CMS Manual System

Pub. 100-16 Medicare Managed Care

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 92 **Date: December 18, 2009**

SUBJECT: Chapter 4, "Benefits and Beneficiary Protections"

I. SUMMARY OF CHANGES: We have totally rewritten and reorganized Chapter 4, "Benefits and Beneficiary Protections." Besides retaining relevant old material we have added several sections with new guidance, consolidated several former sections, and included recent guidances on benefits. Therefore the entire chapter is being replaced.

**NEW / REVISED MATERIAL = EFFECTIVE DATE: ***December 18, 2009
IMPLEMENTATION DATE: December 18, 2009

Disclaimer for manual changes only: Normally, red italic font identifies new material. However, because this release is a complete rewrite of the chapter, normal text font is used for this revision.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

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III. FUNDING: No additional funding is currently provided by CMS; contractor activities are to be carried out within their own FY 2009 and/or future operating budgets determined by the organizations.

IV. ATTACHMENTS:

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***Unless otherwise specified, the effective date is the date of service.**

Medicare Managed Care Manual
Chapter 4 - Benefits and Beneficiary Protections

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(Rev. 92, 12-18-09)

10 - Introduction

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

10.1 - General Requirements

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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, part 422) pertaining to benefits and beneficiary protections. 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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

An MA Organization (MAO) offering an MA plan must provide enrollees in that plan with all Original Medicare-covered services except in the four 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 four circumstances are exceptions to the rule that MAOs must cover the costs of Original Medicare benefits:

- Hospice: Original Medicare (rather than the MAO) will pay the hospice for the services received by an enrollee who has elected hospice while enrolled in the plan. However, the enrollee continues to be covered by the plan for care that is unrelated to the terminal condition for which the member elected the hospice.

- Inpatient hospital stay during which enrollment begins: For the types of hospitals mentioned at 42 CFR 422.318(a), the MAO does not cover an inpatient hospital stay if enrollment begins during that inpatient hospital stay;

- Inpatient hospital stay during which enrollment ends: For the types of hospitals mentioned at 42 CFR 422.318(a), 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 (note that incurred non-inpatient services are paid by Original Medicare or the new MAO the enrollee joined); and

- Clinical trials: Original Medicare, not the MAO, pays for the costs of routine services provided to an MA enrollee who joins a clinical trial.

The requirement for MA plans to cover Original Medicare benefits:

- Is a requirement to provide or pay for covered items and services;

- Does not require the application of Original Medicare cost-sharing; MA plans may charge cost-sharing for a particular item or service that is above or below the Original Medicare cost-sharing for that service, provided the overall cost-sharing under the plan is actuarially equivalent to that under Original Medicare and the plan cost-sharing structure does not discriminate against sicker beneficiaries as specified in section 30.2; and

- Does not dictate access requirements. The access requirements for each MA plan are determined by the MA plan type. If sufficient access is provided to Original Medicare benefits, as determined by CMS using its access standards, an MA plan may choose to limit its provider network.

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 neither covered under Part A nor Part B under Original Medicare, and is not covered as part of a bundled home infusion service under a supplemental Part C benefit, 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 the 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. Optional supplemental benefits are paid for directly by the enrollee or on behalf of the enrollee. 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 must be offered uniformly to all plan enrollees independent of health status. Rebate dollars may not be applied toward optional supplemental benefits. An MA plan may not offer as an optional supplemental benefit reduced cost sharing for Original Medicare 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: (1) at the beginning of the contract year to all Medicare beneficiaries enrolled in the plan, and (2) at the time of initial enrollment to new enrollees who enroll during the contract year. The MA plan may then:

- Continuously offer each optional supplemental benefit uniformly to all enrollees for the remainder of the 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 enrollee's 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 at any time during the contract year upon proper advance notice to the MAO. An enrollee who drops an optional supplemental benefit through proper advance notice – typically 30 days – to the MAO:

- Need not pay further monthly premiums for the optional supplemental benefit; and

- If s/he paid a complete annual premium for the optional supplemental benefit, is entitled to a pro-rated refund of unpaid premium for the remaining portion of the year.

Chapter 2 of this manual, "Enrollment and Disenrollment," located at http://www.cms.hhs.gov/Manuals/IOM/, Publication 100-16), 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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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).

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 in 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	Yes, unless another non-SNP MA plan offered by the same organization in the same service area includes required prescription drug coverage under Part D (42 CFR 422.104(f)(3)). See footnote 1 for details.	No
HMO-POS	Local	Yes, unless another non-SNP MA plan offered by the same organization in the same service area includes required prescription drug coverage under Part D (42 CFR 422.104(f)(3)). See footnote 1 for details.	No
PPO	Either	Yes, unless another non-SNP MA plan offered by the same organization in the same service area includes required prescription drug coverage under Part D (42 CFR 422.104(f)(3)). See footnote 1 for details.	No
Provider-sponsored organization (PSO)	Local	Yes, unless another non-SNP MA plan offered by the same organization in the same service area includes required prescription drug coverage under Part D	No

		(42 CFR 422.104(f)(3)). See footnote 1 for details.	
Special Needs Plan (SNP)	Either	Yes, required	No
Private Fee-for-Service (PFFS) Plan	Local	No	Yes, provided the PFFS plan does not offer Part D coverage.
MA Medical Savings Account (MSA) Plan	Local	Not permitted	Yes
Sec. 1876 Cost Plans			
Cost plan offering qualified Part D prescription drug coverage	NA	No, but Part D coverage can be offered as an optional supplemental benefit	Yes
Cost plan offering non-qualified prescription drug coverage	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[2]	No

Notes to Table I:

1. See section 20.4.4 of Chapter 5 of the Prescription Drug Benefit manual located at http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage for the definition of required drug coverage.

