

Medicare Managed Care Manual

Chapter 4 - Benefits and Beneficiary Protections

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[Transmittals for Chapter 4](#)

PART I: BENEFITS

Part I of this Chapter 4 presents information on benefits that is needed by plans when designing and submitting a PBP package. Part II of this chapter, which begins in section 110, provides information on beneficiary protections, and includes topics such as rules for plan renewals, coordination of benefits and Educating and Enrolling Members in Medicaid and Medicare Savings Programs.

10 - Introduction

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

10.1 - General Requirements

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

These guidelines reflect CMS' current interpretation of the provisions of the Medicare Advantage (MA) statute and regulations (Chapter 42 of the Code of Federal Regulations, part 422) pertaining to benefits and beneficiary protections. The guidance set forth in this document is subject to change as technology and industry practices in plan design and administration continue to evolve and as CMS gains more experience administering the MA program and its new health plan options.

The contents of this chapter are governed by regulations set forth in 42 CFR 422, Subpart C, and consequently, the discussion in this chapter is generally limited to the benefits offered under Medicare Part C of the Social Security Act. Guidance on cost plans may be found in Subpart F of Chapter 17 of this manual. Guidance on Part D requirements may be found in the Prescription Drug Benefit Manual located at http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage. 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.

10.2 - Basic Rule

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

An MA organization (MAO) offering an MA plan must provide enrollees in that plan with all Part A and Part B, Original Medicare services, if the enrollee is entitled to benefits under both parts, and Part B services if the enrollee is a grandfathered “Part B only” 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.

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

The scope of the benefits under Part A and Part B is defined in the Act. The scopes of Part A and Part B are discussed in sections 1812 and 1832 of the Act, respectively, while section 1861 of the Act lays out the definition of medical and other health services. Specific health care services must fit into one of these benefit categories, and not be otherwise excluded from coverage under the Medicare program (see §1862 for exclusions).

In general, the Act lists categories of items and services covered by Medicare, although Congress occasionally adds specific services to be covered by Medicare. Some categories are defined more broadly than others; for example, the Act includes hospital outpatient services furnished incident to physicians’ services (§1861(s)(2)(B)) but also specifically includes diabetes screening tests (§1861(s)(2)(Y)). The Act vests in the Secretary the authority to make determinations about which specific items and services, within categories, may be covered under the Medicare program. Further interpretation is provided in the Code of Federal Regulations and CMS guidance.

Medicare coverage and payment is contingent upon a determination that:

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

These criteria are codified through rulemaking in the Code of Federal Regulations and/or applied in manual guidance, or are applied through coverage determinations. National Coverage Determinations (NCDs) are published on the National Coverage Web site. For further information see sections 90.3, 90.4, and 90.6 of this chapter.

In the absence of a specific NCD, coverage decisions are made at the discretion of local Medicare Administrative Contractors (MACs) as indicated in sections 90.1 and 90.2 below. The guidance concerning the adoption of uniform local coverage determinations by MA local or regional plans is discussed in section 90.2.

Several Original Medicare covered benefits and services are covered only for specific benefit periods, e.g., inpatient hospital services, skilled nursing facility services, and inpatient psychiatric hospital services. While an MA plan may offer additional coverage as a supplemental benefit, it may not limit the Original Medicare coverage.

MA plans must provide their enrollees with all basic benefits covered under Original Medicare. Consequently, plans may not impose limitations, waiting periods or exclusions from coverage due to pre-existing conditions that are not present in Original Medicare.

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

- Benefits: MA plans must provide or pay for medically necessary Part A (for those entitled) and Part B covered items and services.
- Access: 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 same access to providers that is provided under Original Medicare (see accessibility rules for MA plans in section 110 of this chapter).
- Cost-sharing: 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 presented in section 10.5.2 of this chapter. MA plans may require enrollees to pay higher cost sharing amounts for services furnished out-of-network.
- Billing and payment: MA plans need not follow Original Medicare claims processing 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 190.1 of this chapter for rules governing payment amounts to non-contracted providers for Original Medicare non-emergent services.

10.2.1 Exceptions to Requirement for MA plans to Cover FFS Benefits

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

- Hospice: Original Medicare (rather than the MAO) will pay the hospice for the services received by an enrollee who has elected hospice while enrolled in the plan. For detailed information about services furnished to an enrollee who has elected hospice care, see section 10.4 below.
- Inpatient stay during which MA enrollment begins: (42 CFR § 422.318) If a Medicare beneficiary is in an inpatient stay and his enrollment in an MA plan takes effect prior to discharge from that stay:
 - Original Medicare is responsible for the costs of that inpatient stay; and
 - The beneficiary is responsible for payment of cost-sharing as required under Original Medicare.
 - Inpatient stay during which enrollment changes or ends: (42 CFR § 422.318(a)) MAOs must continue to cover, through discharge, inpatient services of a non-plan enrollee if the individual was an enrollee at the beginning of the inpatient 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 cost-sharing amounts as of the entry date into the hospital.
 - If the enrollee is 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 1, the stay continues to be considered a covered stay (if medically required).
- Clinical trials: 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 Original Medicare 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 10.7 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 those outlined in this chapter, Chapter 7, "Payments to Medicare+Choice Organizations," Chapter 8, "Payments to Medicare Advantage Organizations," and other CMS instructions, such as the guidance contained in the annual Call Letter.

10.3 - Types of Benefits

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Basic benefits: All medically necessary Medicare Parts A and Part B services, including Part B prescription drugs, must be offered and identified in plan bids as a basic benefit.

Part D prescription drug benefits: Plans may choose to offer prescription drug Part D benefits as described at 42 CFR 423 and in Chapter 5 of the Prescription Drug Benefit Manual.

Supplemental benefits: Plans may choose to offer some benefits to enrollees in addition to, as supplemental to, the covered Medicare Parts A, B or Part D benefits they are required to offer if the item or service also meets the criteria described in sections 30 and 40 of this chapter.

Supplemental benefits are further classified as either mandatory or optional:

Mandatory supplemental benefits are benefits not covered under Part A, Part B, or Part D that are covered by the MA plan for every person enrolled in the MA plan. Mandatory supplemental benefits are paid for either in full, directly by, or on behalf of, MA enrollees by premiums and cost-sharing, or through the application of rebate dollars. An MA MSA plan may not provide mandatory supplemental benefits.

Optional supplemental benefits are benefits not covered under Part A, Part B, or Part D that are offered uniformly by the plan to all enrollees. Enrollees may choose to pay extra to receive coverage under the optional supplemental benefit. The optional supplemental benefit is paid for directly by the enrollee or on behalf of the enrollee through an additional premium and cost-sharing. Plans may offer their enrollees a group of services as one optional supplemental benefit, offer optional supplemental services individually, or offer a combination of group and individual optional supplemental services. Each plan enrollee chooses whether to elect and pay for any particular optional supplemental benefit as offered under the plan.

Rebate dollars may not be applied toward optional supplemental benefits. An MA plan may not offer as an optional supplemental benefit reduced cost-sharing for Original Medicare benefits (42 CFR § 422.102). An MA plan may not list a dual eligible beneficiary's State Medicaid wraparound benefits as either a mandatory or optional supplemental benefit.

MA MSA plans are permitted to offer optional supplemental benefits, provided that the MSA plan does not offer an optional supplemental benefit that covers expenses that count toward the annual MSA deductible.

Optional supplemental benefits must be offered: (1) at the beginning of the contract year to all Medicare beneficiaries enrolled in the plan, and (2) at the time of initial enrollment to new enrollees who enroll during the contract year. The MA plan may then:

- Continuously offer each optional supplemental benefit uniformly to all enrollees for the remainder of the contract year; or
- Choose to place a time limit of at least 30 consecutive days starting from the enrollee effective date during which a new enrollee can select any particular optional supplemental benefit offered by the MA plan. After the enrollee's 30-day selection period ends, the optional benefits may be closed to that enrollee for the rest of that contract year during which the beneficiary remains continuously enrolled.

Although MAOs may limit the availability of optional supplemental benefits to current enrollees as described above, enrollees may voluntarily drop or discontinue optional supplemental benefits at any time during the contract year upon proper advance notice to the MAO. An enrollee who drops an optional supplemental benefit through proper advance notice as determined by the MAO – typically 30 days - need not pay further monthly premiums for the optional supplemental benefit. Furthermore, if s/he paid a complete annual premium for the optional supplemental benefit, s/he is entitled to a pro-rated refund of unpaid premium for the remaining portion of the year.

Chapter 2 of this manual, “Enrollment and Disenrollment,” linked at <http://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html?redirect=/MedicareMangCareEligEnrol/>, provides the requirements for an involuntary disenrollment of an enrollee from an MAO when that enrollee fails to make timely payments of premium for optional supplemental benefits.

10.4 - Hospice Coverage

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

As defined in 42 CFR § 422.320, an MAO must inform each enrollee eligible to select hospice care about the availability of hospice care if: (1) a Medicare hospice program is located within the plan's service area; or (2) it is common practice to refer patients to hospice programs outside the organization's service area.

An MA enrollee who elects hospice care but chooses not to disenroll from the plan is entitled to continue to receive through the MA plan any MA benefits other than those that are the responsibility of the Medicare hospice. Through the Original Medicare program, subject to the usual rules of payment, CMS pays the hospice program for hospice care

furnished to the enrollee and the MAO, providers, and suppliers for other Medicare-covered services furnished to the enrollee.

Table I summarizes the cost-sharing and provider payments for services furnished to an MA plan enrollee who elects hospice.

Table I: Payments for Services Furnished to an Enrollee who has Elected Hospice

| Type of Services | Enrollee Coverage Choice | Enrollee Cost-sharing | Payments to Providers |
|--|------------------------------|--|--------------------------------|
| Hospice program | Hospice program | Original Medicare cost-sharing | Original Medicare |
| Non-hospice ¹ , Parts A & B | MA plan or Original Medicare | MA plan cost-sharing, if enrollee follows MA plan rules ³ | Original Medicare ² |
| | | Original Medicare cost-sharing, if enrollee does not follow MA plan rules ³ | Original Medicare |
| Non-hospice ¹ , Part D | MA plan (if applicable) | MA plan cost-sharing | MAO |
| Supplemental | MA plan | MA plan cost-sharing | MAO |

Notes:

- 1) The term ‘hospice care’ refers to Original Medicare items and services related to the terminal illness for which the enrollee entered the hospice. The term ‘non-hospice care’ refers either to services not covered by Original Medicare or to services not related to the terminal condition for which the enrollee entered the hospice.
- 2) If the enrollee chooses to go to Original Medicare for non-hospice, Original Medicare services, and also follows plan requirements, then, as indicated, the enrollee pays plan cost-sharing and Original Medicare pays the provider. The MA plan must pay the provider the difference between Original Medicare cost-sharing and plan cost-sharing, if applicable.
- 3) Note: An HMO enrollee who chose to receive services out of network has not followed plan rules and therefore pays FFS cost sharing; a PPO enrollee who receives services out of network has followed plan rules and is only responsible for plan cost sharing. The enrollee need not communicate to the plan in advance his/her choice of where services are obtained.

Please see the following resources for additional information:

- The Social Security Act, Section 1853(h)(2)(B); and

- The Medicare Claims Processing Manual, Chapter 11 - Processing Hospice Claims, Section 30.4

10.5 – Federal Requirements Related to Uniform Benefits and Non-Discrimination

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

10.5.1 Uniformity

The following rules apply to any MA plan, regardless of plan type, and to any category of benefit – basic, mandatory supplemental, and optional supplemental.

- All plan benefits must be offered uniformly to all enrollees residing in the service area of the plan;
- When an MA plan has an authorized service area with one or more approved segments, as defined in section 20 of Chapter 1 of this manual, “General Provisions,” the MA plan may vary premiums and cost-sharing by segment, but the premium and cost-sharing must be uniform within each segment. Furthermore, plan benefits must be uniformly provided throughout the authorized service area of the plan, including any segments in the service area;
- The uniform premium requirement prohibits plans from offering nominal discounts to those enrollees electing to pay premiums electronically;
- All plans must offer to, but may not require of, their enrollees the option of:
 - Having their premiums deducted from their Social Security check or benefit;
 - Having their premiums paid by an electronic transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account); and
 - Paying their premium by check.

10.5.2 Anti-Discrimination

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 Special Needs Plan (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” which is linked at <http://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html?redirect=/MedicareMangCareEligEnrol/>; 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” linked at <http://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html?redirect=/MedicareMangCareEligEnrol/>

The following websites contain useful information about discrimination:

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

10.5.3 Review for Discrimination and Steering

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;
 - Promote discrimination;
 - Discourage enrollment;
 - Encourage disenrollment;
 - Steer specific subsets of Medicare beneficiaries to particular MA plans (with the exception of SNPs);
 - Inhibit access to services; and
 - 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 50.1.1 below, 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; and
- Benefit designs meet other MA program requirements.

Note: Section 50.1 below 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.

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

10.5.4 Confidentiality

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:
 - 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/>).

10.6- Multiple Plan Offerings and Benefit Caps (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

An MAO may offer more than one MA plan in the same service area. However, each plan and its benefit package is subject to the conditions and limitations that are established for the MA program. Financial caps for a supplemental benefit can only be imposed at the MA plan level. For example, if an MAO offers two plans in the same service area, then an enrollee who has exhausted the supplemental benefit of one plan is entitled to the full benefit of the other plan if the enrollee enrolls in that plan (and purchases that supplemental benefit, if the benefit is optional). This rule does not preclude MAOs from providing benefits with periodic caps such as monthly or quarterly caps.

