Medicare Managed Care Manual
Chapter 4 - Benefits and Beneficiary Protections

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(Rev. 87, 06-08-07)

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

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

These guidelines reflect CMS' current interpretation of the provisions of the Medicare Advantage (MA) 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 in light of changes to the MA program enacted in the Medicare Modernization Act (MMA) - in particular the addition of several new health plan options - after careful evaluation by CMS of current technology, coverage rules, and industry practices with respect to plan design. The guidance set forth in this document is subject to change as technology and industry practices in plan design and administration continue to evolve and as CMS gains more experience administering the MA program and its new health plan options.

The contents of this chapter are governed by regulations set forth in 42 CFR 422, Subpart C, and consequently, 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 requirements may be found in the Prescription Drug Benefit Manual located at http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage. Further information on Part D benefits may also be found in the following sections of this chapter: Section 30.7, "Part D Vaccines", section 10.5, "Part D Rules for MA Plans", section 40.7, "Part-B and –D OTC (Over-the-Counter) Benefits", and section 30.6 "Medical Supplies Associated with the Delivery of Insulin."

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

An MA Organization (MAO) offering an MA plan must provide enrollees in that plan with all Original Medicare-covered services except in the three circumstances described in the next paragraph. The MAO must provide Part A and Part B services, if the enrollee is entitled to benefits under both parts, and Part B services if the enrollee is a grandfathered Part B enrollee. The MAO fulfills its obligation of providing Original Medicare benefits by furnishing the benefits directly, through arrangements, or by paying on behalf of enrollees for the benefits.

The following three circumstances are exceptions to the rule that MAOs must provide plan enrollees with Original Medicare benefits:

- Hospice: The MAO does not cover hospice care; rather, Original Medicare covers hospice;

- Inpatient hospital stay during which enrollment begins: The MAO does not cover an inpatient hospital stay if enrollment begins during that inpatient hospital stay; and

- Inpatient hospital stay during which enrollment ends: The MAO must continue to cover an inpatient hospital stay of a non-plan enrollee if the individual was an enrollee at the beginning of the inpatient hospital stay.

In addition to providing Original Medicare benefits, to the extent applicable, the MAO also furnishes, arranges, or pays for supplemental benefits and prescription drug benefits to the extent they are covered under the plan.

CMS reviews and approves an MAO's coverage of benefits by ensuring compliance with requirements described in this manual, including this chapter, Chapter 7, "Payments to Medicare+Choice Organizations" Chapter 8, "Payments to Medicare Advantage Organizations," and other CMS instructions, such as the guidance contained in the annual Call Letter.

10.3 - Types of Benefits

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

If an MAO wishes to offer an item or service as a benefit under an MA plan, then the MAO must first properly classify the potential-benefit type of the item or service as basic (Original Medicare), mandatory supplemental, optional supplemental, or Part D prescription drug. To properly classify the potential-benefit type of an item or service three questions must be asked:

- Is the item or service covered by Original Medicare under Part A or Part B?
- Does the MA plan intend to require that all enrollees purchase the item or service?
- Is the item a Part D prescription drug?

The responses to these three questions are used to establish the type and benefit status of the item or service as follows:

Basic benefits: If the item or service is covered by Original Medicare under Part A or Part B, including Part B prescription drugs, then it must be offered and identified in plan bids as a basic benefit. Basic benefits, also called Original Medicare benefits, are discussed in section 10.4.

Part D prescription drug benefits: If the item is not covered under Part A or Part B under Original Medicare but is covered under Part D then the item must be offered and identified in plan bids as a prescription drug Part D benefit. Prescription drug Part D benefits are discussed and described at 42 CFR 423 and in Chapter 5 of the Prescription Drug Benefit Manual. Section 10.5 below discusses which plan types must, may, or may not offer prescription drug Part D benefits.

Supplemental benefits: If the item or service is not covered under Parts A, B or Part D, and if the item or service also meets the criteria described in section 30.1 of this chapter, then the item or service may be offered as a supplemental benefit. Supplemental benefits are discussed in sections 30 and 40 below.

Supplemental benefits are further classified as either mandatory or optional:

- **Mandatory supplemental** benefits are benefits not covered under Part A, Part B or Part D which 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 not covered under Part A, Part B, or Part D. However, MAOs may offer their enrollees a group of services as one optional supplemental benefit, offer optional supplemental services individually, or offer a combination of group and individual optional supplemental services. Each plan enrollee chooses whether to elect and pay for any particular optional supplemental benefit as offered under the plan. Optional supplemental benefits are paid for directly by the enrollee or on behalf of the enrollee.

  Optional supplemental benefits must be offered uniformly to all plan enrollees independent of health status. Rebate dollars may not be applied toward optional supplemental benefits. MA MSA plans are permitted to offer optional supplemental benefits, provided that the MSA plan does not offer an optional supplemental benefit that covers expenses that count toward the annual MSA deductible.

  Optional supplemental benefits must be offered uniformly at the time of initial enrollment to all current and new Medicare beneficiaries electing enrollment in the MA plan. The MA plan may then:

  - Continuously offer each optional supplemental benefit uniformly to all enrollees for the entire contract year; or

  - Choose to place a time limit of at least 30 consecutive days starting from the enrollee effective date 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.

  Although MAOs 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 MAO.

  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), provides the requirements for an involuntary disenrollment of an enrollee from an MAO when that enrollee fails to make timely payments of premium for optional supplemental benefits.

10.4 - Original Medicare Part A and B Covered Benefits

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As indicated in section 10.2, MAOs must provide coverage of - by furnishing, arranging for, or making payment on behalf of an enrollee for - services that are available to beneficiaries residing in the plan's service area 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 a grandfathered "Part B only" enrollee.

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 section 1812 and 1832 of the Act, respectively, while section 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, but rather 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 provided in the Code of Federal Regulations and CMS guidance.

Medicare payment is contingent upon a determination that:

- A service meets a benefit category;
- A service is not specifically excluded from Medicare coverage by the Act; and
- The item or service is "reasonable and necessary" for the diagnosis or treatment of an illness or injury or to improve functioning of a malformed body member, or is a covered preventive service.

These criteria are applied in 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 Determinations (NCDs) are published on the National Coverage Web site. For further information see sections 80.3, 80.4 and 80.6 of this chapter.

In the absence of a specific NCD, coverage decisions are made, as indicated in section 80.1 and 80.2, at the discretion of local Medicare Administrative Contractors (MACs). The guidance concerning the adoption of uniform local coverage determinations by MA local or regional plans is discussed in section 80.2.

10.5 Part D Rules for MA Plans

As provided in 42 CFR 422.4(c), an MAO cannot offer an MA coordinated care plan in an area unless that plan or another plan offered by the MAO in that same service area includes Part D prescription drug coverage. Part D prescription drug coverage is defined at 42 CFR 423.100 and in section 20.1 of Chapter 5 of the Prescription Drug Benefit Manual. This rule requiring that at least one MA plan be offered in an area with Part D coverage applies only to coordinated care plans. For more information about this rule, refer to section 20.4.4 of Chapter 5 of the Prescription Drug Benefit Manual.

Regardless of whether an MAO offers a coordinated care plan in the area with Part D benefits, all Special Needs plans (SNPs) are required to include Part D prescription drug coverage (see the definition of SNPs in 42 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 include 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). If the beneficiary enrolls in an MA coordinated care plan, however, s/he cannot enroll in a separate PDP even if that MA coordinated care plan does not offer Part D coverage. Since cost plans may only offer Part D coverage as an optional supplemental benefit, a cost plan enrollee may enroll in a PDP at the same time s/he is enrolled in the cost plan if the enrollee does not elect optional Part D from the cost plan.

The guidance provided by this section only applies to the provision of Part D prescription drug benefits. For guidance governing OTC (Over-the-Counter) drug benefits, see section 40 of this chapter

Table I: Part D Prescription Drug Coverage by Plan Type

Plan Type	Regional or Local MA Plan?	Must offer Part D?	Can an enrollee elect a PDP?
MA Coordinated Care Plan (CCP)			
HMO	Local	Generally yes, unless there is another CCP offered in the same area that includes such coverage. See footnote 1 for details.	No
HMO-POS	Local	Generally yes, unless there is another CCP offered in the same area that includes such coverage. See footnote 1 for details.	No
PPO	Either	Generally yes, unless there is another CCP offered in the same area that includes such coverage. See footnote 1 for details.	No
Special Needs Plan (SNP)	Either	Yes, required	No
Provider-sponsored organization (PSO)	Local	Generally yes, unless there is another CCP offered in the same area that includes such coverage. See footnote 1 for details.	No
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 qualified Part D prescription drug coverage	NA	Part D coverage can only be offered as an optional supplemental benefit	Yes
Cost plan offering non-qualified prescription drug coverage[3]	NA	No. The cost plan cannot offer both Part D coverage and non-qualified prescription drug coverage.	Yes
Sec. 1833 HCPP	NA	No	Yes
PACE Programs	NA	Yes[4]	No

Notes to Table I:

1. In accordance with the 423.104(f)(3) Rule cited below at least one of the plans offered by the CCP must offer qualified Part D prescription drug coverage. So a given plan offered by the CCP is not required to offer qualified Part D prescription drug coverage if another plan offered by the CCP in the same area includes such coverage.

   423.104(f)(3) Rule. An MAO 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.

   "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.

   CMS has interpreted this requirement of offering at least one MA-PD plan that is accessible to all potential enrollees in the service area to refer to a non-exclusive SNP plan.

2. This option is unique to the Section 1876 cost plan program. This option of offering non-qualified Part D coverage is not available to MA plans.

3. PACE Providers offering PACE Programs, as defined in section 1894 of the Act, do not receive
   payment for prescription drugs from Medicaid on behalf of dual eligible enrollees. As a result, these programs have elected to provide Part D coverage in order to receive payment for the prescription drug coverage that they are statutorily required to provide.

10.6 – Anti-Discrimination Requirements

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Although the MA program provides MAOs with a great deal of flexibility in designing MA plans, in sections 10.6 – 10.13 we detail requirements that uniformly apply to all plan types.

All MA plans, independent of plan type, must comply with the anti-discrimination prohibitions:

1) An MA plan 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 (with the exception of end stage renal disease (ESRD)*, or in the case of a SNP, with respect to an individual who does not have the condition served by the SNP);

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

  * Note that an individual who develops end-stage renal disease while enrolled in a health plan offered by an MAO is eligible to either stay in that plan if it is an MA plan, or enroll in any MA plan offered by the same MAO. 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).

2) An MAO is also required to comply with the provisions of the Civil Rights Act, Age Discrimination Act, Rehabilitation Act of 1973, Americans with Disabilities Act, and the Genetic Information Nondiscrimination Act of 2008. Similarly, the MAO 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.

3) An MAO 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.

There are three situations where enrollment may be denied based on a medical condition:

- Denial of enrollment to a person with ESRD who is not currently an enrollee of a health plan offered by the MAO, or eligible to enroll because they were enrolled in an MA plan that terminated;
- Denial of enrollment to a person in hospice; and
- Denial of enrollment in a SNP to a person who does not fulfill the eligibility criteria for enrollment in the SNP.

10.7 Confidentiality

Confidentiality and Accuracy of Enrollee Records: For any medical records or other health and enrollment information it maintains with respect to enrollees, an MAO must establish procedures to:

- Abide by all Federal and state laws regarding confidentiality and disclosure of medical records or other health and enrollment information. The MAO 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.

Providing Medical Records: With regard to requests from MAO providers to provide medical records:

- Providers must provide medical records, even if this requirement is not explicitly listed in a contract, or, in the case of a PFFS plan, in the terms and conditions of payment, for purposes of risk-adjustment;
- Providers must provide medical records, provided this requirement is listed in their contracts, or, in the case of a PFFS plan, in the terms and conditions of payment for inquiries about:
  - Advance determination of coverage;
  - Plan coverage;
  - Medical necessity; or
  - Proper billing.

MAOs are prohibited from using medical records for the purpose of inappropriately down-coding submitted claims. MAOs may elect to reimburse providers or send plan staff to obtain medical records.

10.8 Benefit Requirements

All benefits offered by any MA plan, independent of plan type, must satisfy the following:

- As discussed in section 30.1 of this chapter, all supplemental 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. The other requirements in section 30.1 must also be fulfilled;

- 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 http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf.