2. PACE Providers offering PACE Programs, as defined in section 1894 of the Act generally 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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

Although the MA program provides MAOs with a great deal of flexibility in designing MA plans, in sections 10.6 – 10.14 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 enrollment 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:

   - Claims experience;
   - Receipt of health care;
   - Medical history and medical condition including physical and mental illness;
   - Genetic information;

- Evidence of insurability, including conditions arising out of acts of domestic violence; and

- Disability.

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.

3) An MAO must ensure that its 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, gender, 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 in a SNP to a person who does not fulfill the eligibility criteria for enrollment in the SNP;

- Under the circumstances mentioned in section 20.2 of Chapter 2 of this manual, "Enrollment and Disenrollment" located at http://www.cms.hhs.gov/Manuals/IOM/, Publication 100-16, a person with end-stage renal disease (ESRD) may be denied enrollment; and

- Under the limited circumstances mentioned in section 20.7 of Chapter 2 of this manual, "Enrollment and Disenrollment" located at http://www.cms.hhs.gov/Manuals/IOM/, Publication 100-16, a person who has elected hospice may be denied enrollment.

10.7 – Other Federal Requirements

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

An 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.

10.8 - Confidentiality

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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: For purposes of CMS audits of risk adjustment data, upon which health status adjustments to CMS capitation payments to MAOs are based, and for the purposes set forth below, network providers should be required under their contracts (or, in the case of deemed contracting providers under PFFS plans) to provide medical records requested by the MAO.

Purposes for which medical records from providers are used by MAOs include:

- Advance determinations of coverage;

- Plan coverage;

- Medical necessity;

- Proper billing;

- Quality reporting;

- Fraud and abuse investigations; and

- Plan initiated internal risk adjustment validation.

To encourage providers to submit member medical records to the plan an MAO may choose to facilitate the process by sending staff to assist in the record collection or by reimbursing providers for the costs associated with furnishing the records. MAOs are prohibited from using medical record reviews to delay payments to providers. Both required and voluntary provision of medical records must be consistent with HIPAA privacy law.

10.9 - Benefit Requirements

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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

- All MA plans, independent of plan type, must offer basic benefits as described in section 10.3;

- 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;

- All benefits must be priced in the bid; the plan incurred bid-priced cost should not be solely administrative;

- The other requirements in section 30.1, such as anti-steerage, must also be fulfilled;

- All benefits must be specified in the appropriate marketing vehicles as indicated in the Medicare Marketing Guidelines located at http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/R91MCM.pdf.

10.10 - Uniformity

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 enrollees residing in the service area of the 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) to all Medicare beneficiaries with Parts A and B of Medicare;

- 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. Any tiering should be used on a limited basis and in a manner that fully discloses tiered cost-sharing amounts to enrollees.

- The uniform premium requirement prohibits plans from offering nominal discounts to those enrollees electing to pay premiums electronically.

- All plans must offer to, but may not require of, their enrollees the option of:

    - Having their premiums deducted from their Social Security check or benefit;

- Having their premiums paid by an electronic transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account); and

- Paying their premium by check.

10.11 - Caps on Enrollee Financial Responsibility

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

This section provides several distinct situations relating to enrollee financial responsibility. Although MAOs have certain rights of collections, in many instances the enrollee is "held harmless," that is, the enrollee is protected by a limit on his/her financial responsibility:

1) Limitations on Enrollee Liability: CMS considers a contracted plan provider an agent of the MAO offering the plan. Consequently, the services and referrals s/he gives are considered plan-approved unless notice is provided that the services will not be covered. An enrollee who receives a service or item from a contracted plan provider or a provider referred by a contracted plan provider is therefore held harmless and need not pay more than the plan-allowed cost-sharing (e.g., coinsurance, copays and deductibles). The enrollee is held harmless independent of whether:

   - The service is otherwise plan covered;

   - The enrollee was advised of the need for a referral; and

   - The referral was properly done.

   Also note that the MAO cannot retroactively overturn the decision by a contracted provider to provide the service or item or refer the enrollee to another provider.

2) No balance billing: As indicated in Section 10.21, an enrollee should only pay non-contracted providers the plan-allowed cost sharing. The MAO, not the enrollee, is obligated to pay allowed balance billing. Furthermore, if an enrollee inadvertently paid balance billing, the MAO must refund the balance billing amount to the enrollee.

3) No reimbursement relationship: A plan may not require a beneficiary to pay a contracted provider and then receive reimbursement.

4) Provider-enrollee relationships: Providers are frequently called upon to give advice as an enrollee may need services and procedures that are not provided or covered by the plan. A provider who refers a patient to a provider for a non-covered service must ensure 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 the service is not part of the plan benefit package) should also clearly advise the enrollee prior to service of the enrollee's responsibility to pay the full cost of the service. For the requirements for issuance of notices of non-coverage see Chapter 13 of this manual located at http://www.cms.hhs.gov/manuals/downloads/mc86c13.pdf.