10.7 - Clinical Trials (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

10.7.1 Payment for Services

For clinical trials covered under the Clinical Trials National Coverage Determination (NCD) (NCD manual, Pub. 100-3, Part 4, section 310), 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 Original Medicare 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 prior 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 the 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.

10.7.2 Investigational Device Exemption (IDE)

CMS determines Medicare device coverage based on which category the FDA assigns the device. FDA-designated Category A Devices (IDEs that are experimental/investigational) are not covered by Medicare unless they are part of a qualifying clinical trial as discussed above. Category B IDE (non-experimental/investigational) studies may be Medicare covered through local determinations made by the MACs. MAOs are responsible for payment of claims related to Category B IDE studies covered by the local MAC with jurisdiction over the MA plan's service area.

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 Original Medicare 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 Institutes of Health sponsors a website called [Clinicaltrials.gov](http://www.clinicaltrials.gov), which serves as a registry and public database for clinical trials. <http://www.clinicaltrials.gov/>.

10.8 - Drugs that are Covered Under Original Medicare Part B (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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 and regulatory and statutory limitations. Note that these examples are illustrative and do not comprise 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 are administered via durable medical equipment (such as nebulizers) that were authorized by the enrollee’s MA plan.
- Drugs covered under the Act, include but are not limited to:
 - Certain vaccines including pneumococcal, hepatitis B (high or intermediate risk only) influenza, and vaccines directly related to the treatment of an injury or direct exposure to a disease or condition. For further details, see section 50.4.4.2 of Chapter 15 of the Medicare Benefit Policy Manual:
<http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf> ;
 - Certain oral anti-cancer drugs and anti-nausea drugs;
 - Hemophilia clotting factors;
 - Immunosuppressive drugs;
 - Some antigens;

- Intravenous immune globulin administered in the home for the treatment of primary immune deficiency;
- Injectable drugs used for the treatment of osteoporosis in limited situations; and
- Certain drugs, including erythropoietin, administered during the treatment of end stage renal disease.

If an MA enrollee wishes to receive a Part B covered 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 Part B covered drug administered incident to physician services, or impose any uniform policy that prevents enrollees from having a Part B covered drug administered in a physician's office.

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. However, MA enrollees always have the option of receiving the Medicare-covered benefit, i.e., administration of the covered drug, in a physician's office from the physician's stock of drugs.

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

10.9 - Return to Home Skilled Nursing Facility (SNF) (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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.

10.10 - Therapy Caps and Exceptions (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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>.

10.11 – Transplant Services (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

As explained in section 10.2 above, every MA plan must provide all Original Medicare services to its enrollees. For coordinated care plans, in-network transplant services may be provided outside of the plan service area if the services are accessible and available to enrollees, and that service delivery is consistent with community 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 the service is available locally (within the service area), consistent with community 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:

- 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 a mutually agreed upon payment rate, then the MA plan must offer transplants through alternative transplant providers.
- 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 or at a mutually agreed upon rate, then, although the MA plan may also offer transplants at a more distant location, the MA plan must allow enrollees the option of obtaining transplant services locally.

When providing an Original Medicare service at a more distant location, farther 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. More specifically, the transplant center at the distant location must be a Medicare-eligible transplant provider and the waiting time for the transplant should not be significantly longer than the waiting within the normal community patterns of care.

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.

10.12 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

MA plans are required to “provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Medicare Part A and B” (see 42 CFR 422.101(a)), which includes coverage of durable medical equipment, prosthetics and supplies. Integral to that coverage is the requirement that if a beneficiary’s Medicare-covered DME item needs to be repaired or replaced, the MAO is responsible for maintaining continuity of care for its enrollee by ensuring uninterrupted access to the medically necessary covered DME item. If necessary, the MAO must purchase or rent a replacement item for the beneficiary to use.

10.12.1 Designation of DME Providers/Suppliers

Each MA plan, during the application process, identifies specific DME suppliers with whom they have contracted to provide enrollees with all medically necessary DME items and supplies. The plan discloses information on the suppliers contracted to provide DME in the Annual notice of change (ANOC) and the Evidence of Coverage (EOC).

10.12.2 Specifying Brands or Manufacturers of DME

MA plans may specify brands and manufacturers as preferred and charge lower cost sharing for the preferred brands or may limit the DME provided to enrollees to only those preferred brands and manufacturers as long as the following conditions are met:

- The MA plan provides all categories of DME covered under Original Medicare part B;
- The MA plan ensures that enrollees have access to all medically necessary (including non-preferred) DME products or brands;

- The MA plan’s contracted suppliers provide access to all preferred DME brands;
- If the enrollee wishes, the plan provides a 90-day transition period (commencing with the initial time of enrollment) during which the plan provides (and repairs, as applicable) non-preferred DME brands furnished in the previous year;
- Although the MA plan may add brands to its preferred formulary during the year, it may not remove any brands midyear;
- The MA plan treats denials of non-preferred DME products or brands as organization determinations;
- The MA plan discloses DME coverage limitations and beneficiary appeal rights in the case of a denial of a non-preferred DME product or brand as packaged with the Evidence of Coverage and Annual Notice of Change and on its plan website.

10.12.3 Brands/Manufacturers of DME not Subject to Limitation

Some DME items are not interchangeable, that is, they must be tailored to fit individual enrollees. As a result, such items, as designated by CMS annually, will not be subject to limitation based on brand or manufacturer or may not be limited under certain circumstances. This information is annually published in the Call Letter.

10.12.4 Prosthetics and Orthotics

The MA plan must provide all brands and manufacturers of Prosthetics and Orthotics without limitation.

10.12.5 DMEPOS Competitive Bid Program

On January 1, 2011, the Original 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 program affects MA payments in those situations when an MA plan is only required to pay at least the Original Medicare rate, for example, when reimbursing non-contracting suppliers. MAOs must disclose information on the new program to their plan members. MAOs should inform 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.

10.13 – Skilled Nursing Facility (SNF) Coverage
(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Prior to termination of SNF services, the provider must deliver a valid written notice to the enrollee of the MAO's decision to terminate covered services no later than two days before the proposed end of the services (42 CFR § 422.624(b)). The MAO is financially liable for continued services until two days after the enrollee receives valid notice. If the enrollee's services are expected to be fewer than two days in duration, the provider should notify the enrollee at the time of admission to the provider.

10.14 – No Dollar Limits on Provision of Part B Drugs
(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Part B drugs: No dollar limits may 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 90.2 below for more detailed guidance on the obligation of plans to follow local coverage determination.)

10.15 - Part D Rules for MA Plans
(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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. 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).

Note that OTC (Over-the-Counter) drug benefits are not classified as Part D prescription drug benefits. For guidance governing OTC drug benefits, see section 40 below.

Table I: Part D Prescription Drug Coverage by Plan Type

| Plan Type | Regional or Local MA Plan? | Must offer Part D? | Can an enrollee elect a PDP? |
|--|-----------------------------------|---|---|
| MA Coordinated Care Plan (CCP) | | | |
| HMO, 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 may 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-payment Plan) | NA | No | Yes |
| 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.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf> for the definition of required drug coverage.
2. PACE organizations 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.

10.16 – Medical Necessity

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Every MA plan:

- Must have policies and procedures, that is, coverage rules, practice guidelines, payment policies, and utilization management, that allow for individual medical necessity determinations (42 CFR §422.112(a)(6)(ii));
- Must employ a medical director who is responsible for ensuring the clinical accuracy of all organization determinations and reconsiderations involving medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia (42 CFR §422.562(a)(4));
- If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia (42 CFR §422.566(d), MMCM Chapter 13, 40.1.1);
- Must make determinations based on: (1) the medical necessity of plan-covered services - including emergency, urgent care and post-stabilization - based on internal policies (including coverage criteria no more restrictive than Original Medicare's national and local coverage policies) reviewed and approved by the medical director; (2) where appropriate, involvement of the organization's medical director per 42 CFR §422.562(a)(4); and (3) the enrollee's medical

history (e.g., diagnoses, conditions, functional status), physician recommendations, and clinical notes. Furthermore, if the plan approved the furnishing of a service through an advance determination of coverage, it may not deny coverage later on the basis of a lack of medical necessity; (cf. Program Integrity Manual, Chapter 6, Section 6.1.3(A)); and

- Must accept and process appeals consistent with the rules set forth at 42 CFR Part 422, Subpart M, and Chapter 13 of the Medicare Managed Care Manual.

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

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

20.1 – Ambulance Services

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

MAOs are 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 below 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. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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 treat an emergency medical condition.

Urgently-needed services are covered services that:

- Are not emergency services as defined in this section but are medically necessary and immediately required as a result of an unforeseen illness, injury, or condition;
- Are provided when the enrollee is temporarily absent from the plan’s service (or, if applicable, continuation) area, or under unusual and extraordinary circumstances, when the enrollee is in the service or continuation area, and the network is temporarily unavailable or inaccessible; and
- It was not reasonable given the circumstances to wait to obtain the services through the plan network.

We note that an MA organization may choose to cover services outside the network at higher cost-sharing for non-emergency services obtained outside network providers’ normal business hours (e.g., covering services at an urgent care center on weekends or holidays).

20.3 – MAO Responsibilities

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The MAO must inform enrollees of their right to call 911, meaning that:

- No materials furnished to enrollees, including wallet card instructions, may contain instructions to seek prior authorization for emergency or urgently-needed services; and
- No materials furnished to providers, including contracts, may contain instructions to providers to seek prior authorization before the enrollee has been stabilized.

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

- Regardless of whether services are obtained within or outside the plan’s authorized service area and/or network (if applicable);
- Regardless of whether there is prior authorization for the services;
- If the emergency situation is in accordance with a prudent layperson’s definition of “emergency medical condition,” regardless of the final medical diagnosis; and

- Whenever a plan provider - a provider with whom the MAO has a written contract to furnish plan covered services to its enrollees - or other plan representative instructs an enrollee to seek emergency services within or outside the plan.

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

20.4 – Stabilization of an Emergency Medical Condition (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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 20.5 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 may 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 - Post-Stabilization Care Services (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

20.5.1 Definition of Post-Stabilization

Post-stabilization care services are covered services that are:

- Related to an emergency medical condition;
- Provided after an enrollee is stabilized; and
- Provided to maintain the stabilized condition, or under certain circumstances (see below), to improve or resolve the enrollee's condition.

20.5.2 MAO Financial Responsibility

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

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

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

20.5.3 End of Post-Stabilization

The MAO's financial responsibility for post-stabilization care services it has not pre-approved ends when:

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

20.5.4 Cost Sharing

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

30 - Supplemental Benefits

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

30.1 – Definition of Supplemental Benefit

(Rev. 107, Issued: 06-22-12, Effective/Implementation: 06-22-12)

A supplemental benefit is an item or service not covered by Original Medicare, that is primarily health related and for which the MA plan must incur a non-zero direct medical cost. These criteria are defined below.

- (1) A supplemental benefit may not be a Medicare Part A or Part B covered service;
- (2) The item or service must be primarily health related; that is, the primary purpose of the item or service is to prevent, cure or diminish an illness or injury. If the primary purpose of the item or service is comfort, cosmetic or daily maintenance, then it is not eligible as a supplemental benefit. The primary purpose of an item or service is determined by national typical usages of most people using the item or service, or by community patterns of care; and
- (3) 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 requirement is not met.

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. The final determination of benefit status is made by CMS during the annual benefit package review.

Mid-year benefit enhancements are not allowed for non-employer plans. For more information regarding requirements specific to employer group plans, please refer to Chapter 9 of this manual, "Employer/Union Sponsored Group Health Plans."

MAOs are allowed to cover some benefits over more than one contract year. Such benefits, referred to as "multi-year" benefits, are supplemental benefits that are provided to a plan's Medicare enrollees over a period exceeding one contract 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 CMS encourages plans to limit offerings to one contract year where possible.

30.2 – Supplemental Benefits Extending Original Medicare Benefits

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

In designing supplemental benefits that extend Original Medicare benefits, plans should keep in mind:

- **Medical Necessity:** An MAO may offer coverage of a supplemental benefit only if it is medically necessary and additional to the benefit covered by Original

Medicare. For example, an MAO may offer additional inpatient hospital days as a supplemental benefit. 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 in Chapter 7 of the Medicare Benefit Policy manual, located at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf>, publication #11. All Original Medicare manuals may be found in the Internet-only and paper-based manual links located at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>

- **Distinct Naming:** An MAO must be careful in the selection of terminology describing a supplemental benefit that furnishes coverage beyond that of Original Medicare. The terminology should make clear what the supplemental benefit is. An MAO offering a supplemental benefit for which there is no specified service category in the PBP must use CMS-specified terminology, if available.
- **Prohibition of Benefits for Non-enrollees:** An MAO may not offer as a benefit services furnished to a person other than the enrollee (unless Original Medicare specifically allows such services, e.g., Original Medicare coverage of a living donor for medical complications arising from a kidney transplant). Similarly, other than the Original Medicare respite benefit, an MA plan may not offer as a supplemental benefit other types of caregiver support (whether to SNF or non-SNF enrollees). However, an MAO may, and is even encouraged to, include in plan newsletters or other communications to members, information about services available in the community to assist caregivers in obtaining relief so long as the plan does not refer to those services as plan benefits. For information on the Original Medicare respite benefit see publication 100-02, The Medicare Benefit Policy Manual, Chapter 9, section 40.2.2.
- **Benefit Naming Conventions** 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.

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.

