
CMS Manual System

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SUBJECT: Chapter 4, Quality Improvement Program

- I. **SUMMARY OF CHANGES:** Chapter 4 has been revised with new content and clarification of policy in the following areas: hospice coverage, anti-discrimination, review for discrimination and steerage, clinical trials, designation of DME providers/supplies, specifying brands of manufacturers of DME, skilled nursing facility (SNF) coverage, cost-sharing standards, missed appointment and related charges, value-added items and services, multiple A/B macs with different policies, rewards and incentives, provider networks, beneficiary protections related to referrals, explanation of benefits, and education members in Medicaid and Medicare. Additionally, the chapter has undergone a reorganization of sections to provide greater clarity.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 1, 2015

IMPLEMENTATION: January 1, 2015

Disclaimer for manual changes only, There are no red italics indicating differences between the current version and the previous version.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	4/Entire Chapter

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

IV. ATTACHMENTS:

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

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

Medicare Managed Care Manual

Chapter 4 - Benefits and Beneficiary Protections

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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 enrollees in Medicaid and Medicare Savings Programs.

10 – Introduction

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

10.1 – General Requirements

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 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 the Medicare Managed Care Manual. Guidance on Part D requirements may be found in the Prescription Drug Benefit Manual located at: <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>. Part D prescription drug coverage is defined at 42 CFR 423.100 and in Chapter 5 of the Prescription Drug Benefit Manual.

10.2 – Basic Rule

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.

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>.

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. Part A and Part B benefits 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.

In general, 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, 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 (see Section 90). In addition, beneficiaries under part B are entitled to receive an “annual wellness visit,” certain preventive services for which no cost-sharing may be charged, and additional preventive services.

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 Part A and Part 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: With the exception of the services listed at 42 CFR 422.100(j), 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 Sections 10.5.2 and 10.5.3 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 110.1.3 of this chapter for rules governing payment to non-contracted providers for original Medicare non-emergent services.

10.2.1 – Inpatient Stay During Which Enrollment Ends

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 and in an MAO that does not require a prior qualifying 3-day hospital stay and then joins original Medicare on January 1, the stay continues to be considered a covered stay (if medically required).

10.2.2 – Exceptions to Requirement for MA plans to Cover FFS Benefits

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.
- **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.
- **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 after the stay begins, but 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.

In addition to providing original Medicare benefits, the MAO also must furnish, arrange, or pay for supplemental benefits and prescription drug benefits 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 8 of the Medicare Managed Care Manual, titled, "Payments to Medicare Advantage Organizations," and other applicable CMS guidance, such as that contained in the annual Call Letter.

10.3 – Types of Benefits

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Basic benefits: All plans must offer and identify in plan bids all medically necessary Medicare Part A and Part B services, including Part B prescription drugs, as basic benefits.

Part D prescription drug benefits: Plans may choose to offer 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 the covered Medicare Part A and Part B (and Part D, as applicable) 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 but 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, but 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. Plan enrollees choose whether to elect and pay for any particular optional supplemental benefit 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(a)(4)). 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 plan enrollees 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 the Medicare Managed Care 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

As defined in 42 CFR § 422.320, MAOs 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 plan any MA benefits other than those that are the responsibility of the hospice. Under such circumstances, the plan is paid a reduced capitation rate for that enrollee by CMS and the MAO is responsible for continued coverage of supplemental benefits. CMS pays: (a) the hospice program for hospice care furnished to the enrollee and (b) the MAO, providers, and suppliers for other Medicare-covered services furnished to the enrollee through the original Medicare program, subject to the usual rules of payment.

Hospice coverage is effective immediately on the date of election; the reduced rate paid to the MAO begins the next month (42 CFR 422.320).

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 care 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 care 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 original Medicare for coverage of covered, non-hospice-care, original Medicare services and also follows MA plan requirements, then, 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) An HMO enrollee who chooses to receive services out of network has not followed plan rules and therefore is responsible to pay 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 Medicare Requirements Related to Uniform Benefits and Non-Discrimination (Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

10.5.1 – Uniformity (Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 Chapter 1 of the Medicare Managed Care Manual, titled “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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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; or
- Disability.

Additionally, an MAO must:

- Comply with the provisions of Section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, Section 504 of the Rehabilitation Act of 1973, Title II of the Americans with Disabilities Act (ADA) of 1990, and the Genetic Information Nondiscrimination Act of 2008; and

- Have procedures in place for each of its MA plans to ensure that enrollees 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, there are three situations in which enrollment in an MA plan may be denied based on the presence or absence of a medical condition:

- To a person who does not fulfill the eligibility criteria for enrollment in a Special Needs Plan (SNP);
- To a person with end-stage renal disease (ESRD), under the circumstances mentioned in Chapter 2 of the Medicare Managed Care Manual, “Enrollment and Disenrollment,” 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 Chapter 2 of the Medicare Managed Care Manual, “Enrollment and Disenrollment” at: <http://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html?redirect=/MedicareMangCareEligEnrol/>

Additional information about Federal law and regulations related to discrimination may be found at the following sites:

Age

HHS OCR Page on Age Discrimination

- <http://www.hhs.gov/ocr/civilrights/understanding/age/index.html>

Race, color, national origin

HHS OCR Page on Discrimination Based on Race, Color, and National Origin

- <http://www.hhs.gov/ocr/civilrights/understanding/race/index.html>

Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons

- <http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/hhslepguidancepdf.pdf>

The National Culturally and Linguistically Appropriate Services (CLAS) Standards in Health and Health Care

- <http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15>

Medical history/history of mental illness, claims experience, evidence of insurability, genetic information

HHS Health Information Privacy Page

- <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/genetic/>

DOL HIPPA Nondiscrimination Requirements

- http://www.dol.gov/ebsa/faqs/faq_hipaa_ND.html

Disability

HHS OCR Page on Disability Rights

- <http://www.hhs.gov/ocr/civilrights/understanding/disability/>

Medicare Page on Resources for People with Disabilities

- <http://www.medicare.gov/people-like-me/disability/disability.html>

DOJ Civil Rights Division Page on the Americans with Disabilities Act

- <http://www.ada.gov/>

Medicare Provider Applicants

HHS OCR Page on Medicare Provider Applicants

- <http://www.hhs.gov/ocr/civilrights/clearance/index.html>

10.5.3 – Review for Discrimination and Steering

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 is responsible for how its downstream entities present the MAO, the MA plan, and its benefits. If the downstream entity offers other items or services, not part of the MA plan benefit package, then they must not reference the MA plan or in any way characterize such items or services as benefits covered or offered by the MA plan.
- 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 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.
 - 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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

MAOs must establish procedures to ensure the confidentiality and accuracy of all enrollee records, including medical records, as well as other health and enrollment information the MAO maintains. MAOs must ensure that they:

- Abide by all Federal and state laws regarding confidentiality and disclosure of medical records or other health and enrollment information, including the HIPAA privacy rule at 45 CFR part 164. The MAO must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify:
 - For what purpose(s) the information will be used within the organization; and
 - To whom and for what purpose(s) 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, MAO network providers and deemed contracted 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.

Medical records from providers also may be used by MAOs for the following purposes:

- 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 enrollee medical records to the plan, an MAO may choose to send staff to assist in the record collection or to reimburse 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 by providers must be consistent with HIPAA privacy statute and regulations (<http://www.hhs.gov/ocr/privacy/>).

10.6- Multiple Plan Offerings and Benefit Caps

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

An MAO may offer more than one MA plan in the same service area. However, each plan is subject to the conditions and limitations 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, so long as general benefit standards, such as actuarial equivalence for basic benefits and compliance with anti-discrimination provisions, are met.

10.7 – Clinical Trials

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

10.7.1 – Payment for Services

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 qualifying clinical trials. All other Medicare rules apply.

Refer to the Medicare Clinical Trial Policy at: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCID=1&ncdver=2&bc=BAABAAAAAAAAA> and for more information on the definition of routine costs and the clinical trial Medicare qualification process. This policy does not withdraw Medicare coverage for items and services that may be covered according to Local Coverage Determinations (LCDs) or the regulations on category B investigational device exemptions found in 42 CFR 405, Subpart B, 411.15, and 411.406. MAOs may contact the Medicare Administrative Contractor (MAC) for information about qualification and payment for clinical trial items and services.

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 as defined in the NCD manual, Pub. 100-3, Part 4, Section 310.1. MAOs may not choose the clinical trial or clinical trial items and services to which this policy applies. The MAO owes the difference even if the

enrollee has not yet paid the clinical trial provider. Additionally, the enrollee's in-network cost-sharing portion also must be included in the plan's out-of-pocket maximum calculation.

To be eligible for reimbursement, enrollees (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 provider bill. MAOs also are permitted to seek the MA enrollee's 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 participation in a Medicare-qualified clinical trial not sponsored by the plan, nor may it create impediments to an enrollee's participation in a non-plan-sponsored clinical trial, even if the MAO believes it is sponsoring a clinical trial of a similar nature. Examples of impediments to an enrollee's participation include, but are not limited to, requiring enrollees to pay the original Medicare cost-sharing amount for routine care services before being compensated by the MAO for the difference or unduly delaying any required cost-sharing refund. Enrollees retain the right to choose the clinical trial(s) in which they wish to participate. However, an MA plan may request, but not require, enrollees to notify the plan in advance when they choose to participate in Medicare-qualified clinical trials.

