CMS Manual System

Pub. 100-16 Medicare Managed Care

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

Transmittal 97 Date: May 20, 2011

SUBJECT: Chapter 4, "Benefits and Beneficiary Protections"

I. SUMMARY OF CHANGES: The CMS Final Rule, 4144-F was published in the Federal Register (76) on April 5, 2011. This manual update mainly incorporates these regulatory guidances into the manual chapter. This manual update incorporates other recently published changes, such as Call Letter guidance and cost-sharing guidance. We also added guidance and strengthened our beneficiary protections in specific areas such as transplants.

NEW / REVISED MATERIAL = EFFECTIVE DATE: May 20, 2011 IMPLEMENTATION DATE: May 20, 2011

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	4/Table of Contents
R	4/10.2/ Basic Rule
R	4/10.5/ Part D Rules for MA Plans
R	4/10.6/ Anti-Discrimination Requirements
R	4/10.8/ Confidentiality and Accuracy of Enrollee Records
R	4/10.9/ Benefit Requirements
R	4/10.10/ Uniformity
R	4/10.11/ Caps on Enrollee Financial Responsibility
R	4/10.13/ Clinical Trials
R	4/10.14/ Provider Qualifications
R	4/10.15/ Drugs that are Covered Under Part B Original Medicare
R	4/10.18/ Access to Screening Mammography and Influenza Vaccine
R	4/10.19/ Return to Home Skilled Nursing Facility (SNF)
R	4/10.21/ Therapy Caps and Exceptions
R	4/10.22/ Balance Billing
R	4/10.24/ In-network Preventive Services
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R	4/20.4/ Stabilization of an Emergency Medical Condition			
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R	4/30.5/ Meals			
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R	4/40.4/ Benefit Status			
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R	4/50.1/ Guidance on Acceptable Cost-Sharing			
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R	4/60.1/ Definition			
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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 2010 and/or future operating budgets determined by the organizations.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

^{*}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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10.2 - Basic Rule

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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 requirements apply with respect to the rule that MAOs must cover the costs of Original Medicare benefits:

- <u>Benefits:</u> MA plans must provide or pay for medically necessary Part A (for those entitled) and Part B covered items and services;
- <u>Access:</u> MA enrollees must have access to all medically necessary Parts A and B services. However, MA plans are not required to provide MA enrollees the identical access to providers as is provided under Original Medicare (refer to accessibility rules for MA plans in section 110 of this chapter).
- <u>Cost-sharing</u>: Cost-sharing imposed for Original Medicare benefits is subject to the restrictions in section 50.1 and annual guidance issued by CMS. For services not subject to restrictions in section 50.1, MA plans may impose 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;
- <u>Billing:</u> MA plans need not follow fee-for-service (FFS) billing procedures. MA plans may create their own billing and payment procedures as long as providers whether contracted or not are paid accurately, timely and with an audit trail. MA plans may not require enrollees to pay providers whether contracted or not for Original Medicare services and then be reimbursed by the plan. See section 20.7 for rules governing payment amounts to non-contracted providers for Original Medicare non-emergent services; and
- Non-contracted providers (including suppliers): MAOs may negotiate payment rates with their contracted providers and need not follow FFS payment rates. However, in the absence of a mutual agreement between the non-contracted provider and the MAO to receive less than the Original Medicare rate, non-contracted providers must accept the Original Medicare rate as payment in full. For further information on payment to non-contracted providers see Section 100, "Special Rules for Services Furnished by Non-Contract Providers," of Chapter 6, "Relationships with Providers," of this manual. Additional useful information on

payment requirements by MAOs to non-network providers may be found in the "MA Payment Guide for Out-of-network Payments," at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/oon-payments.pdf

• DMEPOS Competitive bid program: On January 1, 2011, the FFS Medicare payment amount for DMEPOS competitive bid items furnished in Competitive Bidding Areas (CBAs) was reduced below the fee schedule payment. The new program only affects certain geographic areas and certain categories of DMEPOS; exceptions may apply. For the latest guidance refer to information at http://www.cms.gov/DMEPOSCompetitiveBid/. The new program will affect MA payments in those situations when an MA plan is only required to pay at least the FFS rate, for example, when reimbursing non-contracting suppliers. MAOs must disclose information on the new program to their plan members. MAOs should advise enrollees how the DMEPOS competitive bidding program will affect them and what they should do if they need to change suppliers, for example, in cases where a member's current supplier is not one of the "Medicare contract suppliers" under the DMEPOS competitive bidding program and they cannot be grandfathered under the DMEPOS competitive bidding program.

The following circumstances are exceptions to the rule that MAOs must cover the costs of Original Medicare benefits:

- <u>Hospice</u>: 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, an MA enrollee who has elected hospice and requires medical treatment for a non-hospice condition can do one of the following:*
 - (1) Use plan providers and services. In such a case, the enrollee only pays plan allowed cost-sharing, and the provider would directly bill FFS for Parts A and B services); or
 - (2) Use non-network providers and be treated under FFS. In such a case, if the service is not emergent/urgent care, the enrollee would pay the total FFS allowed cost-sharing.
- <u>Inpatient hospital stay during which enrollment ends</u>: 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 as of the effective date of the new coverage;
 - Enrollee cost-sharing for the inpatient hospital stay is based on the costsharing amounts as of the entry date into the hospital;

- o If the enrollee was in a SNF in December in an MAO that does not require a prior qualifying 3-day hospital stay and then joined Original Medicare on January 1st, the enrollee may continue staying in the SNF (if medically required) without a three-day qualifying hospital stay.
- <u>Clinical trials</u>: Original Medicare pays for the costs of routine services provided to an MA enrollee who joins a *qualifying* clinical trial. MA plans pay the enrollee the difference between fee-for-service cost-sharing incurred for *qualifying* clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services. For further information on coverage and payment of clinical trials in MA plans, see section 10.13 of this chapter.

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.

10.5 - Part D Rules for MA Plans

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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 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)	<u> </u>		
HMO, Point of Service (HMO-POS), 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 (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
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
Section 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
Section 1833 HCPP (Health Care Pre-	NA	No	Yes
payment Plan) PACE Programs (Program for the All inclusive Care of the Elderly)	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#TopOfP age 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. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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.

Additionally, an MAO must:

- 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; and
- 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.

However, *in certain cases, an MAO may deny enrollment based on medical status*. There are three situations where enrollment may be denied based on the presence or absence of a medical condition:

- In a SNP, to a person who does not fulfill the eligibility criteria for enrollment in the SNP;
- To a person with end-stage renal disease (ESRD), 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; and
- To a person receiving hospice benefits prior to completing an enrollment request for an MSA plan. Refer to section 20.10 of Chapter 2 of this manual, "Enrollment and Disenrollment" located at http://www.cms.hhs.gov/Manuals/IOM/, Publication 100-16.

The following websites contain useful information about discrimination:

- http://www.eeoc.gov/policy/adea.html, and
- <u>http://www.ada.gov/.</u>

10.8 – Confidentiality and Accuracy of Enrollee Records (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

With respect to 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:
 - o 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.

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 *and* deemed contracting providers (of PFFS plans) must be required under their contracts or the plan's Terms and Conditions of Payment 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 statute and regulations (http://www.hhs.gov/ocr/privacy/)

10.9 - Benefit Requirements

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(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)
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All benefits offered by any MA plan, independent of plan type, must:

- Be priced in the bid; the plan incurred bid-priced cost should not be solely administrative;
- Fulfill requirements in section 30.1 and 30.2, such as anti-discrimination; and
- Be specified in the appropriate marketing vehicles as indicated in the Medicare Marketing Guidelines located at http://www.cms.hhs.gov/Manuals/Downloads/mc86c03.pdf.

All plans, independent of plan type:

• Must offer basic benefits as described in section 10.3;

- May only offer supplemental benefits that are directly health-related, that is, health care services or items whose primary purpose is to prevent, cure, or diminish *an* actual or *expected* illness or injury (See section 30.1); and
- Must provide in a timely manner a written advance coverage determination to
 enrollees and non-contract or deemed providers who request this information. A
 written advance coverage determination is a determination by the plan prior to
 provision of a service confirming whether that service is both medically necessary
 and a plan-covered service and in consequence will be paid for by the MA plan
 (see 42 CFR 422.566). All MA plans should provide in their member materials
 clear explanations of the process for requesting a written advance coverage
 determination
- Local PPO, RPPO, PFFS, and MSA plans may not establish prior notification rules under which an enrollee is charged lower cost-sharing when either the enrollee or the provider notifies the plan before a service is furnished (42 CFR 422.4(a)(1)(v), (a)(2), and (a)(3)).

10.10 - Uniformity

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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, to all Medicare beneficiaries with Parts A and B of Medicare (See section 20 of Chapter 1 of this manual, "General Provisions," for the definition of segment);
- 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:
 - o 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
 - o Paying their premium by check.