Examples of benefits that are eligible for plans to offer as supplemental that extend Original Medicare benefits include:

- Additional days or sessions of certain Original Medicare covered services such as inpatient days, sessions of smoking and tobacco cessation counseling, cardiac rehabilitation, pulmonary rehabilitation.
- Expansion of coverage to allow enrollees to receive benefits for which they do not qualify under Original Medicare: Medical nutrition therapy for enrollees that do not meet Original Medicare coverage criteria, waiver of the 3-day inpatient hospital stay requirement for covered skilled nursing facility care, and transportation services for non-emergency purposes.

| Medicare Covered Benefits | Benefits Eligible to be offered as a Supplemental Benefits |
|--|---|
| Inpatient Hospital-Acute | Additional Days Upgrades |
| Inpatient Hospital-Psych | Additional Days |
| Skilled Nursing Facility | Additional Days Waive 3-day inpatient hospital stay prior to admission |
| Emergency Care | Worldwide Coverage |
| Chiropractor | Routine Care |
| Podiatry | Routine Care |
| Outpatient Blood | Waiver of 3 pint deductible |
| Medicare Part B Rx & Home Infusion Drugs | Home Infusion Bundled Services |
| \$0 Cost-sharing Preventive Services | Annual Physical Exam Smoking and Tobacco Use Cessation Counseling |
| Comprehensive Dental Services | Non-routine services, diagnostic services, restorative, endodontic/periodontal/extractive, prosthodontics, Other oral/maxillofacial surgery, other services |
| Eye Exams | Routine eye exams |
| Eye Wear | Contact lenses, eye glasses, lenses, frames, upgrades |
| Hearing Exams and Hearing Aids | Routine hearing exams, fitting/evaluation for hearing aids |

The chart above identifies the Medicare-covered and other benefits for which supplemental benefits are coded into the PBP as options. Other supplemental benefits to extend Original Medicare coverage may be entered in the PBP “Other Supplemental Benefit” fields. CMS will review these benefits during bid review.

30.3 – Examples of Eligible Supplemental Benefits (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The list below identifies items or services that may be offered as supplemental benefits, subject to CMS bid review. Definitions and limitations of the eligible benefits are provided below. This list below is intended to be illustrative, not exhaustive.

Acupuncture and Other Alternative Therapies

With the exception of massage therapy, CMS will continue to permit plans to offer alternative therapies as supplemental benefits. These alternative therapies should be provided by practitioners who are state-licensed or state-certified to furnish the services, are practicing in the state in which they are licensed or certified, and are furnishing services within the scope of practice defined by their licensing or certifying state.

Bathroom Safety Devices

Plans may choose to offer as a supplemental benefit provision of specific non-Medicare-covered safety devices to prevent injuries in the bathroom. In addition to providing safety devices, the benefit may include an in-home bathroom safety inspection conducted by a qualified health professional to identify the need for safety devices, as well as the applicability to the specific enrollee’s bathroom (e.g., to determine whether a specific safety device can be installed into the bathroom) and/or installation of any needed safety devices.

The plan should describe the proposed benefit and, if an in-home assessment is offered, the qualifications of the health professional that will be performing those evaluations, in its submitted plan benefit package for CMS review.

Routine Chiropractic Services

Plans may choose to offer routine chiropractic services as a supplemental benefit as long as the services are provided by a State-licensed chiropractor who provides services within the States’ licensure and practice guidelines. The routine services may include conservative management of neuromusculoskeletal disorders and related functional clinical conditions including, but not limited to, back pain, neck pain and headaches, and the provision of spinal and other therapeutic manipulation/adjustments.

X-rays or other diagnostic or therapeutic services furnished or ordered by a chiropractor may be covered by the plan in the supplemental benefit as long as the chiropractor is State-licensed and is practicing within the States’ licensure and practice guidelines.

An MAO may offer a chiropractor visit as a benefit even when the chiropractor uses preparatory massages during the visit.

Counseling Services

Medicare Part B covers individual and group therapy services to diagnose and treat a mental illness. The Part B coverage usually requires a physician referral for mental health care and is based on a mental health diagnosis.

Counseling services not covered by Original Medicare may be eligible as a supplemental benefit offered to all beneficiaries. These services are not intended to diagnose and treat a mental illness. These supplemental benefits may address general topics, such as: coping with life changes; conflict resolution; or grief counseling and be offered as individual or group sessions.

Gym and Fitness Benefit

Gym and fitness benefits (e.g., gym membership, exercise and yoga classes) may be offered as supplemental benefits. A supplemental gym membership benefit should include an orientation to the facility and the equipment for each beneficiary who comes to the gym. The benefit also may include development of a personalized exercise plan and a limited number of sessions with a certified trainer.

Plans may not offer personal trainers or exercise coaches for in-home sessions.

Plans should describe specifically what is included in the gym and fitness supplemental benefit (e.g., access to facilities, support staff, general goals of the program) in the PBP notes field at section B14c.

Enhanced Disease Management (EDM)

Non-SNP plans may offer EDM as a supplemental benefit. Services that CMS would expect to be included in a supplemental “EDM” benefit for coordinated care plans, and which would be expected to be approved as supplemental benefits, would include the following three activities:

- **Enrollees in the target group are assigned to qualified case managers with specialized knowledge about the disease(s) who contact the enrollee to provide additional case management and monitoring services.** We believe that this should be an essential aspect of an effective EDM program and it is important for MAOs and cost contractors to understand the difference between the assignment of case managers for all enrollees and the assignment of a case manager with specialized knowledge about a specific individual enrollee’s disease(s). The case manager or other qualified health professional assigned to the enrollee should work to ensure that the enrollee makes and keeps appointments

necessary to receive appropriate care from physicians and other health care providers including obtaining preventive services. That assigned staff member should facilitate the enrollee's participation in both standard disease management activities and supplemental EDM programs offered by the plan. The assigned case manager or other qualified plan staff should ensure that all scheduled monitoring of the enrollee takes place and that information is analyzed and communicated to all enrollees of the care team so that early signs of deterioration in the enrollee's condition are detected and action is taken to prevent further deterioration.

- **Educational activities being provided by certified or licensed professionals that are focused on the specific disease/condition.** Educational programs are designed to help enrollees develop knowledge and self-care skills and to foster the motivation and confidence necessary to use those skills to improve health. Examples of educational services that we believe would qualify as a supplemental benefit include provision of information about the specific disease process(es), treatments and drug therapies, signs and symptoms to watch for, self-care strategies and techniques, dietary restrictions, and nutritional counseling.
- **Routine monitoring is conducted of measures, signs and symptoms, applicable to the specific disease(s)/condition(s) of the enrollee.** We expect the MAO or cost contractor to collect and act upon this information in order to coordinate care in an appropriate and timely manner. Clinical staff with specialized knowledge of the enrollee's specific disease/condition should conduct this review.

Health Education

A health education program that is acceptable as a supplemental benefit:

- Is offered to all enrollees or targeted to groups of enrollees based on specific disease conditions.
- Will provide more than written material and go beyond content alone to include interaction with a certified health educator or other qualified health professional.
- The interactive sessions are expected to:
 - Primarily provide health information;
 - Encourage enrollees' adoption of healthy behaviors;
 - Build skills to enhance enrollees' self-care capabilities; and
 - Align with the overall goal to improve participants' health.
- May be provided in a number of modalities including, but not limited to:

- Group sessions in which the educator provides information or skills instruction;
- One-on-one instruction session; and
- Interactive web- and/or telephone-based coaching to reinforce what an enrollee learned in a group or individual session.

Consistent with our description of health education activities and services, plans may develop health education services to address whatever health-related topics they identify as appropriate for their enrollee population and could certainly include as supplemental benefits programs that support and encourage enrollees to adopt healthier lifestyles.

In-Home Safety Assessment

The In-Home Safety Assessment should be performed by an occupational therapist or other qualified health provider. Services included in such a benefit would be provided only to beneficiaries who do not qualify for an in-home safety assessment under Original Medicare's home health benefit and the plan must ensure the following conditions apply:

- The assessment's focus is on the beneficiary's risk for falls and identification of how falls may be prevented; and
- The bathroom safety devices that may be installed should be appropriate for the individual beneficiary's home, determined to be necessary by the occupational therapist or other qualified health provider furnishing the safety assessment, and be approved by the beneficiary.

The assessment may include identification and/or minor modification of some home hazards outside of the bathroom, in order to reduce risk of injury. Such modifications may include removal of rugs that are not attached to the floor and rearrangement of furniture to create clear pathways.

Meals

Home delivery of meals may be offered as a supplemental benefit if the service is:

- 1) Needed due to an illness;
- 2) Consistent with established medical treatment of the illness; and
- 3) Offered for a short duration.

Meals may be offered as a supplemental benefit to address the following two types of circumstances:

- Immediately following surgery or an inpatient hospital stay meals may be offered for a temporary duration, typically a four-week period, per enrollee per year, provided they are ordered by a physician or non-physician practitioner. As discussed in 42 CFR § 422.112(b)(3), after the temporary duration, the provider should refer the enrollee to community and social services for further meals, if needed.
- For a chronic condition, including but not limited to cardiovascular disorders, chronic heart failure or diabetes, provided the meals are:
 - Offered for a temporary period, typically for two weeks, per enrollee per year.
 - Ordered by a physician or non-physician practitioner; and
 - Part of a supervised program designed to transition the enrollee to life style modifications.

Social factors, by themselves, do not qualify an enrollee for supplemental meal services.

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, plans are to:

- Provide information and links to websites with nutritious diet planning information, such as CoverMyPlate.Gov;
- Provide nutritional tips in their plan newsletters and/or on their plan websites; and
- 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.”

Nutritional/Dietary Benefit

General nutritional education for all beneficiaries through classes and/or individual counseling may be provided as a supplemental benefit as long as the services are

provided by practitioners who are practicing in the state in which s/he is licensed or certified, and are furnishing services within the scope of practice defined by their licensing or certifying state. (i.e., physician, nurse, registered dietician, or nutritionist). The number of visits, time limitations, and whether the benefit is for classes and/or individual counseling must be defined in the notes. The data entry for this supplemental benefit can be entered at section B14c of the PBP.

Over-the-Counter (OTC) Benefit

Plans may offer OTC items as a supplemental benefit under Part C. OTC items include non-prescription drugs, also known as OTC drugs and health-related items. See section 40 below for details.

Personal Emergency Response System (PERS)

MAOs and cost contractors may propose a supplemental benefit that provides an enrollee with an in-home device to notify appropriate personnel of an emergency (e.g., a fall). A PERS may not be a cell or portable telephone because those devices do not meet our criteria that a supplemental benefit must be primarily health related.

Preventive Benefits Eligible as Supplemental Benefits

1. Additional sessions of smoking and tobacco cessation counseling –

Plans may offer additional sessions of face-to-face intermediate counseling and/or additional sessions of face-to-face intensive counseling per contract year and/or the plans may offer as a supplemental benefit interactive, on-line or telephone-based coaching and support programs to enhance enrollees' successful smoking and tobacco cessation.

2. Medical Nutrition Therapy (MNT) –

Plans may offer additional hours of one-on-one MNT counseling provided by a registered dietician or other nutrition professional, to all or a disease-defined group of its enrollees. Plans may offer additional hours of one-on-one MNT counseling provided by a registered dietician or other nutrition professional, to enrollees with diabetes and renal disease or who have received a kidney transplant in the last three years in addition to the MNT services those enrollees are entitled to as a required Medicare Part A and B plan benefit.

Physical Exam

Non-SNP MA plans and cost contractors may offer as supplemental benefits physical exams that would provide services not included in the required Annual Wellness Visits. The plans must fully describe in the PBP notes for CMS review the non-Medicare covered activities and services that would be included in the physical exam.

Point of Service (POS)

HMOs may offer a POS option as a mandatory or optional supplemental benefit. This supplemental benefit may not be offered by any other plan type. The POS benefit provides coverage for some plan-covered services outside of the HMO's network. The HMO plan:

- May limit POS benefits to certain items and services, geographic area, or provider(s);
- May require that enrollees pay higher cost-sharing (e.g., deductibles) for POS services;
- May either require or waive prior authorization rules for obtaining POS services;
- May establish a plan maximum dollar amount it will pay for the POS benefit and/or a enrollee maximum out-of-pocket maximum for the POS benefit; if the plan chooses to establish a plan maximum dollar amount, it must inform the enrollee how much cost-sharing is required before the plan reaches this maximum amount and explain that the enrollee is liable for 100% of the cost of services after the plan has reached the plan maximum;
- Must fully disclose and clearly specify for enrollees all limitations (e.g., benefits, geographic area, providers) and describe all POS benefits and cost-sharing;
- Must track enrollee and plan utilization and spending for POS services and provide this information to enrollees (i.e., in advance of meeting limitations and/or upon request by the enrollee); and
- Must be prepared to report to CMS enrollee utilization at the plan-level of both contracting and non-contracting providers in the form and manner prescribed by CMS.

Note: A PPO must cover all plan benefits furnished to its enrollees anywhere in the United States. Therefore, an MAO wishing to furnish specific plan-covered services outside its service area but only in certain geographic locations should offer an HMO plan with a point of service option.

Post discharge In-home Medication Reconciliation

Immediately following discharge (e.g., within the first week) from a hospital or SNF inpatient stay, a qualified healthcare provider, in cooperation with the beneficiary's physician, would review the beneficiary's complete medication regimen that was in place prior to admission and compare and reconcile with the regimen prescribed for the beneficiary at discharge to ensure new prescriptions are obtained and discontinued medications are discarded. This reconciliation of the beneficiary's medications may be

provided in the home and is designed to identify and eliminate medication side effects and interactions that could result in illness or injury.

Re-admission Prevention

Immediately following a beneficiary's discharge from a hospital or skilled nursing facility (SNF) inpatient stay (e.g., within the first week), plans may offer, as a supplemental benefit, non-Medicare covered services that are primarily for the purpose of preventing the beneficiary's readmission to a hospital or other institution.