Missed Appointment Charges: MAOs may charge "administrative fees" to enrollees for missed appointments with contracting providers and for not paying a copay at the time of service with a contracting provider. Under the MA program such charges are only allowable if the charge is priced in the bid and documentation submitted with the bid 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. If an MAO does not charge an administrative fee for miss appointments with contracted providers, or, in the case of non-contracted 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.

10.12 - Multiple Plan Offerings and Benefit Caps

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 supplemental 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 supplemental benefit of one plan is entitled to the full benefit of the other plan if the enrollee enrolls in it (and purchases that supplemental benefit, if the benefit is optional). This rule does not preclude MAOs from providing benefits with periodic caps such as monthly or quarterly caps.

10.13 - Complementary Benefits

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

(42 CFR 422.106(a)(2))Plans may offer their enrollees, through associations, employers, or State Medicaid agencies, 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, but, 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.

10.14 - Provider Qualifications

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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, defined in section 10.3, do not need to be provided through Medicare providers.

10.15 - Drugs that are Covered Under Part B Original Medicare

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 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 (pneumococcal, hepatitis B (high or intermediate risk only) influenza, and vaccines directly related to the treatment of an injury or direct exposure to a disease or condition). For further details, see section 50.4.4.2 of Chapter 15 of the Medicare Benefit Policy Manual: http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf .

    - 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 determine whether 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 Part C 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.

Some drugs are covered under either Part B or Part D depending on the circumstances. For clarification on coverage under Part B versus Part D, see Appendix C of Chapter 6 of the Part D Prescription Drug Benefit Manual located at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/R2PDBv2.pdf. It is critical to understand when a drug is covered under Part B or Part D in order to ensure that Part C and Part D bids properly reflect appropriate coverage under either Part B or Part D.

10.16 - Original Medicare Covered Services with Benefit Periods

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 cannot impose further limitations in fulfilling its obligation to provide all Original Medicare services.

10.17 - Waiting Periods - Exclusions That Are Not Present in Original Medicare

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

All beneficiaries must be provided all medically necessary benefits covered under 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).

10.18 - Screening Mammography, Influenza Vaccine, and Pneumococcal Vaccine

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 impose neither cost sharing nor office visit copays for influenza and pneumococcal vaccines.

10.19 - Return to Home Skilled Nursing Facility (SNF)

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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.

10.20 - Chiropractic Services

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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.

10.21 - Therapy Caps and Exceptions

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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.

10.22 – Balance Billing

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

The guidance in this section applies to HMOs (Health Maintenance Organizations), PPOs (Preferred Provider Organizations), and RPPOs (Regional PPOs). 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-allowed cost-sharing. In situations where providers ordinarily are permitted to balance bill, they must obtain this balance billing from the MAO. The rules for balance billing are listed below by type of provider.

- Contracted provider. There is no balance billing paid by either the plan or the enrollee;
- Non-contracting "participating provider". There is no balance billing paid by either the plan or the enrollee;

- Non-contracting, non-participating provider. The MAO pays permitted balance billing (up to 15% of the Original Medicare rate in the case of physicians' services); the enrollee, only pays plan-allowed 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; the enrollee only pays plan-allowed cost sharing.

  A participating provider is a provider that signs an agreement with Medicare to always accept assignment. The MACs post lists of participating providers. Participating providers may never balance bill because they have agreed to always accept the Medicare allowed amount as payment in full. A non-participating provider may accept assignment on a case-by-case basis and indicates this by checking affirmatively field 27 on the CMS 1500 claims form; in such a case, no balance billing is permitted.

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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

20.1 - Ambulance

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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/Downloads/bp102c10.pdf

20.2 – Definitions of Emergency and Urgently Needed Services

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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, or the plan network is otherwise not available; 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.

20.3 – MAO Responsibility

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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

- Regardless of whether services are obtained within or outside the MAO's authorized service area and/or network (if applicable);

- 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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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

- $50;

- What the enrollee would be charged in-network if s/he obtained the services through the MAO (refer to Table IV in section 110.4).

20.6 - Post-Stabilization Care Services

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 when the patient is stabilized and the emergency ends.

20.7 - Services of Non-contracting Providers and Suppliers

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 he/she 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 10.22 for guidance on balance billing).

30 - Supplemental Benefits

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

30.1 – Definition of Supplemental Benefit

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 MA plans propose as a benefit 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 II in 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.

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".

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 (LMTs), 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.

Original Medicare does not provide payment to non-Medicare beneficiaries, except in rare circumstances, for example, living donors of kidney transplants. Consequently, an MAO may not make payments on behalf of non-enrollees, including family members, for Original Medicare benefits in those situations where Original Medicare does not so provide.

MAOs are similarly prohibited from providing payments to non-enrollees, including family members, for supplemental benefits except for the provision of transportation and lodging for a transplant as provided in section 30.4. For example, an MA plan is prohibited from providing payments for transportation costs of a living donor 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 or homemaker 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 Original Medicare, 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 part of the Original Medicare home health care benefit. However, the plan may not extend the Original Medicare benefit beyond what is provided in the Home Health Manual.

Example 2b: A plan wishes to offer maid service to its enrollees. The plan contends that without the maid service there is a real possibility of either injury due to a fall or injury while cleaning precipitated by weakness or limited range of motion. The plan points out that its goals are to prevent future expected injury.