10.7.2 – Payment for Investigational Device Exemption (IDE) Studies

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

MAOs are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered by the MAC with jurisdiction over the MA plan's service area. The MAO is responsible for payment of routine care items and services in CMS-approved Category A IDE studies and for routine care items and services, as well as the Category B device under study in Category B IDE studies.

The local MAC(s) with jurisdiction over the MA plan's service area determines coverage of IDE studies.

Effective January 1, 2015, a listing of all CMS-approved Category A IDE studies and Category B IDE studies will be posted on the CMS Coverage webpage site located at:

<http://www.cms.hhs.gov/center/coverage.asp> and published in the Federal Register.

10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

In National Coverage Determinations (NCDs) requiring CED, Medicare covers items and services in CMS-approved CED studies. MAOs are responsible for payment of items and services in CMS-approved CED studies unless CMS determines that the significant cost threshold is exceeded for that item or service (see 42 CFR 422.109). Approved CED studies are posted on the CMS Coverage with Evidence Development webpage (see <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>). Billing instructions are issued for each NCD.

10.7.4 – Claims Process Instructions for Clinical Studies

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Complete requirements for payment may be found in the Medicare Claims Processing Manual, Transmittal 2805 (<http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2805CP.pdf>).

10.8 – Drugs that are Covered Under Original Medicare Part B

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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: 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 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 Part B, 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 accessible at <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 enrollees 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.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>. 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html>.

10.11 – Transplant Services

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.

MA plans, 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 transplant services at a distant location, farther 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 enrollee and a companion to the distant facility; and
- Provide reasonable accommodations for the enrollee and a companion while present in the distant location for medical care.

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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 Part B” (see 42 CFR 422.101(a)), which includes coverage of durable medical equipment, prosthetics and supplies. The MAO is responsible for maintaining continuity of care for its enrollee by ensuring uninterrupted access to the medically necessary covered DME item, including when the item needs to be repaired or replaced. If necessary, the MAO must purchase or rent a replacement item for the beneficiary to use.

10.12.1 – Designation of DME Providers/Suppliers

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

During the application process, MA plans identify specific DME suppliers with whom they have contracted to provide enrollees with all medically necessary DME items and supplies. Directories of network providers/suppliers must be sent to enrollees at the time of enrollment and updated versions must be sent at least every three years. The MA plan must maintain an online directory that is up to date.

The plan may disclose information on the suppliers contracted to provide DME to enrollees as an attachment to the Annual Notice of Change (ANOC) and the Evidence of Coverage (EOC) and plans that limit the DME brands and manufacturers it will cover are instructed to attach to the EOC or ANOC, as appropriate, a list of those brands and manufacturers.

10.12.2 – Specifying Brands or Manufacturers of DME

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

MA plans may specify brands and manufacturers as preferred and charge lower cost-sharing for the preferred brands or may limit the DME to only those preferred brands and manufacturers, as long as the following conditions are met (42 CFR 422.100(1)):

- 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;
- During an enrollee’s first year of enrollment in an MA plan, if the enrollee requests, the plan will provide 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 mid-year;
- The MA plan treats denials of non-preferred DME products or brands as organization determinations;

- The MA plan discloses DME coverage limitations and appeal rights in the case of a denial of a non-preferred DME product or brand with the EOC and ANOC and on its website; and
- The MA plan provides full coverage, without limitation on brand and manufacturer, to DME categories or subcategories annually determined by CMS to require full coverage.

10.12.3 – Brands/Manufacturers of DME not Subject to Limitation

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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. Up-to-date information is published annually in the Call Letter.

10.12.4 – Prosthetics and Orthotics

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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

10.12.5 – DMEPOS Competitive Bid Program

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 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 suppliers that are not under contract with the MA plan. MAOs must disclose information on the new program to their plan enrollees. 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 an enrollee'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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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. An enrollee who receives advance notice and agrees with the termination of services earlier than 2 days hence, may waive continuation of services.

10.14 – No Dollar Limits on Provision of Part B Drugs

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 determinations.)

10.15 – Part D Rules for MA Plans

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

As provided at 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. Table II provides a summary of the basic requirements for Part D coverage by MA plans. For complete information, please rely on the Part D prescription drug coverage information provided in 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 at 42 CFR §422.2).

Note that Over-the-Counter (OTC) drug benefits are not classified as Part D prescription drug benefits.

Table II: 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 (HMOPOS), 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 422.4(c)) ¹ .	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 422.4(c)).	No
Special Needs Plan (SNP)	Either	Yes, required. 42	No

		CFR 422.2 (definition of SNP)	
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 II:

1. See Chapter 5 of the Prescription Drug Benefit manual located at <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html> 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 (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 Services (Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

20.1 – Ambulance Services

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 (A) the enrollee is temporarily absent from the plan's service (or, if applicable, continuation) area and therefore, he/she cannot obtain the needed service from a network provider; or (B) when the enrollee is in the service or continuation area but the network is temporarily unavailable or inaccessible; and
- Given the circumstances, it was not reasonable, for the enrollee to wait to obtain the needed services from his/her regular plan provider after the enrollee returns to the service area or the network becomes available.

An MA organization may choose to cover non-emergency services outside the network at higher cost-sharing.

20.3 – MAO Responsibilities for Coverage of Emergency Services
 (Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

The MAO must inform enrollees of their right to call 911 and:

- 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 skin lesions performed while treating the fracture.

20.4 – Stabilization of an Emergency Medical Condition

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 the Medicare Managed Care 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

20.5.1 – Definition of Post-Stabilization

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Enrollee 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 a contracted provider of 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

30.1 – Definition of Supplemental Benefit

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 the Medicare Managed Care 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. While some benefits may be appropriately offered over multiple years, CMS encourages plans to limit offerings to one contract year where possible.

Supplemental benefits need not be provided through Medicare providers.

30.2 – Supplemental Benefits Extending Original Medicare Benefits (Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

In designing supplemental benefits that extend original Medicare benefits, plans should consider:

- **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 100-02. (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. However, an MAO may, and is even encouraged to, include in plan newsletters or other communications to enrollees, 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.
- Benefit Naming Conventions: An MAO should not single out specific aspects of the benefit, in its marketing materials and PBP descriptions of original Medicare benefits. For example:
 - An MAO may state that it offers “ESRD services;” however, it need not further mention that “living donor expenses” are covered because “ESRD services” specifically includes “living donor expenses.” 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 single out any particular aspect of this coverage in its marketing materials, such as massage therapy, or 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 not include the word “massage,” even though the chiropractor may use massage during the visit.

Examples of benefits meeting these standards that are eligible for plans to offer as supplemental 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 such as medical nutrition therapy for enrollees that do not meet original Medicare coverage criteria and transportation services for non-emergency purposes.

Table III: Medicare Covered Benefits with Related Supplemental Benefit Fields in the PBP

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
Emergency Care	Worldwide Emergency 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 (limited to non-SNPs) Additional Smoking and Tobacco Use Cessation Counseling
Comprehensive Dental Services	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
Non-routine Hearing Exams	Routine hearing exams, fitting/evaluation for hearing aids

Table III 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

The list below identifies items or services that may be offered as supplemental benefits, subject to CMS bid review **and** meeting the criteria identified in Section 30.1. Definitions and limitations of the eligible benefits are provided below. This list below is intended to be illustrative, not exhaustive.

Acupuncture

The acupuncture provided as a supplemental benefit must be provided by practitioners who are licensed or certified, as applicable, in the state in which they practice and are furnishing services within the scope of practice defined by their licensing or certifying state.

Alternative Therapies

Plans may offer alternative therapies as supplemental benefits. These alternative therapies must be provided by practitioners who are licensed or certified, as applicable, in the state in which they practice and are furnishing services within the scope of practice defined by their licensing or certifying state. Plans are to provide a description of therapies offered in the PBP Notes section.

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 and installing appropriate safety devices, the benefit may include an in-home bathroom safety inspection conducted by a qualified health professional, in accordance with applicable state and Federal requirements, 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).

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 PBP.

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 practicing in the state in which he/she is licensed and is furnishing services within the scope of practice defined by that state's 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 as a supplemental benefit as long as the chiropractor is state-licensed and is practicing within the states' licensure and practice guidelines.

Counseling Services

Medicare Part B covers individual and group therapy services to diagnose and treat 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 offered as a supplemental benefit to all beneficiaries. 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.

Fitness Benefit

Fitness benefits (e.g., fitness center membership, exercise and yoga classes) may be offered as supplemental benefits designed to improve or maintain good health. A supplemental fitness benefit must, if applicable, include an orientation to the facility and the equipment for each beneficiary that uses the fitness center or other facility. 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 supplemental fitness benefit (e.g., access to fitness center or other facilities, support staff, general goals of the program) in the applicable PBP notes field.