Services included in a supplemental re-admission prevention benefit that CMS would expect to approve would:

- Not duplicate Medicare-covered benefits (e.g., home health which may provide some services to homebound beneficiaries);
- Be initiated immediately after a beneficiary's discharge from an institutional setting (e.g., hospital, SNF);
- Be provided for a limited and specified period of time not to exceed four weeks; and
- Be entered with the title "Re-admission Prevention" in one of the "Other" service category fields in the PBP and be described in the PBP notes for that service category.

The following are examples of benefits that a plan may choose to offer as a supplemental benefit. A plan also may choose to either combine the example benefits as a complete "Re-admission Prevention" benefit or offer the benefits separately. Examples include:

- Post discharge In-home Medication Reconciliation, as described earlier in this section;
- Meals, as described earlier in this section.
- In-Home Safety Assessment as described earlier in this section;

Telemonitoring

MAOs and cost contractors may propose a supplemental benefit that provides in-home equipment and telecommunication technology to monitor enrollees with specific health conditions (e.g., hypertension or chronic heart failure). The benefit should be referred to as "Telemonitoring services" in the PBP and may not duplicate items or services provided under original Medicare (e.g., glucometers for diabetic beneficiaries). In addition, the supplemental benefit description should address the following issues:

- Telemonitoring services should supplement, rather than replace, face-to-face physician visits;
- The enrollee should have had an initial physician visit to diagnose or confirm the diagnosis of the specific condition;
- Except in rare circumstances, the data should be collected/transmitted at least weekly, but may be required daily or more frequently, as appropriate for the particular disease;
- The equipment provided to the enrollee should be disease-appropriate;
- The enrollee should be trained on how to transmit the data properly;
- Health care professionals should monitor and take action, as needed, based on the collected/transmitted data;
- The enrollee’s physician should be included in the communication process; and
- All devices must comply with applicable state and federal requirements. MAOs and cost contractors should include in notes a description of the monitoring services they propose to provide as supplemental benefits.

Transportation Services

There are situations when transportation may be a covered supplemental benefit.

An MA plan may create either a mandatory or optional supplemental transportation to provide transportation not covered by Original Medicare. The transportation offered should be appropriate to accommodate the enrollee’s needs. For example, the plan may offer to enrollees a supplemental benefit that provides transportation to physician office visits.

The plan must describe the proposed benefit in its submitted plan benefit package.

Visitor/Travel Benefit

A Visitor/Travel benefit may be offered as either a mandatory or optional supplemental benefit. 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 who are covered by the benefit but temporarily out of the service area (and still within the United States or its territories) for more than six but less than 12 months (42 CFR § 422.74(d)(4)(iii)). See Chapter 2, section 50.2.1, of the Medicare Managed Care Manual (“Medicare Advantage Enrollment

and Disenrollment”) located at http://www.cms.gov/MedicareMangCareEligEnrol/01_Overview.asp, for further details.

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

- The V/T benefit must furnish all plan-covered services in its designated V/T service 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;
- 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 covered by the benefit 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; and
- Subject to CMS review and approval, an MAO may continue to designate an area where it is not able to form a network of direct-contracted providers as a covered V/T service area as long as the plan can ensure that its members have access to all covered services.

Web- and Telephone-Based Technologies

MAOs and cost contractors may propose a supplemental benefit in which the process of diagnosing and treating some conditions includes the enrollee answering a series of questions online and/or via telephone. We want to ensure that this type of service will not be used as a substitute for an effective, ongoing doctor-patient relationship, but rather, will be supportive of that relationship and of efficient delivery of needed care. Plans offering such a benefit should ensure that:

- Medical protocols are established and regularly updated based on relevant clinical guidelines and that prescribing and/or treatment recommendations are consistent with the State laws in the jurisdiction where the MAO operates and are within the provider’s scope of practice;
- When contacting the system, the enrollee is made aware that he or she is not required to use the system and can contact his/her plan provider directly, although perhaps at a later time;

- The information provided by the enrollees during the web- or phone-based process is directed to his/her PCP or other plan provider specified by the enrollee and will become part of the medical record; and
- A method and protocol for monitoring the use of the system by enrollees will identify potential misuse and supplantation of appropriate PCP visits has been developed and is implemented for the contract year the benefit is offered. The MAO must provide CMS with this information upon request.

A PPO may not use web- and telephone-based technologies services as described above to fulfill its requirement to provide out-of-network services. Email communication between an enrollee and his/her physician would not be acceptable as a supplemental benefit because that communication is an aspect of the Part B physician services MAOs are required to provide.

MAOs must include in the PBP notes field a description of the web- and/or telephone-based services they propose to provide as supplemental benefits.

Wigs for Hair Loss Related to Chemotherapy

An MA plan may offer as a supplemental benefit wigs for hair loss that is a result of chemotherapy. However, wigs may not be offered as a supplemental benefit for any other purpose.

Worldwide Coverage

Although the benefit is labeled “Worldwide Coverage,” this label refers to any coverage of services outside the United States and its territories, whether worldwide or in areas specified by the plan as either a mandatory or optional supplemental benefit. Under the benefit, enrollees may obtain emergency or urgently-needed care when they are temporarily outside of the United States and its territories. MA plans that offer a worldwide coverage benefit may retain enrollees who are covered by the benefit but temporarily outside of the United States or its territories for up to six months.

The specific requirements for the Worldwide Coverage benefit are as follows:

- The nature of the services covered must be clearly stated, for example, an MA plan may limit such coverage to services that would be classified as emergency or urgently needed had they been provided in the United States (see section 20 above for the definition of emergency and urgently needed services in the United States); and
- As explained in section 10.5.2 above, a plan benefit design may not discriminate based on health status. In particular, the cost of a mandatory supplemental Worldwide Coverage benefit should be nominal within the bid or CMS may determine that the benefit discriminates against enrollees who are unable to travel

due to health status.

30.4 – Items and Services Not Eligible as Supplemental Benefits (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The items and services listed in this section have been periodically proposed as supplemental benefits in submitted plan benefit packages. The following items and services are not supplemental benefits:

- Cosmetic services including beauty salon services such as pedicures and manicures;
- Homemaker and maid services (when not covered by the Original Medicare Home Health benefit);
- A massage benefit even when furnished by a state licensed massage therapist;
- Stand-alone peripherals such as hearing aid batteries and contact lens cases when not factory packaged with the hearing aids or contact lens, respectively;
- Meals not meeting the criteria specified in section 30.3 above;
- Smoke detectors and fire extinguishers;
- Screening Pap test/screening pelvic exams provided more frequently than every 24 months for non-high risk beneficiaries, because plans must follow the Medicare Part B schedule;
- Electronic medical records and electronic data storage devices;
- Loaner DME items when the beneficiary's rented or owned DME is being repaired. Loaner DME is a required Medicare Part B service. See section 10.12 above;
- Brain Training/Memory Fitness services because there is no conclusive evidence that any such services improve memory or brain function and they are not accepted clinical treatment modalities;
- Case management and care coordination because these are required services in all coordinated care plans. Those required activities are presented in section 110.4 of this chapter.

Note: For information specific to Special Needs Plan benefit offerings, see Chapter 16B of the Medicare Managed Care Manual, "Special Needs Plans."

40 – Over-the-Counter (OTC) Benefits

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

40.1 Overview of OTC Benefit

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

MA plans may offer as a supplemental benefit health-related items and medications that are: available without a prescription, and are not covered by Medicare Part A, B or D. Plans may never offer as a Part C supplemental benefit an OTC drug or item that also is covered under Part B or that is paid for under Part D for the plan's enrollees. OTC drugs and items that are eligible to be included in a Part C supplemental benefit must meet our criteria for qualification as a supplemental benefit in section 30 of this chapter. Detailed information about OTC drugs paid for under Part D may be found in chapters 5 and 7 of the Medicare Prescription Benefit Manual, Pub 100-18.

Under Part C, plans may cover health-related OTC items such as adhesive or elastic bandages, and OTC drugs such as antihistamines and analgesics, that meet the criteria as eligible supplemental benefits under Part C, presented in section 30.1 above.

Medical supplies associated with the administration of insulin, (e.g., alcohol wipes and syringes) must be paid for under Part D and are not eligible to be covered as a supplemental benefit.

Since, items and drugs that may be covered by the plan in a supplemental benefit are for the enrollee, OTC items may only be purchased for the enrollee. Purchases for anyone else are not allowed.

40.2 - Access to OTC Benefits

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The OTC drugs and/or items offered, regardless of how they are packaged or paid for, must be available at a wide variety of retail outlets or through a mail order catalog. The plan must ensure that the retail outlets through which enrollees may obtain the covered OTC items are distributed within the service area to ensure that the benefit is uniformly offered and that all enrollees have access to the benefit. An MAO that contracts with a single mail order company to provide OTC items has fulfilled its obligation of providing uniform and sufficient access to the OTC benefit.

A catalog may consist of an actual paper catalog that displays covered OTC drugs and/or items, a list on a website, or a simple order form. Enrollees may place their orders either through a secure website, mail, or a toll-free number. A catalog must contain: a list of all plan-covered OTC items and the price of each item. The plan is responsible for the cost of mailing. To avoid excessive mailing costs, the plan may impose a minimum purchase amount per order. All information should be clearly stated in the catalog.

40.3 Payment methods

The MA plan may not give enrollees money to purchase covered OTC items or drugs but may, for example: (1) reimburse enrollees for eligible purchases when receipts are presented; (2) allow purchase by enrollees through a plan catalog or list; or (3) issue a debit card that is electronically linked to eligible OTC items and drugs. The plan may establish a certain dollar amount that each covered enrollee may spend to purchase covered items and drugs on a per-month or per-year basis. The method (debit card, mail order etc.) by which enrollees are able to purchase covered OTC items and drugs is not part of the benefit and may be changed during the year with appropriate prior notification to enrollees and the account manager of the regional office to ensure the new method provides adequate access.

40.3.1 Special Rules for Manual Reimbursement

Every plan, independent of the payment method it chooses, must also allow – under circumstances which it describes, for example, when the debit card network is down – for manual reimbursement based on submitted receipts. The plan must indicate the forms and process (as well as the circumstances) by which manual reimbursement is allowed.

40.4 - Items and Their OTC Status

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Table II below displays examples of categories of OTC items that plans may cover in a supplemental benefit, and also provides guidance to help plans distinguish between items that would be eligible for coverage and those that would not. Those items shown as “eligible” over the counter items may be purchased by the enrollee without restriction. Those items shown as “dual purpose” may only be purchased after the enrollee discusses the purchase with their personal provider (or satisfies other requirements the plan may specify). The plan may require a written note from or a verbal discussion with the enrollee’s personal provider as a condition for purchase of dual purpose or eligible items.

Table III displays examples of categories of items that CMS would not find to be eligible for an OTC supplemental benefit because they are not “health benefits” within the meaning of the statute. Items belonging to these categories should never appear as either eligible or dual purpose items in the catalogs of OTC items that plans offer their enrollees.

Note: Tables II and III display categories of items rather than individual items. A plan not using a mail order catalog 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 OTC cough medicines, it must cover all OTC cough medicines.

The plan must clearly indicate in its listing for enrollees of covered OTC items and drugs, which items may be, under certain circumstances, covered under either Part B or D. For example, gauze may be covered under Part B when it is being used, as prescribed, to perform surgical wound dressing changes.

Table II: Eligibility Status of OTC Items

| Eligible? | Category | Examples of items and drugs included in this category |
|------------------|--|--|
| Dual Purpose | Minerals and vitamins | |
| Dual Purpose | In home testing and monitoring | Equipment to monitor blood pressure, cholesterol, blood sugar, to test for pregnancy, HIV, fecal occult blood. Bathroom scales may be covered for enrollees with CHF or liver disease to monitor fluid retention |
| Dual Purpose | Hormone replacement | Phytohormone, natural progesterone, DHEA |
| Dual Purpose | Weight loss items | Appetite suppressants, fat absorption inhibitors |
| Eligible | Fiber supplements | Pills, powders and non-food liquids that supplement fiber in the diet |
| Eligible | First Aid supplies | Adhesive bandages, gauze and other dressings, antibacterial ointment, peroxide, thermometers, non-sport tapes |
| Eligible | Incontinence supplies. | Diapers, pads |
| Eligible | Medicines, ointments and sprays with active medical ingredients that alleviate symptoms. | Antacids, analgesics, antibacterials, anti-histamines, anti-inflammatories, antiseptics, decongestants, sleep aids |
| Eligible | Topical Sunscreen | |
| Eligible | Supportive items for comfort | Compression hosiery, rib belts, elastic knee support |
| Eligible | Mouth care | Toothbrushes, toothpaste, floss, denture adhesives, denture cleaners and gum stimulators |

Table III: OTC Items Not Eligible as a Supplemental Benefit

| Eligible? | Category | Examples of Items/Drugs Included in this Category |
|------------------|--|--|
| Non-eligible | Alternative medicines | Homeopathic and alternative medicines including botanicals, herbals, probiotics and nutraceuticals |
| Non-eligible | Baby items | Diapers, formula |
| Non-eligible | Contraceptives | Birth control pills, spermicide, prophylactics |
| Non-eligible | Convenience and comfort | Scales, fans, magnifying glasses, ear plugs, insoles, arch supports and gloves |
| Non-eligible | Cosmetics | Mouthwashes, bad breath remedies, deodorants, lip soothers, grooming devices, skin moisturizers, teeth-whiteners |
| Non-eligible | Food product or supplements | Sugar / salt supplements, energy bars, liquid energizers, protein bars, power drinks |
| Non-eligible | Replacement items, attachments, peripherals. | Hearing aid batteries, contact-lens' containers, etc. when not factory packaged with the original item |

50 – Cost-sharing Guidance

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

50.1 – Guidance on Acceptable Cost-sharing

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

50.1.1 Cost sharing standards

CMS, in its annual bid review of proposed plan packages, applies categories of cost-sharing standards whose requirements are detailed below. 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 categories of cost-sharing standards include the following:

Maximum Out-of-Pocket (MOOP) and Combined (Catastrophic) Limits on cost-sharing:

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), Regional PPO (RPPO) and

PFFS plans – are subject to a mandatory maximum out-of-pocket (MOOP) limit on enrollee cost-sharing for all Parts A and B services. In addition, both RPPO and LPPO plans are required to have a combined limit on cost-sharing that is inclusive of both in- and out-of-network cost-sharing for all Parts A and B services. The MOOP dollar limits are set annually by CMS and include all cost-sharing (i.e., deductibles, coinsurance, and co-payments) for Parts A and B services. CMS may also annually establish a lower, voluntary MOOP limit. MAOs that adopt the lower voluntary MOOP limit will have more flexibility in establishing cost-sharing amounts for Parts A and B services than those that do not elect the voluntary MOOP. Organizations must track enrollee out-of-pocket costs and should notify enrollees when they reach, or are near, the plan’s MOOP limit.

