
CMS Manual System

Pub. 100-16 Medicare Managed Care

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

Transmittal 121

Date: 04-22-16

SUBJECT: Chapter 4, Benefits and Beneficiary Protections

I. SUMMARY OF CHANGES: Chapter 4 was updated to reflect clarifications and to provide more robust guidance (most of which has been previously issued via HPMS memos and in the CY 2016 and CY 2017 Call Letters). This update also deleted one old section and added two new sections as part of MCAG’s reorganization of the MMCM overall. The deleted section is moving *to* another chapter and the added sections have been moved *from* other chapters. Finally, Chapter 4 was updated with various editorial changes throughout in order to align with the most up-to-date CMS writing guidelines, such as changing the words “Chapter” and “Section” to the more appropriate lowercase versions, “chapter” and “section.” Red italics indicate differences between the current version and the previous version.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: 04-22-16

IMPLEMENTATION: 04-22-16

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/TOC
R	4/PART I: BENEFITS
R	4/10.1/General Requirements
R	4/10.2/Basic Rule
R	4/10.2.2/Exceptions to Requirements for MA plans to Cover FFS Benefits
R	4/10.3/Types of Benefits
R	4/10.4/Hospice Coverage
R	4/10.5.1/Uniformity
R	4/10.5.2/Anti-Discrimination
R	4/10.5.3/Review for Discrimination and Steering
R	4/10.5.4/Confidentiality
R	4/10.6/Multiple Plan Offerings and Benefit Caps
R	4/10.7.1/Payment for Services
R	4/10.7.2/Payment for Investigational Device Exemption (IDE) Studies
R	4/10.7.4/Claims Processing Instructions for Clinical Studies
R	4/10.8/Drugs Covered Under Original Medicare Part B
R	4/10.9/Return to Enrollee’s Home Skilled Nursing Facility (SNF)
R	4/10.10/Therapy Caps and Exceptions

R	4/10.11/Transplant Services
R	4/10.12.1/Designation of DME Providers/Suppliers
R	4/10.12.5/DMEPOS Competitive Bid Program
R	4/10.14/No Dollar Limits on Provision of Part B Drugs
R	4/10.15/Part D Rules for MA Plans
R	4/10.16/Medical Necessity
R	4/20.1/Ambulance Services
R	4/20.4/Stabilization of an Emergency Medical Condition
R	4/30.1/Definition of Supplemental Benefit
R	4/30.2/Supplemental Benefit Extending Original Medicare Benefits
R	4/30.3/Examples of Eligible Supplemental Benefits
R	4/30.4/Items and Services Not Eligible as Supplemental Benefits
R	4/40.1/Overview of OTC Benefits
R	4/40.2/Access to OTC Benefits
R	4/40.3/Payment Methods
R	4/40.3.1/Special Rules for Manual Reimbursement
R	4/40.4/Items and Their OTC Status
R	4/50.1/Guidance on Acceptable Cost-sharing
R	4/50.2/Cost-sharing for In-Network Preventive Services
R	4/50.3/Total Beneficiary Cost (TBC)
R	4/50.4/Single Deductible Rules for Regional and Local PPOs
R	4/50.5/Guidance on Other Enrollee Out-of-Pocket Liability
N	4/50.6/Cost Sharing for Dual-Eligible Enrollees Requiring an Institutional Level of Care
R	4/60/Meaningful Difference
R	4/70/Non-Renewal Based on Low Enrollment
R	4/80.1/Definition and Requirements
R	4/90.1/Overview
R	4/90.3/General Rules for NCDs
R	4/90.3.1/When the Significant Cost Criterion is Not Met
R	4/90.3.3/Payment for NCD Items and Services
R	4/100/Rewards and Incentives
N	4/100.1/Health-Related Services and Activities
N	4/100.2/Non-discrimination
N	4/100.3/Offering Rewards In Connection With the Entire Service or Activity
N	4/100.4/Valuing Rewards and Incentives
N	4/100.5/Permissible Rewards and Incentives
N	4/100.6/Marketing RI Programs
N	4/100.7/Reporting to CMS
R	4/PART 11 – BENEFICIARY PROTECTIONS
R	4/110/Access to and Availability of Services
R	4/110.1/Access and Availability Rules for Coordinated Care Plans
R	4/110.1.1/Provider Network Standards
R	4/110.1.2/Significant Changes to Networks
N	4/110.1.2.1/General

N	4/110.1.2.2/Notification to CMS
N	4/110.1.2.3/Notification to Enrollees
N	4/110.1.2.4/MAO/Provider Notification
N	4/110.1.2.5/Significant Network Change Special Election Period (SEP)
R	4/110.1.3/Services for Which MA Plans Must Pay Non-contracted Providers and Suppliers
R	4/110.2/Provider Directories
N	4/110.2.1/General
N	4/110.2.2/Provider Directory Updates
N	4/110.2.3/Provider Directory Dissemination and Timing
N	4/110.2.4/Online Provider Directory Requirements
N	4/110.2.5/Provider Directory Disclaimers
N	4/110.2.6/Provider Directory Submissions to CMS
R	4/110.3/Health Maintenance Organization (HMO) and HMO Point of Service (POS) Coverage and Access
D	4/110.3.1/Access through Non-contracted Providers
D	4/110.3.2/Essential Hospitals
R	4/110.4/Preferred Provider Organization (PPO) Coverage and Access
R	4/110.5/Special Rules for RPPOs
N	4/110.5.1/Access through Non-contracted Providers
N	4/110.5.2/Essential Hospitals
N	4/110.6/Ensuring Coordination of Care
N	4/110.7/Access, Gatekeeper, and Cost-Sharing by Plan Type
R	4/120.1/General Rule
R	4/120.2/Requirements, Rights, and Beneficiary Protections
R	4/120.3/Employer/Union Plans
R	4/130.1/Basic Rule
R	4/130.3/Medicare Benefits Secondary to Group Health Plans (GHPs) and Large Group Health Plans (LGHPs) and in Settlements
R	4/130.4/Collecting From Other Entities
R	4/130.5/Collecting From Other Insurers or the Enrollee
R	4/130.7/Medicare Secondary Payer (MSP) Rules and State Laws
R	4/140.1/Service Area Defined
R	4/140.2/Factors That Influence Service Area Approvals
R	4/140.3/Partial County Service Area
R	4/140.3.1/Necessity
R	4/140.3.2/Non-Discriminatory
R	4/140.3.3/Best Interests of Beneficiaries
R	4/150/Benefits during Disasters and Catastrophic Events
D	4/150.1/Introduction
D	4/150.2/New Plan
D	4/150.3/Renewal Plan
D	4/150.4/Consolidated Renewal Plan
D	4/150.5/Renewal Plan with a Service Area Expansion (SAE)
D	4/150.6/Renewal Plan with a Service Area Reduction and No Other MA Options