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 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 case manager or other qualified health professional 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 health professional should ensure that all

scheduled monitoring of the enrollee takes place and that information is analyzed and communicated to all members 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 may 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 of measures, signs and symptoms, applicable to the specific disease(s)/condition(s) of the enrollee.** We expect the MAO 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:

- Must be offered to all enrollees or targeted to groups of enrollees based on a diagnosis of, or risk for, a specific disease condition (e.g., diabetes, heart failure, cognitive impairment);
- Must provide more than written material or a website 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;
- Align with the overall goal to improve participants' health; and
- 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 instructional sessions; 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 above, plans may develop health education services to address health-related topics they identify as appropriate for their enrollee population and could 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 are provided only to enrollees 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 or injuries 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 in order to prevent injury, 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, 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, or

- For a chronic condition, including but not limited to cardiovascular disorders, COPD or diabetes, for a temporary period, typically two weeks, per enrollee per year provided they are ordered by a physician or non-physician practitioner; and are 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 ChooseMyPlate.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 meal benefits 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 enrollees that the supplemental benefit (meal benefit) under the plan will be delivered by “Meals on Wheels.”

Nutritional/Dietary Benefit

General nutritional education for all enrollees 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 PBP notes.

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 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 are not primarily health related, which is one of the key criteria for a qualified supplemental benefit.

Preventive Benefits Eligible as Supplemental Benefits

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.

Medical Nutrition Therapy (MNT)

Plans may offer as a supplemental benefit additional hours of one-on-one MNT counseling provided by a registered dietician or other nutrition professional, to enrollees who are eligible for the Medicare Part B-covered MNT benefit; that is, those with diabetes, renal disease, or who have received a kidney transplant in the last three years. In addition, plans may offer as a supplemental benefit one-on-one MNT counseling provided by a registered dietician or other nutrition professional, to all, or a disease-defined group, of its enrollees.

Physical Exam

Non-SNP MA plans may offer as a supplemental benefit a physical exam that provides services not included in the required Annual Wellness Visit. Plans must fully describe in the PBP notes the non-Medicare covered activities and services included in the physical exam.

Point of Service (POS)

HMOs may offer a POS option as a mandatory or optional supplemental benefit pursuant to 42 CFR 422.105 and 422.111. 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 enrollee reaches this maximum amount and explain that the enrollee is liable for 100% of the cost of services after the enrollee has reached the plan maximum;

- Must fully disclose and clearly specify 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 enrollee utilization of contracting and non-contracting providers, at the plan level and 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 POS option.

Post-discharge In-home Medication Reconciliation

An MA plan may offer a post-discharge medication reconciliation as a supplemental benefit. Immediately following discharge (e.g., within the first week) from a hospital or SNF inpatient stay, a qualified health care provider, in cooperation with the enrollee's physician, would review the enrollee's complete medication regimen that was in place prior to admission and compare and reconcile with the regimen prescribed for the enrollee at discharge to ensure new prescriptions are obtained and discontinued medications are discarded. This reconciliation of the enrollee'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 an enrollee'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 enrollee'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 an enrollee's discharge from an institutional setting (e.g., hospital, SNF); and

- Be provided for a limited and specified period of time not to exceed four weeks.

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:

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

Remote Access Technologies (including Web/Phone based technologies and Nursing Hotline)

MAOs may propose a mandatory supplemental benefit to allow a contracted plan provider to diagnose and treat some conditions via telephone, and/or real time interactive audio and video technologies. MAOs must 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:

- Enrollees are not required to use remote access technologies, but may choose to use those services;
- 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;
- The enrollee is made aware when using the technology that he or she is not required to use it and may contact his/her plan provider directly and request an in-person appointment;
- The information provided by, and to, the enrollee during the interactive process is directed to his/her PCP or other plan provider specified by the enrollee and will become part of the enrollee’s medical record; and
- The plan will have a protocol for monitoring the use of the system by enrollees. The protocol should enable the plan to identify potential misuse and supplantation of appropriate PCP visits. The protocol should be implemented at the beginning of the contract year the benefit is offered. The MAO must provide CMS with this information upon request.

A PPO may not use remote access 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 part of the Part B physician services MAOs are required to provide.

MAOs must include in the PBP notes field a description of the remote access technologies services they propose to provide as a mandatory supplemental benefit. In addition, the remote access technology supplemental benefit may not replace the Medicare telehealth basic benefit described at 42 CFR § 414.65.

Repairs

Repairs of an item furnished as a supplemental benefit may be included as part of that supplemental benefit, as appropriate (e.g., eye glass and hearing aid repairs). However, as indicated in Section 10.12, repairs of Medicare-covered DME are part of the Part B benefit and, consequently, may not be offered as supplemental benefits.

Telemonitoring Services

MAOs may propose a supplemental benefit that provides in-home equipment and telecommunication technology to monitor enrollees with specific health conditions (e.g., hypertension or 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). MAOs should include in the PBP notes field a description of the monitoring services they propose to provide as supplemental benefits. These benefits are distinct from telehealth benefits covered under original Medicare (see 42 CFR § 414.65). In addition, the supplemental benefit description should address the following issues:

- Telemonitoring services supplement, rather than replace, face-to-face physician visits;
- The enrollee should have an initial physician visit to diagnose or confirm the diagnosis of the specific condition prior to the use of the telemonitoring benefit;
- Except in rare circumstances, the data submitted should be collected/transmitted at least weekly, but may be sent 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 use the equipment and 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.

Transportation Services

Transportation may be a covered supplemental benefit in certain situations.

An MA plan may create either a mandatory or optional supplemental transportation benefit to provide transportation not covered by original Medicare. The transportation offered must be used exclusively to accommodate the enrollee’s health care needs: for example, the plan may offer a supplemental benefit that provides transportation to enrollees for physician office visits. The transportation must be arranged, or directly provided, by the MAO and may not be used to transport enrollees for non-health-related purposes. The plan must describe the proposed benefit in the PBP.

Visitor/Travel Benefit

A Visitor/Travel (V/T) benefit may be offered as either a mandatory or optional supplemental benefit as a means to provide covered services outside of the service area of the MA plan. Under plan enrollment rules, MA plans that do not offer a 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 V/T 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 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 Part A and Part 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 compliance with Medicare access requirements and CMS review of bids,

an MAO may 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 enrollees have access to all covered services.

Weight Management Programs

Weight management programs may be offered as supplemental benefits. However, an MA plan may not offer meals as part of those weight management programs.

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 Emergency/Urgent Coverage

Worldwide Emergency Coverage refers to coverage of services, either as a mandatory or optional supplemental benefit, outside the United States and its territories. Under this benefit, enrollees may obtain only services that would be classified as emergency and urgently needed services had they been covered inside the United States. MA plans that offer a Worldwide Emergency/Urgent 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.

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 Emergency/Urgent Coverage benefit should be nominal within the bid; otherwise, 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

The items and services listed in this section have been previously proposed by MA plans as supplemental benefits in submitted plan benefit packages and are not allowable supplemental benefits under CMS rules:

- Cosmetic services, including, but not limited to 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 lenses, 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 enrollees. This policy follows the Medicare Part B schedule;
- Electronic medical records and electronic data storage devices;
- Loaner DME items when the enrollee's rented or owned DME is being repaired. Loaner DME is a required Medicare Part B service. See Section 10.12 above;
- A stand-alone memory fitness benefit (Note: Memory fitness activities may be offered as a component of a health education supplemental benefit); and
- Case management and care coordination services because these are required activities in all coordinated care plans. Those required activities are described 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

40.1 – Overview of OTC Benefit

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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, Part B or Part 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 as supplemental benefits are for the enrollee, OTC items may be purchased for the enrollee only.

40.2 - Access to OTC Benefits

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 MA plan 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 plan's catalog for OTC 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. The OTC 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.

40.3 – Payment methods

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 enrollees to purchase OTC items 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 OTC 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 MA plan's account manager to ensure the new method provides adequate access.

40.3.1 – Special Rules for Manual Reimbursement

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 for the purchase of OTC items 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Table IV below displays examples of categories of OTC items that MA plans may cover as supplemental benefits, 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” OTC items may be purchased by the enrollee without restriction. Those items shown as “dual purpose” may be purchased only after the enrollee discusses the purchase with their personal provider (or satisfies other requirements the plan may specify, to ensure that the covered item or service is health-related and appropriate for the enrollee). The plan may require a written note from, or a verbal discussion with, the enrollee’s personal health care provider as a condition for purchase of eligible or dual purpose items.

Table V displays examples of categories of items that are not eligible as OTC supplemental benefits because they are not “health benefits” within the meaning of the statute.

Note: Tables IV and V display categories of items rather than listing individual items. For example, a plan that chooses to offer cough medicines as a Part C OTC supplemental benefit must cover all items and brands and may not choose to cover only specified items or brands, in order to meet access requirements for the benefit.

The plan must clearly indicate in its OTC listing the items and drugs that, under certain circumstances, may be covered under either Part B or Part D. When an item is covered by Part B or Part D due to particular circumstances, the enrollee would not use his or her OTC benefit to obtain the item because it is Medicare-covered in those circumstances, and not part of the supplemental OTC benefit. For example, gauze may be covered under Part B when it is being used as prescribed, to perform surgical wound dressing changes.

