed. For each coverage topic CMS provides a staff name and e-mail link so interested parties can use the Internet to send questions and to provide feedback.

- NCD MANUAL

  The **Medicare National Coverage Determinations Manual**, Pub. 100-03, is the primary record of Medicare national coverage policies, and includes a discussion of the circumstances under which items and services are covered. This manual may be accessed at *http://www.cms.hhs.gov/Manuals/IOM/list.asp*

- PROGRAM TRANSMITTALS

  Additional information on new coverage can be found in the **Program Transmittals** that transmit CMS' new policies and procedures. Links to the **Program Transmittals** may be found at http://cms.hhs.gov/transmittals/.

100 - Discrimination Against Beneficiaries Prohibited

(Rev. 23, 06-06-03)

100.1 - General Prohibition

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Except for not enrolling most individuals who have been medically determined to have end-stage renal disease, an MA organization may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an MA 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 individual who develops end-stage renal disease while enrolled in an MA plan, or in a health plan offered by the MA organization, is eligible to elect an MA plan. For additional guidance on eligibility and enrollment see Chapter 2 of this manual, "Enrollment *and Disenrollment*" *located at http://www.cms.hhs.gov/HealthPlansGenInfo/Downloads/Chapter_2_+exhibits_Sept_8_2006_update_.pdf).*

100.2 - Additional Requirements

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

An MA 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. *Similarly, the MA organization must comply with all Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse including, but not limited to, applicable provisions of the Federal criminal law, the False Claims Act (31 U.S.C. 3729 et seq.), the anti-kickback statute (section 1128B(b)) of the Act and HIPAA administrative simplification rules at 45 CFR parts 160, 162 and 164.*

100.3 - An MA Organization's Responsibility

(Rev. 23, 06-06-03)

An MA organization must ensure that their MA 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. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

This section, briefly addresses MA Organization disclosure requirements. A more comprehensive discussion of disclosure requirements and CMS's methods for ensuring compliance with the disclosure requirements *is* found *in the CMS Medicare Marketing Guidelines, which may be obtained at* *http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf*

Internet Requirements:

If the MA organization has a website, or provides MA plan information through the Internet, then it must also post copies of it's:

- Evidence of Coverage;
- Summary of Benefits; and
- The entire provider directory: that is, information on names, addresses, phone numbers, and specialty of all contracted providers on an Internet web site. Such posting does not relieve the MA organization of its responsibility to provide copies to enrollees at the time of enrollment and annually thereafter.

110.2 - Disclosure Requirements at Enrollment (and Annually Thereafter)
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

At the time of enrollment (and at least annually thereafter) an MA organization must provide each enrollee electing an MA plan it offers, the information listed below. The description must be presented in a clear, accurate, and standardized manner, including through the Internet, where applicable, as discussed in §110.1 above.

Service Area - The MA 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;

- For an MA-PD plan, the information at 42 CFR 423.128; and

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

Access - The number, mix, and addresses of providers from whom enrollees may reasonably be expected to obtain services; any out-of network coverage; any POS option, including the supplemental premium for that option; and how the MA organization meets the access to service requirements for access to services offered under the plan, which are discussed below in §120. A regional MA plan must also disclose the process MA regional plan enrollees should follow to secure in-network cost sharing when covered services are not readily available in the service area from contracted, network providers.

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 MA 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 (MA 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 MA 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 MA 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 MA 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 MA organization for processing and determination of enrollee liability, if any.

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

Quality Improvement program - A description of the Quality Improvement program that is required for all MA organizations *(except for MA PFFS and MSA plans – see 42 CFR 422.152 (a)).*

Catastrophic caps and single deductible - MA organizations offering MA regional plans are required to provide enrollees a description of the catastrophic stop-loss coverage and single deductible (if any) applicable under the plan.

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 MA plan, an MA organization must provide the following information:

- Benefits covered under original Medicare, as described below in §110.5;
- 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; and
- **Financial Information -** Information on the financial condition of the MA organization, including the most recently audited information regarding, at least, a description of the financial condition of the MA organization offering the plan.