	Available
D	4/150.7/Renewal Plan with a Service Area Reduction When the MAO Will Offer another PBP in the Reduced Portion of the Service Area
D	4/150.8/Terminated Plan (Non-Renewal)
D	4/150.9/Crosswalk Table Summary
R	4/160/Beneficiary Protections Related to Plan-Directed Care
R	4/170/Balance Billing
N	4/170.1/Definitions
N	4/170.2/Balance Billing Provider Type
R	4/180/Information on Advance Directives
R	4/180.1/Definition
R	4/180.2/Basic Rule
N	4/180.3/State Law Primary
N	4/180.4/Content of Enrollee Information and Other MA Obligations
N	4/180.5/Incapacitated Enrollees
N	4/180.6/Community Education Requirements
N	4/180.7/MAO Rights
N	4/180.8/Anti-discrimination Rights
R	4/190/Part C Explanation of Benefits (EOB)
D	4/190.1/Definition
D	4/190.2/Basic Rule
D	4/190.3/State Law Primary
D	4/190.4/Content of Enrollee Information and Other MA Obligations
D	4/190.5/Incapacitated Enrollees
D	4/190.6/Community Education Requirements
D	4/190.7/MAO Rights
D	4/190.8/Anti-discrimination Rights
R	4/200/Educating and Enrolling Members in Medicaid and Medicare Savings Programs
N	4/200.1/Defining Guidance
N	4/200.2/Relationship to D-SNP Eligibility/Enrollment
N	4/200.3/Relationship to Dual Eligible Demonstration Programs
N	4/200.4/Scope of Financial Assistance Programs
N	4/200.5/Targeting Membership
N	4/200.6/Required Elements of Education/Enrollment Assistance Programs
N	4/200.7/CMS Oversight
D	4/210/Educating and Enrolling Members in Medicaid and Medicare Savings Programs
D	4/210.1/Defining Guidance
D	4/210.2/Relationship to D-SNP Eligibility/Enrollment
D	4/210.3/Relationship to Dual Eligible Demonstration Programs
D	4/210.4/Scope of Financial Assistance Programs
D	4/210.5/Targeting Membership
D	4/210.6/Required Elements of Education/Enrollment Assistance Programs
D	4/210.7/CMS Oversight

III. FUNDING: No additional funding is currently provided by CMS.

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

Table of Contents *(Rev121, Issued: 04-22-16)*

Transmittals for Chapter 4

- 10.7.4 – Claims *Processing* Instructions for Clinical Studies
- 10.8 – *Drugs Covered* Under Original Medicare Part B
- 10.9 – Return to *Enrollee's* Home Skilled Nursing Facility (SNF)
- 40.3 – Payment *Methods*
- 50.3 – Total Beneficiary *Cost* (TBC)

- 50.6 – Cost Sharing for Dual-Eligible Enrollees Requiring an Institutional Level of Care*
- 60 – Meaningful *Difference*
- 100.1 – Health Related Services and Activities*
- 100.2 – Non-discrimination*
- 100.3 – Offering Rewards In Connection With the Entire Service or Activity*
- 100.4 – Valuing Rewards and Incentives*
- 100.5 – Permissible Rewards and Incentives*
- 100.6 – Marketing RI Programs*
- 100.7 – Reporting to CMS*

- 110.1.2.1 – General*
- 110.1.2.2 – Notification to CMS*
- 110.1.2.3 – Notification to Enrollees*
- 110.1.2.4 – MAO/Provider Notification*
- 110.1.2.5 – Significant Network Change Special Election Period (SEP)*
- 110.2 – *Provider Directories*
- 110.2.1 – General*
- 110.2.2 – Provider Directory Updates*
- 110.2.3 – Provider Directory Dissemination and Timing*
- 110.2.4 – Online Provider Directory Requirements*
- 110.2.5 – Provider Directory Disclaimers*
- 110.2.6 – Provider Directory Submission to CMS*
- 110.3 – *Health Maintenance Organization (HMO) and HMO Point of Service (POS) Coverage and Access*
- 110.4 – *Preferred Provider Organization (PPO) Coverage and Access*
- 110.5 – *Special Rules for RPPOs*
- 110.5.1 – Access through Non-contracted Providers*
- 110.5.2 – Essential Hospitals*
- 110.6 – Ensuring Coordination of Care*
- 110.7 – Access, Gatekeeper and Cost-Sharing by Plan Type*
- 150 – *Benefits during Disasters and Catastrophic Events*