The following guidance applies to benefit package designs that include tiered costsharing of medical benefits:

- On a limited basis, a plan may tier cost-sharing of medical benefits based on service category for example, inpatient hospital services provided:
 - The plan fully discloses tiered cost-sharing amounts and requirements to enrollees and plan providers;
 - The services at each tier of cost-sharing are equally accessible to all plan enrollees; and√
 - All beneficiaries are charged the same amount for the same service with the same provider.
- Tiered cost-sharing of medical benefits may not be based on the provider group an enrollee selects within an MA plan. For example, if an MA plan offers access to two or more physician groups, it may not require different cost-sharing based on the physician group the member selects upon enrollment. Basing a plan's cost-sharing on the physician group a member selects has the effect of creating multiple MA plans within one MA plan and, therefore, conflicts with the uniformity of premium and cost-sharing requirement (see 42 CFR 422.100(d)(2)).
- The cost-sharing amount for post-stabilization services must be the same or lower for non-plan providers as for plan providers.
- CMS does not classify the following differential cost-sharing as prohibited tiering when the variation in cost-sharing is based on:
 - Facility settings for furnishing some services, such as diagnostic imaging services;
 - In-network versus out-of-network services, as explained in sections 100.1 and 110.4; and
 - DME and Part B drugs, as explained in section 50.1.

10.11 - Caps on Enrollee Financial Responsibility (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

Although MAOs have certain rights of collections, in *the* instances *described below*, the enrollee is "held harmless," that is, the enrollee is protected by a limit on his/her financial responsibility:

1) <u>Limitations on Enrollee Liability:</u> 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:

- o The service is otherwise plan covered;
- o The enrollee was advised of the need for a referral; and
- o 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 10.22, an enrollee *is responsible for paying* non-contracted providers *only* the plan-allowed cost-sharing *for covered services*. The MAO, not the enrollee, is obligated to pay balance billing *when it is allowed under Medicare rules*. 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 *plan* provider who refers a patient to *another* 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 *furnishes* a non-covered service (for example, *a* service *that* is not part of the plan benefit package) should clearly advise the enrollee prior to *furnishing the* 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.

<u>Missed Appointment Charges:</u> MAOs may charge "administrative fees" to enrollees for missed appointments with contracting providers and for not paying *required cost-sharing* at the time of service with a contracting provider. Under the MA program such charges are allowable *only* 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 the MAO itself does not charge an administrative fee for missed appointments then any individual provider — whether or not that provider contracts with the plan - 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.

10.13 – *Clinical Trials* (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled in MA plans, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participating in all qualifying clinical trials. The Clinical Trial National Coverage Determination (NCD) defines what routine costs means and also clarifies when items and services are reasonable and necessary. All other Medicare rules apply. Refer to the Medicare Clinical Trial Policies page at http://www.cms.gov/ClinicalTrialPolicies/ for more information.

MA plans pay the enrollee the difference between Original Medicare cost-sharing incurred for qualified clinical trial items and services and the MA plan's in-network cost-sharing for the same category of items and services. This cost-sharing reduction requirement applies to all qualifying clinical trials. MAOs cannot choose the clinical trials or clinical trial items and services to which this policy applies. The MAO owes this difference even if the member has not yet paid the clinical trial provider. Additionally, the member's in-network cost-sharing portion must also be included in the plan's out-of-pocket maximum calculation.

To be eligible for reimbursement, beneficiaries (or providers acting on their behalf) must notify their plan that they have received qualified clinical trial services and provide documentation of the cost-sharing incurred, such as a Medicare Summary Notice (MSN). MAOs are also permitted to seek MA member FFS cost-sharing information directly from clinical trial providers.

MA plan enrollees are free to participate in any qualifying clinical trial that is open to beneficiaries in Original Medicare. If an MAO conducts its own clinical trial, the MAO can explain to its enrollees the benefits of participating in its clinical trial; however, the MAO may not require pre-authorization for a Medicare qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's use of a non-plan clinical trial, even if the MAO believes it is sponsoring a clinical trial of a similar nature. Examples of impediments include, but are not limited to, requiring enrollees to pay the original Medicare cost-sharing amount for routine care services before being compensated for the difference by the MAO or unduly delaying any required cost-sharing refund. The enrollee has final choice on which, if any, clinical trial to participate in. However, an MA plan can request, but not require, enrollees to pre-notify the plan when they are participating in clinical trials.

CMS's current clinical trial policy (July 2007 NCD) and information about clinical trials may be found on the CMS website at http://www.cms.gov/ClinicalTrialPolicies/ and in

the Clinical Trial NCD located in the NCD manual, Part 4, section 310, http://www.cms.gov/manuals/downloads/ncd103c1 Part4.pdf. The clinical trial policy contains detailed information about the qualification process. Clinical trials that do not automatically qualify under the clinical trial policy are subject to local review and coverage by the MACs. MAOs may contact the clinical trial provider or the MAC for information about qualification and payment for clinical trial items and services. Category B IDE study and clinical trial claims processing instructions for both FFS and managed care enrollees (including required modifiers used to denote IDE studies and clinical trial items and services), are located in Pub. 100-4, the Medicare Claims Processing Manual in chapter 32, sections 68 and 69.

http://www.cms.gov/manuals/downloads/clm104c32.pdf. In addition, the National

http://www.cms.gov/manuals/downloads/clm104c32.pdf. In addition, the National Institutes of Health sponsors a website called Clinicaltrials.gov, which serves as a registry and public database for clinical trials. http://www.clinicaltrials.gov/

10.14 - Provider Qualifications

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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" which may be found at http://www.cms.gov/manuals/downloads/mc86c06.pdf. 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. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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

The following broad categories of drugs may be covered under Medicare Part B – subject to coverage requirements as well as regulatory and statutory limitations. *Note* that 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;
- o Immunosuppressive drugs;
- o 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.

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.

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10.18 – Access to Screening Mammography and Influenza Vaccine (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)
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Enrollees of an MAO may directly access (through self-referral to any plan participating provider) in-network screening mammography and influenza vaccine.

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10.19 - Return to Home Skilled Nursing Facility (SNF) (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)
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An MA plan must provide coverage *through a home SNF* (*defined at 42 CFR 422.133(b)*) of post-hospital extended care services to enrollees *who resided in* a nursing facility prior to *the hospitalization, provided:*

- The enrollee elects to receive the coverage through the home SNF; and
- The home SNF either has a contract with the MAO or agrees to accept substantially similar payment under the same terms and conditions that apply to similar nursing facilities that do contract with the MAO.

This requirement also applies if the MAO *offers* SNF care *without requiring* a prior qualifying hospital stay.

The post-hospital extended care scope of services, cost-sharing, and access to coverage provided by the home SNF must be no less favorable to the enrollee than post-hospital extended care services coverage that would be provided to the enrollee by a SNF that would be otherwise covered under the MA plan (42 CFR 422.133(c)). In particular, in a PPO, in-network cost-sharing applies.

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10.21 - Therapy Caps and Exceptions (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)
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Certain services are exempted from Original Medicare caps for rehabilitation services. 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. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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. *Providers who* are permitted to balance bill must obtain this balance billing from the MAO.

Note: Under Original Medicare rules, an Original Medicare participating provider (hereinafter referred to as 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. An Original Medicare non-participating provider (hereinafter referred to as a non-participating, or non-par, provider) may accept assignment on a case-by-case basis and indicates this by checking affirmatively field 27 on the CMS 5010 claims form; in such a case, no balance billing is permitted.

The rules governing balance billing as well as the rules governing the MA payment of *MA-plan* non-contracting and *Original-Medicare* non-participating providers are listed below by type of provider.

- <u>Contracted provider.</u> There is no balance billing paid by either the plan or the enrollee.
- <u>Non-contracting</u>, <u>participating provider</u>. There is no balance billing paid by either the plan or the enrollee;
- Non-contracting, non-participating provider. The MAO owes the non-contracting, non-participating (non-par) provider the difference between the member's cost-sharing and the Original Medicare limiting charge, which is the maximum amount that Original Medicare requires an MAO to reimburse a provider. The enrollee only pays plan-allowed cost-sharing, which equals:
 - o The copay amount, if the MAO uses a copay for its cost-sharing; or
 - The coinsurance percentage multiplied by the limiting charge, if the MAO uses a coinsurance method for its cost-sharing.
- <u>MA-plan</u> non-contracting, non-participating <u>DME</u> supplier. The MAO owes the non-contracting non-participating (non-par) <u>DME</u> supplier the difference between the member's cost-sharing and the <u>DME</u> supplier's bill; the enrollee only pays plan-allowed cost-sharing, which equals:

- o The copay amount, if the MAO uses a copay for its cost-sharing; or
- The coinsurance percentage multiplied by the total provider bill, if the MAO uses a coinsurance method for its cost-sharing. Note that the total provider bill may include permitted balance billing.

Additional useful information on payment requirements by MAOs to non-network providers may be found in "MA Payment Guide for Out-of-network Payments," at http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/oon-payments.pdf

MA plans must clearly communicate to enrollees through the Evidence of Coverage (EOC) and Summary of Benefits (SB) their cost-sharing obligations as well as their lack of obligation to pay above allowed plan cost-sharing whether the payments go to the provider bill or to balance billing.