The item or service is not a benefit under Part B or Part C. Maid service is not a community pattern of care for weakness or limited range of motion. Note especially that the plan's goal of preventing a reasonably expected injury in the future does not justify classifying the maid service as a benefit. The primary purpose of maid service, as determined by typical usage, is convenience, and convenience is not a justification for benefit status.

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 or availability to the beneficiary. An MAO:
        - May not, for example, 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;
        - As indicated in section 10.10, must clearly disclose any tiered cost-sharing to its enrollees; and
        - May not exclusively design a plan with supplemental benefits, such as gym benefits, that only appeal to healthier beneficiaries. However a plan design that includes gym and other supplemental benefits needed by sicker enrollees would be acceptable.
- Benefit designs meet other MA program requirements.

Section 50.1 of this chapter contains general guidance on proper cost-sharing. The anti-discrimination and anti-steerage prohibitions mentioned above apply to both Original Medicare, mandatory supplemental, and optional supplemental benefits.

30.3 - Examples

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 II 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 II 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 II is intended to be illustrative, not exhaustive. Table II complements Table III, provided in section 40.9, explaining which over-the-counter (OTC) items are offerable as benefits. Although some of the items listed

in Table II may not be offered as supplemental benefits under the MA program, they may be offered under appropriate conditions under the Medicaid program to dual eligibles through an arrangement with the State. However, those items may not be included in a plan's PBP or BPT.

Table II: 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, batteries in an original package from the factory with a hearing aid.	The primary purpose of a battery is to provide electrical current, not to cure hearing loss. (The goal and a secondary effect of battery usage is to power the hearing aid to reduce 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.
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, home repair – 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 home repairs, generally, may 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	No		The primary purpose is

Item / Service	Supplemental Benefit?	Exception	Reason / Justification/ Comment
(including maid service) [2]			convenience.[3]
Gym benefit including exercise classes at a gym, such as Tai Chi, yoga and dance classes.	Yes		The primary purpose of a gym benefit is prevention through exercise.
Manicures / Pedicures	No		The primary purpose is cosmetic.
Massages	No	Chiropractor Visits may be covered (even if preparatory massages are used).	Massages, by themselves, 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.
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 medical purposes does not justify classifying the monthly bus pass as a benefit.

Notes to Table II:

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 (or maid) 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 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. As a rule of thumb, if the Home Health Manual indicates that a particular service is covered under Original Medicare, then the plan must also cover it; however, if the Home Health Manual explicitly indicates that a particular service is not covered under Original Medicare, then an MA plan may not offer it either as an Original Medicare benefit or a supplemental benefit. For further details on the Original Medicare home health aide benefit, see 42 CFR 409.45.

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

There are situations when transportation may be a covered benefit. The following examples are illustrative (but not exhaustive):

Covered by Original Medicare**:** The MA plan must cover transportation in those circumstances where 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, and Original Medicare does not cover transportation related to bariatric surgery. Therefore, an 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**:** As indicated in section 110.1 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.

An MA plan, for reasons of convenience or cost, may wish to provide required transplant services at a distant location even though transplant services and transplant centers are available locally to provide the service consistent with patterns of care for Original Medicare beneficiaries who reside in the same area. If an MA plan provides transplant service at a distant location, (further away than the normal community patterns of care), even though transplant services and

centers are available locally, 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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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, that is, 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, an inpatient hospital stay, or 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). Meals may be offered for a temporary duration, typically a two-week or four-week period, per enrollee per year, 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 not further scrutinize the benefit. 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, per enrollee per year.

- 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 not further scrutinize the benefit. 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 community services as plan benefits. Additionally, an MA plan offering a meal benefit complying with the requirements described in this chapter may not advertise it as a "Meals on Wheels" benefit or use the term "Meals on Wheels" in the name of the benefit. It is important that prospective enrollees not confuse the limited CMS approved meals benefit with the broader services offered under the "Meals on Wheels" program. However, if an MA plan has entered into a contract with "Meals on Wheels" to furnish the approved meals benefit, it may inform its members that the meal benefit under the plan will be delivered by "Meals on Wheels."

30.6 - Medical Supplies Associated with the Delivery of Insulin

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 a supplemental 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 meal benefit that does not meet the criteria in section 30.5.

- Example 2 - Caregiver / Respite: Original Medicare offers respite hospice care. Respite care is short term inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual at home. Respite care may be provided only on an occasional basis (Medicare Benefit Policy Manual, Chapter 9, section 40.2.2, http://www.cms.hhs.gov/Manuals/IOM/list.asp). Other than this respite benefit, an MA plan may not offer as a supplemental benefit other types of caregiver or respite care (whether to SNF or non-SNF enrollees). CMS is studying the possibility of allowing additional respite or caregiver care and will issue guidance on this in the future. 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.

- Example 3 – Legal Services: Legal advice services may never be offered as a benefit.

- Example 4 - Living Donor coverage**:** As indicated above, Original Medicare covers medically necessary services related to the kidney transplant for the living donor of an ESRD patient. Since the living donor is not a member of the MAO plan, the MAO may not offer as a supplemental benefit to the living donor services not covered by Original Medicare, e.g., transportation, 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, 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.”