160 – *Beneficiary Protections Related to Plan-Directed Care*
170 – *Balance Billing*
170.1 – *Definitions*
170.2 – *Balance Billing by Provider Type*
180 – *Information on Advance Directives*
180.1 – *Definition*
180.2 – *Basic Rule*
180.3 – *State Law Primary*
180.4 – *Content of Enrollee Information and Other MA Obligations*
180.5 – *Incapacitated Enrollees*
180.6 – *Community Education Requirements*
180.7 – *MAO Rights*
180.8 – *Anti-discrimination Rights*
190 – *Part C Explanation of Benefits (EOB)*
200 – *Educating and Enrolling Members in Medicaid and Medicare Savings*
200.1 – *Defining Guidance*
200.2 – *Relationship to D-SNP Eligibility/Enrollment*
200.3 – *Relationship to Dual Eligible Demonstration Programs*
200.4 – *Scope of Financial Assistance Programs*
200.5 – *Targeting Membership*
200.6 – *Required Elements of Education/Enrollment Assistance Programs*
200.7 – *CMS Oversight*

PART I: BENEFITS

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Part I of this *chapter provides key information for Medicare Advantage Organizations (MAOs) regarding Medicare Advantage (MA) benefits for use in designing Plan Benefit Packages (PBP)*. Part II of this chapter, which begins at *section 110*, provides information on beneficiary protections, and includes topics such as rules for plan renewals, coordination of benefits, and educating and enrolling *individuals* in Medicaid and Medicare Savings Programs.

10.1 – General Requirements

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

These guidelines reflect CMS' current interpretation of the provisions of the Medicare Advantage statute and regulations (*chapter 42* of the Code of Federal Regulations, part 422) pertaining to benefits and beneficiary protections. *This* guidance is subject to change as technology and industry practices in plan design and administration evolve and as CMS gains *additional* experience administering the MA program.

This chapter *is* governed by regulations set forth *at* 42 CFR 422, Subpart C, and 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 (*MMCM*). 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

An *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 *for the benefits* on behalf of enrollees.

Basic benefits must be furnished through providers meeting requirements that are specified *at* 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 Secretary *has* 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 of this chapter*). 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 *under section 110* of this chapter).
- **Cost-Sharing:** With the exception of the services listed at 42 CFR 422.100(j) *and certain preventive services graded A or B by the United States Preventive Services Task Force and covered by original Medicare without cost-sharing (co-insurance)*, 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 *discussed* 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.

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

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *below*.
- **Inpatient stay during which MA enrollment begins:** (42 CFR § 422.318) If a Medicare beneficiary is in an inpatient stay and his enrollment in an MA plan takes effect 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, “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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Basic benefits: All *MA* 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: *MA 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: *MA 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 *MAO* 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. *MAOs may not impose waiting periods on mandatory supplemental benefits. An MA Medical Savings Account (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 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. *MA 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. *MA plan* enrollees choose whether to elect and pay for any particular optional supplemental benefit offered under the *MA* 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 *MA* 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 *MA plans* 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 *MA plan*. 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 *MMCM*, "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 *MA plan* when that enrollee fails to make timely payments of premium for optional supplemental benefits.

MA plans may impose waiting periods for optional supplemental benefits that require enrollees to have the specified coverage for a period of time before utilization. However, MA plans that choose to impose waiting periods must describe the details, including the length of the waiting period, in their annual bid as well as include the information in any relevant marketing materials.

10.4 – Hospice Coverage

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

As defined in 42 CFR § 422.320, *MA plans* must inform each enrollee eligible for hospice care about its availability. *This is true whether* a Medicare hospice program is located within the plan's service area or *if* it is common practice to refer patients to hospice programs outside the *plan'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 *MA plan* is paid a reduced capitation rate for that enrollee by CMS and the *MA plan* is responsible for continued coverage of supplemental benefits. CMS pays: (a) the hospice program for hospice care furnished to the enrollee and (b) the *MA plan*, 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 *MA plan* begins the next month (42 CFR § 422.320).

Table I *below* 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 <i>original</i> 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

10.5.1 – Uniformity

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *42 CFR § 422.2*, 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;
 - *The option of 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
 - *The option of paying* their premium by check.

10.5.2 – Anti-Discrimination

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

An *MAO* 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. *Discrimination based on “source of*

payment” means, for example, that MA providers cannot refuse to serve enrollees because they receive assistance with Medicare cost-sharing from a State Medicaid program.

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), *under the circumstances mentioned in chapter 16b of the MMCM, “Special Needs Plans,”* at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf>;
- To a person with end-stage renal disease (ESRD), under the circumstances mentioned in *chapter 2* of the *MMCM*, “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 *MMCM*, “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 HIPAA 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

CMS reviews and approves MA *PBPs based on* statutes, regulations, *and* policy guidelines *contained* in this manual and other CMS instructions. *Review is* 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 *PBP*, 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:
 - *Condition* 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *that require MAOs to report the loss of protected health information without delay and, in cases affecting 500 or more individuals, no later than 60 days after discovery.*
- 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

An MAO may offer more than one MA plan in the same service area (*though* each plan is subject to the conditions and limitations established for the MA program). *Caps* for a supplemental benefit can only be imposed at the MA plan level. For example, *during a contract year*, if *an enrollee switches to another MA plan offered by the same* MAO 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. This 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.

10.7.1 – Payment for Services

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

For clinical trials covered under the Clinical Trials National Coverage Determination 310.1 (NCD) (NCD manual, Pub. 100-3, Part 4, *section* 310), *original* 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 *original* 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=BAABAAAAAAAA> 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 (*IDE*) 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.

MAOs 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, *an enrollee* (or providers acting on *the enrollee's* behalf) must notify their plan that *the enrollee* received *a qualified clinical trial service* 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 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 *MAO* 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 and Category B *IDE studies*. *The MAO is also responsible for CMS-approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage.*

CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), 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.