10.24 – In-network Preventive Services (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

MAOs are required to offer all Medicare preventive services that are covered at zero cost-sharing under Original Medicare at zero cost-sharing. CMS will provide annual guidance to MAOs on which Medicare preventive services must be covered at zero cost-sharing for the following contract year.

MAOs may not charge for facility fees, professional services, or physician office visits if the only service(s) provided during the visit is a *preventive service that is covered at zero cost-sharing under Original Medicare*. However, if during provision of the preventive service, additional non-preventive services are furnished, then the plan's cost-sharing standards apply.

The following CMS publications provide valuable information for plans:

- Your Medicare Benefits, http://www.medicare.gov/Publications/Pubs/pdf/10116.pdf, which contains a list of Medicare covered preventive services furnished by Original Medicare. As noted in the publication, the preventive status of certain services is dependent on referrals. For example, as explained in these publications, *abdominal aortic aneurysm screening* is covered as a preventive service only when referral is made as a result of the one-time "Welcome to Medicare" physical exam.
- Medicare and You, http://www.medicare.gov/Publications/Pubs/pdf/10050.pdf.

In addition, the Affordable Care Act of 2010 established a new Medicare covered preventive service, the "annual wellness visit." Information about this benefit may be found at http://www.medicare.gov/navigation/manage-your-health/preventive-services/medicare-physical-exam.aspx.

20.1 – Ambulance *Services* (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

The MAO is financially responsible for ambulance services, including ambulance services dispatched through 911 or its local equivalent, when *either an emergency situation exists as defined in section 20.2*, or other means of transportation would endanger the beneficiary's health. *The enrollee is financially responsible for plan- allowed cost-sharing*. Medicare rules on coverage for ambulance services are set forth at 42 CFR 410.40. For Original Medicare coverage rules for ambulance services, *refer to* 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. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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 medical condition status is not affected if a later medical review found no actual emergency present.

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
 - O 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:

<u>Example</u>: 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 *is financially responsible for the urgently-needed* medical care.

20.4 – Stabilization of an Emergency Medical Condition (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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. *Refer to section* 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 *of* 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. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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

- The limit for emergency service cost-sharing that is published by CMS in its annual guidance;
- What the enrollee would be charged in-network if s/he obtained the services through the MAO (refer to Table *VI* in section 110.4).

20.7 - Services of Non-contracting Providers and Suppliers (**Rev.** 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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, the MA plan *may* provide medical advice and recommend that the enrollee use a qualified dialysis provider *if the enrollee voluntarily requests such advice because* (s)he will be out of area. 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).

30.1 – Definition of Supplemental Benefit

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11) In order for an item or service to be classified as a supplemental benefit, the following three conditions must be met:

(1) <u>Primarily health related</u>: 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.

The primary purpose of an item or service is determined either by 1) national typical usages of most people using the item or service, or by 2) community patterns of care. See the examples below and Table II in section 30.3 for illustrative examples.

- (2) <u>Cost requirement</u>: 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) <u>Classification</u>: 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 proposed *as a* supplemental benefit *in a plan's bid and submitted plan benefit package*. Additional requirements governing approval of a proposed *plan* benefit package are *specified* 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, after which the item or service may be called a supplemental benefit and offered as part of an approved *plan* benefit package.

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 *community* 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 *when* 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.

Except in the special circumstances described in section 30.4, MAOs are similarly prohibited from providing payments to non-enrollees, including family members, for supplemental benefits. For example, an MA plan is prohibited from providing payments for transportation costs of a living donor in the case of a kidney transplant.

For further examples of benefits, refer to Table II in section 30.3. MA plans with questions about whether a proposed benefit meets the definition of a supplemental benefit should email MABenefitsMailbox@LMI.org. This mailbox will typically be functional after release of MA bid and benefit guidance for the following contract year and for the duration of the bid season.

30.2 - Anti-Discrimination Requirements (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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 plan benefits that:
 - Conditions eligibility for a supplemental benefit on utilization. For example, a plan may not condition the offering of a gym benefit based on an enrollee meeting minimal gym attendance requirements;
 - o Promote discrimination;
 - Discourage enrollment;
 - Encourage disenrollment;
 - Steer specific subsets of Medicare beneficiaries to particular MA plans (with the exception of SNPs);

- o Inhibit access to services;
- 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 design a plan with supplemental benefits that only appeal to healthier beneficiaries; *or*
- Benefit designs meet other MA program requirements.

Section 50.1 of this chapter contains general guidance on *acceptable* cost-sharing. The anti-discrimination prohibitions *in this section* apply to both Original Medicare, mandatory supplemental, and optional supplemental benefits.

30.3 - Examples (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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 *included* in the widely circulated Medicare & You Handbook. Table II below contains an alphabetized list *other supplemental* benefits. These examples *are based on our experience with annual benefit reviews*. 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 *IV*, provided in section 40.9, explaining which over-the-counter (OTC) items *may be offered* 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 *plan benefit package* (PBP) or *bid pricing tool* (BPT).

Table II: Alphabetical list of items *and services* and their potential supplemental benefit status

Item / Service	May the item be offered as a	Rationale / Reasons /
	Supplemental Benefit?	Comments / Further
		examples.

Assisted Daily Living (ADL) assistance	No, ADL services may not be offered as a supplement benefit.	The primary purpose of ADL assistance is maintenance.
Batteries	No, batteries may not be offered as a supplemental benefit if they come by themselves (e.g., replacement batteries for hearing aids). Yes, batteries are allowed as a supplemental benefit if they are 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 Salon Services	No, beauty salon services may not be offered as a supplemental benefit.	The primary purpose of beauty salon services are cosmetic.
Cash	No, cash may not be offered as a supplemental benefit.	There is a statutory prohibition on offering cash.
Contact Lens Cases	No, contact lens cases are not allowed as a supplemental benefit if they are offered separately from the contact lens.	See the explanation above under "batteries."
	Yes, contact lens cases are allowed as a supplemental benefit if factory packaged with the contact lens.	
Dentures	Yes, dentures may be offered as a supplemental benefit.	The primary purpose of dentures is to address symptoms of lack of teeth.
Educational Materials	Yes, educational materials may be offered as supplemental benefits, if the subject of the teaching is itself eligible to be a benefit.	Educational pamphlets on gym exercises, Tai chi, etc. are allowed as benefits, since these items can themselves be allowed as benefits.
	No, educational materials may not be offered as supplemental benefits, if the	Educational materials on subjects such as home repairs, which are not

subject of the teaching – for example, home repair – is not eligible to be a benefit. Electronic Monitoring (Notification devices in case of a fall)¹ Wes, electronic monitoring devices as a supplemental benefit. No, cell phones are not allowed as a supplemental benefit, even when intended as monitoring devices). Gym benefit including exercise classes at a gym, such as Tai Chi, yoga and dance classes! Homemaker services (including maid service)² Manicures / Pedicures Massages No, manicures / pedicures may not be offered as a supplemental benefit. Massages No, manicures / pedicures may not be offered as a supplemental benefit. Note: Chiropractor visits may be correct as supplemental benefits. Note: Chiropractor visits may be covered as supplemental benefits. Note: Refer to section 30.5 for exceptional cases when meals may be offered as a supplemental benefit. Safety devices, shower safety bars and other bathroom safety devices Monitoring devices of electronic monitoring devices is to prevent or cure injury; however, the primary purpose of cell phones is communication. Intent to provide them for monitoring does not change their primary purpose of a gym benefit is prevention through exercise. The primary purpose of homemaker services is cosmetic. The primary purpose of manicures / pedicures is cosmetic. Massages by themselves may not be offered as a supplemental benefit. No, meals are generally not allowed as benefits. Note: Refer to section 30.5 for exceptional cases when meals may be offered as a supplemental benefit. Safety devices, shower safety bars and other bathroom safety devices in the bathroom may be offered as a supplemental benefit. No, smoke detectors, fire No, smoke detectors, fire Fires in homes are not expected events. We do not electronic or cure fill provide them for monitoring devices in the pathroom may be giftered as a supplemental benefit. Fires in homes are not expected events. We do not electronic as benefits.		aubiant of the tagething f	allowable bounds and
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No, smoke detectors, fire expected events. We do not			Fires in homes are not
		No, smoke detectors, fire	expected events. We do not

	alarms, fire extinguishers, home assessment, and home repair services such as repair of rugs and stairway rails may not be offered as a supplemental benefit.	allow safety devices to be offered as supplemental benefits outside the bathroom.
Transportation (Medically necessary transportation ⁴	Yes, medically necessary transportation may be offered as a supplemental benefit. No, monthly bus or train passes may not be offered as supplemental benefits.	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.

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 for beneficiaries who qualify. 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. If the Home Health Agency Manual indicates that a particular service is covered under Original Medicare, then the plan must also cover it; however, if the Home Health Agency 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. The Home Health Agency Manual is located at http://www.cms.gov/Manuals/PBM/list.asp, publication #11.
- 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 *more detail about* transportation benefits.