Table IV: 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	Weight loss items	Appetite suppressants, fat absorption

Eligible?	Category	Examples of items and drugs included in this category
Purpose		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, anti-bacterials, 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 V: 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

50.1 – Guidance on Acceptable Cost-sharing

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 Part A and Part 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 Part A and Part B services. The MOOP dollar limits are set annually by CMS and include all cost-sharing (i.e., deductibles, coinsurance, and co-payments) for Part A and Part B services, although an MA plan may also include supplemental benefits as services subject to the MOOP. CMS also may annually establish a lower, voluntary MOOP limit. Plans that adopt the lower voluntary MOOP limit will have more flexibility in establishing cost-sharing amounts for Part A and Part 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 Part A and Part B cost-sharing, the MOOP limit will rarely, if ever, be reached. However, plans must still track out-of-pocket spending for these enrollees.

During a contract year, when an enrollee switches to another plan of the same type (for example, from one HMO to another HMO) offered by the plan, his/her accumulated annual contribution toward the annual MOOP limit in the previous plan to date is to be counted

towards his/her MOOP limit in the new MA plan. As applicable, this transfer of MOOP applies to both in-network and out-of-network MOOP.

Additionally, MA plans may extend the transferability of the enrollee's contribution toward his/her annual MOOP so that it applies to an enrollee's transfer during the contract year to any MA plan type offered by the MAO. For example, if an enrollee makes a mid-year change to move from an HMO to a PPO offered by the same MAO, his/her current contribution toward the MOOP limit may follow the enrollee and be counted towards the MOOP limit in the PPO. This allows those enrollees who are eligible to make mid-year plan changes to freely select among the diverse MA plan options offered by an MAO.

Per Member Per Month (PMPM) Actuarial Equivalent (AE) Cost-sharing Requirement: The actuarially estimated total MA cost-sharing for Part A and Part 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. MA plans 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 Part A and Part 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 Part A and Part 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:

- 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: CMS will, in its annual review of plan cost-sharing, monitor both co-payment amounts and coinsurance percentages. Although MA plans 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
 - The 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: MA plans may use a stratified co-payment arrangement for DME and/or Part B drugs provided that the copayment is non-discriminatory and follows all Medicare rules. Below is one example of stratified copayment which would be acceptable to CMS because it is not discriminatory and does not violate other Medicare rules. In the table below note 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. MA plans may

choose to tier the cost-sharing for contracted providers as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data. The tiered cost-sharing must satisfy the following standards:

- The plan fully discloses tiered cost-sharing amounts and requirements to enrollees and plan providers;
- The services at each tier of cost-sharing are available to all enrollees;
- Enrollees may not be limited to obtaining services from providers/suppliers assigned to a particular tier; and
- All enrollees are charged the same amount for the same service provided by the same provider.

Thus, an MA plan may offer access to two or more physician groups to which different levels of cost-sharing apply, but it may not require that an enrollee receive all needed care during the contract year from a particular provider group. Restricting enrollee choice by requiring that all services be furnished by a specific group within the network has the effect of creating multiple MA plans within one MA plan and, therefore, conflicts with the uniformity of premium and cost-sharing requirement (see 42 CFR § 422.100(d)(2)).

The following scenarios are examples of ‘differential cost-sharing’ rather than tiering of medical benefits and are not prohibited when the variation in cost-sharing is based on:

- Facility settings for furnishing some services, such as diagnostic imaging services; and
- 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.

Renal Dialysis Services: Cost-sharing for renal dialysis services may not exceed the cost-sharing imposed in original Medicare. The cost-sharing for out-of-network (OON) and out of service area, medically-necessary dialysis services may not exceed the in-network 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-network cost-sharing charged by the plan for the services. This guidance is summarized in Table VI.

Table VI: Summary of Renal Dialysis Cost-sharing.

Cost-sharing for renal dialysis	In-network	Out-of-network
In service area		May be higher than the in-network, in service area cost-sharing
Out of service area	Must be the same as in-network, in service area	Must be the same as in-network, in service area

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

50.2 – Cost-sharing for In Network Preventive Services

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

MA plans 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 Part A and Part B services, including the zero cost-sharing preventive services.

MA plans 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 a plan may directly access (through self-referral to any plan participating provider) in-network screening mammography and influenza vaccine.

Please see Section 90 of this chapter for information on National Coverage Determinations (NCDs) which describes the requirements for plan compliance with new NCDs, as well as website resources for monitoring NCDs.

50.3 – Total Beneficiary Cost-sharing (TBC)

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 enrollees are not exposed to significant cost increases from one plan year to the next. Annually, CMS provides TBC requirements and operational information to plans through the Call Letter and other guidance documents.

50.4 – Single Deductible Rules for Regional and Local PPOs

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

A single deductible is a specified dollar amount to be paid annually by the enrollee for health care services or for covered Part D drugs before the plan begins to pay its share of the cost for those benefits. The single deductible amount may apply to all plan services or to specific categories of plan services with the exception of emergency or urgently needed services.

Plans are prohibited from having a deductible that applies to emergency or urgently needed services. Furthermore, any enrollee expenditures for emergency and urgently needed services count toward satisfying the plan 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 and out-of-network (OON). The local or regional PPO may:

- Not apply the deductible to in-network \$0 cost-share preventive services, but may exempt any or all other in-network Medicare Part A and Part B services from the deductible; that is, the regional or local PPO may choose to cover specific in-network 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 Part B services furnished in-network;
- Exempt the OON, \$0 cost-share, preventive services from the plan deductible. However, plans may not exempt from the single deductible any other OON Medicare Part A and Part 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.

Analysis: 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 Part 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.

50.5 – Guidance on Other Enrollee Out-of-Pocket Liability

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Missed Appointment and Other Charges: MA plans may charge "administrative fees" to enrollees for missed appointments with contracting providers and for not paying contracting providers required cost-sharing at the time of service.

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. Furthermore, those additional charges must be clearly outlined in the notes section of the PBP and in the Evidence of Coverage and ANOC, as applicable.

Contracted and non-contracted providers may charge a fee for missed appointments, provided such fees apply uniformly to all Medicare and non-Medicare patients. This applies even if the MAO itself does not charge an administrative fee for missed appointments.

Neither MA plans nor their contracted providers may require enrollees to create a fund or 'escrow account' for a provider to ensure payment of missed appointment fees. Such a practice creates a barrier to access to care and violates CMS anti-discrimination regulations.

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 MA plan, 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 plan must refund the balance billing amount to the enrollee.

No-reimbursement relationship: Plans may not require enrollees to pay a contracted provider more than the plan's specified cost-sharing; that is, plans may not require enrollees to pay the plan's share of the costs for a service and then reimburse the enrollee.

60 – Meaningful Plan Differences

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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, 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 (i.e., MA plan is meaningfully different from an MA-PD); and
- Premiums.

CMS annually publishes guidelines to assist MAOs in creating plan designs in a given area with meaningful differences. MAOs offering more than one plan in a given service area should ensure that enrollees can easily identify the differences in benefit coverage between the plans. Beneficiaries should be able, for example, to determine which plan provides the highest value based on their needs. Plan bids that CMS determines are not meaningfully different during the annual CMS review of submitted plan bids will not be approved and 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 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 MAOs are instructed to either give notice that they are terminating or consolidating the low enrollment plan(s), or submit, within acceptable timeframes, a justification for continuing the plan(s). CMS will then review the submitted justifications and make 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
- Whether the plan is a SNP.

80 – Value-Added Items and Services (VAIS)

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

80.1 – Definition and Requirements

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Value-Added Items and Services (VAIS) are items and services that are not plan benefits, are not part of the MAO plan's benefit package and may not be marketed to prospective enrollees, or used as an inducement or incentive for enrollment. VAIS are non-Medicare covered services or items, typically discounts, offered by a VAIS provider to the enrollees of an MA plan. The plan may choose to facilitate access for its enrollees to the VAIS by acting on behalf of the VAIS provider by performing certain administrative activities, such as notifying enrollees about the VAIS or verifying enrollee membership in the plan.

Thus, the MAO incurs either no cost for facilitating enrollees' access to the VAIS, or the costs are solely administrative. Solely administrative costs are defined as those required to administer the plan's facilitation of enrollee access to the VAIS, e.g., clerical items or equipment and supplies related to communication about the VAIS (such as phone and postage) or database administration (such as verifying enrollment or tracking utilization). Minimal cost, in and of itself, does not qualify a cost as being "solely administrative."

It is important to note the following:

- Plan enrollees who choose to obtain VAIS items or services are responsible for all costs.
- Any notification a plan sends to its enrollees about the availability of VAIS must include a disclaimer explaining that the VAIS is not a plan benefit.
- MAOs may not include VAIS in any marketing materials.
- VAIS is not an alternative to a supplemental benefit. That is, if CMS determines that a specific item or service for which the plan would incur more than administrative cost, is not allowable as a supplemental benefit; the plan may not offer the item or service as a VAIS.