10.7.4 – Claims *Processing* Instructions for Clinical Studies

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Complete requirements for *claims processing* and payment *for clinical studies* may be found in the Medicare Claims Processing Manual, Transmittal 2955 (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2955CP.pdf>).

10.8 – *Drugs Covered* Under Original Medicare Part B

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

For this subsection, the term “drug” means “drug or biological.” Drugs that are covered under Medicare Part B are governed by 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 *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 *and may not* 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 *and enrollees generally may not be denied Part D coverage of a drug based solely on its availability under Part B. It is critical to understand when a drug is covered under Part B or Part D in order to protect beneficiaries from coverage disruption and to ensure that Part C and Part D bids properly reflect appropriate coverage under either Part B or Part D. For detailed guidance and* 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>.

10.9 – Return to *Enrollee's* Home Skilled Nursing Facility (SNF) (Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *MA plan* or agrees to accept substantially similar payment under the same terms and conditions that apply to similar nursing facilities that contract with the *MA plan*.

This requirement also applies if the *MA plan* 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 a PPO, in-network cost-sharing applies.

10.10 – Therapy Caps and Exceptions

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

As explained in *section* 10.2 above, MA plans 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 in the distant location for medical care.

10.12.1 – Designation of DME Providers/Suppliers

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

During the application process, MA plans identify specific DME suppliers with whom they have *a contract* to provide enrollees with all medically necessary DME items and supplies. *MA plans are also expected to update provider/supplier directory information any time they become aware of changes. All updates to the online directory are expected to be done in real-time. For more information about provider directory requirements, see section 110.2 below.*

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.

10.12.5 – DMEPOS Competitive Bid Program

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

10.14 – No Dollar Limits on Provision of Part B Drugs

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 CFR 422.2 (definition of SNP)	No
Private Fee-for-Service (PFFS) plan	Local	No	Yes, provided the PFFS plan does not offer Part D coverage.
MA Medical Savings Account (MSA) Plan	Local	Not permitted	Yes
Section 1876 Cost Plans			
Cost plan offering qualified Part D prescription drug coverage	NA	No, but Part D coverage may be offered as an optional supplemental benefit	Yes
Cost plan offering non-qualified prescription drug coverage	NA	No. The cost plan cannot offer both Part D coverage and non-qualified	Yes

		prescription drug coverage.	
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. *Program for the All-Inclusive Care of the Elderly* (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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *MAO* 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 *MAO* 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 *MMCM*.

20.1 – Ambulance Services

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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>.

20.4 – Stabilization of an Emergency Medical Condition

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *MMCM*, "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.

30.1 – Definition of Supplemental Benefit

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 an *MA* 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 *MMCM*, "Employer/Union Sponsored Group Health Plans."

MA plans 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 an *MA* plan's Medicare enrollees over a period exceeding one contract year. For example, it is permissible for an *MA* plan to cover one new pair of eyeglasses every two years. While some benefits may be appropriately offered over multiple years, CMS encourages *MA* plans to limit offerings to one contract year where possible.

Supplemental benefits need *not* be provided through Medicare providers *nor at Medicare certified facilities*. Please note, however, *MA plans may not make payment to providers who have opted out or been excluded from Medicare through §§422.220 and 422.204(b)(4)/422.752(a)(8)*.

30.2 – Supplemental Benefits Extending Original Medicare Benefits (Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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

- **Medical Necessity:** An *MA plan* 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 *MA plan* 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 *MA plan* 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 *MA plan* 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 *MA plan* 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 other types of caregiver support as a supplemental benefit. However, an *MA plan* may, and is even encouraged, to include information about services available in the community to assist caregivers in obtaining relief so long as the *MA plan* does not refer to those services as plan benefits. *Such information may be included in newsletters or other communications to enrollees, for example.* For information on the original Medicare respite benefit see publication 100-02, the Medicare Benefit Policy Manual, *chapter 9*.
- Benefit Naming Conventions: An *MA plan* should not single out specific aspects of the benefit, in its marketing materials and PBP descriptions of original Medicare benefits. For example:
 - An *MA plan* 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 *MA plan* 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 *MA plan* 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 *MA* 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 <i>Non-Medicare covered stays</i> Upgrades
Inpatient Hospital-Psych	Additional Days <i>Non-Medicare covered stays</i>
Skilled Nursing Facility	Additional Days
Emergency Care	Worldwide Emergency/ <i>Urgent</i> Coverage
Chiropractor	Routine Care/ <i>Other*</i>
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	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/ <i>Other*</i>
Eye Wear	Contact lenses, eye glasses, lenses, frames, upgrades
Non-routine Hearing Exams	Routine hearing exams, fitting/evaluation for hearing aids

**“Other” refers to any Non-Medicare covered service*

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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *by MA plans* 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

MA 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. *MA plans* are to provide a description of therapies offered in the PBP Notes section.

Bathroom Safety Devices

MA 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 *MA* 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

MA 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 *MA* 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 *by MA plans* as supplemental benefits designed to improve or maintain good health. The fitness benefit must, if applicable, include an orientation *for each enrollee* to the facility and the equipment. The benefit also may include development of a personalized exercise plan and a limited number of sessions with a certified trainer.

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

MA 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 *MA* plans may offer *Enhanced Disease Management* (EDM) as a supplemental benefit. *EDM must be targeted to groups of enrollees based on a diagnosis of, or risk for, a specific disease condition (e.g., diabetes, heart failure, cognitive impairment such as Alzheimer's and related dementias).* 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 *MA plans* 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 *MA* 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 *MA plan* to collect and act upon *the* information *gathered from routing monitoring* 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 *of the EDM program*.