See section 30.4 for a full discussion on transportation benefits

30.4 - Transportation Benefits

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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

Not covered by Original Medicare: An MA plan may create either a mandatory or optional supplemental transportation benefit *beyond those circumstances*, *indicated in sections 20.1 where Original Medicare covers transportation*. 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.

<u>Original Medicare transplant services</u>: As <u>explained</u> in section <u>10.2</u>, <u>every MA plan must</u> provide all Original Medicare services <u>to its enrollees</u>. For coordinated care plans, <u>innetwork transplant</u> 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 cost (as explained below), may wish to provide a required Original Medicare transplant service at a distant location (further away than the normal community patterns of care for that service), even though provision of this service is available locally (within the service area) consistent with patterns of care for Original Medicare beneficiaries who reside in the service area.

The MA plan's provision of a transplant service at a distant location, further away than the normal community patterns of care for transplant services, depends on the local cost of transplants:

- o If the local providers of transplants, within the normal community patterns of care for transplants, are willing to cover transplants for MA enrollees at the Original Medicare rate then, although the MA plan <u>may</u> also offer transplants at a more distant location, the MA plan <u>must</u> allow enrollees the option of obtaining transplant services locally;
- o If the local providers of transplants, within the normal community patterns of care for transplants, are not willing to cover transplants for MA enrollees at the Original Medicare rate, then the MA plan <u>must</u> alternatively offer transplants at a more distant location.

When providing an Original Medicare service at a more distant location, further away than the normal community patterns of care for transplants, the MA plan must ensure that the distant location provides at least the same quality and timeliness of services as at the local providers of this service.

In any circumstance in which an MA plan provides transplant services *at a more distant location*, 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.

The policy in this section is summarized in Table III.

Table III: Provision of Original Medicare transplant services at a distant location and related transportation and lodging.

Do the local providers - within the normal community pattern of care for an Original Medicare transplant services – accept Original Medicare rates for treating MA enrollees?	May/Must the plan cover transplant services for enrollees who chose to obtain services locally, within the normal community patter of care for this Original Medicare transplant services?	May/must the plan provide Original Medicare transplant services at a distant location, further than the normal community patterns of care for Original Medicare transplant services?	May/must the plan provide transportation and lodging
Yes	Must provide	May provide	Must provide
No	May provide	Must provide	Must provide

30.5 – Meals

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

As discussed in section 30.1, all benefits must be <u>primarily</u> 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 <u>primarily</u> 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 *offered* 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 *ordered* by a provider (not a social or case worker). As discussed in 42 CFR 422.112(b)(3), 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 approve the benefit without further review. However, if the MAO proposes to offer meals for more than four weeks, CMS will request from the MAO justification for this longer duration and will review the proposed benefit to determine if it should be approved.

- <u>For a chronic condition</u> 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.
 - o *Ordered* by a provider (not a social or case worker); and
 - Part of a supervised program designed to <u>transition</u> 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 approve the benefit without further review. However, if the MAO proposes to offer meals for more than two weeks, CMS will request from the MAO justification for this longer duration and will review the proposed benefit to determine if it should be approved.

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."

30.8 – Supplemental Benefits Extending Original Medicare Benefits (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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

<u>Medical Necessity:</u> All MAOs must cover all medically necessary Original Medicare benefits (section 10.2). An MAO may *only* offer additional coverage, beyond *those* furnished by Original Medicare, as a supplemental benefit, *provided that coverage is medically necessary*.

- <u>Example</u>: 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/.
- Example: An MA plan may not offer home health coverage or home health services beyond that covered by Original Medicare, if the Home Health Agency manual has classified those additional services as not covered by Original Medicare because they are not considered medically necessary. The Home Health Agency Manual is located at http://www.cms.gov/Manuals/PBM/list.asp, publication #11.

<u>Distinct Naming:</u> An MAO should be careful in the selection of terminology describing a supplemental benefit that furnishes coverage beyond that of Original Medicare. For example:

o 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 days," or similar terms in order to distinguish the benefit from the Part A benefit the plan is required to provide in its benefit package.

<u>Enrollee services:</u> An MAO may not 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).

• Example. Other than the Original Medicare respite benefit, an MA plan may not offer as a supplemental benefit other types of caregiver or custodial support (whether to SNF or non-SNF enrollees). However, an MAO may, and is even encouraged to, advise in plan newsletters or other similar vehicles of services to assist caregivers in obtaining relief provided the plan does not refer to these services as benefits. For information on the Original Medicare respite benefit see publication 100-02, The Medicare Benefit Policy Manual, Chapter 9, section 40.2.2. The list of manual links may be found at http://www.cms.hhs.gov/Manuals/IOM/list.asp.

Marketing Requirements: An MAO, in its *marketing materials* and PBP *descriptions* 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 *only* one aspect of the benefit.

- Example: 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. Similarly, although an MAO may offer "chiropractic visits" as a benefit, the description of the benefit should be "chiropractic visits" without use of the word "massage," even though the chiropractor may use preparatory massage therapy during the visit.
- Example: Although an MAO must offer in the PBP "ESRD services" 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.

30.9 - Benefits during Disasters and Catastrophic Events (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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 for MA plans—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 *gatekeeper referrals where applicable*;
- 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.

40.4 - Benefit Status

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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

- If a plan is offering items under its Part D utilization management protocols, then the items it may offer are discussed in section 60.2 of Chapter 7 of the Part D Prescription Drug Benefit Manual as described in section 40.2 above; and
- If the plan is offering a Part C OTC supplemental benefit consisting of either a few items or a packaged benefit, and independent of payment method, then the plan may only cover items belonging to the categories listed in the eligible and dual-purpose item sections of Table *IV* in section 40.9. This table was created based on the guidance in sections 30.1 and 30.3 which discussed the definition of benefit. Items belonging to categories in the non-eligible portion of Table IV 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 IV, 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 *IV* contains:

- Eligible OTC Items: Certain OTC items may always be offered;
- Non-Eligible OTC Items: Certain items may never be offered; and
- <u>Dual Purpose OTC Items:</u> 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 *IV* in section 40.9.

40.9 - CMS Table of OTC Items

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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

- <u>Categories vs. items:</u> As indicated in section 40.4, Table *IV* below lists categories of items. MA plans should not steer enrollees to particular brands of items. For example, if 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;
- <u>Categories not on the list:</u> 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;
- <u>Three eligibility categories</u>: 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.
- <u>Debit card linkages</u>: 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:
 - <u>Dual Purpose</u>: 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;

- O 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
- O 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 IV: Eligibility Status of OTC Items.

Eligible?	Category	Sub-categories	Exceptions
Dual Purpose	Minerals	Includes both multi-vitamins, individual vitamins and minerals.	
Dual Purpose	Vitamins	Includes both multi-vitamins, individual vitamins and minerals.	
Dual Purpose	Items used to assist in weight loss		
Dual Purpose	Diagnostic Equipment	Equipment diagnosing: blood pressure, cholesterol, diabetes, colorectal screenings, HIV, etc.	Thermometers are classified as eligible not dual <i>purpose</i> ; scales are non-eligible; pregnancy diagnosis items are non-eligible (<i>See footnote #4</i>)
Dual Purpose	Hormone replacement	Phytohormone, natural progesterone, DHEA	
Dual Purpose	Weight loss items	Phentermine, 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?	Category	Sub-categories	Exceptions
Eligible	Fiber		Items which are
	supplements		primarily food with
			fiber added.
Eligible	First Aid	Includes: Bandages,	Flashlights are non-
	supplies	dressings, non-sport tapes.	eligible.
Eligible	Incontinence	8,, 1	8
Ziigioic	supplies.		
Eligible	Medicines,	For examples see footnote	Homeopathic and
Eligiole	ointments and	#1.	alternative medicines
	sprays with	"1.	including botanicals,
	active medical		herbals, probiotics,
	ingredients		and neutraceuticals
	_		
	that cure,		are non-eligible. For
	diminish or		further exceptions see
	remove		footnote #2.
T	symptoms.		
Eligible	Sunscreen		
	lotion		
Eligible	Support items	Compression hosiery, rib	Arch and insoles are
		belts, braces, orthopedic	non-eligible.
		supports.	
Eligible	Teeth / denture	Toothbrushes, toothpaste,	Mouthwashes, bad
	-related items /	floss, denture adhesives, gum	breath items, and
	Mouth care	problems	teeth-whiteners are
			non-eligible.
Non-	Alternative	Includes botanicals, herbals,	
eligible	medicines	probiotics and	
		neutraceuticals.	
Non-	Baby items		
eligible			
Non-	Contraceptives		
eligible	1		
Non-	Convenience	Scales, fans, magnifying	
eligible	(non medical)	glasses, ear plugs, foot	
8	items	insoles, gloves.	
Non-	Cosmetics	For examples see footnote	Sun-tan lotions are
eligible		#3.	eligible. Medicated
31151010			soaps, hand
			sanitizers, therapeutic
			shampoos, shampoos
			to fight dandruff are
			non-eligible.
Non-	Food product	Sugar / salt sunnlaments)
	Food product	Sugar / salt supplements,	Fiber products are
eligible	or supplements	energy bars, liquid	eligible unless they
		energizers, protein bars,	are primarily foods

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

Notes to Table *IV*:

- 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 *IV*.
- 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.
- 4. For certain very specific diseases for example, congestive heart failure or liver disease daily or weekly weight fluctuations may indicate fluid buildup and affect medical treatment or medication. For these limited diseases, the MA plan will cover the purchase of scales as a supplemental, Part C, OTC item, provided the enrollee has discussed the purchase with his/her personal provider who orally recommends the purchase due to the specific disease. Similarly, purchase of OTC early-diagnosis pregnancy items are covered by the plan if the enrollee's personal provider orally recommends these diagnostic items for a specific disease or condition where early diagnosis affects medical treatment or medication. We

recommend that MA plans indicate these exceptions in their own OTC lists by using footnotes rather than table entries because scales or pregnancy diagnosis items are not generally dual purpose except in rare cases.