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, if ever, be reached. However, plans must still track out-of-pocket spending for these enrollees.

Per Member Per Month (PMPM) Actuarial Equivalent (AE) Cost-sharing Requirement: The actuarially estimated total MA cost-sharing for Parts A and B services must not exceed cost-sharing for those services in Original Medicare. In addition, CMS evaluates particular service categories; inpatient facility, SNF, home health services, DME, and Part B drugs, for actuarial equivalence. MAOs should refer to annually published guidance regarding the application of this requirement.

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 may not exceed the cost-sharing for those services under Parts A and B.

Discriminatory Pattern Analysis: CMS may perform an additional general discriminatory pattern analysis of cost-sharing to ensure that discriminatory benefit designs are identified and corrected.

Additional Cost-sharing Guidance: The following guidelines should be considered in plan benefit package design.

Deductibles: While high deductibles are required for MSA plans, CMS will closely scrutinize high deductibles in other plan types.

Use of Coinsurance vs. Co-payments: 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).

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 pay less than 50% of the contracted (or Medicare allowable) rate and cost-sharing for services cannot exceed 50% of the total MA plan financial liability for the benefit. Consequently:

- 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%;
- 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;
- 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
- 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.

Stratified co-payments for DME and/or Part B Drugs: 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.

| <u>Cost Range For service</u> | <u>Co-payment</u> |
|-------------------------------|-------------------|
| \$0 - \$199 | \$0 |
| \$200 - \$499 | \$40 |
| \$500 - \$999 | \$100 |
| \$1000 and above | \$200 |

Tiered cost-sharing of medical benefits: The following guidance applies to benefit package designs that include tiered cost-sharing of medical benefits

- On a limited basis, a plan may tier cost-sharing of medical benefits based on service category, e.g., 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)).

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 110.2 and 110.5 below, and in the POS subsection of section 30.3 above; and
- Stratification of copayments for DME and Part B drugs, as explained in this section.

Renal Dialysis Services: The cost-sharing for out-of-network (OON), out of service area, medically-necessary dialysis services may not exceed the in-network (IN) cost-sharing. The cost-sharing charged by MA plans for renal dialysis services furnished in the service

area but OON may be higher than the IN cost-sharing charged by the plan for the services.

Post-Stabilization Services: The cost-sharing amount for post-stabilization services must be the same or lower for non-plan providers as for plan providers.

50.2 – Cost-sharing for In Network Preventive Services (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

MAOs are required to cover without cost sharing all in-network Medicare covered preventive services for which there is no cost sharing under Original Medicare (42 CFR §422.100(k)). Plans are responsible for monitoring CMS' National Coverage Determinations and publications in order to ensure they are offering, in a timely manner, all Medicare Parts A and B services, including the zero cost-sharing preventive services.

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.

Enrollees of an MAO may directly access (through self-referral to any plan participating provider) in-network screening mammography and influenza vaccine.

The Medicare Coverage web page is at: <http://www.cms.gov/center/coverage.asp>.

Please see section 90 of this chapter for information on National Coverage Determinations (NCDs). The section describes the requirements for plan compliance with new NCDs as well as web resources for monitoring NCDs.

50.3 - Total Beneficiary Cost-sharing (TBC) (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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. Annually, CMS provides TBC requirements and operational information to MAOs through the Call Letter and other guidance documents.

50.4 – Deductible Rules for Regional and Local PPOs (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

50.4.1 Single Deductible

In addition to the applicable cost-sharing requirements listed in section 50.1 above, both local and regional PPOs that choose to charge a deductible must establish a single deductible that applies to services furnished in-network (IN) and out-of-network (OON). The local or regional PPO may:

- Not apply the deductible to IN \$0 cost-share preventive services, but may exempt any or all other IN Medicare Part A and B services from the deductible; that is, the regional or local PPO may choose to cover specific IN items or services at plan cost-sharing levels whether or not the single deductible has been met;
- Charge different dollar amounts that count toward the single deductible for specified Medicare Part A and B services furnished in-network;
- Exempt from the deductible the OON, \$0 cost-share, preventive services. However, the plan may not exempt from the single deductible any other OON Medicare Part A and B services; and
- Choose whether or not to require that the single deductible applies to non-Medicare covered services (optional and mandatory supplemental benefits) furnished either IN or OON.

Example: A local or regional PPO charges a single deductible of \$1,000. The plan limits the application and amount of the deductible to IN inpatient hospital services (\$500) and IN physician services (\$100). Additionally, the MA plan exempts Medicare covered OON \$0 preventive services from the deductible.

The local or regional PPO in this example complies with the PPO deductible guidance because it:

- Charges a single plan deductible;
- Has elected to differentiate the applicability of this single deductible for two in-network Medicare Part A and B services (Inpatient hospital and physician services); and
- Does not exempt from the single deductible any Medicare Part A or B benefits furnished out-of-network.

60 – Meaningful Plan Differences **(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)**

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. Although the specific guidelines and criteria for meaningful differences may change annually, the criteria CMS may use to make this determination include:

- Cost-sharing-CMS sets a minimum differential in enrollees' expected out-of-pocket spending between a MAO's plans of the same type in a service area;
- Mandatory supplemental benefits offered;
- Plan type;
- Inclusion of a Part D benefit differentiates two plans of the same type (MA plan is meaningfully different from MA-PD); 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 of submitted plan bids will not be approved. MAOs will be required either to withdraw or consolidate such offerings.

Example: 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;

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

70 – Non-Renewal Based on Low Enrollment (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The guidance in this section applies to non-employer MA plans, including SNPs. CMS may review employer plans for low enrollment in future years.

As provided under 42 CFR §422.506(b)(1)(iv), CMS may non-renew MA plans that do not have a sufficient number of enrollees to be considered a viable independent plan option. Prior to bid submission, CMS annually provides MAOs with criteria CMS uses to identify low enrollment plans and contacts those MAOs that offer plans in the current contract year that CMS has identified as having low enrollment. The contacted MAOs are instructed to either give notice that they are terminating or consolidating the low enrollment plan(s), or submit, within acceptable timelines, justification for continuing the plan(s). CMS reviews the submitted justifications and makes a final decision on the continuation of the plan(s) for the next contract year.

Although the criteria for meeting low enrollment requirements may change from year to year, generally, CMS will announce criteria for low enrollment that take into account, in addition to enrollment, the following:

- The number of years the plan has been in operation; and
- The SNP status of the plan.

80 - Value-Added Items and Services (VAIS) (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

80.1 – Definition and Requirements (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Value-Added Items and Services (VAIS) are items and services, not part of the MAO plan’s benefit package and provided to an MAO’s enrollees for which the cost, if any, incurred by the plan in providing the items or services is solely administrative. A cost is classified as solely administrative if the cost covers those items required to administer the VAIS, e.g., clerical items or equipment and supplies related to communication (such as phone and postage), or database administration (such as verifying enrollment or tracking utilization). Minimal cost, in and of itself, does not justify a status of “solely administrative.”

We allow MA plans to offer VAIS provided that the notification to beneficiaries about the VAIS follows specific marketing guidelines. For details, see the Medicare Marketing Guidelines located at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c03.pdf>.

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 statutes and regulations;
- Comply with all applicable relevant fraud and abuse laws, including the anti-kickback statute and prohibition on inducements to beneficiaries;
- Not price the VAIS in the plan bid;
- Not use any Medicare program dollars to offer the VAIS; and
- Not offer it to non-plan members, for example, dependents and spouses of plan members.

Note that although VAIS is not submitted in PBPs and not reviewed during the CMS annual bid review, CMS reserves the right to review a plan's VAIS on audit or in response to complaints related to VAIS.

80.2 - Examples of VAIS

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

- Example 1: In addition to coverage of an in-network vision-exam benefit (for which the plan incurs a direct medical cost), an MA plan also offers a 5% discount on a vision exam furnished by an out-of-network vision-exam provider. The plan does not incur a direct medical cost for the out-of-network exam, but rather only incurs the administrative cost to verify eligibility and inform its enrollees of the 5% discount.

Analysis: Since the plan does not incur a direct medical cost in providing the vision exam out-of-network, the discount cannot be classified as a benefit, but may be offered as a VAIS. However, since the out-of-network vision exam is not a benefit, it may not be advertised on the Medicare Plan Finder 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 offered 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 Medicare Plan Finder nor mentioned in the PBP.

- Example 2: An MA plan wishes to offer free groceries with vouchers to its enrollees.

Analysis: Such grocery vouchers could not be offered as VAIS if the plan incurs costs for the vouchers. Although the cost is minimal, the cost is not solely administrative, since the MA plan is paying for vouchers.

- Example 3: An MA plan contracts with a provider or another insurer, such as an insurer for dental or vision services, to furnish medical benefits to its enrollees at reduced cost. The provider or insurer requires the plan to collect and aggregate payments from its enrollees.

Analysis: The MA plan cannot contract a medical service for its enrollees outside the plan benefit package because this violates Medigap rules. Consequently, the contract by the MA plan on behalf of its enrollees with the provider or insurer to furnish medical benefits should be classified in the bid as a medical cost, and may not be offered as a VAIS.

However, if the provider or insurer offers its services at a discounted rate to the MA plan enrollees who directly pay the provider or insurer without additional payment from the plan, then the plan may offer this discount as VAIS.

90 - National and Local Coverage Determinations (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

90.1 - Overview (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

As discussed in section 10.2 of this chapter, an item or service is classified as an Original Medicare benefit and, consequently, must be covered by every MA plan if:

- Its coverage is consistent with general coverage guidelines included in Original Medicare regulations, manuals and instructions (unless superseded by written CMS instructions or regulations regarding Part C of the Medicare program);
- It is covered by CMS' national coverage determinations (see sections 90.3 and 90.4, below); or
- It is covered by written coverage decisions of local MACs with jurisdiction for claims in the geographic area in which services are covered under the MA plan, as described in section 90.2 below.

90.2 - Local Coverage Determinations (LCDs) (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

90.2.1 MACS with Exclusive Jurisdiction over a Medicare Item or Service

A MAC outside of the plan's service area sometimes has exclusive jurisdiction over a Medicare covered item or service. In some instances, one Medicare A/B MAC processes all of the claims for a particular Medicare-covered item or service for all Medicare

beneficiaries around the country. This generally occurs when there is only one supplier of a particular item, medical device or diagnostic test (for example; certain pathology and lab tests furnished by independent laboratories). In this situation, MA plans must follow the coverage requirements or LCD of the MAC that enrolled the supplier and processes all of the Medicare claims for that item, test or service.

90.2.2 Multiple MACS with Conflicting Policies

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

Alternative 1: Both local and regional MA plans may choose to adopt the coverage policy that applies to Original Medicare beneficiaries in that county.

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

- **Regional Plans:** A regional plan, if it wishes to adopt a uniform coverage policy, must select a single MAC group in the service area of the plan whose local coverage determinations or policies will apply to all members of the regional plan. Regional plans may not select local coverage policies from more than one MAC.
- **Local Plans:**
 - Must select the uniform coverage policy most beneficial to their enrollees.
 - Must notify CMS, through their regional office representative, 60 days before the date bids are due if they elect to adopt a uniform local coverage policy for any plan or plans in the subsequent year (42 CFR § 422.101(b)(3)(i)). In preparing this notification plans should include, at a minimum:
 1. An identification of the plan(s) and service area(s) to which the uniform local coverage policy or policies will apply;
 2. The competing local coverage policies involved;
 3. A table contrasting the local coverage areas by listing and comparing those policies in each coverage area that represent expansions of Medicare Part A and Part B services;
 4. An explanation as to why the selected local coverage policy or policies is most beneficial to MA enrollees. The justification should be presented so that CMS is independently able to identify which of the coverage areas, on balance, furnishes the most generous Part A and

Part B coverage policies; and

5. CMS pre-approval of the uniform coverage policy. CMS will consider a local plan to have met the “most beneficial” requirement if the MAO offering the local plan elects to adopt:
 - a. The coverage policies of one MAC in its service area whose local coverage policies and determinations will uniformly apply to all enrollees in the area, and CMS determines that the carrier's policies viewed in totality are the most favorable to beneficiaries; or
 - b. Any individual carrier coverage policy or policies to uniformly apply to all enrollees in the service area, and CMS determines that each such individual policy is most favorable to beneficiaries.