An MA organization is expected to comply with the following related to VAIS:

- Offer the VAIS for the entire contract year;
- Offer the VAIS uniformly to all plan enrollees;
- Maintain the privacy and confidentiality of enrollee records in accordance with all applicable statutes and regulations;
- Comply with all applicable fraud and abuse laws, including the anti-kickback statute and prohibition on inducements to enrollees;
- Not price the VAIS in the plan bid;
- Costs incurred, if any for the VAIS, are solely administrative;
- Clearly include a disclaimer in any material provided to enrollees about the VAIS that the VAIS is not a part of the plan's benefits; and
- Only offer the VAIS to plan enrollees. Dependents, spouses and other non-plan enrollees are not permitted to receive VAIS through the MAO.

Note: Although VAIS may not be included in the plan bid, CMS may review a plan's VAIS in its audit of the plan or in response to enrollee complaints related to the VAIS.

80.2 – Explanatory Examples

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

The following are some examples of CMS' approach to VAIS:

- Example 1: In addition to a plan covering an in-network mandatory supplemental routine vision exam benefit (for which the plan incurs a direct medical cost), it offers as a VAIS a 5% discount on a routine vision exam furnished by an out-of-network vision

center. The plan does not incur any medical cost for the out-of-network exam, but does incur some administrative cost to verify enrollee plan membership for the discount and to inform its enrollees about the 5% discount.

Analysis: Because the plan does not incur any medical cost in offering the discount for the routine vision exam out-of-network, by definition, the discount cannot be classified as a benefit, and is therefore, eligible to be offered as a VAIS. Furthermore, because the out-of-network routine vision exam is a VAIS, it may neither be advertised to prospective enrollees nor included in the plan bid.

- Example 2: An MA plan wishes to offer vouchers for free groceries to its enrollees for which it incurs a minimal cost.

Analysis: Grocery vouchers may not be offered as a VAIS if the plan incurs a cost for the vouchers. Although the cost may be minimal, it is not solely administrative and therefore, is not consistent with CMS guidance.

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

Analysis: MA plans must include in the plan benefit package all benefits it furnishes by way of a contract with a provider or insurer on behalf of its enrollees and may not contract to offer such a benefit as a VAIS. The plan may not collect payments from its enrollees for services that are not benefits covered by the plan.

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

90 – National and Local Coverage Determinations

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

90.1 – Overview

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

MAOs are expected to stay apprised of new and/or changing Medicare Part A and Part B coverage policies, including those that result from CMS's National Coverage Determination (NCD) process. Information regarding NCDs is continuously updated on the CMS website at: <http://www.cms.hhs.gov/center/coverage.asp>. See Section 90.6 of this chapter for a list of CMS website sources containing information.

As discussed in Section 10.2 of this chapter, an item or service classified as an original Medicare benefit 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 Medicare Administrative Contractors (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 – Definitions Related to National Coverage Determinations (NCDs)
 (Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

The contents of this section are governed by statutes and regulations including those 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 with respect to whether or not a particular item or service is covered under Medicare. An NCD does not include a determination of what code, if any, is assigned to a service or a determination about the payment amount for the service. HCPCS and other codes are assigned through separate guidance.
- An NCD is issued under procedures that are established in the Federal Register and is published in the Medicare National Coverage Determination (NCD) manual. Each NCD will contain a specific effective date.
- A **legislative change in benefits** is a coverage requirement adopted by the Congress and mandated by statute. The Secretary of Health and Human Services generally 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.

90.3 – General Rules for NCDs

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Medicare coverage policies specify which items and services are covered (or not covered) under Part A or Part B of 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, MA plans 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.

90.3.1 – When the Significant Cost Criterion is Not Met

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

When CMS determines that a NCD or legislative change in benefits does **not** meet a criterion for significant cost, the MA plan 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 MA plans must have payment system edits in place and coverage/non-coverage fully implemented for providers/suppliers. Plans 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 references provided in Section 90.6 below.

90.3.2 – When the Significant Cost Criterion is Met

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 plans are 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 to 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 specifically included in the services MAOs must cover under their contract with CMS, 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.

90.3.3 – Payment for NCD Items and Services

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Chapter 8 of the Medicare Managed Care 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. That manual chapter includes a description of services for which MAOs are responsible. Enrollees are responsible for any applicable coinsurance amounts under original Medicare.

Once the annual MA capitation rate, or other payment adjustment, reflects the new costs, the service or benefit is considered 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 enrollee is responsible for any MA plan cost-sharing, as approved by CMS or unless otherwise instructed by CMS.

90.4 – Local Coverage Determinations (LCDs)

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

90.4.1 – MAC with Exclusive Jurisdiction over a Medicare Item or Service

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 provider of a particular item or service (for example, certain pathology and lab tests furnished by independent laboratories). In this

situation, MA plans must follow the coverage policy reflected in an LCD issued by the A/B MAC that enrolled the provider and processes all of the Medicare claims for that item or service.

90.4.2 – Multiple A/B MACs with Different Policies

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

When there are multiple A/B MACs that have different coverage policies in an MA plan's service area, the MA plan must choose from the following alternatives for its coverage policy. Note: All DME MACs have the same LCDs; therefore, there should not be differences related to DME coverage in a plan's service area.

Local Plans:

1. A local MA plan may choose to adopt the coverage policy that applies to original Medicare beneficiaries. In this alternative, the coverage policy that applies to plan enrollees will be that of the A/B MAC with jurisdiction over the state in which the service is furnished to the enrollee.
2. A local MA plan that chooses to adopt a uniform coverage policy that will apply uniformly to all plan enrollees, may choose the A/B MAC coverage policy applicable in its service area that is the most beneficial to enrollees.
 - The MA plan must make information on the selected coverage policy determinations readily available, including through the plan's website, to all enrollees and health care providers; and
 - The MAO must notify CMS, through its account manager, 60 days before the date bids are due, if it elects 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, the MAO should include, at a minimum:
 - An identification of the plan(s) and service area(s) to which the uniform local coverage policy or policies will apply;
 - The competing local coverage policies involved; and
 - 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.

CMS will review notices provided to evaluate the selected policy or policies on the bases of cost, access, geographic distribution and health status of enrollees. CMS will notify the MAO of its approval or denial of the selected uniform local coverage policy or policies.

Regional Plans:

1. A regional MA plan may choose to adopt the coverage policy that applies to original Medicare beneficiaries. In this alternative, the coverage policy that applies to plan enrollees will be that of the A/B MAC with jurisdiction over the state in which the service is furnished to the enrollee or
2. A regional MA plan that chooses to adopt a uniform coverage policy must select one of the A/B MACs with jurisdiction in the plan service area and apply the policies of that A/B MAC uniformly to all enrollees of the plan.
 - Plans must make information on the selected local coverage policy determinations readily available, including through the plan's website, to all enrollees and health care providers.
 - Regional MA plans may not select local coverage policies from more than one A/B MAC and selection of the coverage policy is not subject to CMS pre-approval (42 CFR § 422.101(b)(4)) but must notify CMS, through their account managers, 60 days before the date bids are due, if the plan elects 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:
 - An identification of the plan(s) and service area(s) to which the uniform local coverage policy or policies will apply;
 - The competing local coverage policies involved; and
 - 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.

Note: If a local or regional MA 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 covered based on the local coverage determinations of that provider's geographic location.

90.5 – Creating New Guidance

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 CMS an objective evidence-based rationale relying 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 MA plan provide coverage for all Medicare-covered services is not intended to dictate care delivery approaches for a particular service. MA plans may encourage enrollees to see more cost-effective provider types than would be the typical pattern in original Medicare, as long as those providers are licensed and working within the scope of their licenses and the plan complies with the provider anti-discrimination rules set forth in 42 CFR §422.205.

An MA plan’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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Generally, legislative changes to Medicare coverage rules are established by statute and 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. These rules are codified in the Code of Federal Regulations. Medicare manual guidance corresponding to legislative changes in benefits may also 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 MA plans 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 information on NCDs and LCDs:

The Medicare Coverage webpage 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 National Coverage Determinations 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 determinations.

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.

100 – Rewards and Incentives

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

An MA plan may create one or more programs that provide rewards and incentives to enrollees for participating in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources (42 CFR § 422.134).

A rewards and incentives program must:

- Not discriminate against enrollees based on race, gender, chronic disease, institutionalization, frailty, health status or other impairments; and
- Must be designed so that *all* enrollees are able to earn rewards and incentives.

MA plans that violate the above requirements will be subject to sanctions at 42 CFR § 422.752(a)(4).

Rewards and incentives must:

- Be offered in connection with participation in the entire health-related service or activity;
- Be offered to all eligible enrollees without discrimination;
- Have a value that may be expected to affect enrollee behavior but not exceed the value of the health related service or activity itself; and
- Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to enrollees.

Rewards and Incentives may not:

- Be offered in the form of cash or other monetary rebates; or
- Be used to target potential enrollees.

MA plans are not precluded from offering rewards and incentives programs that target a specific disease, chronic condition or preventive service. Rather, the goal of having a non-discrimination requirement is to prevent particularly vulnerable populations from being disproportionately underserved. MA plans may not use these programs to "cherry pick" healthier enrollees. Therefore, any rewards and incentives program implemented by an MA

plan must accommodate otherwise qualified enrollees who receive services in an institutional setting or who need a modified approach to enable effective participation.