50.1 – Guidance on Acceptable Cost-sharing (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

CMS, in its annual bid review of proposed plan packages, applies five categories of cost-sharing standards whose requirements are detailed below in items (1) through (5). Organizations should note that benefit design and cost-sharing amounts approved for a previous contract year will not be automatically acceptable for the following contract year because a separate, distinct review is conducted each contract year. Throughout this section, the term "cost-sharing" refers to co-payments, coinsurances and deductibles (42 CFR 422.2)

The five categories of cost-sharing standards are the following:

Maximum Out-of-Pocket (MOOP) and Catastrophic Limits. To ensure that MAO cost-sharing does not discourage enrollment of higher cost individuals, and to provide for transparent plan benefit designs that permit beneficiaries to better predict their out-of-pocket costs, all local MA plans (employer and non-employer) – including HMOs, HMOPOS, local PPO (LPPO), and PFFS plans – are subject to a mandatory maximum out-of-pocket (MOOP) limit on enrollee cost-sharing that includes costs for all Parts A and B services. The mandatory MOOP amount is set annually by CMS.

Note: For any dual eligible enrollee, MA plans must count toward the MOOP limit only those amounts the individual enrollee is responsible for paying net of any State responsibility or exemption from cost-sharing and not the cost-sharing amounts for services the plan has established in its plan benefit package. Effectively, this means that, for dual eligible enrollees who are not responsible for paying the Medicare Parts A and B cost-sharing, the MOOP limit will rarely be reached. However, plans must still track out-of-pocket spending for these enrollees.

In addition, as provided at 42 CFR 422.100(f)(5), both RPPO and LPPO plans are required to have a "catastrophic" limit inclusive of both in- and out-of-network cost-sharing for all Parts A and B services, the dollar amount of which is set annually by CMS. All cost-sharing (i.e., deductibles, coinsurance, and co-payments) for Parts A and B services must be included in plans' MOOPs. Organizations must track enrollee out-of-pocket costs and should notify enrollees when they reach, or are near, a mandatory MOOP, a voluntary MOOP, or a catastrophic limit.

CMS may also annually establish a lower, voluntary MOOP limit. MAOs that adopt the lower voluntary MOOP limit will have more flexibility in establishing costsharing amounts for Parts A and B services than those that do not elect the voluntary

MOOP. Table V below summarizes MOOP and catastrophic limit rules for various MA plan types.

Table V: Summary of MOOP and catastrophic limits by plan type.

	Mandatory MOOP Limit(In-network Parts A/B Services)		Voluntary MOOP Limit (In-network Parts A/B services)		Catastrophic Limit (In and Out-of-network Parts A/B Services)	
Plan Type	Required?	Who sets the maximum amount?	Required?	Who sets the maximum amount?	Required?	Who sets amount?
HMO, HMOPOS ⁽ⁱ⁾ , PFFS ⁽ⁱⁱ⁾	Yes, unless plan adopts voluntary MOOP limit	CMS	No, if plan adopts mandatory MOOP limit	CMS	Not applicable.	CMS
Local PPO and Regional PPO	Yes, unless plan adopts voluntary MOOP limit	CMS	No, if plan adopts mandatory MOOP limit	CMS	Yes	CMS

Notes to Table V:

- (i). In addition to the Original Medicare MOOP and catastrophic limits discussed in this section, an HMOPOS plan may set a separate *limit* on *cost-sharing for* the services furnished by its POS benefit that limits plan liability for the POS benefit during the contract year (Section 100.1).
- (ii). MOOP limits apply to all PFFS plans whether non-network, partial network, or full network.
- 2. Per Member Per Month (PMPM) Actuarial Equivalent (AE) Cost-sharing Maximums. The actuarially estimated total MA cost-sharing for Parts A and B services must not exceed cost-sharing for those services in Original Medicare. MAOs should refer to annually published guidance regarding the application of this requirement to particular service categories. Note that CMS applies this requirement separately to inpatient, SNF, home health service, DME, and Part B drugs.
- 3. Service Category Cost-sharing Standards. As provided under 42 CFR 422.100(f)(6), MA plan cost-sharing for Parts A and B services specified by CMS must not exceed levels annually determined by CMS to be discriminatory. In addition, under Section 1852(a)(1)(B)(iii) of the Act (as amended by the Affordable Care Act) the cost-sharing charged by MA plans for chemotherapy administration services, renal dialysis services, and skilled nursing services for which cost-sharing would apply under

- original Medicare (after the first 20 days) may not exceed the cost-sharing for those services under Parts A and B.
- 4. <u>Discriminatory Pattern Analysis.</u> In addition to the other specific cost-sharing requirements enumerated in this section, CMS may also perform *an* additional general discriminatory pattern analysis to ensure that discriminatory benefit designs are identified and corrected.
- 5. <u>Individual service requirements:</u> CMS has several cost-sharing requirements which apply to <u>individual</u> services. Several of these requirements are referenced elsewhere in this chapter, including the cost-sharing requirements for in-network preventive services (section 10.24), emergency care (section 20.5), and out-of-network dialysis (section 110.3). Additionally, the following cost-sharing requirements for individual services must be adhered to:
 - The 50% cap on Original Medicare services: In order for an Original Medicare in-network or out-of-network item or service *category* to be considered a *plan* benefit, *plans may not just pay a stipend, that is, less than 50% of the contracted (or Medicare allowable rate); rather,* cost-sharing for that service cannot exceed 50% of the total MA plan financial liability for this benefit. *Consequently:*
 - o If a plan uses a coinsurance method of cost-sharing, then the coinsurance for an in-network or out-of-network service category cannot exceed 50%;
 - o If a plan uses a copay method of cost-sharing, then the copay for an out-of-network Original Medicare service category cannot exceed 50% of the average Medicare rate in that area;
 - o If a plan uses a copay method of cost-sharing, then the copay for an in-network Original Medicare service category cannot exceed 50% of the average contracted rate of that service. For example, if the plan's service area consists of two counties with equal frequency of utilization with contracted rates for a particular service of \$90 and \$110 in the two counties, then the plan may uniformly charge no more than a \$50 copay for that service category; and
 - o This 50% cap is in addition to any other caps. Thus, for those service categories subject to fee-for-service cost-sharing limits (e.g. 20% coinsurance) the plan may not charge more than the fee-for-service cost-sharing limit..
 - Part B drugs: No dollar limits can be placed on the provision of Part B drugs covered under Original Medicare unless the Medicare statute imposes the limit on Original Medicare coverage, it is specified in a national or applicable

local coverage determination, or CMS imposes a dollar limit. (See section 80.2 of this chapter for more detailed guidance on the obligation of plans to follow local coverage determination

In addition to the five categories of cost-sharing standards listed above in bullets (1) through (5), MA organizations are subject to the following additional guidance on cost-sharing:

- <u>Deductibles</u>: While high deductibles are required for MSA plans, CMS will closely scrutinize high deductibles in other plan types.
- <u>Use of Coinsurance vs. Co-payments</u>: In our annual review of plan cost-sharing, we will monitor both co-payment amounts and coinsurance percentages. Although MAOs have the flexibility to establish cost-sharing amounts as co-payments or coinsurance, organizations should keep in mind when designing their cost-sharing that enrollees generally find co-payment amounts more predictable and less confusing than coinsurance.
- Organizations may, in certain situations, use co-payments for services that have CMS cost-sharing standards based on Original Medicare coinsurance levels. In those situations, the plan may charge a co-payment that is actuarially equivalent, based on the expected distribution of costs, to the coinsurance standard;
- Plans may not use different co-payment amounts that are based on the cumulative number of visits (e.g., cost-sharing of \$5 for visits 1 through 5, and \$10 for visits 6 and greater); and
- Plans may use a stratified co-payment arrangement for DME and/or Part B drugs provided that: (1) for each strata, the co-payment amount is no greater than the CMS coinsurance requirement for the lower limit of the strata, and (2) the number of co-payment strata does not exceed four. The following example complies with CMS standards.