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

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

- CMS reserves the right to review the determination of any uniform coverage policy;
- Plans must make information on the selected local coverage policy determinations readily available, including through the Internet, to enrollees and health care providers; and
- If choosing the option to apply a uniform set of local coverage policies, or in the case of a local plan, to uniformly apply individual policies, MAOs must apply the policy or policies in question in all parts of the MA plan service area.

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

90.3 – Definitions Related to National Coverage Determinations (NCDs) (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

- A **national coverage determination** (NCD) is a determination by the Secretary of whether a particular item or service is covered under Medicare. An NCD does not include a determination of what HCPCS code, if any, is assigned to a service

or a determination about the payment amount for the service. HCPCS codes are assigned through separate guidance.

An NCD is the final coverage determination issued as part of the National Coverage Analysis (NCA) and is released by CMS as a coverage decision memorandum (Decision Memo) prior to inclusion in the NCD manual. The NCA tracking sheet for each item or service includes the complete public record for the NCD request, and is updated throughout the coverage process. It includes the tracking sheet, proposed decision memo, public comments, and the final decision memo.

- A **legislative change in benefits** is a coverage requirement adopted by the Congress and mandated by statute. Usually, the Secretary implements a legislative coverage change through regulation and/or sub-regulatory guidance.
- The term **significant cost**, as it relates to a particular NCD or legislative change in benefits, means either of the following:
 - The average cost of furnishing a single service exceeds a cost threshold that for a calendar year is the preceding year's dollar threshold adjusted to reflect the national per capita growth percentage described at 42 CFR §422.308(a); or
 - The estimated cost of Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national average per capita costs.

90.4 - General Rules for NCDs **(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)**

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

- NCDs made by CMS;
- Local Coverage Determinations (LCDs);
- Legislative changes in benefits applied through notice and comment rulemaking (often codifying the changes in the Code of Federal Regulations; and
- Other coverage guidelines and instructions issued by CMS (e.g., Change requests and Program Transmittals).

As indicated in section 10.2 above, MAOs must provide all items and services classified as Original Medicare-covered benefits. In applying this rule to NCDs, different rules apply depending on whether the significant cost criterion, described above in section 90.3, has been met.

90.4.1 When the significant cost criterion is not met

When CMS determines that a NCD or legislative change in benefits does **not** meet a criterion for significant cost, the MAO is required to provide coverage for the NCD or legislative change in benefits and assume risk for the costs of that service or benefit as of the effective date of the NCD or as of the date specified in the legislation/regulation. NCDs are effective on the date that CMS releases the Final Decision Memorandum for the NCD. The NCD effective date is the date when the new or changed benefit/service must be made available to enrollees by the plan. The implementation date in the corresponding Medicare Change Request (CR) /Transmittal guidance (TR) is the latest date by which MAOs must have payment system edits in place and coverage/non-coverage fully implemented for providers/suppliers. MAOs must ensure that the items/services are covered, and provider claims paid, retroactive to the NCD effective date. More information related to Medicare CR/TRs and manual guidance may be found in section 90.6 below.

90.4.2 When the significant cost criterion is met

Prior to the adjustment of the annual MA capitation rate, if CMS determines and announces that an individual NCD item, service or legislative change in benefits does meet a criterion for significant cost, then the MAO is not required to assume risk for the costs of that service or benefit until the contract year for which payments are appropriately adjusted to take into account the significant cost of the service or benefit. However, a plan must pay for the following:

- Diagnostic services related to the NCD item, service, or legislative change in benefits and most follow-up services related to the NCD item, service, or legislative change (42 CFR § 422.109(c)(2)(i),(ii));
- NCD items, services, or legislative change in benefits that are already included in the plan's benefit package either as Original Medicare benefits or supplemental benefits.

Although the item or service may not be included in the services MAOs must cover under their contract in exchange for monthly capitation payment, MAOs, must still provide access to the NCD item or service by furnishing or arranging for the service.

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

90.4.3 Payment for NCD Items and Services

Chapter 8 of this manual, “Payments to Medicare Advantage Organizations,” contains the detailed rules on payment for NCD items and services or legislative changes in benefits that meet the significant cost threshold. Included is a description of services for which MAOs are responsible in the contract year prior to the adjustment of the annual MA capitation to account for the significant cost. During this period, MA enrollees are responsible for any applicable coinsurance amounts under Original Medicare.

After adjustment of the annual MA capitation rate, or other payment adjustment reflecting the new costs, is made, the service or benefit is included in the MAO’s contract with CMS and is a covered benefit under the contract. The MAO must furnish, arrange, or pay for the NCD service or legislative change in benefits, subject to all applicable rules. MAOs may establish separate plan rules for these services and benefits, subject to CMS review and approval. CMS may, at its discretion, issue overriding instructions limiting or revising the MA plan rules, depending on the specific NCD or legislative change in benefits. For these services or benefits, the Medicare enrollee is responsible for any MA plan cost-sharing, as approved by CMS or unless otherwise instructed by CMS.

90.5 - Creating New Guidance

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

In coverage situations where there is no NCD, LCD, or guidance on coverage in Original-Medicare manuals, an MAO may adopt the coverage policies of other MAOs in its service area.

However, if the MAO decides not to use coverage policies of other MAOs in its service area, the MAO:

- Must make its own coverage determination;
- Must provide a rationale using an objective-evidence based process based on authoritative evidence such as:
 - Studies from government agencies (e.g. the FDA);
 - Evaluations performed by independent technology assessment groups (e.g. BCBSA); and
 - Well-designed controlled clinical studies that have appeared in peer review journals; and
- In providing its justification, the MAO may not use conclusory statements with no accompanying rationale (e.g., “It is our policy to deny coverage for this service.”)

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

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

90.6 - Sources for Obtaining Information

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Generally, legislative changes to Medicare coverage rules are implemented through notice-and-comment rulemaking. For example, if Medicare Part B coverage is affected, the changes are usually included in the annual Medicare Physician Fee Schedule (MPFS) proposed and final rules, published in the Federal Register every summer and fall, respectively. Medicare manual guidance corresponding to legislative changes in benefits may be released in the Medicare Benefit Policy Manual (Pub. 100-02) and/or the Medicare Claims Processing Manual (Pub. 100-04).

Implementation of coverage changes resulting from the NCD process and all related changes to original Medicare claims processing are made through Change Requests (CRs) and Transmittals (TRs) that also are used to update the Medicare National Coverage Determinations Manual (Pub. 100-03) and the Medicare Claims Processing Manual (Pub. 100-04).

Although MAOs have not been required to use Original Medicare claims processing systems, MAOs must follow the coverage instructions in the original Medicare CRs/TRs. We also encourage plans to use claims processing guidance as a source of information that will support their implementation of the new benefit/service or other change in coverage.

The following Internet resources provide valuable information:

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

- Provide a listing of all NCDs;

- Provide a listing of all National Coverage Analyses (NCAs) and final Decision Memos;
- 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;
- Provide a list of all email coverage updates sorted by year; 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 that interested individuals can send questions and provide feedback.

The Medicare NCD Manual, Publication 100-03, accessible at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>, includes the Medicare national coverage policies in manual form.

Program Transmittals and Change Requests transmit CMS' new policies and procedures on new coverage determinations and Medicare benefits. Links to the Program Transmittals and Change Requests can be found at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/index.html>; and

Medicare Internet-Only Manuals, located at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>. These manuals, including the Benefit Policy Manual and Claims Processing manuals, as described above, present information on Medicare coverage of items and services and claims processing. Changes to these manuals are released through Program Transmittals and Change Requests.

PART II – BENEFICIARY PROTECTIONS

Part II of this chapter, which begins in section 110, provides information on beneficiary protections, and includes topics such as rules for plan renewals, coordination of benefits, providers, provision of benefits during disaster situations, and Educating and Enrolling Members in Medicaid and Medicare Savings Programs

110 - Access to and Availability of Services

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

110.1 - Access and Availability Rules for Coordinated Care Plans

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

An MAO may specify the providers through whom enrollees may obtain services if it ensures that all Original Medicare covered services and supplemental benefits contracted for, by, or on behalf of Medicare enrollees are available and accessible under the coordinated care requirements.

MAOs are required to maintain and monitor a network of appropriate providers, supported by written arrangements, that is sufficient to provide adequate access to covered services to meet the needs of the population served. This involves ensuring that services are geographically accessible and consistent with local community patterns of care. In other words, the MAO must ensure that providers are distributed so that no member residing in the service area must travel an unreasonable distance to obtain covered services. An example of CMS standards for access is provided by the Health Service Delivery (HSD) tables during a plan's initial application. The HSD process uses a partially automated procedure that measures access by county and specialty. The assessment measures used include measuring the number of providers as well as the average distance and time needed for projected plan members to access each specialist in each county.

MAOs are required to establish and maintain provider network standards that:

- Define the types of providers to be used when more than one type of provider can furnish a particular item or service;
- Identify the types of mental health and substance abuse providers in their network; and
- Specify the types of providers who may serve as a member's primary care physician.
- Employ written standards for timeliness of access to care and member services that meet or exceed such standards as may be established by CMS, make these standards known to all first tier and downstream providers, continuously monitor its provider networks' compliance with these standards, and take corrective action

as necessary. These standards must ensure that the hours of operation of the MAO's providers are convenient to, and do not discriminate against, members. The MAO must also ensure that, when medically necessary, services are available 24 hours a day, 7 days a week. This includes requiring primary care physicians to have appropriate backup for absences. The standards should consider the member's need and common waiting times for comparable services in the community. (Examples of reasonable standards for primary care services are: (1) urgently needed services or emergency - immediately; (2) services that are not emergency or urgently needed, but in need of medical attention - within one week; and (3) routine and preventive care - within 30 days.

- Establish, maintain, monitor and validate credentials for a panel of primary care providers from which the member may select a personal primary care provider. All MA plan members may select and/or change their primary care provider within the plan without interference. MAOs that require members to obtain a referral before receiving specialist services typically require this referral be obtained from a primary care provider. However, some members do not select primary care providers. Consequently, MAOs must ensure that there is a mechanism for assigning primary care providers (for purposes of referral) to members who do not select a primary care provider.
- Provide or arrange for necessary specialist care, and in particular give female enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services. The MAO must arrange for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet a member's medical needs.
- Ensure that all services, both clinical and non-clinical, are provided in a culturally competent manner and are accessible to all members, including those with limited English proficiency, limited reading skills, hearing incapacity, or those with diverse cultural and ethnic backgrounds. Examples of how an MAO may meet these accessibility requirements include but are not limited to provision of translator services, interpreter services, teletypewriters or TTY (text telephone or teletypewriter phone) connection
- Establish and maintain written standards, including coverage rules, practice guidelines, payment policies and utilization management protocols that allow for individual medical necessity determinations. These standards must be available to both enrollees and providers. Section 90.5 of this chapter provides guidance and criteria for formulating such standards.
- Provide coverage for ambulance services, emergency and urgently-needed services, and post-stabilization care services in accordance with the requirements in section 20 above.

- Has a quality improvement program plan as outlined in Chapter 5 of this Manual. The quality improvement program plan must include a chronic care improvement program and a quality improvement project.

MAOs may not implement utilization management protocols that create inappropriate barriers to needed care. (Prior) authorization and referral are two utilization management approaches frequently used by MAOs; the following definitions and requirements clarify the meaning and appropriate use of these two approaches:

- (Prior) Authorization: A process through which the physician or other health care provider is required to obtain advance approval from the plan that payment will be made for a service or item furnished to an enrollee. Unless specified otherwise with respect to a particular item or service, the enrollee is not responsible for obtaining (prior) authorization.
- Referral: A process through which the enrollee's primary care physician or, depending on the plan policy, other network physician, permits or instructs the enrollee to obtain an item or service from another physician or other provider type.

110.2 – Preferred Provider Organization (PPO) Coverage and Access (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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 area:

- 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.
- 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/providing 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.

- 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.

110.3 – Special Rules for RPPOs

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

110.3.1 Access through Non-contracted Providers

In those portions of an RPPO's defined service area where it cannot establish contracts with providers to meet Medicare access to services requirements, the RPPO, may also meet Medicare access to services requirements by demonstrating to CMS' satisfaction that there is adequate access to all plan-covered services through alternative arrangements (42 CFR §422.112(a)(1)(ii)) -- that is, the RPPO is providing adequate access but not through a contracted network. Plan-covered services received by enrollees in non-network areas of an RPPO must be covered at in-network cost-sharing levels for the enrollee.

110.3.2 Essential Hospitals

42 CFR §422.112(c) describes the requirements for an RPPO to apply to CMS to designate a noncontracting hospital as an essential hospital. If CMS approves the application and the hospital continues to meet the requirements then the essential hospital is "deemed" to be a network hospital of the RPPO and normal in-network inpatient hospital cost sharing levels (including the catastrophic limit described in 42 CFR §422.101(d)(2)) apply to all plan members accessing covered inpatient hospital services in that hospital.

110.4 - Rules for All MAOs to Ensure Coordination of Care

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The MAO must ensure continuity of services through arrangements that include, but are not limited to, the following:

Implementing policies that specify under what circumstances services are coordinated and the methods for coordination. The policies should specify whether the services are coordinated by the enrollee's primary care provider or in conjunction or through some other means, e.g. a care management system, a nurse case manager, clinical prompts, etc.;

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

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

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

- The MAO makes a good faith effort to conduct an initial health assessment of all new members within 90 days of the effective date of enrollment and follows up on unsuccessful attempts to contact an enrollee. The Original Medicare initial preventive visit (i.e. “Welcome to Medicare” preventive visit), an Annual Wellness Visit, or a recent previous physical examination in a commercial plan (to which the MAO has access) would fulfill this obligation;
- The MAO makes a good faith effort to annually notify enrollees about the Annual Wellness Visit;
- Each provider, supplier, and practitioner furnishing services to enrollees maintains an enrollee health record in accordance with standards established by CMS and the MAO, taking into account professional standards;
- Enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, information to support and promote their own health;
- Systems are employed to identify and address barriers to enrollee compliance with prescribed treatments or regimens; and
- There is appropriate, timely, and confidential exchange of clinical information among provider network components. For an example of this standard as it applies to Special Needs Plans (SNPs), see section 90.6 of Chapter 16b of this manual.