- 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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 Department of Health and Human Services (DHHS) website, (http://www.dhhs.gov/) and the CMS web site (http://www.cms.hhs.gov/). 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, requirements for authorization or pre-notification;

3. Temporarily reduce plan-approved out-of-network cost sharing to in-network cost sharing amounts;

4. Waive the 30-day notification requirement to enrollees as long as 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 or her authority under Section 1135, information about the waivers is posted on the Department of Health and Human Services (DHHS) website. The CMS web site 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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

40.1 - Issues with Provision of OTC Benefits

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

MA plans may offer an OTC benefit as long as the benefit conforms to the detailed guidance in this section.

OTC items include both:

- Non-prescription drugs (such as Prilosec® and Claritin®), also known as OTC drugs; and
- Health-related items (such as bandages in situations where Original Medicare does not cover them as surgical supplies).

There are a variety of OTC items as described below:

- 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 (in situations where Original Medicare does not cover them as surgical supplies), may be offered only as a Part C supplemental benefit and 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.

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 below.

40.2 - OTC Under Part C and Under Part D

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 non-Original Medicare covered bandages, Prilosec® and Claritin® as benefits. The MAO could:

- Offer the non-Original Medicare covered 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 non-Original Medicare covered 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 non-Original Medicare covered 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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

The OTC items offered, regardless of how they are packaged or paid for, must be available at a wide variety of both chains and stores. For example, an MAO may deliver the OTC benefit in one pharmacy chain through an electronically linked debit card and at other pharmacy chains through manual reimbursement with a minimum monthly cap.

This multiple-chain requirement does not apply to delivery through a catalog method. In other words, an MAO that contracts with a single mail order company to provide OTC items, whether few or packaged, has fulfilled its obligation of providing sufficient access to the OTC benefit.

40.4 - Benefit Status

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 III 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 in the non-eligible portion of Table III may not be offered as a Part C supplemental benefit. Should a plan wish to include on its OTC list categories of items not listed as eligible or dual purpose which are not found on Table III, it must first obtain permission from CMS.

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 a plan not using a catalog delivery method that chooses to offer cough medicines as a Part C OTC supplemental benefit may not choose to cover only specified items and brands. Once the plan chooses to cover cough medicines, it must cover all cough medicines.

Table III 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 enrollee's 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 Table III in section 40.9.

40.5 - Specific or Packaged OTC Benefit

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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, for the reason explained immediately below in the next bullet;

- 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 visible, the plan will provide enrollees with information about this benefit, 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, or in the case of delivery by a catalog, which items are covered, locations where the item can be purchased, and how the OTC item(s) may be purchased.

40.6 - Payment Methods

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 non-Original Medicare covered 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. 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 items that can be obtained by the enrollee (this list of items should typically follow the list of categories of items in section 40.9);

- 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 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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 Regarding OTC Benefits

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 enrollee's 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. All OTC marketing materials must be submitted and approved consistent with chapter 3 of this manual.

40.9 - CMS Table of OTC Items

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

Table III 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 III below lists categories of items. MA plans should not steer enrollees to particular brands of items. For example, if an MA plan does not deliver its OTC benefit though a catalog, and its Part C OTC list includes headache medications such as Excedrin, it must cover all brands of headache medications;

- Categories not on the list: Each plan must publish, on its plan website, or in catalogs or other marketing materials, the list of categories of items, or in the case of delivery by a catalog payment method, 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 some 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 that they may only purchase items on the plan list, even if other items are prohibited, and 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.

- Part B/D: As indicated above several of the items in the table, under certain circumstances, may be covered under Part B or Part D.

Table III: 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	

Eligible?	Category	Sub-categories	Exceptions
		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 classified as eligible 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		Items which are primarily food with fiber added.
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, 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 / denture -related items / Mouth care	Toothbrushes, toothpaste, floss, denture adhesives, gum problems	Mouthwashes, bad breath items, and teeth-whiteners are non-eligible.
Non-eligible	Alternative medicines	Includes botanicals, herbals, probiotics and	

Eligible?	Category	Sub-categories	Exceptions
		neutraceuticals.	
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 product or supplements	Sugar / salt supplements, energy bars, liquid energizers, protein bars, power drinks, ensure, glucema.	Fiber products are eligible unless they are primarily foods with fiber added.
Non-eligible	Replacement items, attachments, peripherals.	Includes: Hearing aid batteries, contact-lens' containers, etc. when not factory packaged with the original item.	

Notes to Table III:

1. Each item in the following alphabetized 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, respiratory 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, 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 III.

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

50 – Cost Sharing and Deductible Guidance

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

50.1– Guidance on Acceptable Cost Sharing

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 annually. 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 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. 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.

- Out of Pocket Cap: With acceptable justification, CMS may accept plans with member out-of-pocket caps above the 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. High deductibles are required for MA MSA plans. However, CMS will closely scrutinize high deductibles in other plan types;

- Coinsurance and co-payments: CMS, in its review of plan cost sharing, will monitor both co-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 co-payment amounts more predictable and 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 received outside the authorized service area 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: In order for an Original Medicare in-network or out-of-network item or service to be considered a reasonable benefit, 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 CMS Regional Office (RO) to determine that the network now meets CMS standards for access and availability. Once the network is approved by the RO the plan must notify 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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 a separate deductible for out-of-network Original Medicare services.