\mathbf{C}	ost Range For service	Co-payment
•	\$0 - \$199	\$0
•	\$200 - \$499	\$40
•	\$500 - \$999	\$100
•	\$1000 and above	\$200

50.2 – Total Beneficiary Cost-Sharing (TBC) (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

As provided under section 1854(a)(5)(C)(ii) of the Affordable Care Act, and regulations at 42 CFR 422.256(a), CMS may deny bids on a case-by-case basis, if CMS determines that a bid proposes too significant an increase in cost-sharing or decrease in benefits from one plan year to the next. CMS uses the Total Beneficiary Cost (TBC) metric as a

means of evaluating changes in plan benefits from one year to the next, and evaluating whether such changes impose significant increases in cost-sharing or decreases in benefits. The change in TBC from one year to the next captures the combined financial impact of premium changes and benefit design changes (i.e., cost-sharing changes) on plan_enrollees; an increase in TBC is indicative of a reduction in benefits. By limiting the change in the TBC from one year to the next, CMS is able to ensure that beneficiaries are not exposed to significant cost increases from one plan year to the next.

TBC is the sum of plan-specific premium and estimated beneficiary out-of-pocket costs. For those plans that include a Part B premium buy-down as part of their benefit package, this sum of plan-specific premium and estimated beneficiary out of pocket costs is then adjusted by applying a factor to account for the Part B premium buy-down. Information on the TBC metric for the following contract year will be provided in annual guidance issued by CMS.

50.3 - Cost-Sharing Rules for RPPOs (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11.)

As specified in section 50.1, MA regional PPO (RPPO) plans are required to establish a MOOP limit for in-network cost-sharing and a catastrophic limit inclusive of both in-and out-of-network cost-sharing for Parts A and B services. Table V in section 50.1 summarizes MOOP and catastrophic limit rules for various MA plan types, including RPPOs.

In addition to the applicable cost-sharing 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:
 - o Uses a single combined deductible;
 - O 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
 - o 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
 - o 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 innetwork 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 <u>may</u> 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 innetwork 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.

60.1 - Definition

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

Value-Added Items and Services (VAIS) are non-benefit items and services provided to an MAO's enrollees for which the cost, if any, incurred by the plan in providing the item or service is solely administrative. VAIS may not be funded with Medicare program dollars. A cost is not automatically classified as solely administrative simply because it is either minimal or non-medical; rather, the cost, if any, is classified as solely administrative if the cost only covers clerical items or equipment and supplies related to communication (such as phone and postage), or database administration (such as verifying enrollment or tracking usage).

Since VAIS may be of value to some beneficiaries and may be commonly available to commercial enrollees, we allow MA plans to offer VAIS provided that the notification to the beneficiaries about the VAIS follows specific marketing guidelines. For details, see sections 110 and 170 of the Medicare Marketing Guidelines located at http://www.cms.hhs.gov/ManagedCareMarketing/Downloads/R91MCM.pdf.

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. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

The following are some examples of permissible and non-permissible VAIS:

• Example 1: An MA plan offers an in-network vision-exam benefit (for which it incurs a direct medical cost). The MA plan also offers a 5% discount on a vision-exam out-of-network. Enrollees are instructed to pay for the vision-exam out-of-network and receive a 5% discount. The discount is covered by the vision-exam center to broaden its market. Consequently, the MA plan does not incur a direct medical cost as a result of this discount. The MA plan may incur administrative

costs related to negotiating the discount, notifying members, and verifying eligibility.

Since the plan does not incur a direct medical cost in providing the vision exam out-of-network, the discount may not be classified as a benefit. The plan may offer the discount on out-of-network vision exams as a VAIS. However, since the out-of-network vision exam is not a benefit it may not be advertised on the Medicare Options Compare site nor mentioned in the PBP. Other restrictions on advertising apply.

Similarly, if the plan offered a vision-exam benefit and the *vision* 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. *Although the cost is minimal*, the cost is not solely administrative, since the MA plan is paying for vouchers.

60.3 - Additional VAIS Requirements

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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/privacy/. 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 *applicable* relevant fraud and abuse laws, including the anti-kickback statute and prohibition on inducements to beneficiaries.

70.4 - Content of Enrollee Information and Other MA Obligations (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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.

Section 40 of the Medicare Marketing Guidelines, http://www.cms.gov/manuals/downloads/mc86c03.pdf includes additional marketing requirements.

80.6 - Sources for Obtaining Information (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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, located at http://www.cms.hhs.gov/center/coverage.asp has links that:
 - o Provide a listing of all NCDs;
 - Provide a listing of all National Coverage Analyses (NCAs);
 - Provide an index of Local Coverage Determinations (LCDs);
 - Enable users to subscribe to the CMS Coverage Listserv and receive weekly notifications when national coverage documents are updated, such as national coverage analyses (NCAs) and national coverage determinations (NCDs). Listserv subscribers also receive special updates, including CMS announcements of new topics opened for national decision, posting of decision memos, and posting of final technology assessment (TA) reports; 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 Medicare NCDs Manual, Publication 100-03, accessible at http://www.cms.hhs.gov/Manuals/IOM/list.asp, is the primary record of Medicare national coverage policies, and includes a discussion of the circumstances under which items and services are covered.

- Program Transmittals and Program Memoranda, transmit CMS' new policies and procedures on new coverage determinations and Medicare benefits. Links to the
 - Program Transmittals can be found at http://www.cms.hhs.gov/transmittals/01_overview.asp; and
 - Program Memoranda can be found at http://www.cms.hhs.gov/transmittals/CMSPM/List.asp.

Medicare Internet-Only Manuals, located at

http://www.cms.hhs.gov/Manuals/IOM/list.asp. These manuals present information on Medicare coverage of items and services. Changes to these manuals are released through Program Memoranda and Program Transmittals.

90.2 - Multi-Year Benefits

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

Supplemental 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 two years. We understand that some benefits are appropriately offered over multiple years, but encourage plans to limit offerings to one contract year where possible.

100.1 - HMO Point Of Service (POS)

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

Under a POS option, an HMO coordinated care plan permits enrollees to obtain specified items and services from non-network providers, *whether inside the authorized service area or outside*. 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
- Specify the provider group(s) that will furnish the POS benefit to enrollees. 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 maximum contribution for POS benefits, after which the beneficiary assumes full liability*.

<u>Example</u>: 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. 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 *and the beneficiary is 100% liable for all future costs*.

100.6 - PPO Out-of-Network Coverage

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11) PPOs must furnish all services in-network and out-of-network but may charge higher cost-sharing for plan covered services obtained out-of-network. The following rules apply to PPO coverage outside the service:

- MAOs must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization requirements. However, both enrollees and providers have the right to request a prior written advance determination of coverage from the plan prior to receiving services.
- PPO plans offering an optional supplemental benefit must offer the same benefit in-network and out-of-network.
- PPO plans wishing to cap the dollar value of supplemental benefits must use the same cap for both in-network and out-of-network benefits.
- As provided in section 10.9, PPO plans are prohibited from establishing prior notification rules under which an enrollee is charged lower cost-sharing when either the enrollee or the provider notifies the plan before a service is furnished.
- The out-of-network requirement for PPOs applies to the entire United States and its territories. For example, a PPO with a service area in Puerto Rico must *cover all plan* benefits *furnished* to its enrollees on the mainland. An MAO wishing to furnish all plan-covered services outside its service area but only in certain geographic locations should offer an HMOPOS plan.

100.7 - The Visitor/Travel (V/T) Program

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

Under plan enrollment rules, MA plans that do not offer a visitor / travel (V/T) supplemental benefit must disenroll *current* enrollees who are *temporarily* absent from the plan's service area for *more than* six *consecutive* months. However, MA plans that offer a visitor / travel benefit may retain enrollees temporarily out of their service area but within the United States or its territories for up to twelve months (42 CFR 422.74(d)(4)(iii)). *See section 50.2.1 of Chapter 2, "Medicare Advantage Enrollment and Disenrollment," of the Medicare Managed Care Manual located at http://www.cms.gov/MedicareMangCareEligEnrol/01_Overview.asp <i>for further details.*

The specific requirements for the V/T benefit are as follows:

- The MAO must define the geographic areas within the United States and its territories where the V/T benefit is available;
- The V/T benefit must be available to all plan enrollees who are temporarily in the designated geographic areas where the V/T benefit is offered;
- V/T benefits may not be offered outside the United States and its territories;
- The V/T benefit must furnish all plan covered services in its designated V/T area(s), including all Medicare Parts A and B services and all mandatory and optional supplemental benefits, at in-network cost-sharing levels, consistent with Medicare access and availability requirements at 42 CFR 422.112;
- An MAO that is not able to form a network of direct contracted providers to furnish supplemental benefits in an area in which it offers a V/T benefit may, with CMS approval, allow its enrollees to obtain plan covered services from non-contracted providers, *but at in-network cost-sharing*, as long as the plan can ensure that its members have access to providers willing to furnish services in that area;

110.3 - Access for Emergency, Urgently Needed Services and Dialysis (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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

• Cost-sharing:

- <u>Emergency:</u> As indicated in section 20.5, cost-sharing is capped at the lesser of 1) the limit for emergency service cost-sharing that is published by CMS in its annual guidance, and 2) the in-network plan cost-sharing for that service in a non-emergency situation.
- Urgently Needed services: There are no special restrictions on cost-sharing;
 rather, urgently needed services are subject to the same cost sharing
 requirements that apply to all other plan-covered services.
- 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.
- <u>Urgently needed services:</u> 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 *prior* authorization.
- Medically necessary dialysis: A coordinated care plan may use a gatekeeper in-network, but is prohibited from using a gatekeeper out-of-network.