110.4 - Information Pertaining to an MA Organization Changing *Its* Rules or Provider Network
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

If an MA organization intends to change its rules for one of its MA plans, it must do the following:

- Submit the changes for a CMS review by following the procedures and time frames specified in the *Marketing Guidelines located at url http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf* and codified in regulation at 42 CFR 422.80;

- For changes that take affect on January 1, the MA organization must notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period defined in §1851(e)(3)(B) of the act; and

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

An MA 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 Upon Request

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

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/ManagedCareMarketing/.* 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 CMS Web site at http://www.medicare.gov/, under Medicare Personal Plan Finder. The MA organizations are obligated to assist MA plan enrollees in obtaining the information provided by CMS.

- **Benefits under original Medicare -** Including covered services, beneficiary cost sharing (such as co-payments 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 -** A general description of procedural rights (including grievance and appeal procedures) under original Medicare and the MA program, and the right to be protected against discrimination based on the factors that are addressed in §110 of this chapter;

- **Potential for contract termination -** The fact that an MA 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 MA plan;

- **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 MA MSA plan, the amount of the annual MSA deposit;
- 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 MA monthly basic beneficiary premiums, the MA monthly supplemental beneficiary premium, and any reduction in Part B premiums;
- **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 MA requirements; and
    - Other performance indicators.
- **Supplemental benefits -** Whether the plan offers:
    - mandatory supplemental benefits including;
    - reductions in cost sharing offered as a mandatory supplemental benefit; or
    - optional supplemental benefits; and

- the terms, conditions and premiums for those benefits.

- **Network providers in other parts of the plan's service area** - The names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other parts of the plan's service area.

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. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

An MA organization may specify the providers through whom enrollees may obtain services if it ensures that all original Medicare covered services and supplemental benefits 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 MA 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 can be obtained from the geographic area.

    - Additionally, an MA regional plan, upon CMS preapproval, can use methods other than written agreements to establish that access requirements are met;

    - An MA regional plan, may seek upon application to CMS, and upon the following requirements being met and demonstrated to CMS:

        1) The plan needs to contract with a general acute hospital to meet access requirements;

2) The plan has first made a good faith effort to contract with this hospital;

3) There are no competing Medicare participating hospitals in the area to which MA regional plan enrollees could reasonably be referred for inpatient hospital services;

4) The plan designates this hospital for all in-network inpatient hospital services; and

5) All requirements in 42 CFR 422.112(c)(1)-(4) are satisfied--- then the plan may designate this hospital as an essential hospital with normal in-network cost sharing levels applying to all plan members;

- 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 MA organization's providers are convenient to, and do not discriminate against, members. The MA organization must also ensure that, when medically necessary, services are available 24 hours a day, 7 days a week. This includes requiring primary care physicians to have appropriate backup for absences. 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-emergency - 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 MA plan members may select and/or change their primary care provider within the plan without interference. The MA

organizations that require members to obtain a referral before receiving specialist services must ensure that their MA plans have a mechanism for assigning primary care providers to members who do not select a primary care provider. *Furthermore, the MA plan must:*

- 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 MA 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, limited reading skills, hearing incapacity, or those with diverse cultural and ethnic backgrounds. Examples of how an MA organization can meet these accessibility requirements include provision of translator services, interpreter services, teletypewriters or TTY connections;

- 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 MA plan, the MA organization has criteria for a chronic care improvement program that provides:

  - *Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program; and*

  - *Mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program (See Chapter 5 of his manual, "Quality Improvement and Reporting," for further guidance on chronic care improvement programs).*

120.3 - Rules for All MA Organizations to Ensure Continuity of Care

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

The MA 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 MA plan, including nursing home and community-based services;

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

    - The MA 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 and follows up on unsuccessful attempts to contact an enrollee;

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

    - There is appropriate, *timely*, and confidential exchange of *clinical* 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. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

The MA 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. For original Medicare coverage rules for Ambulance services see chapter 10 of the Medicare Benefit Policy Manual, *publication 100-02*, located at *http://www.cms.hhs.gov/Manuals/IOM/list.asp*.

130.2 - Emergency and Urgently Needed Services

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

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;*
- *are provided when an enrollee is temporarily absent from the MA plan's service (or, if applicable, continuation) area (Note: Urgent care received within the service area is an extension of primary care services); and*
- *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 MA plan's participating provider network*

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.

The following example is an illustration of urgently-needed services.