10.9 Uniformity

The following rules apply to any MA plan, independent of plan type:

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

- An MAO 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.) ;

- Although an MAO 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), 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 plans may not charge or discount for this option. Furthermore, plans may not require electronic payment of premiums. The following chart summarizes a variety of payment options:

Table II: Sources of Payment for Part C and D Premiums

Source of payment / Type of premium	Part D premium	Part C premium including premium for Optional Supplemental Benefits
Payment from Social Security check	**Must**: All enrollees must be offered the right to pay for Part D premium from their Social Security check	**Must**: All enrollees must be offered the right to pay for Part C and D premiums from their Social Security check
Payment from other electronic sources	**Must offer / Cannot require**: All enrollees must be offered, but cannot be required to, pay for Part C and D premiums from electronic sources other than their Social Security check – such as an EFT from, a bank account, or a credit or debit card	**Must offer / Cannot require**: All enrollees must be offered, but cannot be required to, pay for Part C and D premiums from electronic sources other than their Social Security check – such as an EFT from, a bank account, or a credit or debit card
Payment by personal check	**Must**: All enrollees must be offered the right to pay for Part C and D premiums by personal check	**Must**: All enrollees must be offered the right to pay for Part C and D premiums by personal check

Generally, Part C and D premiums cannot be "split." An MAO cannot permit one premium (e.g., Part D) to be paid through premium withholding and another (e.g. Part C) to be paid through another mechanism for the same enrollee.

10.10 Caps On Enrollee Financial Responsibility

This section provides several distinct situations relating to enrollee financial responsibility. Although plans have certain rights of collections, in many instances the enrollee is protected with a capped financial responsibility.

1) Cost Sharing Cap: An MA enrollee should never pay more for services covered under the plan than the plan required cost sharing – i.e. coinsurance, deductibles and copays. This cap on beneficiary liability:

    - Applies even if a provider or delegated provider declares insolvency;

    - 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

    - Prohibits a plan from requiring a beneficiary to first pay a contracted provider, except for co-payments, and then receive reimbursement from the MAO except for co-payments or coinsurances.

An MAO may not provide cash to an MA plan enrollee as an inducement for enrollment or for any other purpose. A plan may not require a beneficiary to pay a contracted provider and then receive reimbursement.

2) Provider / Enrollee Relationships: In the following situations, an enrollee who has correctly identified him/herself as a plan enrollee has no liability beyond plan cost-sharing:

Situation 1:

- The enrollee 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 in this situation and 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:

If a plan provider either:

- Refers the enrollee to a plan specialist for a plan-covered service but the plan-provider does not follow the required referral or prior-authorization requirements, such as completion of a properly filled out referral form;
- Refers the enrollee to a non-plan provider;
- Refers the enrollee to a provider who contracts with the plan to furnish other services but does not contract with the plan to furnish the particular service received by the enrollee; or
- Refers the enrollee to a provider who contracts with the MAO offering the plan to provide services in other plans offered by the MAO but does not provide services for the plan to which the enrollee belongs,

Then, unless the provider can demonstrate the enrollee was notified prior to receiving the item or service that the item or service is covered only if further action is taken by the enrollee, the plan must treat this enrollee’s health care as if a proper referral and prior authorization had been made, and, consequently, the enrollee is only liable for plan cost-sharing.

CMS encourages a personal relationship between providers and enrollees. 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. Similarly, a network provider who is providing a non-covered service (for example, if a required referral was not obtained) should also clearly advise the enrollee prior to service of required fees.

In general, MAOs have a responsibility to educate their plan providers so that they are knowledgeable about the plan's network of specialists as well as the plan's referral and prior-authorization requirements.

3) 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.

4) Missed Appointment Charges: MAOs may charge "administrative fees" to enrollees for missed appointments and for not paying a copay at the time of service. Under the MA program such charges are only allowable if the charge is priced in the bid and documentation is submitted that clearly shows these charges are priced in the bid. Furthermore, these additional charges must be clearly outlined in the notes section of the PBP and be included in the Evidence of Coverage. In the absence of a plan policy or for non-contracting providers, providers may still charge a fee for missed appointments provided such fees apply uniformly and at the same amount to all Medicare and non-Medicare patients.

10.11 Multiple Plan Offerings and Benefit Caps

An MAO 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, and plans should not be duplicative of each other. Financial caps for a benefit can only be imposed at the MA plan level. For example, if an MAO 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 if the enrollee enrolls in it.

10.12 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 section 130.1 of this chapter for further guidance on complementary benefits.

10.13 - Provider Qualifications
(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, SNF, 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.

10.14 - Drugs That Are Covered Under Part B Original Medicare

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In the remainder of section 10 we discuss requirements related to specific Original Medicare benefits.

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. For more coverage details, see the Medicare Benefits Policy Manual Publication 100-02, Chapter 15, Section 50 "Drugs and Biologicals" and the Medicare Claims Processing Manual, Publication 100-04, Chapter 17, and sections of the Manual referenced therein.

Subject to coverage requirements as well as regulatory and statutory limitations, the following broad categories of drugs may be covered under Medicare Part B. Please note, these examples are illustrative and are not a comprehensive list.

- Injectable drugs that have been determined by Medicare Administrative Contractors (MACs) to be "not usually self-administered" and that are administered incident to physician services. For further information, see the Medicare Policy Benefits Manual Publication 100-02, Chapter 15, Section 50.2 and 50.3.

- Drugs that the MA enrollee takes through durable medical equipment (such as nebulizers) that were authorized by the enrollee's MA plan;

- Drugs covered under the statute, including but not limited to:

    - Certain vaccines

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

    - Hemophilia Clotting factors;

    - Immunosuppressive drugs;

    - Some antigens;

    - Intravenous Immune globulin administered in the home for the treatment of primary immune deficiency;

    - Injectable drugs used for the treatment of osteoporosis in limited situations; and

- Certain drugs, including erythropoietin, administered during the treatment of end stage renal disease.

Effective August 1, 2002, if an MA enrollee wishes to receive a "not usually self-administered" drug in a physician's office, then the MAO must cover the drug and the service of administering the drug. MAOs may not make a determination that it was reasonable and necessary for the patient to choose to have his or her drug administered incident to physician services. MAOs 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 MAOs as a Part D benefit, and cannot be offered as 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.

10.15 - Original Medicare Covered Services with Benefit Periods

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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.

10.16 - Waiting Periods / 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 MAO can deny coverage of Medicare-covered services when the services do not meet the standard of being medically necessary and appropriate. In addition, an MAO 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 80.2 for guidance on selection of local coverage decisions).

10.17 - Screening Mammography, Influenza Vaccine, and Pneumococcal Vaccine

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

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

10.18 - 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 SNF - 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 SNF (42 CFR 422.133). This requirement of providing post-hospital extended care through a home SNF also applies if the MAO elects to furnish SNF care in the absence of a prior qualifying hospital stay.

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

Manual manipulation of the spine to correct a subluxation is a standard Medicare Part B benefit and, consequently, must be made available to enrollees in all MAOs. The definition of a physician for Medicare coverage purposes (Section 1861(r) of the Social Security Act) includes a chiropractor for treatment of manual manipulation of the spine to correct a subluxation. The statute specifically references manual manipulation of the spine to correct a subluxation as a physician service. Thus MAOs 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. MAOs may continue to use physical therapists to treat enrollees for conditions not requiring physician services, as defined in section 1861(r) of the Act.

10.20 - 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 can be found in section 10.2 of chapter 5 of publication 100-04, the Medicare Claims Processing Manual, at http://www.cms.hhs.gov/Manuals/IOM/list.asp#TopOfPage.

10.21 – Balance Billing

An important protection for beneficiaries when they obtain plan-covered services in an HMO, PPO, or RPPO, is that they do not pay more than plan cost-sharing. In situations where providers ordinarily are permitted to balance bill they must obtain this balance billing from the MAO if the plan cost-sharing does not expressly provide for enrollee payment of such balance billing amounts. The rules are as follows for services obtain from an HMO, PPO, or RPPO from a:

- Contracted provider. There is no balance billing paid by either the plan or the enrollee unless provided for in the plan's cost-sharing structure;

- Non contracting "participating provider" (a provider that agrees to accept assignment from Medicare when treating a Medicare patient). There is no balance billing paid by either the plan or the enrollee;

- Non contract non participating provider. The MAO pays permitted balance billing (up to 15% of the Original Medicare rate); the enrollee, as indicated above only pays plan-cost sharing; and

- Non contracting non participating DME supplier. The MAO owes the non-contracting non-participating (non-par) DME supplier the difference between the member's cost sharing and the DME supplier's bill.

10.22 – Inpatient Hospital and SNF Stays

MAOs are required to provide all Original Medicare benefits (42 CFR 422.100). More specifically, coverage limits for Original Medicare benefits apply equally to Original Medicare and Medicare Advantage enrollees. Original Medicare coverage of inpatient hospital stays, SNF stays, and psychiatric inpatient hospital stays requires knowledge of up to four numbers to make accurate payments: (1) the number of days elapsed since the last hospital or SNF discharge (if there was such a prior discharge), (2) the number of fully paid days remaining, (3) the number of copaydays remaining, and (4) for inpatient and psychiatric inpatient hospital stays, the number of irreplaceable lifetime reserve days remaining.

Historically, MAOs have not had full access to the data required to properly implement the coverage limits of the Original Medicare benefits and, consequently, have not always communicated the appropriate data with Original Medicare and with other MAOs. However, this data is now available on screens accessible to the MAO and, consequently, we expect plans to fully comply with all Original Medicare coverage limits beginning in CY 2010.

An MAO may review a specific enrollee's remaining full, copay, and inpatient and psychiatric inpatient lifetime reserve hospital days on MARx screen M233 in the utilization tab. As of April 2010 this screen is also expected to include SNF days and discharge dates.

The obligation on providers to follow coverage limits for Original Medicare benefits (as provided in 42 CFR 422.100) must be met whenever a provider furnishes Original Medicare, SNF and inpatient hospital services to enrollees of Medicare Advantage organizations. This obligation applies to all SNFs and applies to both teaching and non-teaching hospitals. This obligation can be implemented by providers submitting to Medicare Administrative Contractors (MACs) no-pay claims (with condition code, 04).

Contracts between providers and MAOs require adherence with all Medicare regulations. Consequently, CMS expects MAOs to specifically communicate to their providers the requirements of submission of no-pay claims and the obligation to keep an audit trail on these submissions. CMS in its routine and special monitoring visits will place a special emphasis on reviewing MAO compliance with these requirements.

Note that MAOs may still offer additional inpatient hospital and SNF copay days – beyond those covered by Original Medicare –as a supplemental benefit. These supplemental copay days are available for use in those situations when no Original-Medicare copay days are available. The irreplaceable lifetime reserve days are only used when both Original-Medicare copay days and supplemental copay days are exhausted.

The copay and irreplaceable lifetime reserve days require submission of no-pay claims; however, plans do not submit no-pay claims for supplemental copay days. Consequently, a plan that offers supplemental inpatient (or SNF) days must instruct its providers when dealing with a stay that requires both copay days and supplemental days that no-pay claims submitted to MACs should only reflect the copay days used, while the full claim – copay days and supplemental days – should be submitted to the MA plan.

The MA plan should also explain to enrollees how providers are submitting claims since inaccurate reporting could lead to enrollees losing valuable, irreplaceable, lifetime reserve days. The Medicare summary notices (MSNs) sent by Original Medicare to enrollees reflect coverage reported on no-pay claims, allowing enrollees to verify the accuracy of reporting.

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

(Rev. 23, 06-06-03)

20.1 - Ambulance

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

The MAO is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, when 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.

20.2 – Definitions of Emergency and Urgently Needed Services

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

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 that urgent care received within the service area is an extension of primary care services); and

- Are medically necessary and immediately required, meaning that:

    - The urgently needed services are a result of an unforeseen illness, injury, or condition; and

    - Given the circumstances, it was not reasonable to obtain the services through the 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 many 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 plan must provide the enrollee with medical care in a physician's office.