A reward or incentive would have to be earned by completing the entire health related service or activity and may not be offered for completion of less than all required components of the eligible service or activity. An MA plan would define what qualifies as an "entire service or activity" within its program design. This proposed requirement is tied to interpreting the value of the service provided as it relates to the value of the reward.

An MA plan that offers a rewards and incentives program must make information available to CMS upon request and should be prepared to demonstrate any evaluation of the effectiveness of such programs.

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 enrollees in Medicaid and Medicare savings programs.

110 – Access to and Availability of Services

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

110.1 – Access and Availability Rules for Coordinated Care Plans

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

An MA plan 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.

Plans 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 plan must ensure that providers are distributed so that no enrollee residing in the service area must travel an unreasonable distance to obtain covered services. CMS standards for access is provided by the Health Service Delivery (HSD) tables used to evaluate plan networks during the initial application. The HSD process uses a mostly automated process to measure 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 enrollees to access each provider and facility in each county.

110.1.1 – Provider Network Standards

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

MAOs are required to establish and maintain provider networks that:

- Define the types of providers to be used when more than one type of provider can furnish a particular item or service;
- Identify the types of mental health and substance abuse providers in their network;
- Specify the types of providers who may serve as an enrollee's primary care physician;
- Are accurately reflected in up-to-date directories. Plans are responsible for verifying and regularly updating their network directories to ensure that providers included in the directories are available to their enrollees (i.e., listed providers accept new patients who are enrolled in the plan).
- 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 plan's providers are convenient to, and do not discriminate against, enrollees. The plan 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 enrollee'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 enrollee may select a personal primary care provider. All MA plan enrollees may select and/or change their primary care provider within the plan without interference. Plans that require enrollees to obtain a referral before receiving specialist services typically require this referral be obtained from a primary care provider. However, some enrollees do not select primary care providers. Consequently, plans must ensure that there is a mechanism for assigning primary care providers (for purposes of referral) to enrollees who do not select a primary care provider;
- Regardless of the MA plan type being offered (e.g., HMO, PPO), arrange for specialty care outside of the network, but at in-network cost-sharing, in order to provide all Medicare Part A and Part B benefits. That is, if an enrollee requires a very specialized covered service that is not provided by the physicians in the network, the plan must arrange for that service to be provided by a qualified non-contracted 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;

- Ensure that all services, both clinical and non-clinical, are provided in a culturally competent manner and are accessible to all enrollees, including those with limited English proficiency, limited reading skills, hearing incapacity, or those with diverse cultural and ethnic backgrounds. Examples of how a plan 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; and
- Has a quality improvement program plan as outlined in Chapter 5 of the Medicare Managed Care Manual. The quality improvement program plan must include a chronic care improvement program and a quality improvement project.

Plans 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 plans; 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 other network physician (depending on the plan policy) permits or instructs the enrollee to obtain an item or service from another physician or other provider type.

110.1.2 – Significant Changes to Networks

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

When MAOs submit plan benefit packages (PBPs) for CMS' review and approval, they attest that the benefits included in those packages "...will be offered in accordance with all applicable Medicare program authorizing statutes and regulations and program guidance that CMS has issued to date..." Thus, MAOs' PBPs for the upcoming contract year must meet, and continue to meet, Medicare network adequacy standards, as outlined in applicable regulations and guidance.

When an MAO makes significant changes to its network(s) of contracted providers without cause, it must make a good faith effort to notify all affected enrollees at least 30 days prior to the effective date of the change and CMS may require the MAO to augment its network by contracting with additional providers or, if necessary in order to meet immediate access needs, to allow enrollees to access care from non-contracted providers and limit enrollee cost-sharing to in-network amounts. Furthermore, it may be necessary for MAOs to allow care to continue to be furnished on an interim, transitional basis, by providers who have been terminated from the network in order to adequately address continuity of care needs for affected enrollees.

As a best practice, MAOs should include the following information in notices to enrollees in addition to the mandatory identification of the provider(s) being terminated from the network:

- Names and phone numbers of in-network providers that enrollees may access for continued care (Note: This information may be supplemented with information for accessing a current provider directory, including both online and direct mail options);
- Information regarding how enrollees can request continuation of ongoing medical treatment or therapies with their current providers; and
- Customer service number(s) where answers to questions about the network changes will be available.

MAOs should also develop detailed scripts, call center talking points and frequently asked questions so it can effectively respond to phone inquiries from enrollees and other stakeholders.

When an MAO is planning network changes that it deems significant, the MAO must first notify CMS and CMS will determine, after consultation with the MAO, whether the planned change requires certain additional actions on the part of the MAO in order for the organization's network to continue to meet Medicare standards. An MAO that does not notify CMS of network changes that are ultimately deemed significant will be subject to appropriate compliance actions. Therefore, MAOs are expected to take a conservative approach in determining whether a network change is significant.

When an MAO is making any planned, no-cause contract terminations that it deems to be significant, it must notify its respective CMS Account Manager (AM) no less than 90 days prior to the effective date of the termination(s). Upon CMS notification, the MAO will demonstrate its continued compliance with applicable network access requirements (e.g. through the submission of GeoNetwork reports, Quest reports, or HSD tables or other data sources that demonstrate the adequacy of the remaining provider network). In addition, upon request, the MAO would develop and submit to CMS a written plan that provides a detailed description of the steps the MAO will take to ensure that affected enrollees are able to locate new providers that meet their individual needs and describe how continuity of care would be maintained for affected enrollees. MAOs would also provide, upon request, information

about the number and outcome of continuity of care requests that they receive so that CMS may confirm that the MAO is in compliance with all applicable requirements.

In addition, pursuant to 42 CFR § 422.62(b)(4), enrollees affected by substantial mid-year provider network terminations initiated by an MAO without cause may be afforded a special enrollment period (SEP). If CMS determines that a SEP is warranted, the MAO may be required to notify its members of the SEP as part of the 30-day notification about the network change. For more information regarding a SEP due to significant network changes, please see Chapter 2 of the Medicare Managed Care Manual.

110.1.3 – Services for Which MA Plans Must Pay Non-contracted Providers and Suppliers

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 Sections 20.2 through 20.4 of this chapter;
- Maintenance and post-stabilization care services under the circumstances described in Section 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 enrollee that the plan will pay for care from any qualified dialysis provider the enrollee may independently select. Furthermore, the cost-sharing for out-of-network medically necessary dialysis may not exceed the cost-sharing for in-network dialysis;
- 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; and
- Regardless of the MA plan type being offered (e.g., HMO, PPO), arrange for specialty care outside of the network, but at in-network cost-sharing, in order to provide all Medicare Part A and Part B benefits. That is, if an enrollee requires a very specialized

covered service that is not provided by the physicians in the network, the plan must arrange for that service to be provided by a qualified non-contracted provider.

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 *amounts* 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 amount as payment in full. For further information on payment to non-contracted providers and suppliers refer to the section titled, “Special Rules for Services Furnished by Non-Contract Providers,” in Chapter 6, “Relationships with Providers,” of the Medicare Managed Care 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 an 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 enrollee is only responsible for in-network cost-sharing.

For further information on an MA plan’s obligation to pay non-contracted providers when a referral to such a provider was made, see Section 170 below.

110.2 – Preferred Provider Organization (PPO) Coverage and Access (Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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; and
- 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

110.3.1 -- Access through Non-contracted Providers

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

In those portions of an RPPO's defined service area where it cannot establish contracts with providers to meet Medicare access requirements, the RPPO may also meet Medicare access 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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

42 CFR §422.112(c) describes the requirements for an RPPO to apply to CMS to designate a non-contracting 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 enrollees accessing covered inpatient hospital services in that hospital.

110.4 – Rules for All MAOs to Ensure Coordination of Care

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

The MA plan 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 contracted providers or non-contracted providers in the area served by the MA plan, including nursing home and community-based services;
- Developing and implementing procedures to ensure that the plan and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that:
 - The plan makes its best effort to conduct an initial health assessment of all new enrollees 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 plan 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.

110.5 – Access, Gatekeeper and Cost-Sharing by Plan Type

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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

Table VII: 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-network and OON?	May Cost-sharing requirements differ In-network/OON
HMO	Optional	Must contract	Must provide In-network	Not applicable
HMOPOS	Optional	Must contract	Must provide in-network; may provide OON	May have higher cost-sharing OON
PPO, RPPO	Optional, In-network; Prohibited Out-of-network (OON)	Must contract ²	Must provide both in-network/OON	May have higher cost-sharing OON
MSA and PFFS	Prohibited	May use full, partial, or non-network model	Must provide both in-network/OON	May have higher cost-sharing OON

Notes:

1) A gatekeeper, when allowed, is typically, but not necessarily, a PCP. A primary purpose of a gatekeeper 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

If an MAO contracts with an employer, labor organization, or the trustees of a fund established by one or more employers or labor organizations that cover enrollees in an MA plan, or contracts with a State Medicaid agency to provide Medicaid benefits to individuals who are eligible for both Medicare and Medicaid, and who are enrolled in an MA plan, the enrollees must be provided the same benefits as all other enrollees in the MA plan, with the employer, labor organization, fund trustees, or Medicaid benefits supplementing the MA plan benefits.