> *Example: A beneficiary has been under the care of a dermatologist for years for a chronic skin condition. However, while the member was out of the service area, the condition flared up and the beneficiary needed to see a local doctor.*

The required services are urgently-needed and therefore the plan is obligated to provide for them. Even though the enrollee was aware of the chronic skin condition the flare up was unforeseen. Although the flare up is not a medical emergency, it does require immediate medical attention and it was unreasonable for the enrollee to return to the service area. Therefore, the enrollee can seek medical care in a physician's office.

MA organization responsibility. The MA organization is financially responsible for emergency services and urgently-needed services:

- Regardless of whether services are obtained within or outside the MA 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 MA organization representative instructs an enrollee to seek emergency services within or outside the plan.

The MA organization is not responsible for the care provided for an unrelated non-emergency problem during treatment for an emergency situation. For example, the MA organization is not responsible for any costs, such as a biopsy, associated with treatment of skin lesions performed by the attending physician who is treating a fracture.

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 MA organization.

Chapter 13 of this manual, "Medicare Advantage Beneficiary Grievances, Organization Determinations, and 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 MA organization declines to pay for the services, appeal rights are available to the enrollee.

Limit on Charges for Emergency Services

Enrollees' charges for emergency department services, cannot exceed the lesser of:

- $50; or
- What the enrollee would be charged if he or she obtained the services through the MA organization.

130.3 - Post-Stabilization Care Services

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

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.

MA Organization Financial Responsibility

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

- **Are pre-approved** by a plan provider or other MA organization representative;
- **Are not pre-approved** by a plan provider or other MA organization representative, but are administered to **maintain** the enrollee's stabilized condition **within one hour** of a request to the MA organization for pre-approval of further post-stabilization care;
- **Are not pre-approved** by a plan provider or other MA organization representative, but administered to **maintain, improve, or resolve** the enrollee's stabilized condition if:

- The MA organization does not respond to a request for pre-approval within one hour;

- The MA organization cannot be contacted; or

- The MA 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 MA 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 MA 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 MA 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 MA organization. For purposes of cost sharing, post-stabilization care services begin upon admission.

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 MA 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 MA 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 (PFFS) Plans

150.1 - General Description

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

An MA private fee-for-service plan is an MA plan that pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk. An MA Organization wishing to offer a PFFS plan must meet general requirements for MA Organizations required by law including without limitation:

- Providing for all original Medicare covered services (see §10 of this chapter);

- Providing for emergency and urgent care (see §140 of this chapter);

- Complying with the Medicare Advantage appeals and grievance requirements which allow beneficiary appeals for services that are limited, not provided, not paid for, or not allowed (see Chapter 13 of this Manual, “Medicare Advantage Beneficiary Grievances, Organization Determinations, and Appeals″);

- Disclosing its terms and conditions of payment and a list of services it provides (see §120 of this chapter and §150.2 below);

- *Abiding by the prompt payment requirements (see section 150.7 of this chapter).*

However, an MA Organization offering a PFFS plan:

- Does not vary the rates for a provider based on the utilization of that provider's services;

- Does not restrict enrollees' choices among providers that (a) agree to accept the plan's terms and conditions of payment and (b) are lawfully authorized to provide services;

- Does not limit enrollees to a provider network (no “lock in”);

- *Does not require a quality improvement program. Note: Although PFFS plans are not required to provide HEDIS and HOS information, CMS is strongly encouraging PFFS plans to participate in HEDIS and Health of Seniors surveys (HOS). A PFFS plan that does not participate in HEDIS and HOS will not be included in the “report cards” CMS will issue and, as a result, may be at a disadvantage when people seeking to chose a plan review this comparative information. CMS will review enrollment, appeals, and other data for trends and, if necessary, require appropriate corrective action, and will require MAOs to provide CMS, on an annual basis, with information on especially those grievances related to marketing and access to care; and*

- Special access rules apply to PFFS plans. These are described in §150.4 of this chapter.

Members of a PFFS plan may go to any doctor or hospital in the U.S. that is:

- Eligible to be paid by Medicare (that is: (a) The provider is state licensed, (b) Is eligible to receive, or has received, a Medicare billing number, and (c) For Institutional providers, such as hospitals and skilled nursing facilities, is certified to treat Medicare beneficiaries); and

- Is willing to accept the plan’s terms of payment (as defined below in §150.2).