20.3 – MAO Responsibility

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

The MAO is financially responsible for emergency services and urgently-needed services:

- Regardless of whether services are obtained within or outside the MAO;

- Regardless of whether there is prior authorization for the services. Additionally enrollees must be informed of their right to call 911, meaning that:

    - No materials furnished to enrollees, including wallet card instructions, may contain instructions to seek prior authorization for emergency or urgently-needed services, and;

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

- If the emergency situation is 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 MAO representative instructs an enrollee to seek emergency services within or outside the plan.

The MAO is not responsible for the care provided for an unrelated non-emergency problem during treatment for an emergency situation. For example, if the attending physician is treating a fracture, the MAO is not responsible for any costs connected with a biopsy of associated skin lesions performed while treating the facture.

20.4 – Stabilization of an Emergency Medical Condition
(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

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 MAO. See 20.6 below for the MAO's obligations regarding services provided following stabilization. Chapter 13 of this manual, "MA 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 MAO declines to pay for the services, appeal rights are available to the enrollee.

20.5 - Limit on Enrollee Charges for Emergency Services
(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

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

- $50; or

- What the enrollee would be charged if s/he obtained the services through the MAO.

20.6 - Post-Stabilization Care Services
(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

Post-stabilization care services are covered services that are:

- Related to an emergency medical condition;

- Provided after an enrollee is stabilized; and

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

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

- Are pre-approved by a plan provider or other MAO representative;

- Although not pre-approved by a plan provider or other MAO representative, are administered to maintain the enrollee's stabilized condition within one hour of a request to the MAO for pre-approval of further post-stabilization care; or

- Although not pre-approved by a plan provider or other MAO representative, are administered to maintain, improve, or resolve the enrollee's stabilized condition when:

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

    - The MAO cannot be contacted; or

    - The MAO 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 MAO 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 MAO'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 MAO representative and the treating physician reach an agreement concerning the enrollee's care; or

- The enrollee is discharged.

Enrollees' charges for post-stabilization care services may not be greater than what the organization would charge the enrollee if s/he had obtained the services through the MAO. For purposes of cost sharing, post-stabilization care services begin upon admission.

20.7 - Services of Non-contracting Providers and Suppliers
(Rev. 23, 06-06-03)

An MAO 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 MAO 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 section 20.1 of this chapter;

- Emergency and urgently needed services under the circumstances described in section 20.2 of this chapter;

- Maintenance and post-stabilization care services under the circumstances described in section 20.6 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 for these services. 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. Furthermore, the cost-sharing for out-of-network medically necessary dialysis may not exceed the cost sharing for in-network dialysis; and

- Services for which coverage has been denied by the MAO 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 MAO.

An MA plan (and an MA MSA plan, after the annual deductible has been met) offered by an MAO 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 (see section 10.21 for guidance on balance billing.).

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

30.1 – Definition of Supplemental Benefit
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

In order for an item or service to be classified as a supplemental 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.

In determining the primary purpose of an item or service, care must be exercised in distinguishing the primary purpose from intent, secondary purposes and goals. Many items and services in proposed MA plan benefit designs have as their goal the prevention of expected illness or injury. Furthermore, very often the items and services do have secondary effects of preventing illness or injury. However, it is the immediate primary purpose that determines benefit status. As a rule of thumb, primary purpose is determined either by 1) national typical usages of most people using the item or service or by 2) nationwide community patterns of care. See the examples below and Table III section 30.3 for illustrative examples of this important principle.

(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 MAO 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 a supplemental benefit that is not furnished by Original Medicare. In reviewing whether this classification 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.

An item or service that meets the above three conditions may be called a supplemental benefit. CMS accepts a plan's benefit package by approving its submitted bid. However, CMS does not automatically approve all benefit packages. Additional requirements governing approval of a benefit package are provided in sections 30.2, 30.3 and 40 of this chapter. The final determination of benefit status is made by CMS during the annual benefit package review. Therefore, it is the MAO's responsibility to provide adequate documentation to support its proposed benefit design.

In limited circumstances and for a limited short duration, an item or service that is normally classified as cosmetic, for-comfort or for-maintenance may, in a specific context, be classified as a health benefit provided the provision of the item or service is:

- Based on an underlying illness or hospital stay;
- Consistent with the normal pattern of delivery of care for this illness; and
- Provided for a limited and short duration, typically two weeks or less.

Supplemental benefits may be provided by doctors, naturopaths, acupuncturists and chiropractors that are state licensed. Supplemental benefits may not be provided by licensed massage therapists (LMT), since as explained in section 30.3, an MAO may not offer a massage benefit.However an MAO may offer a "chiropractor visit" as a benefit even though the chiropractor uses preparatory massages during the visit. Similarly, MAOs may cover as a supplemental benefit provider

referred LMT visits, if medical necessity, not covered by Original Medicare, is present.

Original Medicare does not provide payment to non-Medicare beneficiaries, except in rare circumstances such as (1) living donors of kidney transplants and (2) respite care provided to family members for an Original Medicare enrollee in a hospice. Consequently, an MA plan may not make payments on behalf of non-enrollees, including family members, except in those circumstances when Original Medicare so provides. An MA plan may not provide payments to non-enrollees for supplemental benefits except for providing transportation and lodging for a transplant for the specific situation provided in section 30.4. In particular, an MA plan may not extend Original Medicare benefits to non-enrollees; for example, it is prohibited to provide payments for other living-donor expenses in the case of a kidney transplant.

The examples and analyses below should clarify the definitions of benefit presented in this section and are offered in an attempt to prevent misapplication of the concepts:

Example 1a: An MAO wishes to provide a benefit of one delivered meal per day during the month of December. It asserts that its goal is to minimize the possibility of injuries due to falls during the winter months when it is more difficult for elderly and disabled people to go out and shop. It further contends that lack of one meal per day would eventually lead to illness, which the delivery of meals would prevent. Finally, the plan points out that many of its enrollees have poor muscle tone, as measured by tests administered in their physician offices, and therefore the enrollees would have difficulty carrying groceries.

Poor muscle tone is not an illness. Even if it were, delivery of meals is not a community pattern of care for poor muscle tone. There is not sufficient justification – such as the presence of illness – to justify offering the meals as a benefit. Without the presence of an underlying illness, meals are a maintenance item and hence cannot be offered as a benefit. The MAO's goals - to prevent injury and illness –are not sufficient justification to offer the meals as a benefit.

Example 1b: An MAO wishes to offer meals immediately post-surgery or post-hospitalization for up to a four week period.

The item or service may be classified as a benefit. Here, the nutritional service is consistent with the normal pattern of delivery of care for post-surgery or post-hospital, and consequently, the nutritional service may be classified as primarily health related. The underlying illness, the normal pattern of delivery of care, and the limited duration of provision of meals justifies the re-classification of the nutritional service as primarily health related as opposed to maintenance (See section 30.5 for further requirements on a non-standard meal benefit).

Example 1c: An MAO, upon physician approval and request, wishes to offer a four week supply of meals to counteract the exacerbation of a chronic illness with debilitation (i.e., ulcerative colitis or Crohn's disease with weight loss and diminished nutrition) or for an acute incident (i.e., pneumonia with weight loss and decompensation).

The item or service may be classified as a benefit even if no hospitalization took place. In this example the illness and unusual weight loss could justify the meals as a normal pattern of delivery of care. Note that without the excessive weight loss, diminished nutrition, or

decompensation, there would be no justification to classify the item or service as a benefit. Also note that physician approval is required; social worker or case worker approval is not sufficient.

Example 2a: An MAO wishes to offer maid service to enrollees with sudden medical requirements that prevent them from performing household chores. The medical requirements are consistent with criteria listed in the Home Health Manual.

The item or service may not be offered as a Part C supplemental benefit. In fact, a home health aide, covered by Part B, may sometimes perform the house chores when there is time after other covered services are completed. Consequently, all plans must cover home health aides as an Original Medicare Part B benefit. Furthermore, the plan may not engage in misleading advertising since the benefit is not unique to Part C, and is only offered under specific medical conditions and when time permits. Additionally, the plan may not extend the Part B benefit beyond what is provided in the Home Health Manual.

Example 2b: A plan wishes to offer maid service to its enrollees. The plan asserts that its enrollees score poorly on standard muscle tone tests administered in a physician's office. The plan further contends that without the maid service there is a real possibility of either injury due to a fall or injury while cleaning precipitated by overuse of infrequently used muscles. The plan points out that its goals are to prevent future expected injury.

The item or service is neither a benefit under Part B nor Part C. Poor scoring for muscle tone is not an illness. Furthermore, maid service is not a community pattern of care for poor muscle tone. Note especially that the plan's goal to prevent a future reasonably expected injury does not justify classifying the maid service as a benefit. The primary purpose of maid service as determined by typical usage of most people is convenience, and convenience is not a justification for benefit status. The stated goal of prevention of a reasonably expected injury only applies to a small number of people without an underlying illness.

Example 2c: A plan wishes to offer shower safety bars to all enrollees.

The safety bars may be offered as a benefit because the sole purpose for anyone - whether healthy, sick, young, or old - using a safety bar is the prevention of an injury due to a fall. Since the sole purpose of the item is prevention of injury, it may be offered as a benefit.

For further examples, see Table II in section 30.3. We encourage plans who have thoroughly reviewed the examples above as well as Table II in section 30.3, to inquire with CMS on new proposed benefit designs by emailing the MA benefits mailbox at "CMS MA_Benefits@cms.hhs.gov".

30.2 - Anti-Discrimination and Anti-Steerage Requirements (Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

CMS reviews and approves MA benefit packages using statutes, regulations, policy guidelines and requirements in this manual, and other CMS instructions to ensure that:

- An MAO provides Medicare-covered services that meet CMS guidelines under Original Medicare;

- An MAO does not offer a cost sharing structure or benefits in plans that:
    - Discriminate against beneficiaries;
    - Promote discrimination;
    - Discourage enrollment;
    - Encourage disenrollment;
    - Steer specific subsets of Medicare beneficiaries to particular MA plans (with the exception of SNPs);
    - Inhibit access to services; or
    - Design cost sharing differentials in such a way as to unduly limit choice by or availability to the beneficiary (for example, an MAO 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.

Section 50.1 of this chapter contains general guidance on proper cost-sharing. Further detailed guidance is provided in the CMS annual Call Letter.

30.3 Examples

The two previous sections – 30.1 and 30.2 - outline the general theory of supplemental benefits. Many supplemental benefits – for example, vision, hearing, and dental – are standard, well known, and presented in the widely circulated Medicare & You Handbook. Table III provided below contains an alphabetized list of less well-known benefits. These examples have generally arisen from plan inquiries. Each example is classified as being, or not being, a potential supplemental benefit; Table III also provides an explanation of the classification based on the guidance provided in sections 30.1 and 30.2. The list of examples in Table III are intended to be illustrative, not exhaustive. Table III complements Table IV, provided in section 40.9, explaining which over-the-counter (OTC) items are offerable as benefits.