Health Education

A health education program *may be offered* as a supplemental benefit *if it*:

- *Is* 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 *such as Alzheimer's and related dementias*);
- *Provides* 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, MA 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 *MA* 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

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.

Home delivery of meals may be offered as a supplemental benefit if the services are:

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

Social factors, by themselves, do not qualify an enrollee for 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, *MA* plans are to:

- Provide information and links to websites with nutritious diet planning information, such as ChooseMyPlate.Gov;
- Provide nutritional tips in their newsletters and/or on their 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 meal services offered as a supplemental benefit* with the broader services offered under the “Meals on Wheels” program. However, if an MA plan has entered into a contract with “Meals on Wheels” to furnish the approved meals benefit, it may inform its enrollees that the supplemental benefit (meal benefit) under the MA 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.

Over-the-Counter (OTC) Benefit

MA 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)

MA plans may provide enrollees with in-home Personal Emergency Response devices designed to notify appropriate personnel of an emergency (e.g., a fall), provided that they are primarily health related. A PERS may not include cellular telephones because such devices are not primarily health related (a definitive component of being a supplemental benefit).

Preventive Benefits Eligible as Supplemental Benefits

An example of a preventive benefit that is eligible as a supplemental benefit is providing additional sessions of smoking and tobacco cessation counseling. MA 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 MA 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)

MA 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, MA 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. As with all supplemental benefits, the MNT benefit's primary purpose must be to improve health outcomes.

Physical Exam

Non-SNP MA plans may offer as a supplemental benefit a physical exam that provides services beyond those services required to be provided in the Annual Wellness Visit. To be considered an Annual Physical Exam that qualifies as a supplemental benefit by CMS, the exam would be provided by a qualified physician or qualified non-physician practitioner, hereafter referred to as a practitioner. At a minimum, the exam would include a detailed medical/family history and the performance of a detailed head to toe assessment with hands-on examination of all the body systems. For example, the practitioner uses visual inspection, palpation, auscultation and 133 manual examination in his/her full examination to assess overall general health and detect abnormalities or signs that could indicate a disease process that should be addressed. We consider these components minimum elements and not an exhaustive list.

Other aspects of the Annual Physical Exam may include, as appropriate, follow-up orders for referral to other practitioners, lab tests, clinical screenings, EKG, etc. The Annual Physical Exam also should emphasize prevention, i.e., the recommendations for preventive screenings, vaccination(s), and counseling about healthy behaviors.

Practitioners should exercise clinical judgment when determining the additional components necessary for an Annual Physical Exam to meet the individual needs of the enrollee. MA plans do not need to fully describe in the PBP notes the non-Medicare covered activities and services included in the physical *exam if the benefit is consistent with our guidance.*

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 *MA* 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. *For example, immediately* following discharge (e.g., within the first week) from a hospital or SNF inpatient stay, MA plans may offer, as a supplemental benefit, the services of a qualified health care provider *who*, 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.

Readmission Prevention

MA 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, *immediately following an enrollee's discharge from a hospital or skilled nursing facility (SNF) inpatient stay (e.g., within the first week).*

Services included in a supplemental readmission 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.

An MA plan may combine the benefits, *suggested as examples below*, as a complete "*Readmission 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)

MA plans may propose a supplemental benefit to allow a contracted provider to diagnose and treat some conditions via telephone, and/or real time interactive audio and video technologies. MA plans 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. *MA 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 *MA plan* 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 *MA plan* will have a protocol for monitoring the use of the system by enrollees. The protocol should enable the *MA plan* to identify potential misuse *and instances where the system is supplanting* appropriate PCP visits. The protocol should be implemented at the beginning of the contract year the benefit is offered. The *MA plan* 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 *MA plans* are required to provide.

MA plans must include in the *110.1* 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

MA plans may *offer* 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). *MA plans* 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). *Telemonitoring equipment may not include a cellular telephone because such devices are not primarily health related.* 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

An MA plan is *not obligated* to provide transportation *to obtain non-emergent, covered Part A and Part B services. However, such transportation may be offered as a supplemental benefit.*

The transportation offered must be used exclusively to accommodate the enrollee’s health care needs: for example, the *MA* 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 *MA plan* and may not be used to transport enrollees for non-health-related purposes. The *MA* plan must describe the proposed benefit in the PBP.

Visitor/Travel Benefit

A Visitor/Travel (V/T) benefit may be offered as a 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 *MA* 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 *MMCM*, "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 *MA plan* 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 *MA plan* 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 a supplemental benefit *designed to promote healthy behaviors that help* an individual to lose weight and keep it off, but the program may not offer meals as part of the benefit. *As with all supplemental benefits, Weight Management Programs must be health driven and aim to improve health outcomes. For CMS to consider a Weight Management Program sufficiently health related, the benefit includes:*

- *A plan to keep the weight off over the long run;*
- *Guidance on how to develop healthier eating and physical activity habits; and*

- *Ongoing feedback, monitoring, and support.*

The weight management program *should provide structured lessons on a weekly basis that are tailored to the beneficiaries' personal goals. The program should support self-monitoring of eating and physical activity as well as offer regular feedback from a counselor on goals, progress, and results. The program may be offered online (fully or partly), but must also be entirely available to enrollees without access to online capabilities.*

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/*Urgent* 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. *This coverage may also include ambulance services worldwide.*

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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

The items and services listed in this section have been previously proposed by MA plans as supplemental benefits in submitted plan benefit packages and, *because they are not sufficiently health related*, are not allowable supplemental benefits:

- 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* 110.5 of this chapter.

Note: For information specific to Special Needs Plan benefit offerings, see chapter 16b of the *MMCM*, "Special Needs Plans."

40.1 – Overview of OTC Benefit

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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. MA 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, *MA 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 *MA* plan as supplemental benefits are

for the enrollee, OTC items may be purchased for the enrollee only.