110.5 – Access, Gatekeeper and Cost Sharing by Plan Type
(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

MAOs may offer a variety of plan types, as shown in Table IV below.

Table IV: Plan Type and Access Attributes for Non-emergent Non-urgent care Services

| Plan Type | Is a gatekeeper¹ allowed? | Is a network required? | Must benefits be provided IN and OON? | May Cost-sharing requirements differ IN/OON |
|------------------|--|---|--|--|
| HMO | Optional | Must contract | Must provide IN | Not applicable |
| HMOPOS | Optional | Must contract | Must provide IN; may provide OON | May have higher cost-sharing OON |
| 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:

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 necessary referrals to in-network specialists. A coordinated care plan may require referral by a gatekeeper for in-network dialysis services but is prohibited from requiring gatekeeper referral for out-of-network dialysis services.

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

120 - Coordination of Medicare Benefits with Employer/Union Group Health Plans and Medicaid

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

120.1 - General Rule

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

(42 CFR §422.106(a)(2)) An MAO may contract with employers, unions, 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, union 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, union, or 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. Refer to Chapter 9, "Employer/Union Group Health Plans," of this manual, for further information.

120.2 - Requirements, Rights, and Beneficiary Protections

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

120.3 – Employer/Union Plans

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

130 - Medicare Secondary Payer (MSP) Procedures (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

130.1 - Basic Rule (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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 chapters of this manual entitled, “Premiums and Cost-sharing,” as well as “Employer/Union Sponsored Group Health Plans,” 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/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/PDMChapt14COB.pdf>.

130.2 - Responsibilities of the MAO (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The MAO must, for each MA plan:

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

130.3 - Medicare Benefits Secondary to Group Health Plans (GHPs) and Large Group Health Plans (LGHPs) and in Settlements (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

In the case of an enrollee’s coverage by another Medicare insurance plan, secondary payer status may, in certain circumstances, depend on:

- Whether the enrollee entitlement to Medicare is due to 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 the enrollee:
 - 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 the enrollee:
 - 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 be triggered due to 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 compensation, 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. MAOs cannot withhold primary payment unless there is a reasonable expectation that another insurer will actually promptly pay primary to Medicare. Thus for example, if an MA enrollee 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.

130.4 - Collecting From Other Entities

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The MAO may bill, or authorize a provider to bill, other individuals or entities for covered Medicare services for which Medicare is not the primary payer, as specified in section 130.5 and 130.6 below.

130.5 - Collecting From Other Insurers or the Enrollee

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

- The insurance carrier, the employer/union, or any other entity that is liable for payment for the services under section 1862(b) of the Act and section 130 of this chapter; and
- The Medicare enrollee, to the extent that s/he has been paid by the carrier, employer/union, or entity for covered medical expenses.

130.6 - Collecting From Group Health Plans (GHPs) and Large Groups Health Plans (LGHPs)

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

If an MAO is the secondary payer to a GHP/LGHP and, for a given service, the cost-sharing required by the GHP/LGHP is greater than the cost-sharing required by the MAO then:

- The enrollee must pay the MAO's plan cost sharing; and
- The MAO pays the GHP/LGHP the difference between that higher cost sharing and the MAO plan cost sharing (see 42 CFR § 422.504(g), which obligates the MAO, even if it is a secondary payer, to protect the beneficiary from paying more than plan cost sharing).

Example: If the GHP (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.

130.7 – Medicare as Secondary Payer (MSP) Rules and State Laws (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Consistent with Federal preemption of state law that is addressed at 42 CFR § 422.402, and at 42 CFR § 422.108, a State cannot take away an MAO's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. The MAO may exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations as they apply to MA Plans.

(See Chapter 8 of the Medicare Managed Care Manual (“Payments to Medicare Advantage Organizations”) for further discussion of Medicare Secondary Payer and Coordination of Benefits.)

140 - MAO Renewal Options and Crosswalk (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

140.1 - Introduction (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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).
- 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. However, a non-segmented plan may renew as, or consolidate into, a segmented plan and request that current enrollees be transitioned to plan segments.

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 renewal and non-renewal beneficiary options should protect enrollment choices of beneficiaries and foster future beneficiary access and choice.

Table V, in section 140.9 below, 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 V includes, where applicable, instructions and important deadlines that 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 V or described in sections 140.2-140.8 below, or is not specified in annual CMS guidance, it is not a permissible renewal option for an MAO.

140.2 – New Plan

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

An MAO may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year in the HPMS Plan Crosswalk. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the MAO offering the MA plan must submit enrollment transactions to CMS.

140.3 – Renewal Plan

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

An MAO may continue to offer (“renew”) a current PBP that retains all of the same service area for the following year. The renewing plan must retain the same PBP ID number as in the previous contract year in the HPMS Plan Crosswalk. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MAO will not submit enrollment transactions to CMS for current enrollees. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to CMS for those new enrollees. Current enrollees of a renewed PBP must receive a standard Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan.

140.4 – Consolidated Renewal Plan (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

MAOs are permitted to combine two or more entire PBPs offered in the current contract year into a single renewal plan in the HPMS Plan Crosswalk so that all enrollees in the combined plans are under one PBP with the same benefits in the following contract year. However, an MAO may not split a current PBP among more than one PBP for the following contract year.

An MAO consolidating one or more entire PBPs with another PBP must designate which of the renewal PBP IDs will be retained following the consolidation. The renewal PBP ID will be used to transition current enrollees of the plans being consolidated into the designated renewal plan. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees.

Current enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the organization will not submit enrollment transactions to CMS for those current members. However, the MAO may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the MAO will submit enrollment transactions to CMS for those new enrollees. Current enrollees of a consolidated renewal plan must receive a standard ANOC.

140.5 – Renewal Plan with a Service Area Expansion (SAE) (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

An MAO may continue to offer the same local MA PBP but add one or more new service areas (i.e., counties) to the plan's service area in the following contract year. Organizations that include any new service area additions to a PBP should have submitted an SAE application to CMS for review and approval. An MAO renewing a plan with an SAE in the HPMS Plan Crosswalk must retain the renewed PBP's ID number in order for all current enrollees to remain enrolled in the same plan in the following contract year.

Current enrollees of a PBP that is renewed with a SAE will not be required to take any enrollment action, and the MAO will not submit enrollment transactions to CMS for those current enrollees. New enrollees must complete enrollment requests and the MAO will submit enrollment transactions to CMS for those new enrollees. Current enrollees of a renewed PBP with an SAE must receive a standard ANOC notifying them of any changes to the renewing plan.

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

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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 to CMS 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 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. 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 may 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. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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 CMS 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 CMS 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 may 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 CMS for those members.

140.8 - Terminated Plan (Non-Renewal)
(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

An MAO may elect to terminate a current PBP for the following contract year. In this situation, the sponsor will not submit disenrollment transactions to CMS for affected enrollees. CMS will disenroll these individuals from the MA plan at the end of the contract year and these individuals must make a new election for their Medicare coverage. Regardless of whether these individuals elect to enroll in another plan offered by the same or another MAO or to revert to Original Medicare and enroll in a PDP, they must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to CMS. If these individuals do not make a new MA plan election prior to the beginning of the following contracting year, they will have Original Medicare coverage as of January 1 of the following year. Enrollees in terminated PBPs will be sent a termination notice by the terminating plan that includes notification of a special election period and Medigap guaranteed issue rights.

140.9 - Crosswalk Table Summary
(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

Table VII: Guidance for Plan Renewals

| Section | Activity | Guidelines | HPMS Plan Crosswalk | Systems Enrollment Activities | Enrollment Procedures | Beneficiary Notifications |
|----------------|----------------------|--|--|--|---|---|
| 140.2 | New Plan (PBP) Added | An MAO creates a new plan benefit package (PBP). | <p>HPMS Plan Crosswalk Definition: A new plan added for the following contract year that is not linked to a current contract year plan.</p> <p>HPMS Plan Crosswalk Designation: New Plan</p> | The MAO must submit enrollment transactions for the following contract year. | New enrollees must complete an enrollment request. | None. |
| 140.3 | Renewal Plan | 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. | <p>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.</p> <p>HPMS Plan Crosswalk Designation: Renewal Plan</p> | <p>The renewal PBP ID must remain the same so that current enrollees will remain in the same PBP ID.</p> <p>The MAO does not submit enrollment transactions for current enrollees.</p> | <p>No enrollment request for current enrollees to remain enrolled in the renewal PBP in the following contract year.</p> <p>New enrollees must complete enrollment request.</p> | Current enrollees are sent a standard ANOC. |

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| 140.4 | Consolidated Renewal Plan | <p>An MAO combines one or more whole MA PBPs of the same type offered in the current contract year into a single renewal PBP so that all current enrollees in combined PBP are offered the same benefits in the following contract year.</p> <p>The MAO must designate which of the renewal PBP IDs will be retained in the following contract year after consolidation. CMS will not allow for consolidations across contracts (with limited exceptions for some renewal 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.</p> <p>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.</p> | <p>HPMS Plan Crosswalk Definition: One or more current contract year plans that consolidate into one plan for the following contract year. The plan ID for the following contract year must be the same as one of the consolidating current contract year plan IDs.</p> <p>HPMS Plan Crosswalk Designation: Consolidated Renewal Plan</p> | <p>The MAO's designated renewal PBP ID must remain the same so that CMS may consolidate enrollees into the designated renewal PBP ID in CMS systems.</p> <p>The MAO does not submit enrollment transactions for current enrollees. The MAO may have to submit 4Rx data for individuals whose PBP number changed.</p> | <p>No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in the following contract year.</p> <p>New enrollees must complete enrollment request.</p> | <p>Current enrollees are sent a standard ANOC.</p> |

| Section | Activity | Guidelines | HPMS Plan Crosswalk | Systems Enrollment Activities | Enrollment Procedures | Beneficiary Notifications |
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| 140.5 | Renewal Plan with an SAE | <p>This option is available to local MA plans only. An MAO continues to offer a current contract year local MA PBP in the following contract year and retains all of the same PBP service area, but also adds one or more new service areas.</p> <p>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.</p> | <p>HPMS Plan Crosswalk Definition: A following contract year plan that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.</p> <p>HPMS Plan Crosswalk Designation: Renewal Plan with an SAE</p> <p>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.</p> | <p>The renewal PBP ID must remain the same so that current enrollees in the remaining in the service area will remain in the same PBP ID.</p> <p>The MAO does not submit enrollment transactions for current contract year enrollees. The MAO submits enrollment transactions for new enrollees.</p> | <p>No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in the following contract year.</p> <p>New enrollees must complete enrollment request.</p> | <p>Current enrollees are sent a standard ANOC.</p> |

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| 140.6 | Renewal Plan with a SAR and no other MA options available | <p>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.</p> <p>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)).</p> <p>Note: One renewal plan with a SAR may have counties that should follow the guidance provided in 5, and other counties in the SAR that should follow the guidance provided under 6 (i.e., the guidance provided in 5 and 6 may both apply to a single plan).</p> | <p>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.</p> <p>HPMS Plan Crosswalk Designation: Renewal Plan with a SAR</p> <p>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</p> | <p>The MAO must submit disenrollment transactions for individuals residing in the reduced portion of the service area for which it does not collect an enrollment request.</p> <p>The MAO does not submit enrollment transactions for current enrollees in the renewal portion of the service area.</p> | <p>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)).</p> | <p>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.</p> <p>Current enrollees in the renewal portion of the service area receive the standard ANOC.</p> |

| Section | Activity | Guidelines | HPMS Plan Crosswalk | Systems Enrollment Activities | Enrollment Procedures | Beneficiary Notifications |
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| 140.7 | Renewal Plan with a SAR when the MAO will offer another PBP in the reduced portion of the service area | <p>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 part of a new or renewal PBP offered by that MAO in the following contract year.</p> <p>The MAO may market to enrollees in the reduced service area any other PBP offered in the reduced service area for the following contract year. Affected enrollees who elect to enroll in another MA plan offered in the reduced service area must submit an enrollment request.</p> <p>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).</p> | <p>HPMS Plan Crosswalk Definition: A following year contract 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.</p> <p>HPMS Plan Crosswalk Designation: Renewal Plan with a SAR</p> <p>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.</p> | <p>The MAO must submit transactions to disenroll individuals residing in the reduced portion of the service area.</p> <p>The MAO submits enrollment transactions to enroll beneficiaries who have requested enrollment in other PBP offered in the reduced service area.</p> | Enrollees impacted by the SAR need to complete enrollment requests if they elect to enroll in another PBP (plan) in the same organization or a different MA plan. | The MAO sends a termination notice to current enrollees in the reduced portion of the service area that includes notification of SEP and guaranteed issue Medigap rights. The MAO may also provide additional information, in addition to the termination notice, including instructions on how to complete an enrollment request to switch to another PBP offered by the same organization. Current enrollees in the renewal portion 84 of the service area receive the standard ANOC |

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

150 - Service Area

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

150.1 – Service Area Defined

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

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

- Payment Rate: The service area designation determines the benchmark applicable to the plan, and therefore, CMS' payment rate to the MA organization for the MA plan;
- Required Benefits: The designation affects which benefits will be provided under the MA plan, because benefits and premiums must be uniform for all Medicare beneficiaries residing in the plan's service area.
- Eligibility: The designation determines which Medicare beneficiaries are able to elect the plan. With the exception of SNPs, which can limit enrollment based upon statutory and regulatory parameters, MAOs are obligated to enroll any MA eligible resident in the service area who elects the plan during an applicable enrollment period (provided an approved capacity limit has not yet been reached (see Chapter 2 of this manual, "Enrollment and Disenrollment")." located at <http://www.cms.hhs.gov/Manuals/IOM/>, Publication 100-16.);
- Access Requirements: For coordinated care plans, the designation identifies the geographical area in which the plan's covered services must be "available and accessible;" and
- Urgently-needed Services: For coordinated care plans, the designation defines the boundaries beyond which the organization must cover urgently-needed services.