PFFS plans may offer supplemental benefits. Additionally a PFFS plan offered by an MA Organization has the option of offering a Part D prescription drug benefit.

150.2 - PFFS Terms and Conditions of Participation

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

The PFFS terms and conditions of payment establish the rules that providers must follow if they choose to furnish services to an enrollee of a PFFS plan. At a minimum the terms and conditions will specify:

- *An explanation of the deeming process (see section 150.3 of this chapter) including provider eligibility requirements (see section 150.1 of this chapter);*

- A list of all services that the plan provides;

- The amount the PFFS organization will pay for all plan-covered services;

- Provider billing procedures *including prompt payment and hold-harmless requirements (see section 150.7 of this chapter below as well as sections 100.2*

and 100.3 of chapter 11, "Contracts"), as well as the provider-payment dispute process;

- The amount the provider is permitted to collect from the enrollee including balance billing;

- Whether the provider must obtain advance authorization from the PFFS organization before furnishing a particular service; and

- *Beneficiary Appeal and Grievance requirements*.

The PFFS plan is not required to reimburse providers for services to PFFS plan enrollees, if these services are not covered by the plan.

A private fee-for-service organization is required to make its terms and conditions of payment reasonably available--through phone, fax, email, or websites-- to providers in the U.S. from whom its enrollees seek health care services.

CMS annually reviews the Terms and Conditions of PFFS Organizations. The Medicare Advantage organization MAO must submit them to their Regional Office for review prior to publishing them. The terms and conditions must be updated each year since they include benefit information. Typically they are submitted in December.

150.3 - Provider Types---Direct Contracting, Deemed Contracting, Non-Contracting

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

When an enrollee in a PFFS plan offered by an MA Organization obtains services from a provider, then for those services, that provider is classified into one of the following three mutually exclusive provider types:

- A provider is a **direct-contracting provider** if that provider has a direct contract (that is, a signed contract) with the MA Organization;

- A provider is a **deemed-contracting provider** if:

    - The provider is aware in advance of furnishing services, that the person receiving the services is enrolled in a PFFS plan;

    - The provider has reasonable access to the plan's terms and conditions of payment; and

    - The service provided is covered by the plan;

- A provider is **non-contracting** provider if that provider does not have a **direct contract** and is not **deemed**.

A provider is aware in advance of enrollment if notice of enrollment for this enrollee was obtained from:

- The enrollee (e.g., presentation of an enrollment card);
- CMS;
- A Medicare intermediary;
- A carrier; or
- The MA Organization itself.

A provider has reasonable access to the plan's terms and conditions of payment if the plan makes accessible its terms and conditions of payment through:

- Postal service;
- Electronic mail;
- Fax;
- Telephone; or
- A plan Web site.

It is then the provider's responsibility to call or fax the PFFS plan or to visit the PFFS Web site to obtain the plan's conditions of participation. However, announcements in newspapers, journals, or magazines or on radio or television are not considered communication of the terms and conditions of payment.

It is important to emphasize that although a provider who does not have a **direct contract** with the plan may choose to provide, or not to provide services, the provider does not have the option of becoming **non-contracting**. Rather, once the provider provides services, the provider automatically becomes **deemed-contracting** provided the deeming conditions listed above have been met.

EXAMPLES: The following examples illustrate typical situations in which the provider becomes **deemed contracting.**

- An enrollee walks into a physician's office for the first time, advises the physician that he or she is a member of the PFFS plan and presents his or her plan enrollment card. Since the provider had the opportunity to call the plan phone number on the enrollee card, the provider is considered **deemed contracting** as

soon as s/he provides services, even though the provider did not actually check the terms and conditions of payments.

- *An enrollee enters a hospital for non-emergency care, advises the hospital that he or she is a member of the PFFS plan and presents his or her plan enrollment card. All providers that contract with this hospital, or are employed by this hospital, are considered **deemed contracting** as soon as they provide services, even though hospital providers typically do not themselves verify plan enrollment*.