40.2 - Access to OTC Benefits

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 **MA** 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.

An **MA** 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 **MA** plan is responsible for the cost of mailing. To avoid excessive mailing costs, the **MA** plan may impose a minimum purchase amount per order.

40.3 – Payment Methods

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Every **MA** plan, independent of the payment method it chooses, must also allow – under circumstances which it describes (for example, when the debit card network is *not operating correctly*) – for manual reimbursement for the purchase of OTC items based on submitted receipts. The **MA** 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 Purpose	Weight loss items	Appetite suppressants, fat absorption inhibitors, <i>food scales</i>

Eligible?	Category	Examples of items and drugs included in this category
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

50.1 – Guidance on Acceptable Cost-sharing

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

CMS, in its annual bid review of proposed plan packages, applies categories of cost-sharing standards *as* detailed below. *MAOs* should note that benefit design and cost-sharing amounts approved for a previous contract year *are* not automatically *considered* acceptable for the following contract year. A separate *and* distinct *CMS* 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. *MAOs* 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, 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, 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:

- *MAOs* 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);
- *Any foundation or organization that is owned and operated by an MA plan cannot pay cost-sharing for MA plan enrollees;*
- 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 *MAOs* have the flexibility to establish cost-sharing amounts as co-payments or

coinsurance, *MAOs* should keep in mind, when designing their cost-sharing, that enrollees generally find co-payment amounts more predictable and less confusing than coinsurance;

- 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 *allowed* 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, *110.3* and *110.6* below, and in the POS subsection of *section* 30.3 above.

However, while MA plans may have ‘differential cost-sharing’ based on facility settings, they should include the enrollee’s entire cost sharing responsibility in a single copay. This is consistent with Medicare Advantage disclosure requirements at 42 CFR §422.111(b)(2) which require that MA plans clearly and accurately disclose benefits and cost sharing. Accordingly, in situations where there is a difference in cost sharing based on place of service, those fees should be combined (bundled) into the cost sharing amount for that particular place of service and clearly reflected as a total copayment in appropriate materials distributed to beneficiaries.

- Dialysis Services: Cost-sharing for 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 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 Dialysis Cost-sharing.

Cost-sharing for 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 cost-sharing	Must be the same as in-network, in service area cost-sharing

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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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* (TBC)

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 may not charge enrollees the plan-level deductible prior to receiving Emergency Care/Urgently Needed Services and the cost sharing for those services must always contribute to satisfying the MOOP. Plans may count Emergency Care/Urgently Needed Services cost sharing towards the plan-level deductible or plans may choose to not have enrollee cost sharing count towards the plan-level deductible. However, plans must apply this policy uniformly across the entire plan and marketing materials provided to enrollees must be transparent regarding whether or not cost sharing applies toward the plan-level 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 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 170* 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 *for Part A and Part B services*; that is, plans may not require enrollees to pay the plan's share of the costs for a service and then reimburse the enrollee.

50.6 – Cost Sharing for Dual-Eligible Enrollees Requiring an Institutional Level of Care

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

As provided under section 1860D-14 of the Act, Full Medicaid institutionalized individuals have no cost sharing for covered Part D drugs under their PDP or MA-PD plan. Effective January 1, 2012, section 1860D-14 of the Act also eliminates Part D cost sharing for Full Medicaid individuals who would be institutionalized if they were not receiving home and community-based services (HCBS) either through:

- *A HCBS waiver authorized for a state under section 1115 or subsection (c) or (d) of section 1915 of the Act;*
- *A Medicaid State Plan Amendment under section 1915(i) of the Act; or*
- *A Medicaid managed care organization with a contract under section 1903(m) or section 1932 of the Act.*

A SNP must determine or an enrollee must demonstrate that s/he is a Full Medicaid individual receiving HCBS under title XIX with the following:

- *A copy of a state-issued Notice of Action, Notice of Determination, or Notice of Enrollment that includes the enrollee's name and HCBS eligibility date during a month after June of the previous calendar year;*
- *A copy of a state-approved HCBS Service Plan that includes the enrollee's name and effective date beginning during a month after June of the previous calendar year;*
- *A copy of a state-issued prior authorization approval letter for HCBS that includes the enrollee's name and effective date beginning during a month after June of the previous calendar year; or*
- *Other documentation provided by the state showing HCBS eligibility status during a month after June of the previous calendar year.*

See chapter 16b of the MMCM, "Special Needs Plans" for more information on dual eligible enrollees, SNPs, and D-SNPs at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf>.

60 – Meaningful *Difference*

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *difference* 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 an 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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

Pursuant to 42 CFR §422.514, CMS may not enter into or renew an MA contract with an organization unless the organization has enrollment of at least:

(1) 5,000 individuals (or 1,500 individuals if the organization is a PSO) are enrolled for the purpose of receiving health benefits from the organization; or

(2) 1,500 individuals (or 500 individuals if the organization is a PSO) are enrolled for purposes of receiving health benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in §412.62(f) (or, in the case of a PSO, the PSO meets the requirements in §422.352(c)).

However, a waiver of this enrollment may be provided at the time of an initial contract or for the first three years the MA plan is offered. CMS will consider the experience of the organization, its management personnel and its providers; the administrative and marketing abilities of the organization; and the financial solvency and resources of the organization in determining whether the organization is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract to grant a waiver.

As provided under 42 CFR §422.506(b)(1)(iv), CMS may non-renew MA plans that have *an insufficient* 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 are* 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 review the submitted justifications and make a final decision on the continuation of the plan(s) for the next contract year.

Determining whether an MA plan has sufficient enrollment to remain or be a viable plan option each year requires consideration of many factors, including overall enrollment in the MA program and enrollment in individual plans. CMS will announce in the spring its interpretation and parameters for applying the regulation. These will 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.