Table III: Alphabetical list of items and their potential supplemental benefit status

Item / Service	Supplemental Benefit?	Exception	Reason / Justification/ Comment
Assisted Daily Living (ADL) assistance	No		Its primary purpose is maintenance.
Batteries	No - if it comes by itself (e.g.,replacement batteries for hearing aids).	Yes - if it is factory-packaged with a benefit item – for example,	The primary purpose of a battery is to provide electrical current, not to cure hearing loss. (The goal and a secondary effect of battery

Item / Service	Supplemental Benefit?	Exception	Reason / Justification/ Comment
		batteries in an original package from the factory with a hearing aid.	usage are curing a hearing loss; however, benefit status is determined by primary purpose, not by goals or secondary effects.) This example applies generally to add-ons.
Beauty Salons	No		Its primary purpose is cosmetic.
Cash	No		Statutory prohibition.
Contact Lens Cases	No – if offered separately.	Yes, if factory packaged with the contact lens.	See the explanation above under "batteries."
Dentures	Yes		Its primary purpose is to address symptoms of lack of teeth.
Dance classes	No	If offered by a gym	Dance classes, for example dance classes offered in a gym, may be offered as a benefit when their primary purpose in the given setting is preventive exercise.
Educational Materials	Yes – if the subject of the teaching is itself eligible to be a benefit.	No – if the subject of the teaching – for example, nutritious meals – is not eligible to be a benefit.	Educational pamphlets on gym exercises, Tai chi, etc. are allowed as benefits, since these items – gyms and Tai chi – can themselves be allowed as benefits. Educational materials on nutritious meal planning are not a benefit, since meals may generally not be offered as a benefit.
Electronic Monitoring (Notification devices in case of a fall)[1]	Yes	Cell phones	The primary / sole purpose of electronic monitoring devices is to prevent or cure injury; however the primary purpose of cell phones is communication.
Homemaker services (including maid service) [2]	No		The primary purpose is assistance in maintenance.[3]
Gym benefit	Yes		The primary purpose of a gym benefit is prevention through exercise.
Manicures / Pedicures	No		The primary purpose is

Item / Service	Supplemental Benefit?	Exception	Reason / Justification/ Comment
			cosmetic.
Massages	No	Chiropractor Visits may be covered (even if preparatory massages are used). Similarly, a provider referred LMT visit is covered if medical necessity is present.	Massages, by themselves (without a provider referral based on medical necessity), are not benefits (even if offered by a state licensed massage therapist).
Meals	No	See sections 30.1 and 30.5 for exceptions.	The primary purpose of meals is maintenance. See sections 30.1 and 30.5 for further elaboration.
Shower safety bars and other bathroom safety devices	Yes	Smoke detectors, fire alarms, fire extinguishers, smoke detectors, home assessment, home repair services such as repair of rugs and stairway rails	Falls in a shower are reasonably expected and hence shower safety bars and grab bars in the bathroom are allowed as benefits. However CMS is not allowing fire extinguishers and smoke detectors as benefits since the injuries they are preventing are more indirect and significantly less expected.
Tai chi	Yes		Although Tai chi is technically a martial art, as practiced today, Tai chi, whether offered in, or outside a gym, has a primary purpose of exercise.
Medically necessary transportation[4]	Yes	Monthly bus or train passes	The primary purpose of medically necessary transportation (to and from medical appointments) is to treat disease. However the primary purpose of a monthly bus pass is convenience. The plan goal and intention that the monthly pass be used for

Item / Service	Supplemental Benefit?	Exception	Reason / Justification/ Comment
			medical purposes does not justify classifying the monthly bus pass as a benefit.

Notes to table III:

1. Original Medicare covers certain electronic monitoring. The service / item in the table refers to additional electronic monitoring not covered by Original Medicare.

2. 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. In specific circumstances described in the Home Health Manual, Original Medicare Part B covers home health aides. Under extremely limited circumstances, a home health aide who has performed his/her duties and has extra time may help out in the performance of household chores. Consequently, (i) the home health aide may not be offered as a Part C supplemental benefit; (ii) an MAO may not offer extensions of the home health benefit as a Part C supplemental benefit since the exclusion, from the home health manual, of the criteria justifying the extension of the home health benefit indicates that the extension is not medically necessary.

3. Here, primary purpose is measured by the typical usage of most people: most people employ maid service for purposes of convenience.

4. See section 30.4 for a full discussion on transportation benefits.

30.4 - 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**:** The MA plan must cover transportation in those circumstances that Original Medicare covers transportation. For example, ambulance transportation in a medical emergency is a covered service because 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 – see section 20.1.)

Not covered by Original Medicare**:** An MA plan may create either a mandatory or optional supplemental transportation benefit. 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 MA plan can provide this transportation as a supplemental benefit. If the MAO covers transportation as a supplemental benefit it must be priced in the bid and advertised in appropriate plan disclosure statements.

Mandatory MA Coverage**:** An MA plan must provide all Original Medicare services 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.

When an MA plan offers required transplant services and transplant centers are available to provide the service consistent with patterns of care for Original Medicare beneficiaries who reside in the same area, 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.

30.5 – Meals

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

As discussed in section 30.1, all benefits must be primarily health related. 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 need based on an actual illness, cannot be classified as a health care benefit, because it is not primarily health-care related in nature

However, as mentioned in section 30.1, in specific non-standard situations, meals may be offered as a supplemental benefit provided the nutritional service is:

1) Based on an underlying illness,

2) Consistent with the normal pattern of delivery of care for this illness - requiring either home delivery of meals, a special diet, or special diet foods, and

3) Offered for a short duration.

Below we provide examples of specific illness situations for which meal benefits may be offered as well as the meaning of the term “short duration.”

Non-standard meal benefits may be used to address the following two types of illnesses.

- For a traumatic illness – For example, immediately following surgery, immediately following an inpatient hospital stay, immediately following exacerbation of a chronic illness with debilitation (i.e., ulcerative colitis or Crohn’s disease with weight loss) or immediately following an acute incident (e.g., pneumonia with weight loss and decompensation).

  For a traumatic illness meals may be offered for a temporary duration, typically a two-week or four-week period provided they are recommended by a provider (not a social or case worker). As discussed in 42 CFR 422.112(b), after this temporary duration the

provider should refer the enrollee to community and social services for further meals if needed.

If an MAO chooses to offer meals for a traumatic illness for four weeks or less CMS will grant latitude to the proposed benefit and not further scrutinize it. However if the MAO proposes to offer meals for more than four weeks, CMS will more closely scrutinize the proposed benefit and request justification.

- For a chronic condition - For example, hypertension, high cholesterol, or diabetes. For a chronic condition meals may be offered, but only if they are:

    - Offered for temporary period, typically for two weeks.

    - Recommended by a provider (not a social or case worker); and

    - Part of a supervised program designed to transition the enrollee to life style modifications.

  If an MAO chooses to offer meals for a chronic condition for two weeks or less (and the other conditions listed above are fulfilled then) CMS will grant latitude to the proposed benefit and not further scrutinize it. However if the MAO proposes to offer meals for more than two weeks, CMS will more closely scrutinize the proposed benefit and request justification.

Social factors by themselves cannot justify classification of a nutritional service as an MA benefit. Social factors include:

- Limited income,
- An inability to pick up meals,
- Poverty,
- Dual eligible status,
- Poor diet – even if measured by recognized survey instruments, or
- General statements by a provider that improved nutrition would result in better health status.

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)). Therefore, CMS encourages plans to:

- Provide links to websites with nutritious diet planning information, such as MyPyramid.gov;

- Provide nutritional tips in their plan newsletters or on their plan websites; or

- Partner with social community services such as “Meals on Wheels”.

However, the MA plan may not classify any of these items or services as benefits Additionally, an MA plan offering a legitimate non-standard benefit of meals, that has been accepted in a priced bid, may not, for example, call the benefit a “Meals of Wheels” benefit or use the term “Meals on Wheels” in the name of the benefit. This prohibition, of using the “Meals on Wheels” terminology in marketing material applies even when the physical delivery of the accepted, non-standard, meal benefit is done by “Meals on Wheels.”

30.6 - Medical Supplies Associated with the Delivery of Insulin
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Medical supplies associated with the delivery of insulin -- including syringes, needles, alcohol swabs, and gauze – and that are not otherwise covered under Part B are covered under Part D. MAOs offering these supplies as benefits may not offer them as either an Original Medicare or supplemental benefit, but rather must offer them as a Part D benefit. An MAO cannot offer medical supplies associated with the delivery of insulin as a Part C over-the-counter (OTC) benefit. (See section 40 of this chapter for further guidance on OTC benefits).

30.7 – Part D Vaccine Administration
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Since January 1, 2008, the Part D program covers vaccine administration costs associated with Part D vaccines. For more information about Part D vaccine administration costs, refer to section 10.14 of Chapter 6 of the Prescription Drug Benefit Manual.

30.8 Supplemental Benefits Extending Original Medicare Benefits

In designing supplemental benefits that resemble Original Medicare benefits, four important principles must be observed:

- Medical Necessity: All MAOs must cover all medically necessary Original Medicare benefits (section 10.2). When medical necessity is present an MAO may offer additional coverage, beyond that furnished by Original Medicare, as a supplemental benefit. For example, an MAO may offer additional inpatient hospital days as an Original Medicare benefit. All Original Medicare manuals may be found in the Internet-only and Paper-based Manual links located at http://www.cms.hhs.gov/Manuals/

- Distinct Naming**:** An MAO should be careful in the selection of terminology describing a supplemental benefit that furnishes coverage beyond that of Original Medicare. For example, an MAO offering additional inpatient hospital coverage as a supplemental benefit should preferably refer to this benefit as “extended inpatient hospital coverage”, “additional inpatient hospital stays” or similar terms.

- Enrollee services**:** An MAO may never offer as a benefit services furnished to a person other than the enrollee (unless Original Medicare specifically allows such services, for example, Original Medicare coverage of a living donor for medical complications arising from a kidney transplant).

- Marketing Requirements**:** An MAO, in its PBP description of Original Medicare benefits, should not single out specific aspects of the benefit. For example it suffices for an MAO to state that it offers “ESRD services”; it need not further mention that “living donor expenses” are covered since “ESRD services” specifically includes “living donor expenses” and it would be misleading from a marketing perspective to single out one aspect of the benefit.

The following five examples illustrate applications of the above principles.

- Example 1 - Nutritional Benefits**:** Original Medicare offers, upon a doctors’ recommendation, nutrition therapy to diabetics and people with End Stage Renal disease. An MAO offering a legitimate non-standard supplemental meal benefit (section 30.1) should preferably avoid calling this benefit a "nutrition therapy benefit" since this term refers to an Original Medicare benefit. An MAO may not offer as a supplemental benefit a nutrition therapy benefit that does not meet the criteria in section 30.5.

- Example 2 - Caregiver / Respite: Original Medicare offers respite hospice care. Under this benefit an enrollee is covered for hospice care while the caregiver is given respite. CMS has allowed, as a supplemental benefit, caregivers who provide extra watching of patients in SNFs provided the patient is diagnosed as having erratic behavior. Besides this exception, an MA plan may not offer as a supplemental benefit other types of caregiver or respite care (whether to SNF enrollees or non-SNF enrollees). However, an MAO may, and is even encouraged, to advise, in plan newsletters, of services to assist caregivers in obtaining relief provided the plan does not refer to these services as benefits. Also, benefits may only be furnished to enrollees not to their relatives. Legal advice services may never be offered as a benefit.

- Example 3 - Living Donor coverage**:** As indicated above, Original Medicare covers services related to the kidney transplant for the living donor of an ESRD patient. The MAO may not offer as supplemental benefits extension of these services beyond those of Original Medicare since the MAO may only furnish supplemental services to the enrollee, not to enrollee relatives. The MAO may offer in the PBP "ESRD services" but it may not specifically mention "living donor coverage," as this is already included in the Original Medicare benefit, and separately identifying it could imply that it is a supplemental benefit.

- Example 4 - Massage Therapy: Under specific and limited circumstances, for certain injuries, Original Medicare will cover massages as part of an occupational therapy benefit. While an MAO must offer "Occupational Therapy," it should not in its marketing materials single out any particular aspect of this coverage, such as massage therapy and indicate that it offers “massage therapy” as a benefit. An MAO may, however, offer “chiropractic visits” as a benefit, for example, even though the chiropractor may use preparatory massage therapy during the visit. However, the description of the benefit

should be “chiropractic visits” without use of the word “massage.” Similarly, MAOs may cover as a supplemental benefit provider referred LMT visits, if medical necessity, not covered by Original Medicare, is present.

- Example 5 - Home Health Aides / Maid service: All MA plans offered by an MAO must include the Original Medicare benefit of home health aides when appropriate criteria apply. An MA plan generally may not include as a supplemental benefit services specifically excluded by the home health manual because they lack medical necessity. For example, while under extremely limited circumstances, a home health aide who has performed his/her duties and has extra time may help out in the performance of household chores, an MA plan may not offer additional housekeeper help beyond that covered by Original Medicare as such services effectively have been determined by Medicare to not meet the test of being primarily medical benefits. Similarly an MA plan may not offer assistance in daily living activities as a benefit beyond that assistance explicitly covered in the Home Health Manual.

30.9 Benefits During Disasters and Catastrophic Events

If, in addition to a Presidential declaration of a disaster or emergency under the Stafford Act or National Emergencies Act, the Secretary of Health and Human Services declares a public health emergency under Section 319 of the Public Health Service Act, the Secretary of Health and Human Services has the right to exercise her waiver authority under Section 1135 of the Social Security Act. If the Secretary exercises her Section 1135 waiver authority, detailed guidance and requirements -- including timeframes associated with those requirements -- for MA plans will be posted on the HHS and CMS websites noted above.