The following examples illustrate when a provider is considered **non-contracting**:

- A provider who provides care in an emergency to an unconscious enrollee is **non-contracting** if the provider did not know prior to furnishing services that the enrollee belonged to a PFFS plan;

- A provider who, prior to furnishing services, did not have reasonable access to the PFFS plan's terms and conditions of payment, is also considered **non-contracting**.

150.4 Access to Services

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

An MA private fee-for-service plan must offer sufficient access to health care. CMS will find that a PFFS plan meets the access requirement if, for a category of health care professional, or provider, the plan has:

- Payment rates that are equal to or greater than original Medicare; or

- Contracts or agreements with a sufficient number and range of such category of health care professional or provider.

A PFFS plan offered by an MA Organization may meet the access requirement for different categories of health care professional or provider in different ways:

EXAMPLE: *An MA PFFS plan decides not to directly contract with any providers and to pay all providers at the original Medicare rate.*

In this case, the PFFS plan has complied with all access requirements. Any provider who was aware in advance of furnishing services, that the person receiving the services is enrolled in the PFFS plan and had reasonable access to the plan's terms and conditions of payment becomes a deemed contracting provider for the services they furnish that enrollee.

EXAMPLE: An MA PFFS plan pays at the Medicare rate for all but two categories of provider. For one category it pays more than Medicare and in one category it pays less.

In this case the PFFS plan only has to demonstrate that it has a sufficient range and number of direct contracts for the category of provider where it pays less than the Medicare rate.

150.5 - Payments and Balance Billing

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Disclosure: The plan must makes accessible, by the methods described in §150.3, its terms and conditions of payment.

FFS Basis: Providers must be reimbursed on a Fee-For-Service basis.

When applying this rule, one should be aware that FQHC (Federally Qualified Health Center) providers are reimbursed by original Medicare at a different rate from community based providers. For further information on FQHCs review pages 9 and 10 at url http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/Downloads/oon-payments.pdf.

Total reimbursement amount: The total reimbursement amount of a service is the total amount the provider is entitled to receive, from both the plan and the enrollee, excluding *permitted* balance billing. As indicated in §150.4, a PFFS plan may choose to pay less than original Medicare for a given service. In such a case the plan must demonstrate that it can meet access requirements through a network of direct-contracting providers. The total reimbursement amount paid to deemed-contracting providers must be the same as the total reimbursement amount paid to direct-contracting providers *and may differ from (i.e., be higher or lower than) the original Medicare amount.* However, the total reimbursement amount for non-contracting providers is always the amount they would *have received* under original Medicare.

Cost Sharing: Although the total reimbursement amount must be uniform for direct-contracting and deemed-contracting providers, the plan may allow different cost-sharing amounts based on provider type.

***EXAMPLE**: Suppose the plan's total reimbursement amount for a service is less than the original Medicare amount. Then, as indicated in §150.4, the plan must demonstrate to CMS that it has a sufficient number and range of providers (the 'network') to provide the service. The plan may then also charge less cost-sharing in-network than out-of-network.*

Balance Billing: Medicare regulations allow, but do not require, an MA PFFS plan to permit direct-contracting and deemed-contracting providers to balance bill up to 15 percent of the PFFS plan total-reimbursement rate for a service *provided to a PFFS plan enrollee. A PFFS plan must specify the types or categories of health care provider or professional that are permitted to balance bill.* The balance billing amount is in addition to the cost-sharing established under the plan and is collected from the enrollee. Non-contracting providers may not balance bill these additional amounts to the beneficiary. The amount of balance billing allowed, if any, must be explicitly mentioned by the MA Organization in its terms and conditions of payment. *Information on permitted balance*

billing must also be communicated to current and potential enrollees. Permitted balance billing may never exceed 15 percent of the total reimbursement amount.

EXAMPLE*: A PFFS plan decides not to directly contract with any providers because it pays all categories of providers at the original Medicare rate*. The plan determines a total reimbursement rate for a particular service to be $80. The cost-sharing, listed in the terms and conditions of payment, is 20%. The plan allows the maximum balance-billing amount allowed under the PFFS regulations, 15%.