120.1 – General Rule

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

(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; or
- The employer, union or State Medicaid Agency purchases a non-Part D drug benefit from the MAO.

These complementary benefits may not be classified as MA benefits and therefore are not regulated or reviewed by CMS. However, the MAO must comply with all state regulations governing such benefits. Refer to Chapter 9, “Employer/Union Group Health Plans,” of the Medicare Managed Care Manual, for further information.

120.2 – Requirements, Rights, and Beneficiary Protections

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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, labor organization, fund trustees 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 the Medicare Managed Care Manual entitled, “Premiums and Cost-sharing,” for further discussion.)

Medicaid benefits provided through a contract with an MA organization to provide coverage for individuals eligible for both Medicare and Medicaid and who are enrolled in an MA plan are subject to Medicaid rules and regulations, including CMS review where applicable.

120.3 – Employer/Union Plans

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

For more details on employer/union coverage see Chapter 9 of the Medicare Managed Care Manual, “Employer/Union-Sponsored Group Health Plans.”

130 – Medicare Secondary Payer (MSP) Procedures

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

130.1 – Basic Rule

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 the Medicare Managed Care Manual entitled, “Premiums and Cost-sharing,” as well as “Employer/Union Sponsored Group Health Plans,” for further discussion.)

This section only applies to 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 Part D rules are found in Chapter 14, “Coordination of Benefits,” of the Prescription Drug Benefit Manual, publication 100-18, located at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/Pub100_18.pdf.

130.2 – Responsibilities of the MAO

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Secondary payer status can arise from legal settlements, as well as other insurance plans. MA organizations should refer to the Medicare Secondary Payer Manual, publication 100-05, located at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019017.html> for additional information.

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

- Whether the enrollee entitlement to Medicare is due to age, ESRD, or disability;
- Who is the primary beneficiary of the other insurance plan;
- Whether the primary beneficiary is covered by the employer Group Health Plan (GHP) as an active or former employee; and/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 GHP because of either:
 - The enrollee's current employment; or
 - Current employment of a spouse of any age; and
 - The employer that sponsors or contributes to the GHP 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 legal 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 may not 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 have auto insurance, the MAO cannot withhold primary payment on the grounds that the enrollee should have had this insurance because it is a state requirement.

130.4 – Collecting From Other Entities

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 Sections 130.5 and 130.6 below.

130.5 – Collecting From Other Insurers or the Enrollee

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

If an MA enrollee receives plan-covered services that are also covered under an employer group health plan, 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
- The enrollee, to the extent that s/he has been paid by the insurance carrier, employer/union, or entity for covered medical expenses.

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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 enrollee 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 enrollee properly received (following all plan requirements), the enrollee may not be held liable for paying more than the MA plan's co-payment of \$10. The MAO must hold the enrollee harmless 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Consistent with Federal preemption of state law, addressed at 42 CFR § 422.402 and 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 – Service Area

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

140.1 – Service Area Defined

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 enrollees in an MA plan's service area and must provide 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 the Medicare Managed Care Manual, "Enrollment and Disenrollment") located at: <http://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html?redirect=/MedicareMangCareEligEnrol/>);
- **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.

140.2 – Factors That Influence Service Area Approvals

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 the Medicare Managed Care 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 in § 422.2 (definition of service area) and below in Section 140.3;
- 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 any other manner. In this regard, CMS also considers the extent to which the proposed service area mirrors service areas of existing commercial or MA plans.

140.3 – Partial County Service Areas

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

This subsection only applies 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. 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.

140.3.1 – Necessity

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 local MA plan may have a health care network that is limited to one part of a county and cannot be readily extended to encompass an entire county.

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 local 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.

140.3.2 – Non-Discriminatory

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 plans operating in the entire county may provide evidence that approving a partial county service area application would be discriminatory.

140.3.3 -Best Interests of Beneficiaries

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 their request. Supporting documentation could include data obtained from enrollee satisfaction surveys, grievance and appeal files, or utilization information.

An MA organization may not create a 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.

150 – MAO Renewal Options and Crosswalk

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

150.1 – Introduction

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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

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

With limited exceptions specified in annual renewal and non-renewal guidance by CMS or based on application of 42 CFR §§ 422.550 – 422.553, CMS 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 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 also must adhere to certain notification requirements, some of which are indicated below. Most renewal options must be completed in the HPMS Crosswalk module, 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 options should protect enrollment choices of beneficiaries and foster future beneficiary access and choice.

Table VIII, in Section 150.9 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 VIII 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 VIII or described in Sections 150.2-150.8 below, or is not specified in annual CMS guidance, it is not a permissible renewal option for an MAO.

150.2 – New Plan

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 module. 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.

150.3 – Renewal Plan

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 module. 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.

150.4 – Consolidated Renewal Plan

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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. This is referred to as a plan consolidation. However, an MAO may not split a current PBP among more than one PBP for the following contract year.

MAOs that are 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.

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 MAO does not submit enrollment transactions to CMS for those current enrollees. However, the MAO may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New

enrollees in the consolidated renewal plan must complete enrollment forms and the MAO must submit the enrollment transactions to CMS for those new enrollees. Plans are required to provide a standard ANOC to all current enrollees in the consolidated renewal plan.

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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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

Current enrollees of a PBP that is renewed with a SAE are not required to take any enrollment action, and the MAO does not submit enrollment transactions to CMS for those current enrollees. New enrollees must complete enrollment forms and the MAO must submit the enrollment transactions to CMS for those new enrollees. MA plans are required to provide a standard ANOC to all current enrollees of a renewed PBP with a SAE.

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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

An MAO offering a local MA plan may reduce the service area of a current contract year 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 module so that current enrollees in the renewal portion of the service area remain enrolled in the same plan the following contract year. Current enrollees in the renewal portion of the service area are not required to take any enrollment action, and the MAO does not submit enrollment transactions to CMS for these current enrollees. Plans are required to provide a standard ANOC to all current enrollees in the renewal portion of the service area.

Enrollees in the reduced service area(s) of the MA plan will be disenrolled at the end of the contract year. These enrollees will need to elect another plan. The MAO must submit disenrollment transactions to CMS for these enrollees. In addition, the MAO must 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 the affected enrollees in the reduced portion of the service area the option of remaining enrolled in the renewal plan consistent with CMS's 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. Enrollees in the reduced portion of the service area who wish to continue their enrollment must complete an enrollment request.

150.7 – Renewal Plan with a Service Area Reduction When the MAO will Offer another PBP in the Reduced Portion of the Service Area

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 module 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 are not required to take any enrollment action, and the MAO should not submit enrollment transactions to CMS for these enrollees. Plans must provide enrollees with a standard ANOC.

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 must 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 enrollees.

150.8 – Terminated Plan (Non-Renewal)

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

An MAO may elect to terminate a current PBP for the following contract year. In this situation, the MAO should not submit disenrollment transactions to CMS for affected enrollees. CMS will disenroll these enrollees 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, the enrollee must complete an enrollment request, and the enrolling organization or sponsor must submit enrollment transactions to CMS. If these enrollees 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. Plans must provide enrollees in terminated PBPs a termination notice that includes notification of a special election period and Medigap guaranteed issue rights.

150.9 – Crosswalk Table Summary

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

The following table summarizes the guidance from Sections 150.2 – 150.8. Please send all inquiries related to MA or MA-PD contract consolidation to the following mailbox: <https://dmao.lmi.org>. Please note that this is a URL, not an email address.

Table VIII: Guidance for Plan Renewals

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

Section	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
150.4	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. The MAO must designate which of the renewal PBP IDs will be retained in the 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</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. 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. New enrollees must complete an 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
		<p>consolidated; a current contract year PBP may not be split among different PBPs in the following contract year. Note: If an MAO reduces a service area when consolidating PBPs, it must follow the rules for a plan renewal with SAR described elsewhere in this guidance.</p>				
150.5	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. The same PBP ID number must</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. HPMS Plan Crosswalk Designation: Renewal Plan with an SAE. 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. The MAO does not submit enrollment transactions for current contract year enrollees. The MAO submits</p>	<p>No enrollment request is required for current enrollees to remain enrolled in the renewal PBP in the following contract year. New enrollees must complete an 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
		be retained in order for all current enrollees to remain in the same MA PBP in the following contract year.		enrollment transactions for new enrollees.		
150.6	Renewal Plan with a SAR and no other MA options available	This option is available to local MA plans only. An MAO reduces the service area of a current contract year MA PBP and the reduced service area is not contained in another MA PBP offered by the same organization or any other MAO. The MAO may offer the option to individuals in the reduced portion of the service area for the following contract year to enroll in its remaining PBP if no other MA plans are available (see	<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. 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>	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. The MAO does not submit enrollment transactions for current enrollees in the renewal portion of the service area.	Enrollees impacted by the SAR need to complete an enrollment request if the MAO offers the option of continued enrollment (see 42 CFR 422.74(b) (3) (ii)).	The MAO sends a termination notice to current enrollees in the reduced service area that includes notification of SEP and guaranteed Medigap issue rights.