In the event of a Presidential emergency declaration, a Presidential (major) disaster declaration, a declaration of emergency or disaster by a Governor, or an announcement of a public health emergency by the Secretary of Health and Human Services – but absent an 1135 waiver by the Secretary –MA plans are expected to:

1. Allow Part A/B and supplemental Part C plan benefits to be furnished at specified non-contracted facilities (note that Part A/B benefits must, per 42 CFR 422.204(b)(3), be furnished at Medicare certified facilities);

2. Waive in full, or in part, requirements for authorization or pre-notification;

3. Temporarily reduce plan approved cost sharing amounts;

4. Waive the 30-day notification requirement to enrollees provided all the changes (such as reduction of cost sharing and waiving authorization) benefit the enrollee.

Typically, the source that declared the disaster will clarify when the disaster or emergency is over. If, however, the disaster or emergency time frame has not been closed 30 days from the initial declaration, and if CMS has not indicated an end date to the disaster or emergency, plans should resume normal operations 30 days from the initial declaration.

CMS still reserves the right to assess each disaster or emergency on a case-by-case basis and issue further guidance supplementing or modifying the above guidance.

During emergencies or disasters in which the Secretary has invoked his authority under Section 1135, information about the waivers is posted on the Department of Health and Human Services (DHHS) website (http://www.dhhs.gov/). The CMS web site (http://www.cms.hhs.gov) also will provide detailed guidance for MA plans in the event of a disaster or emergency in which the Secretary's 1135 waiver authority is being exercised. During these disasters and emergencies, MA plans should check these web sites frequently.

If the President has declared a major disaster or the Secretary of DHHS has declared a public health emergency then MA plans must follow the guidance in Chapter 5 of the Prescription Drug Benefit Manual, Section 50.12, regarding refills of Part D medications. The Prescription Drug Benefit Manual may be found at http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage.

40 – Over-The-Counter (OTC) Benefits

40.1 Issues with Provision of an OTC Benefit

The MMA expanded the MA program and increased the availability of prescription drug benefits to enrollees. Along with the increased purchase of prescription drugs there emerged an interest in non-prescription OTC items. Many MAOs have developed innovative ways to offer OTC benefits. For example, whereas most MA benefits consist of single items or services, MAOs introduced the idea of a packaged OTC benefit. The packaged OTC benefit guarantees plan enrollees the right to purchase groups of OTC items whose aggregate cost falls below an annual or monthly cap. Additionally MA plans attempted to use new technologies such as the item-linked debit card. Consequently, the design of OTC benefits creates new challenges unique to MA benefits.

OTC items include both:

- Non-prescription drugs (such as Prilosec® and Claritin®), also known as OTC drugs; and

- Health-related items (such as bandages).

It is important to be aware that there are a variety of OTC items:

- Part C or D OTC Items: As indicated in section 40.2, certain OTC items, such as Claritin ®, may be offered as a Part C supplemental benefit, or, if the plan is providing a Part D benefit, as an OTC drug at zero cost to enrollees as part of a plan's Part D utilization management protocols;

- Exclusively Part C OTC Items: Other OTC items, such as bandages, may be offered only as a Part C supplemental benefit but may not be offered as part of the Part D utilization management protocols;

- Non-benefit OTC Items: There are also OTC items, for example, fans, which may not be offered as a benefit at all; and
- Part B/D OTC Items: While, in general, neither Part B nor Part D cover OTC items, certain regulatory exceptions exist where OTC items are covered under Part B or Part D.

This variety of OTC item types leads to a variety of methods and issues related to the offering of OTC items. When a plan wishes to offer OTC items, it must first address the following issues:

1. Part C or D: Will the plan offer the item under Part C or under Part D utilization management protocols at zero cost to their enrollees?

2. Access: Where (at what stores and chains) can plan enrollees obtain the item?

3. Specific items: Which OTC items are being offered?

4. Few or packaged: Is the plan offering a few specific OTC items or a packaged group of OTC items?

5. Payment method: Which method will be used to pay for the item:

    - By receipt: Will enrollees first purchase the item and then be reimbursed upon submitting receipts;

    - By catalog: Will enrollees receive a catalog allowing them to send in a check and a list of items to be mailed to them; and /or

    - By debit card: Will enrollees have a specially produced debit card, whose characteristics are described below, which allows direct purchase of OTC items in pharmacies?

6. Part B/D Conflicts: Certain OTC items, in certain circumstances, are covered by Part B or Part D. However money allocated for a Part C supplemental benefit may not be used to cover Part B or Part D benefits. Consequently guidance must be provided to avoid these conflicts.

7. Marketing Issues: There are a variety of marketing disclosures that must be made when a plan offers a packaged Part C OTC benefit.

In addition to addressing issues about the OTC benefit itself, the plan must address the following issues about communications about the benefit:

- PBP: What information will the plan include in the bid and PBP (Note: This information affects what is displayed on Medicare Options Compare and the Summary of Benefits (SB)); and

- Enrollee communication: What additional information, if any, must the plan communicate to its enrollees, either on its plan website or through direct enrollee communications, about the OTC benefit.

Each of these issues will be addressed in the other subsections of section 40.

40.2 OTC Under Part C and Part D

OTC drugs may not be covered as benefits under Part D because they do not meet the definition of a Part D drug (see 42 CFR 423.100 and section 20.1 of Chapter 6 of the Prescription Drug Benefit Manual). However, CMS allows Part D sponsors the option of paying for OTC drugs and providing those OTC drugs at zero cost to their enrollees as part of their Part D utilization management protocols (refer to section 60.2 of Chapter 7 of the Prescription Drug Benefit Manual for more information). OTC drugs provided to Part D enrollees under a Part D sponsor's utilization management protocols would be paid for out of the administrative cost portion of its bid.

Health-related OTC items – with the exception of medical supplies associated with the delivery of insulin, (e.g., gauze and syringes) – cannot be covered as benefits under Part D, nor can they be paid for as part of a Part D sponsor's utilization management protocols.

An MAO that wishes to provide an OTC item to its enrollees:

- May offer the OTC item as a Part C supplemental benefit (mandatory or optional), or,

- If it offers Part D coverage, may offer the OTC item (provided it is an OTC drug) at zero cost to its enrollees as part of its Part D utilization management program. Such an offering must be consistent with the principles of utilization management as outlined in section 60.1 of Chapter 7 of the Prescription Drug Benefit Manual.

An MAO may use a combined approach, offering some OTC items as supplemental benefits under Part C and paying for others (provided they are OTC drugs), and providing them at zero cost to enrollees, under its Part D utilization management protocols. No individual OTC item may simultaneously be offered under both Parts C and 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, the provision of an OTC drug under a Part D sponsor's Part D utilization management protocols must be classified in the sponsor's Part D bid as an administrative cost.

Example: Suppose an MAO offering an MA-PD plan wishes to offer bandages, Prilosec® and Claritin® as benefits. The MAO could:

- Offer the bandages as a Part C supplemental benefit and offer the Prilosec® and Claritin® at zero cost to its enrollees under its Part D utilization management protocols;

- Offer the bandages and Claritin® as Part C supplemental benefits, but offer the Prilosec® at zero cost to its enrollees under its Part D utilization management protocols; or

- Offer the bandages and Prilosec® as Part C supplemental benefits, but offer the Claritin® at zero cost to its enrollees under its Part D utilization management protocols; or

- Offer all 3 items as a Part C supplemental benefit. In such a case the plan would be prohibited from offering any of these items at zero cost to its enrollees under its Part D utilization management protocol.

40.3 Access to OTC Benefits

The OTC items offered, whether a few or packaged, whether under Part C or Part D, and independent of payment method, must be available at a wide variety of both chains and stores. We especially emphasize that a plan may not offer a packaged Part C OTC benefit which is paid through a debit card that can be used at only one or two pharmacy chains, even if these chains have many individual stores. Rather, the benefit must be available at a variety of both stores and chains.

This variety of access in stores and chains applies both to the places where OTC items are purchased as well as to the payment method. For example, it is prohibited for a plan to provide OTC items at one or two pharmacy chains by debit card and at other pharmacy chains by catalog. In this example, although the OTC items are accessible at a wide variety of chains, the payment method by debit card is only available at a few chains and therefore this arrangement is not allowed. The plan must use a payment method that can be used at a wide variety of chains and stores.

40.4 Benefit Status

As indicated in the introduction to this section, not all OTC items may be offered as benefits. More specifically:

- If a plan is offering items under its Part D utilization management protocols then the items it may offer are discussed in section 60.2 of Chapter 7 of the Part D Prescription Drug Benefit Manual as described in section 40.2 above; and

- If the plan is offering a Part C OTC supplemental benefit consisting of either a few items or a packaged benefit, and independent of payment method, then the plan may only cover items belonging to the categories listed in the eligible and dual-purpose item sections of Table IV in section 40.9. This table was created based on the guidance in sections 30.1 and 30.3 which discussed the definition of benefit. Items belonging to categories not in this table may not be offered as a Part C supplemental benefit.

We emphasize that this table outlines categories of items rather than individual items. As a simple example, since cough medicines are listed as an eligible category of OTC items – that is, they may be offered as a benefit - therefore, if a plan chooses to offer cough medicines as a Part C OTC supplemental benefit - whether individually or as part of a packaged offering, and independent of payment method - then the plan may not choose to cover only specified items and brands. Once the plan chooses to cover cough medicines it must cover all particular cough medicines.

Table IV contains:

- Eligible OTC Items: Certain OTC items may always be offered;

- Non-Eligible OTC Items: Certain items may never be offered; and

- Dual Purpose OTC Items: Certain items may be offered after appropriate conversations with the enrollees personal provider who orally recommends the OTC item for a specific diagnosable condition.

Among the items that may be offered as benefits, only certain items are typically electronically linked to a debit card. In the remainder of this chapter we will use the phrases “admissible OTC item” or “permissible OTC item” to refer to an OTC item that is classified as either eligible or dual-purpose in the Table IV in section 40.9.

40.5 Specific or Packaged OTC Benefit

As indicated in section 40.2, a plan may chose to offer individual OTC items, either as a Part C supplemental benefit or, if appropriate as indicated in section 40.2, as part of their Part D utilization management protocols at zero cost to the enrollee. When offering individual items the plan commits itself to covering the item independent of cost.

However, a plan may also chose to offer a packaged Part C supplemental benefit. This means that the plan will allocate a fixed amount, typically, per month, which will cover enrollee purchases of any combination of permissible OTC items.

It is important to emphasize that when offering a packaged OTC benefit:

- The packaged OTC benefit may only be offered under Part C; it may not be offered under Part D. Furthermore, no particular category or particular item that is offered under Part C may be offered under Part D;

- The packaged OTC benefit must be submitted in the bid and PBP as “a packaged OTC benefit.” The plan does not enumerate specific items or categories in its June bid/PBP submission (The reason for this is explained below);

- The benefit consists of the right of the enrollee, to purchase admissible OTC items up to a certain cost per month. Consequently, the payment method is not an intrinsic part of the benefit and should not be listed in the bid/PBP; and

- After the bid has been accepted and information on Medicare Options Compare is up, the plan will send all enrollees notifications including:

    - A specific list of admissible categories that it will cover;

    - The payment methods by which it will cover the benefit; and

- Information (including information posted on a plan website) indicating which categories of items are covered, locations where the item can be purchased, and how the OTC item(s) may be purchased.

40.6 Payment Methods

There are three primary methods by which a plan may cover a packaged OTC Part C supplemental benefit. A plan wishing to use a payment method other than the three methods listed below must seek prior CMS approval.

(1) Direct Reimbursement - A plan can use a direct-reimbursement method under which the enrollee purchases approved items, sends in the receipts, and any further proofs of purchase. Subsequently, the enrollee is reimbursed by the plan.

A plan whose primary payment method for a packaged OTC Part C supplemental benefit is through a catalog or debit card must have a written process for filing occasional paper claims for reimbursement of purchased permissible OTC items (for example the purchase of bandages and bacterial ointments for cuts and bruises which require immediate attention).