150.2 - Factors That Influence Service Area Approvals

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

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

- The plan will offer a uniform premium, benefit package and cost-sharing arrangement to all beneficiaries in the service area, or segment of a service area;
- The service area meets the “county integrity rule” described below in section 150.3;
- For coordinated care plans, the contracting provider network meets CMS access and availability standards for the service area, as explained in section 110 of this chapter, even if some of the contracting providers are physically located outside of the service area; and
- There is any evidence that the service area is being manipulated to avoid areas with “sicker” people or that it would be discriminatory in some other way. In this regard, CMS also considers the extent to which the proposed service area mirrors service areas of existing commercial or MA plans offered by the MA organization.

150.3 - The “County Integrity Rule” for Partial County Service Areas (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

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

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

150.3.1 Necessity

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

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

The following examples illustrate how an HMO or other type of MA plan has a health care network that is limited to one part of a county and cannot be readily extended to encompass an entire county.

Example 1: A section of a county has an insufficient number of providers (or insufficient capacity among existing providers) to ensure access and availability to covered services.

Example 2: Geographic features, such as mountains, water barriers, and exceptionally large counties create situations where the pattern of care in the county justifies less than a complete county because covered services are not available and accessible throughout the entire county.

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

150.3.2 Non-Discriminatory

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

- The anticipated enrollee health care cost of the portion of the county it proposes to serve is similar to the area of the county that will be excluded from the service area. For example, if the MA organization is requesting a service area reduction (creating a new partial county) the organization can demonstrate its anticipated cost of care (in the partial county area) by using data from the previous year of MA contracting comparing the health care costs of its enrollees in the excluded area to those in the area of the county it proposes to serve; and
- The racial and economic composition of the population in the portion of the county it wants to serve is comparable to the excluded portion of the county. For example, the MA organization can use U.S. census data to show the demographic make-up of the included portion of the county as compared to the excluded portion.

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

150.3.3 Best Interests of Beneficiaries

In order for CMS to determine whether a partial county is in the **best interest of beneficiaries**, an MA organization must provide reasonable documentation to support this premise. Supporting documentation could include data obtained from enrollee satisfaction surveys, grievance and appeal files; and utilization files.

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

160 - Benefits during Disasters and Catastrophic Events (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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 (the Secretary) declares a public health emergency under section 319 of the Public Health Service Act, the Secretary has the right to exercise his or her waiver authority under section 1135 of the Social Security Act. If an 1135 waiver is issued, CMS will identify consequent requirements and responsibilities to plans. Detailed guidance and requirements for MA plans, including timeframes associated with those requirements and responsibilities, will be posted on the Department of Health and Human Services website, (<http://www.hhs.gov/>) and the CMS web site (<http://www.cms.hhs.gov/>). MAOs are expected to check these sites frequently during such disasters and emergencies.

Under the Secretary's section 1135 waiver authority, CMS may authorize Medicare Administrative Contractors to pay for Part C-covered services furnished to beneficiaries enrolled in MAOs and seek reimbursement from MAOs for those health care services, retrospectively.

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, or prior to the issuance of, an 1135 waiver by the Secretary, MAOs are expected to:

- 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);
- Waive in full, requirements for gatekeeper referrals where applicable;
- Temporarily reduce plan-approved out-of-network cost-sharing to in-network cost-sharing amounts; and
- 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. MAOs not able to resume normal operations after 30 days should notify CMS.

CMS 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.

If the President has declared a major disaster or the Secretary has declared a public health emergency, MAOs 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.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

170 - Beneficiary Protections from Improper Referrals and Insolvency (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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:

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

- The service is otherwise plan covered;
- The enrollee was advised of the need for a referral; and
- The referral was properly done.

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

No balance billing: As indicated in section 180 below, 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 which is the plan's responsibility, the MAO must refund the balance billing amount to the enrollee.

No-reimbursement relationship: A plan may not require an enrollee to pay a contracted provider more than his/her cost sharing amount; that is, the plan may not require the enrollee to pay the plan's share of the costs for the service(s) and then reimburse the enrollee.

Provider-enrollee relationships: A plan ("network") provider who refers an enrollee 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.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c13.pdf>.

Missed Appointment and Other Charges: 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.

180 – Balance Billing

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The guidance in this section applies to HMOs (Health Maintenance Organizations), HMO-POS (HMO Point of Service), PPOs (Preferred Provider Organizations), and RPPOs (Regional PPOs).

An important protection for enrollees 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 the balance billed for services directly from the MAO.

180.1- Definitions

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.

180.2 - Balance Billing by Provider Type

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.

- Contracted provider. There is no balance billing paid by either the plan or the enrollee.
- Non-contracting, Original Medicare, participating provider. There is no balance billing paid by either the plan or the enrollee.
- Non-contracting, non-(Medicare)-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:
 - 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.
- MA-plan, non-contracting, non-participating DME supplier. The MAO owes the non-contracting non-participating (non-par) DME supplier the difference between the member's cost-sharing and the DME supplier's bill; the enrollee only pays plan-allowed cost-sharing, which equals:
 - 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.

For information about payment to providers that have “opted-out” of Medicare, refer to section 60.2 of Chapter 6 of the Medicare Managed Care Manual, “Relationships with Providers” at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c06.pdf>

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 more than the allowed plan cost-sharing as described above.

190 - Provider Guidance

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

190.1 - Services for Which MA Plans must Pay Non-contracted Providers and Suppliers

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

HMOs and all other MA plan types must make timely and reasonable payment to, or on behalf of, plan enrollees for the following services obtained from a provider or supplier that does not contract with the MAO:

- 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 sections 20.3 through 20.5 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 180 for guidance on balance billing).

MAOs may negotiate payment rates with their contracted providers and need not follow Original Medicare 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 and suppliers 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>.

When a plan enrollee visits an in-network provider, even though that in-network provider may work with an out of network provider, (e.g., a diagnostic lab that sends specimens to a central location), then the member is only responsible for in-network cost-sharing.

190.2 - Provider Qualifications

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c06.pdf>. Supplemental benefits, defined in section 10.3 above, do not need to be provided through Medicare providers.

200 - Information on Advance Directives

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

200.1 - Definition

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

200.2 - Basic Rule

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The MAO must:

- Maintain written policies and procedures that meet the requirements for advance directives that are set forth in this section; and
- Provide to its adult enrollees, at the time of initial enrollment, written information on their rights under the law of the state in which the MAO furnishes services to make decisions concerning their medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives.

The MAO is permitted to contract with other entities to furnish information concerning advance directive requirements. However, the organization remains legally responsible for ensuring that the requirements of this section are met. Further details concerning the written information that must be given to enrollees as well as other obligations are outlined below in section 200.4.

200.3 - State Law Primary

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The MA program's advance directive requirements are guidelines that refer to State law, whether statutory or recognized by the courts of the State. Therefore, MAOs must comply with the advance directive requirements of the states in which they provide services. CMS cannot provide detailed guidelines as to what constitutes best efforts in each State. Medicare regulations give MAOs and states a great deal of flexibility, and CMS will work with the MAO (and the State, if needed) to ensure that advance directive requirements conform to Federal law. Changes in State law must be reflected in the information MAOs provide their enrollees as soon as possible, but no later than 90 days after the effective date of the State law or the date of the court order.

200.4 - Content of Enrollee Information and Other MA Obligations

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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 200.3 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.

The Medicare Marketing Guidelines, <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c03.pdf>, includes additional marketing requirements.

200.5 - Incapacitated Enrollees

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

200.6 - Community Education Requirements

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

The MAO must provide for community education regarding advance directives either directly or in concert with other providers or entities. Separate community education materials may be developed and used at the discretion of the MAO for separate parts of the community. Although the same written materials are not required for all settings, the

material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. An MAO must be able to document its community education efforts.

200.7 - MAO Rights

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

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

200.8 - Appeal and Anti-discrimination Rights

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

An MAO may not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive. Furthermore, the MAO must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State Survey and Certification Agency.

210 – Educating and Enrolling Members in Medicaid and Medicare Savings Programs

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

210.1 – Defining Guidance

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

This guidance pertains to Medicare contracting organizations (and entities with which they contract) that educate their current Medicare (including Part C, Part D and Cost plan) members about Medicaid and/or Medicare Savings Programs, assist members with determining potential eligibility for those programs and helping members actually enroll in those programs. This guidance also pertains to organizations that help members maintain their eligibility and enrollment in these programs.

210.2 – Relationship to D-SNP Eligibility / Enrollment

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

This guidance on educating and enrolling members in financial assistance programs in no way affects or relates to a Medicare Advantage Organization's (MAO) responsibility for determining a member's or potential member's eligibility to enroll in the MAO's Dual-Eligible Special Needs Plan (D-SNP). Refer to the Medicare Managed Care Manual Chapter 2 for guidance on D-SNP eligibility and enrollment.

210.3 – Relationship to Dual Eligible Demonstration Programs (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Organizations should be aware of how enrolling plan members into Medicaid and various levels of the Medicare Savings Programs might affect their members' continued plan enrollment in those states or counties where dual eligible demonstration programs with mandatory enrollment exist.

210.4 – Scope of Financial Assistance Programs (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Medicare contracting organizations that provide education and/or enrollment assistance must provide this across the full scope of Medicaid and Medicare Savings Programs:

- Qualified Medicare Beneficiaries (QMBs) without other Medicaid (QMB Only)
- QMBs with full Medicaid (QMB Plus)
- Specified Low-Income Medicare Beneficiaries (SLMBs) without other Medicaid (SLMB Only)
- SLMBs with full Medicaid (SLMB Plus)
- Qualified Disabled and Working Individuals (QDWIs)
- Qualifying Individuals (QIs)
- Medicaid-Only Dual Eligibles (Non QMB, SLMB, QDWI, QI)

210.5 – Targeting Membership (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

Medicare contracting organizations may conduct education and enrollment assistance for only a portion of its plan membership. Selection of the focus population may be based upon demographic data or on a specific geographic area. However, the organization must provide outreach to all individuals within those pre-identified population segments. Additionally, if the organization receives an inquiry from a plan member not previously identified in the targeted group, it must provide assistance to that member as if he or she had been included in the initial group.

210.6 – Required Elements of Education / Enrollment Assistance Programs (Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

In its education and enrollment assistance programs, the organization must include the following elements in its written and oral communications with plan members:

- Clarification that the member may voluntarily offer information, including financial information, for assistance with enrolling in or maintaining enrollment in state financial assistance, but that the member is not obligated to provide this information.
- Clarification that the member's failure to provide information will in no way adversely affect the beneficiary's membership in his or her health plan.
- Clarification that the Medicare Savings Programs are part of either the "State Medicaid program" or "State medical assistance programs."
- Clarification that the plan sponsor is only providing an initial eligibility screening and that only the appropriate State Agency can make a final eligibility determination.
- Guidance to a member on how to proceed with the application process even if the organization's screening process indicates that the member is probably not eligible for assistance under any of the dual eligibility programs.
- Alternate sources of information, including the telephone number for beneficiaries to call the SHIP and the appropriate State Agency. Outreach materials may also include the 1-800-MEDICARE (1-800-633-4227) number and the (1-800-486-2048) TTY number.

The organization must coordinate its education and enrollment efforts with the appropriate State Medicaid Agency and local SHIP offices so that these entities are aware of the organization's efforts.

Medicare contracting organizations MAY provide assistance to the member in completing applications for financial assistance including submitting the paperwork to the appropriate State office.

210.7 – CMS Oversight

(Rev. 108, Issued: 05-24-13, Effective/Implementation: 05-24-13)

At any time, CMS may request, and the organization must provide, any information related to the education and enrollment assistance program. This includes, but is not limited to, the information listed below. Should any of that information be unavailable or show lack of compliance with the required elements of the program, CMS may take compliance actions against the organization.

- A detailed description of each step in the outreach process and the entity responsible for each step. (CMS recommends a flow chart showing the result of each action.)

- A timeline showing the proposed dates of outreach activities, the number of members involved in each activity, and the service area, (e.g., county), included in the activities.
- Executed contracts with all external entities involved in the outreach process. This includes contracts with any subcontractors taking part in the activities.
- Supporting documentation from the appropriate State Agency providing specific State income requirements for each savings program level, and names and contacts within the appropriate State Agency/agencies.
- Internal training programs the organization is using to educate staff involved in education and enrollment assistance.
- An internal plan for protecting the confidentiality of the member's financial or other personal information gathered in the outreach process.
- Outreach letters and other materials, (e.g., brochures, Authorization to Represent form), going to plan sponsor members.
- Telephone scripts or other outreach assistance scripts that will guide representatives in answering members' questions or discussing the assistance available to them. Such scripts must include a privacy statement clarifying that the member is not required to provide any information to the representative and that the information provided will in no way affect the beneficiary's membership in the plan.