- Exempt for specific items or services from the deductible - 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 requirements 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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

60.1 - The Basic Definition

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

Value-Added Items and Services (VAIS) are non-benefit items and services provided to an MAO's enrollees that meet the definition of VAIS below. VAIS may not be funded with Medicare program dollars. However, VAIS may be of value to some beneficiaries and may be commonly available to commercial enrollees. MAOs wishing to advertise VAIS must follow specific marketing guidelines. For details, see section 110 and 170 of the Medicare Marketing Guidelines located at http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/R91MCM.pdf.

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

Note that this definition does not require that VAIS be health-related. A VAIS is not a benefit since no direct medical or pharmaceutical cost is incurred to the MAO in providing the VAIS.

60.2 - Examples of VAIS

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 - Additional VAIS Requirements

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

VAIS is not a benefit: therefore, it:

- May not be priced in the bid;
- May not be offered to non-plan members, for example, dependents and spouses of plan members; and
- Is not reviewed during the annual review of plan benefit package design. While, VAIS are not typically the subject of CMS site visits, CMS reserves the option to review VAIS, either during an ordinary or special monitoring visit, especially if problems or complaints arise.

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 prohibition on inducements to beneficiaries.

70 - Information on Advance Directives

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

70.1 - Definition

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

80.1 - Overview

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 80.3 and 80.4, 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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 cover 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, that if a local or regional plan adopts a uniform coverage policy as indicated above, that uniform coverage policy only applies to its service area. Services for an enrollee from a provider outside the service area are reimbursed based on the local coverage determinations of that provider's geographic location.

80.3 – Definitions Related to National Coverage Determinations (NCDs)

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 a calendar year 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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

In an effort to make the coverage process more transparent, 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://www.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://www.cms.hhs.gov/transmittals/01_overview.asp.

90 - Benefits For Duration Different Than a Full Contract Year

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

90.1 - Mid-Year Benefit Enhancements (MYBE)

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

100.1- HMO Point Of Service (POS)

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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: 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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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

100.4 - Enrollee Information and Disclosure

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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, plans must provide information about how close they are to reaching the financial cap on the benefit upon request. In addition, the plan must 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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

110.1 - Access and Availability Rules for Coordinated Care Plans

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 in 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.

- 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. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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. The Original Medicare initial preventive physical exam or a recent previous physical examination in a commercial plan (to which the MAO has access) would fulfill this obligation;

- 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 (Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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: As indicated in section 20.5, cost sharing is capped at the lesser of $50 and the in-network 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 for out-of-network (OON), out of service area, medically necessary dialysis cannot exceed the in-network (IN) cost-sharing (see section 20.7 for further details).

- Access:

  - Emergency and medically necessary dialysis: Plans must provide access both IN and OON, and

  - Urgently needed services: As explained in section 20, urgently needed services, only apply OON (or IN when normal access is temporarily unavailable).

- Gatekeeper:

- Emergency and urgently needed services: Plans are prohibited from requiring gatekeeper authorization or even pre-notification; and

- Medically necessary dialysis: The plan may use a gatekeeper in network, but is prohibited from using a gatekeeper out of network.

110.4 - Access and Plan Type

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 IV below summarizes important access attributes of several plan types.

Table IV: 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[1]	Must provide IN; may provide OON	No, except for HMOPOS
PPO	Optional	Must contract	Must provide both IN/OON	No, except for HMOPOS
RPPO	Optional.	Must contract[1]	Must provide both IN/OON	May have higher cost sharing OON
MSA and PFFS	Prohibited	May use full, partial, or non-network model	Must provide both IN/OON	May have higher cost sharing OON

Notes to Table IV:

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

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

120.1 - General Rule

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

(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 provided 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.

120.2 - Requirements, Rights, and Beneficiary Protection

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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.)

120.3 – Employer/Union Plans

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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

130 - Medicare Secondary Payer (MSP) Procedures

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

130.1 - Basic Rule

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 130, only discusses collections related to Part C benefits.

130.2 - Responsibilities of the MAO

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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.

130.3 - Medicare Benefits Secondary to Group Health Plans (GHPs) and Large Group Health Plans (LGHPs)

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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:

- When 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.
- When 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 is available.

  Medicare does not pay at all for services covered by a primary GHP. In the case of the presence of workers comp, no-fault and liability insurance (including self-insurance), Medicare makes conditional payments if the other insurance does not pay promptly. These conditional payments are subject to recovery when and if the other insurance does make payment. However, if an MA enrollee illegally did not own auto insurance the MAO cannot withhold primary payment on the grounds that the enrollee should have owned this insurance because it is a state requirement. MAOs cannot withhold primary payment unless there is a reasonable expectation that another insurer will actually promptly pay primary to Medicare.

130.4 - Collecting From Other Entities

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 130.5 and 130.6 below.

130.5 - Collecting From Other Insurers or the Enrollee

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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.

130.6 - Collecting From GHPs and LGHPs

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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 a plan-covered service that the beneficiary properly received (following all plan requirements), 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.

130.7 - MSP Rules and State Laws

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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.)

140 - MAO Renewal Options and Crosswalk

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

140.1 - Introduction

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

As a result of business decisions, pre-bid discussions with CMS, or bid negotiation with CMS, current MAOs may change their current year offerings for the following contract year. Each year, MAOs are required to complete the HPMS Plan Crosswalk in a way that reflects the results of the MAOs' plan renewal decisions and allows them to delineate the relationships between MA plans offered under each contract they currently hold with CMS, and those PBPs they propose to offer under the same contract in the following contract year. Beneficiary notification requirements depend on the renewal option each sponsor MAOs (i.e., renewal, non-renewal, consolidation) for its current plans.