(2) Catalogs - A plan may allow enrollees to order approved items from a catalog without payment. A catalog can consist of an actual paper catalog, a list on a website, or a simple order form, that is, a bound collection of sheets. Enrollees may place their orders either through a secure website, mail, or a toll-free number. The catalog must contain:

- A list of all permissible OTC categories of items (as listed in section 40.9) that can be obtained by the enrollee;

- Their price;

- Their status (eligible or dual-purpose) and

- Appropriately and clearly placed footnotes identifying items covered under Part B or Part D, as indicated below in section 40.7.

The plan is responsible for the cost of mailing. To protect the plan from excessive mailing costs the plan may impose a minimal purchasing amount per purchase. All this information should be clearly stated in the catalog.

As indicated above in this section, a plan that covers a packaged Part C OTC benefit by a catalog must additionally have a written policy indicating when it will honor requests for reimbursements through mailed in receipts.

A plan that offers a packaged supplemental Part C benefit that is paid using a website catalog method must allow all enrollees the right to obtain a hard copy of the catalog. Similarly, if the plan allows submission of orders through a secure website, then the plan must offer all enrollees the right to submit orders through a mail-in form or a toll-free

number.

(3) Debit Cards – MAOs may use debit cards for their OTC benefits. Debit cards must be prepaid by the MAO and supplied to the enrollee. The debit card must electronically limit the enrollee's purchases to admissible items. If however the debit card is electronically linked to items that are never admissible, it may not be used. CMS has imposed the following additional requirements on the use of debit cards for OTC benefits.

- Since the MA regulations prohibit an MAO from offering cash as a benefit (see 42 CFR 422.80(e)(i)), the MAO must clearly state that: a) the debit card is not a credit card; b) the debit card cannot be converted to cash or loaned to other people; and c) any unused allocated money reverts to the plan at the end of the appropriate period;

- As explained in section 30.2 above, steerage prohibitions require that plans may not use a debit card in a manner that would steer enrollees to particular stores or chains. Therefore, as indicated above in section 40.3, the debit card should be usable at a wide variety of stores and chains with product-linked debit technology;

- As indicated in section 40.9, typically, not all admissible items are electronically linked to debit cards. The plan has a variety of options to deal with items not electronically linked to debit cards:

    1. The plan may decide to only offer admissible items linked to debit cards. In such a case the plan must have a written process for filing paper claims for allowed OTC items purchased from stores without the product-linked debit technology or from stores where the product-linked debit technology failed or was unavailable;

    2. The plan may decide to offer those admissible items that are linked to debit cards through a debit card and offer other admissible items either through direct reimbursement or a catalog. In such a case the access requirements of section 40.3 must be met.

- The MAO must clearly state the rules relating to debit card balances rolling over from month to month; and

- Plans are responsible for ensuring that debit cards are usable only for admissible items.

40.7 Part B and D OTC Items

In general, neither Part B nor Part D cover OTC items. However, certain regulatory exceptions exist where OTC items are covered under Part B or Part D: For example, Part D sponsors must cover certain OTC medical supplies associated with the delivery of insulin, such as syringes and alcohol pads (consistent with the definition of a Part D drug at 42 CFR 423.100 and as detailed in section 10.5 of Chapter 6 of the Prescription Drug Benefit Manual). In addition, Part B covers

glucose meters and testing strips as durable medical equipment (refer to Section 110 of Chapter 15 of the Medicare Benefit Policy Manual located at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf).

Money allocated for a Part C supplemental benefit may not be used for an item also available under Part B or Part D. In other words, an MAO cannot offer the same OTC drug under both its Part C supplemental benefit and its Part D benefit utilization management protocols. Should an MAO elect to offer an OTC supplemental Part C benefit, it cannot include any of the Part C OTC drugs as part of its Part D drug utilization management protocols as outlined in Chapter 7, section 60.1 of the Medicare Prescription Drug Benefit Manual. Consequently, an MAO offering a Part C packaged OTC benefit must educate its members on the benefits to which they are entitled under Original Medicare coverage, Part B or Part D, as well as the associated cost-sharing. The MAO must specifically advise and instruct enrollees on those items covered under Part B or paid for under Part D utilization management protocols. If the MAO is using a catalog or website listing the OTC items, it must clearly footnote (or otherwise clearly indicate) all items covered under Part B or paid for under Part D utilization management protocols. Member materials must also explicitly identify all items covered under Part B or paid for under Part D utilization management protocols. The plan must explicitly advise enrollees that if an item is covered under Part B or paid for under Part D utilization management protocols, then they must purchase these items in the same way that they purchase other Part B or D items; however, enrollees may not purchase these items through the Part C supplemental OTC benefit.

40.8 Marketing Guidance

The following guidance applies specifically when a plan offers a supplemental, Part C, packaged, OTC benefit independent of payment method. Certain beneficiary protections must appear in plan marketing materials. Plan instructional materials must explicitly advise enrollees that:

- For enrollee, not family: The plan must notify enrollees that OTC items may only be purchased for the enrollee. Purchases for family members are not allowed;

- Oral discussion with provider: As indicated in section 40.4, certain OTC items, for example vitamins and minerals, are only allowed as a benefit after provider approval. CMS is not requiring written notes for non-prescription drugs. The emphasis in this requirement is on marketing disclosure to the enrollee who must be advised that s/he may only purchase the item(s) after appropriate conversations with the enrollees personal provider who orally recommends the OTC item for a specific diagnosable condition.

  The intent in this requirement is, for example, to prevent an enrollee from purchasing a blood pressure (BP) monitor without initial guidance from his/her provider. While BP monitoring is an important component of disease management, typically, provider measurements during office-visits suffice. We do not want an enrollee steered into continuously taking BP as this is medically unnecessary. Furthermore, the BP monitor by itself will not help the enrollee unless s/he is aware of the natural volatility of measurements and guided to understand what types of patterns should cause concern.

- Part B/D: As indicated in section 40.7, Part B items and, if applicable, Part D items may not be purchased via the Part C benefit but rather as Part B or, if applicable, Part D items. Appropriate guidance must be given to the enrollee.

Ensuring that the Part C OTC benefit functions in compliance with CMS guidelines is the responsibility of the MAO.

40.9 OTC Items

Table IV below presents a detailed list of items. The items are presented by category. The following principles will facilitate correct usage of the list:

- Categories vs. items: As indicated in section 40.4, Table IV below lists categories of items. MA plans should not steer enrollees to particular brands of items. For example, if a plan Part C OTC list includes headache medications such as Excedrin, it must allow all brands of headache medications;

- Enrollee vs. Family: The plan must explicitly notify enrollees in its plan materials that OTC items may only be purchased for the plan enrollee. The plan must instruct enrollees that it is prohibited to purchase OTC items for family members and friends. The plan is responsible to see that the Part C OTC benefit is properly used;

- Categories not on the list: Each plan must publish, on its plan website, or in catalogs or other marketing materials, the list of items that a plan enrollee may purchase. The plan list need not be identical with the list below however the plan list may not include as eligible, any items marked non-eligible. Should the plan wish to include on its own list categories of items not listed as eligible or dual purpose which are not found on the list below they must first obtain permission from CMS;

- Three eligibility categories: The list has three types of items. The type is listed in the first column:

    - The purchase of eligible items, if listed on the plan OTC list, are covered by the plan;

    - The plan OTC list must include non-eligible items. Enrollees must be instructed that non-eligible items, if purchased, will not be covered by the plan;

    - The purchase of dual Purpose items, if listed on the plan OTC list, are covered by the plan but the plan must, in their marketing materials, advise enrollees that prior to purchase the enrollee must have appropriate conversations with his/her personal provider who orally recommends the OTC item for a specific diagnosable condition. CMS does not require written recommendations. However, MAOs may require written recommendations for purchase of dual purpose or eligible items.

- Debit card linkages: If the plan provides a packaged Part C OTC benefit paid by a debit card then it should be aware of differences between its own plan Part C OTC list and the official list of items electronically linked to the debit card. The following three examples illustrate the situations that plans must formulate instructions for:

    - Dual Purpose: Many electronically linked cards may not allow purchase of dual-eligible items. Consequently the plan must explicitly provide instructions to

enrollees on how to purchase such dual-eligible items, for example vitamins and minerals;

- Acne / Sunscreen: Certain items – for example, acne treatment or sunscreen lotion– are classified as eligible on the CMS list, but are classified as dual-purpose or non-eligible on other lists listing the items linked to certain electronic debit cards. In this case (should the plan for example, wish to cover acne treatment or sunscreen lotion), the plan must notify the enrollee that acne treatment or sunscreen lotion may only be purchased through a catalog or direct reimbursement after a mail-in of receipts; and

- Baby Items: Many electronically linked cards allow purchase of baby items. The plan must explicitly notify enrollees of those categories of items which are prohibited, even if they are electronically linked to the plan debit card. As indicated in the last section, it is the plan's responsibility to ensure that the debit card is properly used.

Table IV: Eligibility status of OTC items.

Eligible?	Category	Sub-categories	Exceptions
Dual Purpose	Minerals	Includes both multi-vitamins, individual vitamins and minerals.	
Dual Purpose	Vitamins	Includes both multi-vitamins, individual vitamins and minerals.	
Dual Purpose	Items used to assist in weight loss		
Dual Purpose	Diagnostic Equipment	Equipment diagnosing: blood pressure, cholesterol, diabetes, colorectal screenings, HIV, etc.	Thermometers are eligible items not dual eligible; scales are non-eligible. Pregnancy diagnosis items are non-eligible.
Dual Purpose	Hormone replacement	Phytohormone, natural progesterone, DHEA	
Dual Purpose	Weight loss items	Phenermine, FucoThin, Alli, Hoodia	All OTC foods, such as protein shakes, even if heavily supplemented by nutrients, may not be offered as an OTC benefit
Eligible	Fiber supplements		Fiber supplements which are primarily food with fiber added.

Eligible?	Category	Sub-categories	Exceptions
Eligible	First Aid supplies	Includes: Bandages, dressings, non-sport tapes.	Flashlights are non-eligible.
Eligible	Incontinence supplies.		
Eligible	Medicines, ointments and sprays with active medical ingredients that cure, diminish or remove symptoms.	For examples see footnote #1.	Homeopathic and alternative medicines including botanicals, herbals, probiotics, vitamins minerals, and neutraceuticals are non-eligible. For further exceptions see footnote #2.
Eligible	Sunscreen lotion		
Eligible	Support items	Compression hosiery, rib belts, braces, orthopedic supports.	Arch and insoles are non-eligible.
Eligible	Teeth-releated items / Dentures / Mouth care	Toothbrushes, toothpaste, floss, denture adhesives, gum problems, thrush, mouth sores.	Mouthwashes, bad breath items, and teeth-whiteners are non-eligible.
Non-eligible	Alternative medicines	Includes botanicals, herbals, probiotics and neutraceuticals.	Vitamins and minerals are dual eligible.
Non-eligible	Baby items		
Non-eligible	Contraceptives		
Non-eligible	Convenience (non medical) items	Scales, fans, magnifying glasses, ear plugs, foot insoles, gloves.	
Non-eligible	Cosmetics	For examples see footnote #3.	Sun-tan lotions are eligible. Medicated soaps, hand sanitizers, therapeutic shampoos, shampoos to fight dandruff are non-eligible.
Non-eligible	Food Supplements	Sugar / salt supplements, energy bars, liquid energizers, protein bars, power drinks, ensure, glucema.	Vitamins and minerals are dual eligible. Probiotics are non-eligible. Fiber products are eligible unless they are primarily foods with fiber added.

Eligible?	Category	Sub-categories	Exceptions
Non-eligible	Replacement items, attachments, peripherals.	Includes: Hearing aid batteries, contact-lens' containers, etc. when not factory packaged with original item.	