This plan has no direct-contracting providers. Deemed-contracting providers collect:

- *20% of $80 = $16 cost-sharing from the enrollee;*
- *the total reimbursement amount less cost sharing, $80 - $16 = $64, from the plan; and*
- *An additional 15% of $80=$12, balance-billing from the enrollee.*

EXAMPLE: *A plan uses both direct and deemed contracts.* The plan determines a total reimbursement rate for a service to be $80. The in-network cost sharing, *for direct contracting providers*, is 20% and the out-of-network cost sharing, *for deemed contracting providers*, is 25%. The plan allows the maximum balance-billing amount, 15%.

For Direct-Contracting, In-Network Providers:

- The provider collects 20% of $80 = $16 cost sharing from the enrollee;
- The provider collects the total reimbursement amount less cost sharing, $80 - $16 = $64, from the plan;
- The provider collects 15% of $80 = $12 from the enrollee.

For Deemed-Contracting, Out-of-Network Providers:

- The provider collects 25% of $80 = $20 cost sharing from the enrollee;
- The provider collects the total reimbursement amount less cost sharing, $80 - $20 = $60 from the plan;
- The provider collects 15% of $80 = $12 from the enrollee.

Services and Supplies: The rules of payment presented in this subsection apply equally to the provision of services, supplies and DME; the payment rules also apply equally to both Institutional providers, such as Hospitals, SNFs, etc., and non-institutional providers.

Collection Errors: If a provider mistakenly collects more from the enrollee than the plan allows, then the provider must refund the difference to the enrollee. For example, if a non-contracting provider billed the enrollee for the total amount that original Medicare pays for this service, then the provider must: (a) Return to the enrollee the total reimbursement amount less enrollee cost-sharing, and (b) Collect the total reimbursement amount less enrollee cost-sharing from the PFFS plan. In other words, the provider must refund the enrollee even though he or she ends up with the same amount of reimbursement.

150.6 Advance Notice of Coverage

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

An enrollee and provider may seek an advance determination of coverage from the MA organization under the organization determination regulations in Part 422 Subpart M. Thus, the enrollee and provider have the opportunity to seek a plan determination of coverage before receiving the service, and we encourage them to avail themselves of this option.

With respect to the notice of anticipated cost sharing, the law requires such a notice for hospital services, but not for other services. The MA organization could, however require that contracting and deemed contracting providers of other types furnish such a notice in advance of providing care as a term and condition of payment, and could set whatever tolerance they chose for such a notice. We allow the $500 threshold for a notice of out-of-pocket expenses that a hospital may collect from the enrollee because it mirrors the $500 threshold long established by law at §1842(m)(1) of the Act. Section 1842(m)(1) of the Act requires that a nonparticipating physician who does not accept assignment on the Medicare claim must give the beneficiary advance notice if the actual charges that will be collected from the beneficiary equal or exceed $500. While the benefit to which the threshold applies is different, the concept of advance notice of amounts to be collected from the enrollee is the same, and therefore the same threshold is justified.

150.7 - Prompt Payment Requirements

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

The clean claim standards explained in 42 CFR 422.520 apply to all claims submitted by, or on behalf of an MA private fee-for-service enrollee for the services of a non-contracting provider. The written agreements with PFFS plan providers must address this issue, and better terms may be negotiated.

The PFFS access requirements at 42 CFR 422.114(a)(2)(ii) require that a PFFS plan which establishes payment rates that are less than original Medicare must establish contracts or agreements with a sufficient number and range of providers to furnish the services covered under the PFFS plan.

The MA prompt payment requirement at 42 CFR 422.520(b) specifies that contracts between MA organizations and suppliers must contain a prompt payment provision, the terms of which are developed and agreed to by both the MA organization and the relevant provider.

This means that a network PFFS plan must include a prompt payment provision in the written contracts it establishes in order to meet Medicare access requirements as required under 42 CFR 422.114. The contract prompt payment provision will then become part of the PFFS plans terms of payment that will also apply to any non-network provider that chooses to furnish services as a deemed provider.

For those services which the PFFS plan does not have a network because it is paying at the original Medicare rate, the prompt pay requirement at 42 CFR 422.520(a)(2) applies and therefore at a minimum:

- The MA organization must pay 95 percent of the ``clean claims'' within 30 days of receipt, if they are submitted by or on behalf of an enrollee of the MA PFFS plan; and

- the MA organization must pay interest on clean claims that are not paid within 30 days (Sections 1816(c)(2)(B) and 1842(c)(2)(B) of the Act).