80.1 – Definition and Requirements

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 **MAO** 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.

90.1 – Overview

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

90.3 – General Rules for NCDs

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

90.3.3 – Payment for NCD Items and Services

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Chapter 8 of the *MMCM*, “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.

100 – Rewards and Incentives

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

An MA plan may create one or more *Rewards and Incentives (RI) Programs* that provide rewards and/or incentives to enrollees *in connection with participation* in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. *The overall goal of RI Programs is to encourage enrollees to be actively engaged in their health care and, ultimately, improve and sustain their overall health and well-being.*

An RI Program incentivizes an enrollee to participate in health-promoting services or activities while inspiring a long-term commitment to healthy behaviors. Accordingly, in addition to providing rewards and/or incentives, plans should consider including an enrollee support component within their RI Program design (e.g., coaches or motivators to encourage and assist the enrollee with RI Program engagement).

At this time, RI Programs apply only to Part C (Medicare Advantage) at 42 CFR § 422 and may not be offered in connection with any Part D benefits governed by 42 CFR § 423.

Pursuant to 42 CFR § 422.134, each RI Program offered by an MA plan:

- *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.

Rewards and incentives *associated with the RI Program* must:

- Be offered in connection with the entire 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 *associated with the RI Program* may not:

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

*An RI Program is **not** a benefit. It must be included in the bid as a non-benefit expense but must not be entered in the Plan Benefit Package. Per CMS Office of the Actuary Bidding Guidance, “non-benefit expenses are all of the bid-level administrative and other non-medical costs incurred in the operation of the MA plan.”*

The timeframe for earning and redeeming rewards and/or incentives must be within the contract year in which the RI Program has been implemented. In order to prevent the use of rewards as motivation to stay in a plan, RI Programs may not allow enrollees to carry over rewards and/or incentives from one contract year to the next.

100.1 – Health-Related Services and Activities

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

MA plans have significant flexibility in designing RI Programs that are specific to their populations’ interests, abilities and needs. Plans are free to determine the specific services, activities, or behaviors that are subject to rewards or incentives within their RI Program design. Health-related services and activities associated with an RI Program may include, for example, the utilization of a particular service(s) or preventive screening benefit(s), adherence to prescribed treatment regimens, attending education/self-care management lessons, meeting nutritional goals, and making and keeping appointments with the doctor.

Plans may not discriminate based on health status, therefore, rewards and incentives based on health outcomes may not be offered. However, enrollees may be rewarded for continued healthy behaviors over time. For example, plans may not provide rewards and incentives for the amount of weight lost or a lowered blood pressure, as those are health outcomes and health status factors. Instead, the plan may provide rewards and/or incentives to enrollees for reporting their weights or blood pressures at regular intervals.

Plans also may reward sustained behavior changes by enrollees in order to support and promote the ultimate goal of RI Programs, which is lasting, positive changes in health-related behaviors. For example, an RI Program might include rewards and incentives for those enrollees that report that they remain smoke-free at several time intervals after completion of a smoking cessation program.

*Note: Completion of a federally mandated survey, though arguably a health-related activity, may **not** be included in an RI Program because of the potential for biased responses due to the influence of rewards or incentives.*

100.2 – Non-discrimination

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Any RI Program offered by an MA plan 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.

The non-discrimination and equal access requirements do not preclude plans from offering RI Programs that target enrollees with a specific disease or chronic condition as long as the RI Program does not discriminate against any enrollee who would otherwise qualify for participation. Thus, any RI Program must accommodate otherwise qualified enrollees who receive services in an institutional setting or who need a modified approach to enable effective participation and attainment of designated rewards and incentives.

For example, while internet-based RI Programs are allowed, an alternate method of earning and/or claiming rewards and incentives must be offered to those enrollees who do not have internet access. Another example is an RI Program in which participants earn a reward for participating in an exercise class. An alternate method of fulfilling an exercise activity must be offered to those individuals who are unable to attend the class, perhaps due to institutionalization, lack of transportation, or are disabled or wheelchair bound.

A caretaker may not participate in place of the enrollee in the services or activities in order to earn rewards or incentives on behalf of the enrollee. The goal of an RI Program is to encourage and maintain healthy behaviors that have a positive impact on enrollees; therefore, the enrollee must participate directly in the RI Program.

All RI Programs must provide the same rewards to all qualifying participants who perform the same action(s). An RI Program may not distinguish enrollees based on their medical encounter history. In other words, plans may not reward enrollees who have historically not utilized appropriate/recommended services at a higher level than other enrollees for participating in a RI Program activity. While RI Programs may aim to encourage more participation in preventive care, they may not discriminate against enrollees who have a good record of participation.

100.3 – Offering Rewards In Connection With the Entire Service or Activity

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Within an RI Program, rewards and incentives must be earned by completing an entire service or activity (or combination of services/activities), as established by the MA plan, and may not be offered for completion of less than any/all required component(s) of the eligible service or activity. This requirement allows CMS and MA plans to interpret the

value of a reward or incentive in relation to the service or activity for which it is being offered.

Plans are expected to reasonably define the scope of the “entire service or activity” within their RI Program design and assign a value of the reward or incentive accordingly. For example, a plan may decide to offer rewards and/or incentives for participation in a smoking cessation program. The plan may decide to give smaller rewards for each class or counseling session attended or may offer a single, larger reward for completing a pre-determined number of classes or counseling sessions.

Consistent with the requirement that rewards and incentives be of a value that may be expected to affect enrollees’ behavior, the service or activity for which rewards and/or incentives are being offered should be at a level that is meaningful.