Notes to Table IV:

1. Each item in the following alphabeticized list is either a medicine, ointment or spray, or a condition which is addressed by a medicine, ointment or spray: acid , acne, allergy, analgesics (which reduce pain, inflammation), anti-arthritics, antibiotics, antiradicals, anti-diarrheas, anti-fungals,anti-gas,anti-histamines, anti-inflammatory, anti-insect, anti-itch, anti-parasitic, antiseptics, antipyretics(fever reducing), arthritis, asthma, blood clotting, bruises, burns, calluses, corns, colds, cold sores, cough, diabetes, flu, decongestants, dermatitis, eczema, digestive aids, ear drops, expectorants (mucus), eye drops, gastro-intestinal, hay fever, headaches, hemorrhoidal, incontinence, influenza, laxatives, (medicated) lactose intolerance products, lice, (medicated) lip products, menopausal, menstrual, sinus, motion sickness, nasal, osteoporosis, pain, psoriasis, pediculicide, rash, respitory, scars, sleep, smoking, snoring, sore throat, stomach, travel sickness, steroids, sunscreen, thrush, wart, worms, wounds, etc.

2. The following are not eligible: Baby medicines, contraceptives, dairy care (because it is non-medicated), dehydration drink, dry skin lotions (e.g. eucerin, aquaphor), hair-loss products, lactaid milk (because it is a food not a medicine), and shampoos to fight dandruff. Certain smoking cessation may be Part B. Certain diabetic supplies may be Part B or Part D. For the status of food supplements see Table IV.

3. Chap stick, deodorants, facial cleansers, feminine products, grooming devices, hair conditioners, hair removal, hair bleaches, moisturizers, perfumes, perspirants, shampoos, shaving and men's grooming, and soaps.

50 – Cost Sharing and Deductible Guidance

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

50.1 Guidance on Acceptable Cost-Sharing

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

As indicated in section 30.2, 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 against enrollees based on health status. CMS will closely scrutinize the cost-sharing and deductible structures of all plans.

Each year, CMS' Office of the Actuary establishes an appropriate level for a cap on aggregate out-of-pocket expenses for Original Medicare covered services, excluding the basic monthly premium. This amount is announced in the annual Call Letter. This target amount applies, in the

manner indicated below, to coordinated care plans, including regional MA plans. MA Plans with 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 cost sharing:

- For MA plans at or below the recommended maximum level: These plans will be granted latitude in establishing cost-sharing amounts for individual items or services, subject to scrutiny for particular services as discussed below;
- For MA plans above the recommended maximum level: These plans will be granted less latitude in establishing cost-sharing amounts for individual items or services, and the cost sharing under these plans will be subject to scrutiny;
- Specific services to be closely scrutinized: Each bid season CMS, based on the distribution of data, uniformly scrutinizes the distribution of cost sharing on several particular service categories. Additionally, independent of the aggregate cost-sharing level of the plan, CMS closely scrutinizes 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, cost-sharing above the recommended maximum. These are services that are typically used by Medicare beneficiaries in poorer health and consequently, high cost sharing for these services has the potential to be discriminatory:
    - Dialysis;
    - Part B, including chemotherapy, drugs;
    - Inpatient acute/psych stays;
    - Inpatient SNF stays;
    - Home health services; and
    - DME and supplies.

  Each year, as appropriate, and based on submitted bid data, additional high-cost sharing service categories may be added to this list of closely scrutinized services, and announced in the Call Letter.
- With acceptable justification, CMS may accept plans with member out-of-pocket caps above the above target level, or with no out of pocket caps, 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 required for MA MSA plans, for example. 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-payment amounts and coinsurance percentages. Although the Medicare program allows cost-sharing to take the form of either co-payments or coinsurance, MAOs should keep in mind when designing their cost-sharing that enrollees generally find absolute co-payment amounts less confusing then coinsurance;

- Part B drugs covered under Original Medicare: No dollar limits can be placed on the provision of drugs covered under Original Medicare unless the Medicare statute imposes the limit on Original Medicare coverage, or it is specified in a national or applicable local

coverage determination. (See section 80.2 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;

- Out-of-network medically necessary dialysis: The cost-sharing for out-of-network medically necessary dialysis cannot exceed the cost-sharing for in-network medically necessary dialysis; and

- MA Regional PPO Plans (RPPO): Detailed guidance on deductibles for RPPOs is provided in the next section 50.2 of this chapter. In addition to the one-deductible requirement described in section 50.2 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. RPPOs must also provide for a total catastrophic limit on beneficiary expenditures for in-network and out-of-network benefits under Original Medicare.

- Original Medicare Cost-Sharing Caps: CMS has determined that in order for a services to be considered to be covered, cost-sharing for that service cannot exceed 50% of the total MA plan financial liability for this benefit.

- RPPO Cost Sharing: Special rules apply to RPPOs. 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, an 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' satisfaction that there is adequate access to 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 the RPPO, upon the inclusion of additional contracted network providers, 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 110.3 of this chapter for the enrollees in the affected parts of its service area.

50.2 - Cost-sharing Rules for RPPOs

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

In addition to the requirements listed in section 50.1, RPPOs must provide for the following:

(1) 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.

- Exempt the deductible for specific items or services - that is, the RPPO may choose 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 examples below illustrate the policies described above.

- 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 inpatient hospital services to $500, and the amount that will apply to in-network physician services to $100. It also exempts 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 (Inpatient hospital and physician services);
- Does not differentiate the single deductible for out-of-network services; and
- Exempts preventive and home-health services from the deductible.

- 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 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 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: An RPPO may not have a single deductible of $3,000 with a $1,000 cap on Part A services (in- and out-of network) 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 may have a single deductible of $3,000 with a $1,000 cap on specific in-network Part A services because the RPPO meets its requirement of a single deductible and differentiated for specific in-network services without affecting out-of-network services.

  Additionally, 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.

(2) In-Network catastrophic limit: RPPOs are required to provide a catastrophic limit on beneficiary out-of-pocket expenditures for Original Medicare in-network benefits;

(3) Total catastrophic limit: RPPOs 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.

The examples below illustrate the policy above:

- Example 1: 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

- Example 2: 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.

(4) Tracking of deductible and catastrophic limits and notification: RPPOs are required to:

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

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

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

60 - Value-Added Items and Services (VAIS)

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

60.1 Definition

Value-Added Items and Services (VAIS) are non-benefit items and services provided to an organization's enrollees by an organization that meet the definition of VAIS provided below. VAIS may not be funded by Medicare program dollars. However, VAIS may be of value to some beneficiaries, and 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 any cost 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). Note that this definition does not require that VAIS be health-related.

60.2 Examples of VAIS

Example 1: An MA plan offers an in-network vision-exam benefit (for which it incurs a direct medical cost). The MA plan also offers a 5% discount on a vision-exam out of network. Enrollees are instructed to pay for the vision-exam out-of-network and receive a 5% discount. The discount is covered by the vision-exam center to broaden its market. Consequently, the MA plan does not incur a direct medical cost as a result of this discount. The MA 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 vision exam out-of-network, the discount may not be classified as a benefit. The plan may offer the discount on out-of-network vision exams as a VAIS. However, since the out-of-network vision exam is not a benefit it may not be advertised on the Medicare Options Compare site nor mentioned in the PBP. Other restrictions on advertising apply.

A similar analysis would apply if the plan offered a vision-exam benefit and the Center providing the vision-exam provided a 10% discount on glasses purchased by those enrollees obtaining vision exams. The discount on glasses is a VAIS, not a benefit; it may not be advertised on the Medicare Options Compare site nor mentioned in the PBP.

Example 2: An MA 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 the MA plan is paying for vouchers even if the cost is minimal.

60.3 Further Requirements

The fact that a VAIS is not a benefit is a consequence of the definition given above. 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 package design; and
- May not appear in the PBP, SB ANOC or the EOC. (MAOs 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, and 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, see http://www.hhs.gov/ocr/hipaa/. In particular, an MAO may not directly contact Medicare beneficiaries if a VAIS item or service is not directly health related. This prohibition on contact includes the prohibition on 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; and
- Comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries.

70 - Information on Advance Directives
(Rev. 23, 06-06-03)

70.1 - 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.

70.2 - Basic Rule
(Rev. 23, 06-06-03)

The MAO 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 MAO 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 MAO 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 MAO are outlined below in section 70.4.

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

The MA program's advance directive requirements, which Original Medicare 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, MAOs must comply with the advance directive requirements of the states in which they provide services. CMS cannot provide detailed guidelines as to what constitutes best efforts in each State. Medicare regulations give MAOs and states a great deal of flexibility, and CMS will work with the MAO (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 MAOs 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.

70.4 - 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 MAO'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 MAO is required to comply with State law (See section 70.3 for details);

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

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

If the MAO 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.

70.5 - 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 MAO may give advance directive information to the enrollee's family or surrogate. The MAO is not relieved of its obligation to provide this information to the enrollee once s/he is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given directly to the individual at the appropriate time.

70.6 - Community Education Requirements
(Rev. 23, 06-06-03)

The MAO 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 MAO 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 MAO must be able to document its community education efforts.

70.7 - MAO Rights
(Rev. 23, 06-06-03)

The MAO is not required to provide care that conflicts with an advance directive. The MAO is not required to implement an advance directive if, as a matter of conscience, the MAO cannot implement an advance directive and State law allows any health care provider or any agent of the provider to conscientiously object.

70.8 - Appeal and Anti-Discrimination Rights
(Rev. 23, 06-06-03)

An MAO 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 MAO must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State Survey and Certification Agency.

80 - National and Local Coverage Determinations
(Rev. 23, 06-06-03)

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

As discussed in section 10.4 of this chapter, an item or service is classified as an Original Medicare benefit and, consequently, must be covered by every MA plan if:

- Its coverage is consistent with general coverage guidelines included in Original Medicare manuals and instructions (unless superseded by written CMS instructions or regulations regarding Part C of the Medicare program);

- It is covered by CMS' national coverage determinations (see section 70.3 and 70.4, below); or
- It is covered by 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 in section 80.2.

80.2 - Local Coverage Determinations:
(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

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 and regional MA plans may cover in each county according to what the MACs covers for Original Medicare 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)). In preparing this notification plans should at a minimum include:

1. An identification of the plan(s) and service area(s) to which the uniform local coverage policy or policies will apply;
2. The competing local coverage policies involved;
3. A table contrasting the local coverage areas by listing and comparing those policies in each coverage area that represent expansions of Medicare Part A and Part B services;
4. A justification explaining why the selected local coverage policy or policies is most beneficial to MA enrollees. The justification should be presented so that CMS is independently able to identify which of the coverage areas on balance furnishes the most generous Part A and Part -B coverage policies; and

- Must obtain CMS pre-approval of the uniform coverage policy. CMS will consider a local plan to have met the "most beneficial" requirement if the MAO offering the local plan elects to adopt:

  The coverage policies of one MAC 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

  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 MAO must comply with the notification requirements as indicated above.

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

- CMS reserves the right to review the determination of any uniform coverage policy;

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

- 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, MAOs 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 based on the local coverage determinations of that area.

80.3 – Definitions Related to National Coverage Determinations (NCD)
(Rev. 72, Issued: 09-30-05, Effective Date:09-30-05)

The contents of this section are governed by regulations set forth at 42 CFR 422.109. The following definitions related to national coverage determinations apply:

- 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:

  1) The average cost of furnishing a single service exceeds a cost threshold that 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

  2) 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.

80.4 - General Rules For NCDs
(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. NCDs made by CMS;

2. Local Coverage Determinations (LCDs);

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

4. Legislative changes in benefits.

As indicated in section 10.2, MAOs must provide all items and services classified as Original Medicare-covered benefits. In applying this rule to NCDs different rules apply depending on whether the significant cost criterion has been met. If it has been met different rules apply depending on whether the annual MA capitation rate has been adjusted. The rules for providing NCDs are as follows:

- 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 section 80.3 above, then the MAO 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:

        1. 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

        2. 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.

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

      The MACs are responsible for reimbursements for NCD services or legislative changes that are not the legal obligation of the MAO.

      Chapter 8 of this manual, "Payments to Medicare Advantage 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 MAOs 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.

    - After adjustment of the annual MA capitation rate, or other payment adjustment reflecting the new costs, 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 MAO's contract with CMS and is a covered benefit under the contract. Subject to all applicable rules under the MA program, the MAO must furnish, arrange, or pay for the NCD service or legislative change in benefits. MAOs 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, that is, if CMS determines that an NCD or legislative change in benefits does not meet a criterion for significant cost described in section 80.3 above, the MAO 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.