110.4 - Access and Plan Type

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

In the past decade a variety of statutes 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 *VI* below summarizes important access attributes of several plan types.

Table VI: Plan Type and Access attributes for non-emergent non-urgent-care service

Plan Type	Is a gatekeeper ¹ allowed?	Is a network required?	Must benefits be provided IN and OON?	May Cost- sharing requirements differ IN/OON
НМО	Optional	Must contract ²	Must provide IN; may provide OON	No, except for HMOPOS
PPO, RPPO	Optional, In- network (IN), Prohibited Out- of-network (OON)	Must contract ²	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 VI:

- 1. A gatekeeper, when allowed, is typically, but not necessarily, a PCP. The primary purpose of a gatekeeper, when allowed, is to comply with plan requirements for medically necessarily referrals to in-network specialists. Prior authorization is never allowed OON in a PFFS or MSA plan.
- 2. Although an RPPO must contract with a network it may, upon obtaining a waiver from CMS, only contract with a network in part of its service area (42 CFR 422.112(a)(1)(ii))

120.1 - General Rule

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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

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

• The employer, the State Medicaid Agency purchases a non-Part D drug benefit from the MAO.

These complementary benefits may not be classified as MA benefits and are therefore not regulated by CMS. However, the MAO must comply with all State regulations governing such benefits.

130.1 - Basic Rule

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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.)

This section only discusses collections related to Part C benefits. Special rules apply to the collection of cost-sharing related to Part D benefits offered in an MA-PD plan. These special rules may be found in sections 50.13 and 60, as well as in Appendix E, section 30, and sections 50.6, 50.7 and 50.11 of Chapter 14, "Coordination of Benefits," of the Prescription Drug Benefit Manual, located at http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter14.pdf.

130.3 - Medicare Benefits Secondary to Group Health Plans (GHPs) and Large Group Health Plans (LGHPs) *and in Settlements* (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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
 - o 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
 - o 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; or
- 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.

130.6 - Collecting From GHPs and LGHPs (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

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 *hold harmless* the beneficiary of the liability for any amount in excess of the MA plan co-payment of \$10.

140.1 - Introduction

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

The guidance in this section specifically applies to non-SNP HMOs, HMOPOS and PPOs. CMS does not permit plan renewals across product types. For example:

- An MA-only plan cannot be renewed as, or consolidated into, an MA-PD plan (and vice versa);
- Health Maintenance Organization (HMO) plans cannot renew as, or consolidate into, a Preferred Provider Organization (PPO) plans (and vice versa);
- HMO plans or PPO plans cannot renew as, or consolidate into, Private-Fee-for-Service (PFFS) plans (and vice versa);
- Special Needs Plans (SNPs) cannot renew as, or consolidate into, non-SNP MA plans (and vice versa); and
- Section 1876 cost contract plans cannot renew as, or consolidate into, MA plans (and vice versa).

With limited exceptions specified in annual renewal and non-renewal guidance by CMS, we will not permit consolidation of PBPs across contracts, independent of plan type.

As a result of business decisions, or pre- or post-bid discussions with CMS, MAOs may choose to change their current year offerings for the following contract year. Each year, current MAOs must indicate Plan Benefit Package

(PBP) renewal and non-renewal decisions and delineate, for enrollment purposes, the relationships between PBPs offered under each of their contracts for the coming contract year. MAOs must also adhere to certain notification requirements, some of which are indicated below. Most renewal options must be completed in the HPMS Crosswalk, but there are limited exceptions to this requirement.

The renewal and non-renewal guidance presented in this section facilitates the opportunity for beneficiaries to make active enrollment elections that best fit their particular needs. Annual renewals and non-renewals options should simultaneously protect previously made enrollment choices of beneficiaries as well as foster future beneficiary access and choice.

Table *VII*, in section 140.9, presents all permissible renewal and non-renewal options for MAOs with HMO, HMOPOS, PPO, and RPPO plan types, including their method of effectuation, systems enrollment activities, enrollment procedures, and required beneficiary notifications. Each renewal/non-renewal option presented in Table VII includes, where applicable, instructions and important deadlines which MAOs should carefully adhere to in order to ensure smooth year-to-year transitions.

If a renewal or non-renewal scenario is not explicitly presented in Table VII or described in sections 140.2-140.8 below, or is not specified in annual CMS guidance as a renewal or non-renewal scenario that CMS may approve contingent upon receipt of specific information from an MAO, it is not a permissible renewal option for an MAO.

140.6 Renewal Plan with a Service Area Reduction and No Other MA Options Available

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

An MAO offering a local MA plan may reduce the service area of a current contract year's PBP. This is known as a service area reduction, or SAR. An MAO renewing a plan with a SAR must retain the renewed PBP's ID number in the HPMS Plan Crosswalk so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year. Current enrollees in the renewal portion of the service area will not be required to take any enrollment action, and the MAO will not submit enrollment transactions in MARx for these current 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.

Current plan enrollees in reduced service areas will be disenrolled at the end of the current contract year. These individuals affected by the SAR will need to elect another plan. The MAO will submit disenrollment transactions to CMS.

The MAO will send a termination notice to enrollees in the reduced portion of the service area that includes notification of special election period (SEP) and Medigap guaranteed

issue rights. Only when there are no other MA options in the reduced service area, the MAO may offer current enrollees in the reduced portion of the service area the option of remaining enrolled in the renewal plan consistent with CMS continuation area policy as provided under 42 CFR 422.74(b)(3)(ii). If an MAO elects to offer current enrollees in the reduced service area the option of remaining enrolled in the renewal plan, the MAO may provide additional information, in addition to the termination notice, about the option to remain enrolled in the plan for the following contract year. However, no specific plan information for the following contract year can be shared with any beneficiaries prior to October 1 of the current contract year. Any current enrollees in the reduced portion of the service area who wish to continue their enrollment must complete an enrollment request.

140.7 Renewal Plan with a Service Area Reduction When the MAO will Offer Another PBP in the Reduced Portion of the Service Area (Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

An MAO offering a local MA plan 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. An MAO renewing a plan with a SAR must retain the renewed PBP's ID number in the HPMS Plan Crosswalk so that current enrollees in the renewal portion of the service area remain enrolled in the same plan in the following contract year.

Current enrollees in the renewal portion of the service area will not be required to take any enrollment action, and the MAO will not submit enrollment transactions to MARx for these current members. These individuals must receive a standard ANOC notifying them of any changes to the renewing plan.

Current enrollees in the reduced portion of the service area must be disenrolled, and the MAO must submit disenrollment transactions to MARx for these individuals. The MAO will send a termination notice to current enrollees in the reduced portion of the service area that includes notification of special election period (SEP) and Medigap guaranteed issue rights. If the MAO offers one or more MA plans in the reduced portion of the service area, it may offer current enrollees in the reduced portion of the service area the option of enrolling in that plan (or those plans). However, no specific plan information for the following contract year can be shared with any beneficiaries prior to October 1 of the current contract year. Any current enrollees in the reduced portion of the service area who wish to enroll in another MA plan offered by the same organization in the reduced service area must complete an enrollment request, and the organization must submit enrollment transactions to MARx for those members.

140.9 - Crosswalk Table Summary

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

The following table summarizes the guidance from sections 140.2 - 140.8.

Table VII: *Guidance* for plan renewals

Section				Systems Enrollment	Enrollment	Beneficiary
	Activity	Guidelines	HPMS Plan Crosswalk	Activities	Procedures	Notifications
140.2	New Plan (PBP) Added	An MAO creates a new plan benefit package (PBP).	HPMS Plan Crosswalk Definition: A new plan added for the following contract year that is not linked to a current contract year plan. HPMS Plan Crosswalk Designation: New Plan	The MAO must submit enrollment transactions for the following contract year.	New enrollees must complete an enrollment request.	None.
140.3	Renewal	An MAO continues to offer a current contract year MA PBP in the following contract year and retains all of the same service area. The same PBP ID number must be retained in order for all current enrollees to remain in the same MA PBP in the following contract year.	HPMS Plan Crosswalk Definition: A plan in the following contract year that links to a current contract year plan and retains all of its plan service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan. HPMS Plan Crosswalk Designation: Renewal Plan	The renewal PBP ID must remain the same so that current enrollees will remain in the same PBP ID. The MAO does not submit enrollment transactions for current enrollees.	No enrollment request for current enrollees to remain enrolled in the renewal PBP in the following contract year. New enrollees must complete enrollment request.	Current enrollees are sent a standard ANOC.