150.8 - Original Medicare vs. Estimated Payment Amounts

(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

An estimated Medicare payment amount is an estimate of the dollar amount that original Medicare would have paid for certain Medicare covered services. In many cases providers are entitled to receive from a PFFS organization the same dollar amount they would have been paid by original Medicare for a given service. A provider will be paid an estimated Medicare payment amount for those services where original Medicare lacks a fee schedule or prospective payment amount that could readily be used by the PFFS plan to pay providers.

The PFFS plan’s terms and conditions of participation will inform providers if they are entitled to receive a payment amount equal to what they would have received under original Medicare. In addition, the terms and conditions of participation will disclose if the payment amount is going to be an estimated Medicare payment amount. If the payment amount a provider receives from the PFFS organization (including the enrollee cost sharing collected) is less than the provider would have received under original Medicare for the service, the provider can appeal the payment amount to the plan.

To appeal the payment amount the provider must provide reasonable documentation to the plan of the original Medicare payment amount that applies to the service. If the provider is paid less than the amount they are entitled to receive, the PFFS organization must pay the provider the difference.

150.9 - Table Summarizing PFFS Provider Types and Rules

(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

The following table summarizes the PFFS provider types and their attributes.

	Direct Contracting[1]	**Deemed Contracting**[2]	**Non-Contracting**[3]
The following items differentiate between direct contracting and deemed contracting providers			
Included in network (When applicable[4])	In Network	Out of Network	Out Of Network
Access requirements, when applicable[4], may be met with such providers	Yes	No	No
Cost-Sharing	The plan may allow lower cost-sharing[5]	The plan may allow higher cost sharing[5]	Member cost sharing is governed by the PFFS plan Terms and Conditions [5]
For the following items, direct contracting and deemed contracting providers are treated the same			
Reimbursement	Receive the Total Reimbursement rate indicated in the Terms and Conditions of the plan[5]	Receive the Total Reimbursement rate indicated in the Terms and Conditions of the plan[5]	PFFS plan pays the original Medicare amount less the cost sharing due from the member.[5]
Balance Billing, if allowed in the plan's Terms and Conditions of payment	May be allowed up to 15% of the plan's Total reimbursement rate.[6]	May by allowed up to 15% of the plan's Total reimbursement rate.[6]	*After collecting the plan allowed cost-sharing from the enrollee*, non-contracting physicians are permitted to balance bill *the enrollee* up to the Limiting Charge (see §1848(g) of the Act*), to the same extent that they are permitted to balance bill original Medicare enrollees.* PFFS enrollees, like other Medicare beneficiaries, are not permitted to access "opt out" physicians for covered services – except in limited cases related to the provision of emergency care. *See §422.220*
Prompt Payment	The plan must specify prompt payment	The prompt payment provisions in the plans	The plan has to pay promptly according to the

	provisions in its Terms and Conditions of payment	Terms and Conditions of payment apply to deemed contracted providers	clean claim standards. - See §422.520.

Notes to table:

1. A direct contracting provider is a provider with whom the PFFS plan has a written contract.

2. A deemed contracting provider is a provider that: (a) Does not have a written contract with the plan, but (b) Is aware that the enrollee belongs to the plan, (c) Has a reasonable opportunity—either *through* the internet, fax or 800 numbers---to the plan's Terms and Conditions, and (d) Agrees to treat the enrollee. (NOTE: Agreeing to treat the beneficiary under these conditions automatically confers deemed status on a provider.) (See §422.216(f) for deeming rules.)

3. A non-contracting provider has neither (a) signed a written contract with the plan nor (b) met the requirements to be a deemed provider. A typical example is a provider who treats a PFFS enrollee in an emergency room. A PFFS plan of any type is required to pay a non-contracting provider (in combined plan and member payment) up to the amount the provider could collect (in combined CMS and beneficiary payment) if the member were enrolled in original Medicare.

4. In determining whether a provider is in-network or whether access requirements are met we must consider 3 cases:

Case 1: A PFFS plan that reimburses at, or above, the original Medicare rate is deemed to meet access requirements. In this case the distinctions in the above table between direct contracting, deemed contracting and non-contracting providers are not relevant.