80.5 Creating New Guidance

In coverage situations where there is no NCD, LCD, or guidance on coverage in Original-Medicare manuals:

- An MAO may use the coverage policies of other MAOs in its service area; but

- If the MAO 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:

        1. Studies from government agencies (e.g. the FDA);

        2. Evaluations performed by independent technology assessment groups (e.g. BCBSA); and

        3. Well designed controlled clinical studies that have appeared in peer review journals; and

    - 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 MAO provide coverage for all Medicare-covered services is not intended to dictate care delivery approaches for a particular service. MAOs 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 MAO complies with the provider anti-discrimination rules set forth in 42 CFR 422.205).

An MAO’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.

80.6 - Sources for Obtaining Information
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

In an effort to make the coverage process more transformation, understandable, and predictable, CMS has redesigned its Medicare coverage process. Part of the redesign includes using the Internet to provide information about how NCDs are made and the progress of each issue under coverage review. The following Internet resources provide valuable information:

- The Medicare Coverage Homepage.

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

- Provide a listing of all NCDs; and

- Enable users 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 individuals can use the Internet to send questions and provide feedback.

- The NCD Manual.

The Medicare NCDs 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 determination can be found in the Program Transmittals that transmit CMS' new policies and procedures. Links to the Program Transmittals can be found at http://cms.hhs.gov/transmittals/.

90 Benefits For Duration Different Than a Full Contract Year
90.1 - Mid-Year Benefit Enhancements (MYBE)
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Mid-year benefit enhancements (MYBE) are not allowed. After a plan's bid is approved by CMS no changes are permitted

90.2 - 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, it is permissible for a plan to cover one new pair of eyeglasses every 2 years.

100 – Benefits Outside of the Network and Service Area
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

100.1- HMO Point Of Service (POS)
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Under a POS option, an HMO coordinated care plan permits enrollees to obtain specified items and services from non-network providers. The HMO plan may:

- Include a POS option as a mandatory or optional supplemental benefit;
- Require or waive prior authorization rules for POS;
- Require that enrollees pay higher cost sharing for POS services;
- Establish a cap on the dollar amount of services that will be covered under the POS option;
- Restrict the set of plan-covered services available under the POS option; and
- Restrict the receipt of services offered under the POS at a location distant from the plan's authorized service area to 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.

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 are aware in advance of the plan's and member's maximum financial risk for POS benefits.

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.

100.2- PPO Point Of Service (POS)
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

Since an MA PPO, 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 MAO 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 stipulated by the plan. 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.

100.3- PPO Coverage Out of Service area:
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

MAOs offering a PPO plan are required to provide reimbursement for covered services out-of-network. MAOs must also provide reimbursement for covered services received from non-contracted providers outside the plan's service area.

100.4 - 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, MAOs must maintain written rules on how to obtain health benefits through the POS benefit. The MAO 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.

100.5 - 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.

100.6 - POS-Related Data
(Rev. 23, 06-06-03)

An MAO 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.

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

An MAO 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. MAOs offering these programs may limit their availability to certain areas and may impose other restrictions on obtaining benefits, for example, requiring prior authorization or use of network providers, 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 MAOs without this program must continue to disenroll members once they have been out of the service area for more than 6 months.

110 - Access to and Availability of Services
(Rev. 23, 06-06-03)

110.1 - Access and Availability Rules for Coordinated Care Plans
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

An MAO 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 requirements. 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 MAO 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.

- An RPPO, upon CMS preapproval, can use methods other than written agreements to establish that access requirements are met;

- An RPPO may seek, upon application to CMS, and upon the following requirements being met and demonstrated to CMS, that a hospital is an essential hospital with normal in-network cost-sharing levels applying to all plan members:

    1) The plan contracts 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 RPPO 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 other requirements in 42 CFR 422.112(c)(1)-(4) are satisfied.

- 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 MAO's providers are convenient to, and do not discriminate against, members. The MAO 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 MAOs 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 female 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 MAO 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 MAO 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 in section 20;

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

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

- Mechanisms for monitoring MA enrollees who 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).

110.2 - Rules for All MAOs to Ensure Continuity of Care

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

The MAO 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 MAO and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that:

    - The MAO 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 MAO, 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.

110.3 Access for Emergency, Urgently Needed Services and Dialysis

As explained in section 20, all plan types must provide emergency, urgently-needed services and medically necessary dialysis. However these three situations have slightly different rules for cost-sharing and access:

- Cost-sharing:
  - Emergency: Cost sharing is capped at the lesser of $50 and the plan cost-sharing for that service in a non-emergency situation;
  - Urgently Needed services: There are no restrictions on cost-sharing; and
  - Medically necessary dialysis: The cost-sharing out-of-network (OON) cannot exceed the in-network (IN) cost-sharing.
- Access:
  - Emergency and medically necessary dialysis: Access must be provided both IN and OON, and
  - Urgently needed services: As explained in section 20, urgently needed services, definitionally, only apply OON (or IN when normal access is temporarily unavailable).
- Gatekeeper:
  - Emergency and urgently needed services: It is prohibited for a plan to require gatekeeper authorization or even pre-notification; and
  - Medically necessary dialysis: The plan may use a gatekeeper IN, but is prohibited from using a gatekeeper OON.

110.4 Access and Plan Type

In the past decade a variety of statutes – including the Balanced Budget Act and the Medicare Modernization Act – have created flexibility in the Medicare program by providing a variety of plan types that MAOs may offer. Some of the newly created plan types may allow provision of services out-of-network and some plan types may allow provision of services without a gatekeeper. Table V below summarizes important access attributes of several plan types.

Table V: Plan Type and Access attributes for non-emergent non-urgent-care services

Plan Type	Is a gatekeeper allowed?	Is a network required?	Must benefits be provided IN and OON?	May Cost sharing requirements differ IN/OON
HMO	Optional.	Must contract[2]	Must provide IN; may provide OON	May have higher cost sharing OON
PPO[1]	Optional. For PPOs, authorization can only effect cost-sharing, not coverage.	Must contract[2]	Must provide both IN/OON	May have higher cost sharing OON
RPPO	Optional. For RPPOs, authorization can only effect cost-sharing, not coverage.	Must contract[2]	Must provide both IN/OON	May have higher cost sharing OON
MSA and PFFS[1]	Prohibited	May use full, partial, or non-network model	Must provide both IN/OON	May have higher cost sharing OON

Notes to Table V:

1. These plans may allow lower cost-sharing for prior-notification for OON services, that is if the enrollee notifies the plan prior to obtaining OON services.

2. Although an RPPO must contract with a network it may, upon obtaining a waiver from CMS, only contract with a network in part of its service area (42 CFR 422.112(a)(1)(ii))

120 - Disclosure Requirements
(Rev. 23, 06-06-03)

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

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

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

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

120.2 - 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 MAO must provide each enrollee electing an MA plan it offers the information listed below. The information must be presented in a clear, accurate, and standardized manner, including through the Internet, where applicable, as discussed in section 120.1 above.

1. 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;
    - For an MA MSA plan:
        - The amount of the annual MSA deposit and deductible; and
        - The benefits under other types of MA plans than MSA plans (42 CFR 422.111(b)(2)(ii)). We have interpreted this requirement, not as requiring a narrative on all plan types, but rather, as requiring, in its discussion of how MSA plan benefits differ from other plan types:
            i. A discussion of those features unique to MSA plans, including the annual deductible that is substantially higher than those of other plan types, the differences in enrollee financial responsibility before and after the annual deductible is met, the obligation to open a bank account, and the prohibition on an MSA plan of providing Part D prescription drug coverage; and

ii. A contrast of the features of MSA plans with those of coordinated care plans including the optional nature of providing access through a network of contracted providers; and

2. Service Area - The MA plan's service area and any enrollment continuation area.

3. 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 MAO meets the access to service requirements for access to services offered under the plan, which are discussed in section 110. A regional MA plan must also disclose the process RPPO enrollees should follow to secure in-network cost sharing when covered services are not readily available in the service area from contracted network providers.

4. Out-of-area coverage – The 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).

5. Emergency coverage - Coverage of emergency services, including:

   - An explanation of what constitutes an emergency (MAOs must use the definitions of emergency services and emergency medical condition that are provided in section 20);

   - The appropriate use of emergency services. The MAO 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.

6. Urgent Care Services – Information about urgent care services including:

   - An explanation of what constitutes an urgent care situation (as explained in section 20 of this chapter);

   - The procedures for obtaining urgent care services including the cost-sharing that applies; and

   - A clarification that in-network urgent-care centers are not urgent care services and different cost-sharing applies to them;

7. Medically necessary out-of-area dialysis – Information about medically necessary out-of-area dialysis, including:

- A statement that the plan must provide out-of-area medically necessary dialysis;

- An explanation that the cost-sharing for out-of-area medically necessary dialysis may not exceed the cost-sharing for in-network dialysis; and

- Any other guidance, such as prior notification with a clear statement that enrollees are always free to obtain out-of-network dialysis at the provider of their choice.

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

9. 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 MAO 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 MAO for processing and determination of enrollee liability, if any.

10. 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)).

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

12. Disenrollment rights and responsibilities – Information about disenrollment rights and responsibilities.

120.3 - Disclosure Upon Request
(Rev. 23, 06-06-03)

Upon request by an individual who is eligible to enroll in an MA plan, an MAO must provide the following information:

- Benefits covered under Original Medicare, as described below in section 120.5;

- 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 MAO, including the most recently audited information containing, at least, a description of the financial condition of the MAO offering the plan.

120.4 - Information Pertaining to an MAO Changing Its Rules or Provider Network

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

If an MAO 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 http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf and codified in regulation at 42 CFR 422.80;

- For changes that take effect on January 1, the MAO must notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act; and

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

An MAO must make a good faith effort to provide written notice of the 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 and advised of the procedures of selecting another PCP.

120.5 - Other Information That Is Disclosable Upon Request

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

This section lists other disclosable information that must be disclosed upon request of any individual eligible to elect an MA plan. Information for many (but not all) of the topics is found in the Evidence of Coverage (EOC). The EOC template is annually posted 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 "Find a Medicare Publication." MAOs 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 section 10.6 of this chapter;

- Potential for contract termination - The fact that an MAO 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 - Disclosure of benefits, including disclosure of:

  - 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 – 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;

  - Optional supplemental benefits; and

  - The terms, conditions and premiums for those supplemental 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.

130 - Coordination of Benefits With Employer/Union Group Health Plans and Medicaid

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

130.1 - General Rule

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

(42 CFR 422.106(a)(2)) An MAO 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 include 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 MAO. As pointed out in section 10.12 these complementary benefits are not within CMS jurisdiction as they are not considered benefits offered by the MAO under an MA plan.

130.2 - 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 – that is, 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.)

130.3 – 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.”

140 - Medicare Secondary Payer (MSP) Procedures
(Rev. 23, 06-06-03)

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

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 for the collection of cost sharing related to Part D benefits offered in an MA-PD plan. This section 140, only discusses collections related to Part C benefits.

140.2 - Responsibilities of the MAO
(Rev. 23, 06-06-03)

The MAO 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.

140.3 - 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 MAO 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.
- During the first 30 months of eligibility or entitlement to Medicare for an MA enrollee whose entitlement to Medicare is solely on the basis of ESRD 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 MAO 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 are available.

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

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

The MAO 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 section 140.5 and 140.6 below.

140.5 - Collecting From Other Insurers or the Enrollee
(Rev. 87; Issued: 06-08-07; Effective/Implementation: 06-08-07)

If an MA enrollee receives covered services from an MAO 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 MAO 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 section 1862(b) of the Act and section 130 of this chapter; and

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

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

When an MAO 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 MAO and CMS, the MAO is responsible for relieving the beneficiary of responsibility for payment of health care costs other than the MA cost sharing, and therefore, the MAO must relieve the enrollee of his or her liability under the terms of the employer/union group health plan.

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 for paying more than the MA's co-payment of $10. The MAO must absolve the beneficiary of the liability for any amount in excess of the MA plan co-payment of $10.

140.7 - 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 section 130 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 MAO'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 MAO may exercise the same rights to recover from a primary plan, entity, or

individual that the Secretary of DHHS exercises under the MSP regulations as they apply to MA Plans.

(See chapter 8, "Payments to Medicare Advantage Organizations," for further discussion of how Medicare Secondary Payer and Coordination of Benefits affects the adjusted community rate filing.)