It is extremely important that MAOs review each scenario listed in the HPMS Plan Crosswalk when planning for and making final determinations with regard to each contract's plan structure for the following contract year. CMS uses the HPMS Plan Crosswalk to continue beneficiary enrollment in CMS systems for the following contract year in the correct plan. MAOs do not need to submit enrollment transactions to CMS to effectuate the renewal option selected in the HPMS Plan Crosswalk for each of its current plans. If an MAO is unable to submit a renewal scenario in the HPMS Plan Crosswalk, it is very likely that the scenario is not a permissible

renewal option under the crosswalk. CMS may approve plan-to-plan transitions that are not permissible renewal options in the HPMS Plan Crosswalk on a case-by-case basis.

There are various renewal options for MAOs offering MA plans: (1) new plan; (2) renewal plan; (3) consolidated renewal plan; (4) renewal plan with a service area expansion (SAE); (5) renewal plan with a service area reduction (SAR); and (6) terminated plan (non-renewal). Additional guidance regarding these options is provided immediately below.

140.2 – New Plan

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

An MAO may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the MAO offering the MA plan must submit enrollment transactions to MARx. No beneficiary notice is required in this case.

140.3 – Renewal Plan

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

An MAO may retain a current PBP for the following year, even while changing benefits, premiums, and cost-sharing from year to year. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions for existing members. Current enrollees of a renewed PBP must receive a standard Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan. Based on their review of the ANOC, current enrollees may elect to enroll in another plan offered by either the same or another MAO or the Original Medicare program during the Annual Coordinated Election Period.

140.4 – Consolidated Renewal Plan

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

MAOs are permitted to combine two or more PBPs (i.e., plans) offered in the current contract year into a single renewal plan so that all enrollees in the combined plans are offered the same benefits under one PBP in the following contract year. An MAO consolidating the number of plans it offers is permitted to designate the plan that is the "continuing plan." MAOs combining two or more PBPs into a single renewal PBP must designate which of the consolidating plan IDs will be retained in the following contract year after consolidation; the organization's designated renewal plan ID must remain the same in order for CMS to consolidate the beneficiary's election by moving him or her into the designated renewal plan ID. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees. Enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions for existing members, though it may need to submit updated Rx data for the enrollees affected by the consolidation to CMS.

MA plans may only consolidate plans which are the same plan type (e.g., HMO, PFFS). A SNP and non-SNP plan that are both HMO or PPO are nevertheless considered to be different types. Similarly an MA plan and an MA-PD plan are considered different plan types. Therefore, an

MA-PD plan cannot be considered a "continuation" of an MA-only plan, and vice versa. Additionally, an MA-only plan and MA-PD plan cannot be consolidated into a single plan type (e.g., MA-PD) in the following contract year. The MAO will be responsible for sending a standard ANOC to any enrollees whose current plans are being consolidated into a renewal plan. Based on their review of the ANOC, beneficiaries whose enrollment has been consolidated into a renewal PBP may then elect another plan offered by either the same or another MAO or the Original Medicare program during the Annual Coordinated Election Period.

140.5 – Renewal Plan with a Service Area Expansion (SAE)

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

An MAO may continue to offer a current contract year's PBP in the following contract year and retain all of the plan service area, but also add one or more new service areas (i.e., counties) to the plan. An MAO renewing a plan with a SAE must retain the renewed PBP's ID number in order for all currently enrolled beneficiaries to remain enrolled in the same plan in the following contract year. Current enrollees of a PBP that is renewed with a SAE will not be required to take any enrollment action, and the MAO will not submit enrollment transactions for existing members. Current enrollees of a renewed PBP with a SAE must receive a standard ANOC notifying them of any changes to the renewing plan. Based on their review of the ANOC, current enrollees may elect to enroll in another plan offered by either the same or another MAO or the original Medicare program during the Annual Coordinated Election Period. Note that cost plans may not expand into areas where two or more coordinated care plans are being offered.

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140.6 – Renewal Plan with a Service Area Reduction (SAR)

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

An MAO may elect to reduce the service area of a current contract year's PBP and make the reduced area part of a new or renewal MA PBP service area in the following contract year. This option is available only to local MA plans. An MAO renewing a plan with a SAR must retain the renewed PBP's ID number so that beneficiaries in the renewal portion of the service area remain enrolled in the same plan in the following contract year. These enrollees will not be required to take any enrollment action, and the MAO will not submit enrollment transactions for existing members. Current enrollees in the renewal portion of the service area must receive a standard ANOC notifying them of any changes to the renewing plan. Based on their review of the ANOC, these enrollees may elect to enroll in another plan offered by either the same or another MAO or the Original Medicare program during the Annual Coordinated Election Period.

When another PBP (existing or new) under the same contract is available in the reduced service area, the organization must move the affected enrollees into that PBP. To do this, the MAO must submit enrollment transactions to enroll current enrollees in the reduced service area into the existing/new PBP. These enrollees will receive a standard ANOC along with a notice approved by CMS explaining their Medicare options, including guaranteed issue Medigap rights.