Case 2: A PFFS plan that reimburses below the original Medicare rate must demonstrate through a network of direct-contracting providers that it meets access requirements. In this case the distinctions in the above table between direct contracting, deemed contracting and non-contracting providers have relevance, particularly related to cost-sharing and total-reimbursement.

Case 3: A PFFS plan that chooses to reimburse: (a) Some categories of health professionals or providers at, or above, the original Medicare rate, and (b) Other categories of health professionals or providers below the original Medicare rate, must demonstrate access through a network of direct-contracting providers for the categories of health care professionals and providers that are reimbursed below the original Medicare rate. For the categories of health care professionals and providers that are reimbursed below the original Medicare rate, the distinctions in the above table between direct contracting, deemed contracting and non-contracting providers have relevance, particularly related to cost-sharing and total-reimbursement.

5. The following example illustrates a typical situation in which the differentials of the above table apply:

EXAMPLE: Suppose a particular service has a reimbursement rate of $120 in original Medicare. Then the plan may fix a $100 Total reimbursement rate for its direct-contract in-network providers, if it has demonstrated adequate access through this network

For purposes of illustration we assume:

- The plan allows balance billing at 15%;
- The PFFS plan has established cost sharing of 20% for services of non-contracting providers; and
- That cost sharing related to this service in-network is $5 and $10 out-of-network

The following table of hypothetical payments illustrates the following points:

- The direct contracting and deemed contracting providers both receive the same total reimbursement;
- Non contracting providers receive the original Medicare amount;
- Cost sharing may be lower for direct contracting providers; and
- Non-contracting provider cost sharing is governed by original Medicare (although PFFS plans are permitted to raise or lower the amount, subject to regulatory limits, that members must pay).

Provider Type	Cost Sharing received	Amount paid by plan	Total Reimbursement Rate	Balance Billing allowed by plan	Total amount received by Provider
Direct Contracting	$5	$95	$100	$15, paid by enrollee	$115
Deemed Contracting	$10	$90	$100	$15, paid by enrollee	$115
Non Contracting	$24 (20% of $120)	$96	$120	$0	$120

6. Note the distinction between PFFS and non-PFFS MA plans.

- *For PFFS plans, the sponsoring MAO can allow providers to balance bill up to 115% of the PFFS plans normal fee schedule – see §1852(k)(2)(A)(i).*

For non-PFFS MA plans (including MSA plans), "permitted balance billing" is limited to the amounts permitted under the original Medicare program –1852(k)(1), 1852(a)(2)(A)(ii).

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 MA 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 MA 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 MA 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 MA organization are outlined below in §160.4.

160.3 - State Law Primary
(Rev. 23, 06-06-03)

The MA 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, MA 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 MA organizations and states a great deal of flexibility, and CMS is prepared to work with the MA 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 MA 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 MA Obligations
(Rev. 23, 06-06-03)

The written information provided to enrollees must, at a minimum, include a description of the MA 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 MA organization is required to comply with State law (See §160.3 for details);

- That the MA organization must educate its staff about its policies and procedures for advance directives; and

- That the MA organization must provide for community education regarding advance directives.

If the MA 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 MA organization may give advance directive information to the enrollee's family or surrogate.

The MA 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 MA 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 MA 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 MA organization must be able to document its community education efforts.

160.7 - MA Organization Rights
(Rev. 23, 06-06-03)

The MA organization is not required to provide care that conflicts with an advance directive.

The MA is not required to implement an advance directive if, as a matter of conscience, the MA 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 MA 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 MA organization must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State Survey and Certification Agency.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R87MCM	06/08/2007	Update of Chapter 4,"Benefits and Beneficiary Protection"	06/08/2007	N/A
R72MCM	09/30/2005	Changes in Manual Instructions for Benefits and Beneficiary Protections	N/A	N/A
R61MCM	09/03/2003	Emergency and Urgently Needed Services	N/A	N/A
R49MCM	04/09/2004	Access and Availability Rules for Coordinated Care Plans and Continuity of Care	N/A	N/A
R43MCM	01/09/2004	Sources for Obtaining Information	N/A	N/A
R36MCM	10/31/2003	Miscellaneous Changes	N/A	N/A
R23MCM	06/06/2003	Initial Issuance of Chapter	N/A	N/A