Section	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
		<p>42 CFR 422.74(b)(3)(i)).Note: One renewal plan with a SAR may have counties that should follow the guidance provided in 150.5, and other counties in the SAR that should follow the guidance provided under 150.6 (i.e., the guidance provided in 150.5 and 150.6 may both apply to a single plan).</p>				

Section	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
150.7	Renewal Plan with a SAR when the MAO will offer another PBP in the reduced portion of the service area.	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. 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>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. 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>	The MAO must submit transactions to disenroll individuals residing in the reduced portion of the service area. The MAO submits enrollment transactions to enroll beneficiaries who have requested enrollment in other PBP offered in the reduced service area.	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 of the service area receive the standard ANOC.

Section	Activity	Guidelines	HPMS Plan Crosswalk	Systems Enrollment Activities	Enrollment Procedures	Beneficiary Notifications
150.8	Terminated 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 disenroll 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.

160 – Benefits during Disasters and Catastrophic Events

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

The Secretary of Health and Human Services (the Secretary) has the right to exercise his or her waiver authority under Section 1135 of the Social Security Act if, in addition to a Presidential declaration of a disaster or emergency under the Stafford Act or National Emergencies Act, the Secretary declares a public health emergency under Section 319 of the Public Health Service Act. If an 1135 waiver is issued, CMS will identify all plan requirements and responsibilities. Detailed guidance and requirements for MA plans under the Section 1135 waiver, 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 website (<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 DME and A/B MACs to pay for Part C-covered services furnished to enrollees 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, a Section 1135 waiver by the Secretary, MAOs are expected to:

- Allow Part A and Part B and supplemental Part C plan benefits to be furnished at specified non-contracted facilities (note that Part A and Part 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 timeframe 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.

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, regarding refills of Part D medications. The Prescription Drug Benefit

Manual may be found at: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/Pub100_18.pdf .

170 – Beneficiary Protections Related to Plan-Directed Care

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Organization Determinations: An enrollee, or a provider acting on behalf of the enrollee, always has the right to request a pre-service organization determination if there is a question as to whether an item or service will be covered by the plan. If the plan denies an enrollee’s (or his/her treating provider’s) request for coverage as part of the organization determination process, the plan must provide the enrollee (and provider, as appropriate) with the standardized denial notice (Notice of Denial of Medical Coverage (or Payment)/CMS-10003). For the requirements related to organization determinations and issuance of the standardized denial notice (CMS-10003), see Chapter 13 of the Medicare Managed Care Manual located at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c13.pdf>.

Limitations on Enrollee Liability: CMS considers a contracted provider an agent of the MAO offering the plan. As stated in the preamble to the January 28, 2005 final rule (CMS-4069-F):

“MA organizations have a responsibility to ensure that contracting physicians and providers know whether specific items and services are covered in the MA plan in which their patients are enrolled. If a network physician furnishes a service or directs an MA beneficiary to another provider to receive a plan-covered service without following the plan’s internal procedures (such as obtaining the appropriate plan pre-authorization), then the beneficiary should not be penalized to the extent the physician did not follow plan rules.”

Consequently, when a contracted provider furnishes a service or refers an enrollee for a service that an enrollee reasonably believes is a plan-covered service, the enrollee cannot be financially liable for more than the applicable cost-sharing for that service. If a contracted provider believes an item or service may not be covered for an enrollee, or could be covered only under specific conditions, the appropriate process is for the enrollee or provider to request a pre-service organization determination from the plan.

If a contracted provider refers an enrollee to a non-contracted provider for a service that is covered by the plan upon referral, the enrollee is financially liable only for the applicable cost-sharing for that service. Contracted providers are expected to coordinate care or work with plans prior to referring an enrollee to a non-contracted provider to ensure, to the extent possible, that enrollees are receiving medically necessary services covered by their plan. Furthermore, plans are expected to work with their contracted providers to ensure that clear processes are in place and providers are educated about those processes, including appropriate documentation, to substantiate that a referral has been made.

If a service is never covered by the plan and the plan's Evidence of Coverage (EOC) provided to the enrollee is clear that the service or item is never covered, the plan is not required to hold the enrollee harmless from the full cost of the service or item. For a service or item that is typically not covered, but could be covered under specific conditions (e.g., dental care that is necessary to treat an illness or injury), the EOC, in and of itself, is not adequate notice of non-coverage for purposes of determining enrollee liability. In such instances, the appropriate process is for the enrollee, or the provider acting on behalf of the enrollee, to request a pre-service organization determination. If the plan denies the service, the plan must issue the standardized denial notice with appeal rights. The enrollee has the right to appeal any denial of a service or item. Plans also must educate their contracted providers about the limits of plan coverage and the need to correctly advise enrollees when providing referrals for covered services. This will prevent confusion related to plan coverage and enrollee financial liability as well as ensure coordination of the care furnished.

When the provider, or the plan acting on behalf of the provider, can show that an enrollee was notified (via a clear exclusion in the EOC or the standardized denial notice) prior to receipt of the item or service that the item or service is not covered by the plan or that coverage is available only if the enrollee is referred for the service by a contracted provider but the enrollee nonetheless receives that item or service in the absence of a referral, the regulation at §422.105(a) does not require the MA plan to hold the enrollee harmless from the full cost of the service or item charged by the provider.

180 – Balance Billing

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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

When enrollees obtain plan-covered services in an HMO, PPO, or RPPO, they may not be charged or held liable for more than plan-allowed cost-sharing. Providers who are permitted to 'balance bill' must obtain the amount in excess of the enrollee's cost-sharing (the balance) for services, directly from the MAO and not from the enrollee.

180.1– Definitions

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Note: Under original Medicare rules, a 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 Medicare 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 in field 27 on the CMS 5010 claims form. In these instances, no balance billing of enrollees by the provider is permitted.

180.2 – Balance Billing by Provider Type

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

The rules governing balance billing as well as the rules governing the MA payment of MA-plan contracting providers, non-contracting providers and original Medicare participating and 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 must pay the non-contracting, non-participating (non-par) provider the difference between the enrollee'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 must pay the non-contracting non-participating (non-par) DME supplier the difference between the enrollee'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 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 the enrollees' lack of obligation to pay more than the allowed plan cost-sharing as described above.

190 – Information on Advance Directives

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

190.1 – Definition

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.

190.2 – Basic Rule

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

Pursuant to 42 CFR § 422.128, 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 190.4.

190.3 – State Law Primary

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.

190.4 – Content of Enrollee Information and Other MA Obligations

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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 190.3 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.

190.5 – Incapacitated Enrollees

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.

190.6 – Community Education Requirements

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.

190.7 – MAO Rights

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.

190.8 – Anti-discrimination Rights

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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.

200 – Part C Explanation of Benefits (EOB)

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

The Part C EOB is an ad hoc enrollee communication that provides MA enrollees with clear and timely information about their medical claims to support informed decisions about their healthcare options. MAOs are required to issue EOBs that include the information reflected in the CMS-developed templates. For additional information, please see the final templates and instructions at: <http://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.html>.

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

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

210.1 – Defining Guidance

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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) enrollees about Medicaid and/or Medicare Savings Programs, assist enrollees with determining potential eligibility for those programs and helping enrollees actually enroll in those programs. This guidance also pertains to organizations that help enrollees maintain their eligibility and enrollment in these programs.

210.2 – Relationship to D-SNP Eligibility / Enrollment

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

This guidance on educating and enrolling enrollees in financial assistance programs in no way affects or relates to an MAO's responsibility for determining an enrollee's, or potential enrollee'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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

MAOs should be aware of how an enrollee's eligibility for Medicaid and various levels of the Medicare Savings Programs might affect their enrollees' 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

MAOs that provide education and/or enrollment assistance to enrollees 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.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

MAOs 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 enrollees within those pre-identified population segments. Additionally, if the organization receives an inquiry from a plan enrollee not previously identified in the targeted group, it must provide assistance to that enrollee as if he or she had been included in the initial group.

210.6 – Required Elements of Education / Enrollment Assistance Programs

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

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

- Clarification that the enrollee may voluntarily offer information, including financial information, for assistance with enrolling in or maintaining enrollment in state financial assistance, but that the enrollee is not obligated to provide this information.
- Clarification that the enrollee’s failure to provide information will in no way adversely affect the enrollee’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 an enrollee on how to proceed with the application process even if the organization’s screening process indicates that the enrollee is probably not eligible for assistance under any of the dual eligibility programs.
- Alternate sources of information, including the telephone number for enrollees 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.

MAOs may provide assistance to the enrollee in completing applications for financial assistance including submitting the paperwork to the appropriate State office.

210.7 – CMS Oversight

(Rev.120, Issued 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)

At any time, CMS may request, and the MAO 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 MAO.

- 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 enrollees 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 enrollee'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 enrollees; and
- Telephone scripts or other outreach assistance scripts that will guide representatives in answering enrollees' questions or discussing the assistance available to them. Such scripts must include a privacy statement clarifying that the enrollee is not required to provide any information to the representative and that the information provided will in no way affect the enrollee's membership in the plan.