If no other MA plans are offered in the reduced area (either by the MAO pursuing the SAR or by other MAOs), the MAO may request CMS approval to offer enrollees in some or all of the reduced service area the option to continue enrollment in the organization by agreeing to be enrolled in a local MA plan offered by the organization (see 42 CFR 422.74(b)(3)(ii) and Medicare Managed Care Manual Chapter 2, Section 50.2.4). MAOs offering the continuation of

enrollment option must include information regarding the option in the nonrenewal notice, including the need for individuals to contact the MAO to indicate their desire to continue enrollment in the MAO, as well as their acknowledgement of the need to use providers and facilities designated by the MAO in order to access plan benefits. The MAO will submit transactions to enroll individuals who elect the continuation of enrollment option in the MA local plan. If the organization does not offer this option to the enrollees in the reduced area, the MAO must submit transactions in order to disenroll these beneficiaries from the reduced service area,

140.7 – Terminated Plan (Non-Renewal)

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

An MAO may elect to terminate a current PBP for the following contract year. In this situation, the sponsor will not submit disenrollment requests for affected enrollees. When an MAO terminates a PBP, plan enrollees must make a new election for their Medicare coverage in the following contract year. Absent exceptional circumstances and CMS approval, CMS will not allow an MAO to use the passive enrollment method (under which the default option, if no choice is made, is moving to another plan) in order to move enrollees from a terminating plan into other plans offered by the MAO. To the extent that an affected enrollee elects to enroll in a PBP offered by the current or another MAO, he/she must complete an enrollment request, and the enrolling organization must submit enrollment transactions so that those individuals are enrolled in the PBP the enrollee has selected. If the enrollee does not make a new MA plan election prior to the beginning of the following contracting year, he or she will be placed in Original Medicare coverage. Enrollees of terminated PBPs will be sent a termination notice that includes notification of guaranteed issue Medigap rights. For more information about non-renewal processes and beneficiary notification requirements, refer to the annual summer HPMS memo providing non-renewal and service area reduction guidance.

150 - Service Area

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

150.1 - Definitions

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

A service area is a geographical area approved by CMS within which an MA eligible individual may enroll in a particular MA plan offered by an MA organization. A local MA plan's service area does not need to be contiguous. A regional PPO's service area must be the entire MA region. The basic requirement of service area is that each MA plan offered by an MA organization must be offered to all beneficiaries in an MA plan's service area with a uniform benefit package and uniform cost sharing arrangements.

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

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

- Required Benefits**:** The designation affects which benefits will be provided under the MA plan, because benefits and premiums must be uniform for all Medicare beneficiaries residing in the plan's service area.

- Eligibility: The designation determines which Medicare beneficiaries are able to elect the plan. The MA organizations -- other than SNPs, which can limit enrollment based upon statutory and regulatory parameters -- are obligated to enroll any MA eligible resident in the service area who elects the plan during an applicable enrollment period (provided an approved capacity limit has not yet been reached (see Chapter 2 of this manual, "Enrollment and Disenrollment")." located at http://www.cms.hhs.gov/Manuals/IOM/, Publication 100-16.);

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

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

150.2 - Factors That Influence Service Area Approvals

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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

- Whether each MA plan (except for Employer/Union-Only plans; see Chapter 9 of this Manual, "Employer/Union-Sponsored Group Plans") will be made available to all MA eligible individuals within the plan's service area;

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

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

- Whether, for coordinated care plans, the contracting provider network meets CMS access and availability standards for the service area, as explained in section 110 of this chapter, even if some of the contracting providers are physically located outside of the service area; and

- Whether there is any evidence that the service area is being manipulated to avoid areas with "sicker" people or that it would be discriminatory in some other way. In this regard, CMS also considers the extent to which the proposed service area mirrors service areas of existing commercial or MA plans offered by the MA organization.

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

150.3 - The "County Integrity Rule"

(Rev. 92, Issued: 12-18-09; Effective/Implementation Date: 12-18-09)

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

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

CMS will consider approving a service area that includes a partial county, if it determines that the inclusion of a partial county is: (1) **necessary**, (2) **non-discriminatory**, and (3) in the **best interest of the beneficiaries**. All three of these factors must be present in order for CMS to approve an exception to the county integrity rule. The CMS may also consider the extent to which the proposed service area mirrors the service area of existing commercial health care plans or MA plans offered by the organization.

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

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

  Examples include the following:

  Example 1: A Provider Sponsored Organization or other type of MA plan has a health care network that is limited to one part of a county and cannot be readily extended to encompass an entire county.

  Example 2: A section of a county has an insufficient number of providers (or insufficient capacity among existing providers) to ensure access and availability to covered services.

  Example 3: Geographic features, such as mountains, water barriers, and exceptionally large counties create situations where the pattern of care in the county justifies less than a complete county because covered services are not available and accessible throughout the entire county.

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

For CMS to determine if a partial county is **non-discriminatory**, an MA organization must be able to demonstrate the following:

- The anticipated enrollee health care cost of the portion of the county it proposes to serve is similar to the area of the county that will be excluded from the service area. For example, if the MA organization is requesting a service area reduction (creating a new partial county) the organization can demonstrate its anticipated cost of care (in the partial county area) by using data from the previous year of MA contracting comparing the health care costs of its enrollees in the excluded area to those in the area of the county it proposes to serve; and

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

Note, that the existence of other MA organizations in the same county with adequate provider networks could contribute evidence that it would be discriminatory to approve a partial county service area.

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

- Enrollee satisfaction surveys;

- Grievance and appeal files; and

- Utilization files.

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