Section				Systems Enrollment	Enrollment	Beneficiary
	Activity	Guidelines	HPMS Plan Crosswalk	Activities	Procedures	Notifications
140.4	Consolid	An MAO combines one or	HPMS Plan Crosswalk	The MAO's	No	Current
	ated	more whole MA PBPs of the	Definition:	designated renewal	enrollment	enrollees are
	Renewal	same type offered in the	One or more current	PBP ID must remain	request is	sent a standard
	Plan	current contract year into a	contract year plans that	the same so that CMS	required for	ANOC.
		single renewal PBP so that all	consolidate into one plan	can consolidate	current	
		current enrollees in combined	for the following contract	enrollees into the	enrollees to	
		PBP are offered the same	year. The plan ID for the	designated renewal	remain	
		benefits in the following	following contract year	PBP ID in CMS	enrolled in	
		contract year.	must be the same as one	systems.	the renewal	
			of the consolidating		PBP in the	
		The MAO must designate	current contract year	The MAO does not	following	
		which of the renewal PBP	plan IDs.	submit enrollment	contract year.	
		IDs will be retained in the		transactions for	N7 11	
		following contract year after	HPMS Plan Crosswalk	current enrollees. The	New enrollees	
		consolidation. CMS will not	Designation:	MAO may have to	must	
		allow for consolidations	Consolidated Renewal	submit 4Rx data for	complete	
		across contracts (with limited	Plan	individuals whose	enrollment	
		exceptions for some renewal		PBP number changed.	request.	
		options, as described				
		elsewhere in this guidance).				
		Only whole PBPs may be				
		consolidated; a current				
		contract year PBP may not be				
		split among different PBPs in				
		the following contract year.				
		Note: If an MAO reduces a				
		service area when				
		consolidating PBP, it must				
		follow the rules for a renewal				
		plan with SAR described				
		elsewhere in this guidance.				

Section	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
140.6	Renewal Plan with a SAR and no other MA options availabl e	This option is available to local MA plans only. An MAO reduces the service area of a current contract year MA PBP and the reduced service area is not contained in another MA PBP offered by the same organization or any other MAO. The MAO may offer the option to individuals in the reduced portion of the service area for the following contract year to enroll in its remaining PBP if no other MA plans are available (see 42 CFR 422.74(b)(3)(ii)). Note: One renewal plan with a SAR may have counties that should follow the guidance provided in 5a, and other counties in the SAR that should follow the guidance provided under 5b (i.e., the guidance provided in 5a and 5b may both apply to a single plan).	HPMS Plan Crosswalk Definition: A following contract year plan that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. HPMS Plan Crosswalk Designation: Renewal Plan with a SAR Note: If the following contract year plan has both an SAE and a SAR, the plan must be renewed as a renewal plan with a SAR	The MAO must submit disenrollment transactions for individuals residing in the reduced portion of the service area for whom it does not collect an enrollment request. The MAO does not submit enrollment transactions for current enrollees in the renewal portion of the service area.	Enrollees impacted by the SAR need to complete an enrollment request if the MAO offers the option of continued enrollment (see 42 CFR 422.74(b) (3) (ii)).	The MAO sends a termination notice to current enrollees in the reduced service area that includes notification of SEP and guaranteed issue Medigap rights. The MAO may also provide affected enrollees additional information, in addition to the termination notice, about the option to remain enrolled in the plan if the MAO elects to offer enrollment to enrollees in the reduced portion of the service area. Current enrollees in the renewal portion of the service area receive the

Section				Systems Enrollment	Enrollment	Beneficiary
	Activity	Guidelines	HPMS Plan Crosswalk	Activities	Procedures	Notifications
140.7	Renewal	This option is available to	HPMS Plan Crosswalk	The MAO must submit transactions	Enrollees	The MAO sends
	Plan	local MA plans only. An	Definition:	to disenroll	impacted by	a termination
	with a	MAO reduces the service	A following year contract	individuals residing	the SAR need	notice to
	SAR	area of a current contract	plan that links to a	in the reduced portion	to complete	current
	when the	year MA PBP and the	current contract year	of the service area.	enrollment	enrollees in the
	MAO	reduced service area is part	plan and only retains a	The MAO submits	requests if	reduced portion
	will offer	of a new or renewal PBP	portion of its plan service	enrollment	they elect to	of the service
	another PBP in	offered by that MAO in the	area. The following	transactions to enroll	enroll in another PBP	area that includes
	the	following contract year.	contract year plan must	beneficiaries who	(plan) in the	notification of
	reduced	The MAO may market to	retain the same plan ID as the current contract	have requested		SEP and
	portion	enrollees in the reduced	year plan.	enrollment in other	same organization	guaranteed
	of the	service area any other PBP	year pian.	PBP offered in the	or a different	issue Medigap
	service	offered in the reduced service	HPMS Plan Crosswalk	reduced service area.	MA plan.	rights. The
	area	area for the following	Designation:		mn pian.	MAO may also
	area	contract year. Affected	Renewal Plan with a SAR			provide
		enrollees who elect to enroll	Note : If the following			additional
		in another MA plan offered in	contract year plan has			information, in
		the reduced service area must	both an SAE and a SAR,			addition to the
		submit an enrollment request.	the plan must be renewed			termination
		N (O)	as a renewal plan with a			notice,
		Note: One renewal plan with	SAR.			including
		a SAR may have counties that				instructions on
		should follow the guidance				how to complete
		provided in 5a and other counties in the SAR that				an enrollment
						request to
		should follow the guidance				switch to
		provided under 5b (i.e., the guidance provided in 5a and				another PBP
		5b may both apply to a single				offered by the
						same
		plan).				organization.
						Current
						enrollees in the
						renewal portion
						of the service
						area receive the
						standard

Section				Systems Enrollment	Enrollment	Beneficiary
	Activity	Guidelines	HPMS Plan Crosswalk	Activities	Procedures	Notifications
140.8	Termina	An MAO terminates the	HPMS Plan Crosswalk	The MAO does not	Terminated	Terminated
	ted Plan	offering of a current contract	Definition:	submit	enrollees	enrollees are
	(Non-	year PBP.	A current contract year	disenrollment	must	sent a
	Renewal		plan that is no longer	transactions. If the	complete an	termination
)		offered in the following	terminated enrollee	enrollment	notice that
			contract year.	elects to enroll in	request if they	includes
				another MA plan with	choose to	notification of
			HPMS Plan Crosswalk	the same or any other	enroll in	SEP and
			Designation:	MAO, that	another PBP,	guaranteed
			Terminated Plan.	organization must	even in the	issue Medigap
				submit enrollment	same	rights.
				transactions to enroll	organization.	
				the beneficiary.		

160 – Meaningful Plan Differences

(Rev. 97, Issued: 05-20-11, Effective: 05-20-11, Implementation: 05-20-11)

The guidance in this section applies to non-employer MA and MA-PD plans of all types. CMS reserves the right to extend the guidance in this section to employer plans in future years.

As provided under 42 CFR 422.254(a)(5) and 422.256(b)(4)(i), CMS annually reviews bids to ensure that an MAO's plans in a given service area are meaningfully different from one another in terms of key benefits or plan characteristics. The criteria CMS may use include:

- Cost-sharing;
- *Mandatory supplemental*_benefits offered;
- Plan type; and
- Premiums.

CMS annually publishes guidelines to assist MAOs in creating plan designs and plan cost structures in a given area with meaningful differences. MAOs offering more than one plan in a given service area should ensure that beneficiaries can easily identify the differences in costs and benefits between the plans. Beneficiaries should be able, for example, to determine which plan provides the highest value at the lowest cost based on their needs. Plan bids that CMS determines are not meaningfully different as determined during the annual *CMS* review will not be approved by CMS. *CMS will not approve bids that it determines are not meaningfully different from one another. MAOs will have to withdraw or consolidate such offerings*.

Although the specific guidelines and criteria for meaningful differences may change annually, CMS has considered the presence of any of the following characteristics to represent meaningful differences among plans offered by an MAO in a service area:

- Part D benefit. The plan offers a Part D benefit.
- SNP status. The plan is a SNP that serves a unique population; or
- <u>Distinct plan types</u>. Plans offered are of distinctly different types (e.g., HMO, local PPO, RPPO, PFFS plans).

<u>Example</u>: An MAO offers three plans in a service area with the characteristics listed below. Since each plan differs from the other two plans by one of the characteristics described above, this MAO is considered to be offering plans with meaningful differences; no further tests need be done.

- Non SNP, MA-only;
- Non SNP, MA-PD; and
- SNP, MA-PD.

If an MAO offers two plans in a given service area that either both cover drugs, have the same SNP status, and are of the same plan type, then CMS conducts further tests based on other criteria, such as cost-sharing or benefits, to determine if the two plans are meaningfully different from one another.