100.4 – Valuing Rewards and Incentives

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Rewards and incentives for each RI Program must have values that are expected to elicit intended enrollee behavior but may not exceed the value of the health related service or activity (§ 422.134(C)(1)(iii)).

At this time, CMS has not identified the monetary values that exceed what is necessary to influence enrollee behavior. There is also no express limit on how often rewards and/or incentives may be offered to enrollees throughout a contract year. Instead, MA plans are to establish reasonable and appropriate values for rewards and/or incentives that comply with §422.134.

If necessary, in the future, we may issue additional guidance applying the regulation standards to specify limits on the value of rewards and incentives.

100.5 – Permissible Rewards and Incentives

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Rewards and/or incentives may not be offered in the form of cash or monetary rebates, including reduced cost-sharing or premiums. Otherwise, MAOs have considerable flexibility with regard to what may be offered as a reward or incentive.

Gift cards are a permissible form of reward or incentive as long as they are not redeemable for cash. MA plans are encouraged to offer enrollees a choice of gift cards from which to choose in order to account for differences in enrollees’ preferences and accessibility of retailers.

Discount coupons are also a permissible form of reward or incentive as long as they are not transferable for cash and follow the valuing guidelines addressed above. However, we would note that coupons that provide only nominal discounts may not provide

adequate incentive to drive the intended changes in enrollee behavior and thus not align with CMS valuing guidelines.

An RI Program that is designed so that enrollees earn “points” or “tokens” that can be used to “purchase” rewards (or some variation of this type of program) is permissible as long as the “points” and the rewards that may be “purchased” are earned and valued (according to CMS guidelines as set forth within this guidance and in accordance with §422.134) and are redeemed during the contract year in which they are earned.

*Rewards and/or incentives must be tangible items that align with the purpose of the RI Program and must directly benefit the enrollee. For example, a plan’s charitable contribution made on behalf of the enrollee does **not** satisfy the CMS criteria as a permissible reward or incentive because the enrollee who earned the reward does not benefit from such a contribution by the plan. However, the use of points (which are not themselves tangible), to purchase a reward, does satisfy CMS criteria because the points are used by each enrollee to obtain a tangible reward that is of value to the enrollee.*

*Rewards and/or incentives that are to be won based on probability, including programs in which an enrollee may earn entries into a lottery or drawing in order to receive a reward or incentive of a significant value, are **not** permissible because all enrollees who participate in and complete the services or activities required of them within the RI Program’s design must receive a tangible reward and incentive. The potentially negligible chance of winning the reward in such a scheme (depending on the pool of eligible enrollees) does not qualify as a tangible reward or incentive. Furthermore, RI Programs structured in this manner are potentially vulnerable to fraud and abuse implications.*

100.6 – Marketing RI Programs

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

MA plans may include information about RI Programs in marketing materials as long as those communications are provided to all current and prospective enrollees without discrimination. Additionally, any marketing of RI Programs must be done in conjunction with marketing of plan covered benefits.

Importantly, reward and/or incentive “items” may not be offered to potential enrollees under any circumstances. Nominal gifts as part of promotional activities are separate and distinct from RI Programs. For more information about the marketing aspects of RI Programs as well as promotional activity guidance, see the Medicare Marketing Guidelines at <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html>.

100.7 – Reporting to CMS

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

MA plans will be required to report on RI Programs through the annual Part C Medicare Advantage Reporting Requirements. MA plans offering an RI Program are expected to document and track information regarding their RI Programs and be prepared to provide that information to CMS upon request. Appropriate documentation includes, but is not limited to: date(s) of enrollee-specific participation in RI Program services and activities, rewards and/or incentives attained, how enrollee participation is measured, and available alternative methods of participation.

PART II: BENEFICIARY PROTECTIONS

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

110.1 – Access and Availability Rules for Coordinated Care Plans

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *contracted* 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 *are* provided by the Health Service Delivery (HSD) tables used to evaluate plan networks during the initial application, *service area expansion application, and continued operations throughout the contract year*. 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 enrollees to access each provider and facility in each county.

All MAOs are expected to continuously monitor their networks to ensure compliance with contractual obligations and in accordance with 42 CFR 422.112(a)(1)(i). CMS encourages MAOs to use the “organization-initiated” automated review feature in the Network Management Module (NMM) in HPMS. For more information, please refer to

the December 23, 2015, HPMS memo “Release of Network Management Module in Health Plan Management System (HPMS).”

In addition, as part of this continuous network self-monitoring, CMS expects that if an MAO becomes aware of network deficiencies at any time or believes that an exception is warranted for a particular specialty in a given service area, then the MAO will alert its CMS Account Manager.

110.1.1 – Provider Network Standards

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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). *Please see section 110.2 below for more information on provider directory updating requirements.*
- 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, arrange for *medically necessary* 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 *medically necessary* covered service that is not provided by the *providers* 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
- *Have* a quality improvement program plan as outlined in *chapter 5* of the *MMCM*. The quality improvement program plan must include *a Chronic Care Improvement Program (CCIP)* and a *Quality Improvement Project (QIP)*.

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 *and are entered in the PBP*; 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

110.1.2.1 – General

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

When MAOs submit 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, CMS network adequacy standards, as outlined in the guidance in this chapter and current MA HSD Network Adequacy Criteria Guidance, which can be found on the MA Applications webpage at: <https://www.cms.gov/MedicareAdvantageApps>. See 42 CFR § 422.112(a)(1)(i).

MAOs have considerable discretion to select the providers with whom to contract in order to build high-performing, cost effective provider networks. They are able to make changes to these networks at any time during the contract year, as long as they continue to furnish all Medicare-covered services in a non-discriminatory manner, meet established access and availability standards and timely notice requirements, and ensure continuity of care for enrollees.

CMS recognizes that significant no-cause network changes may occur during the contract year. MAOs may be in the best position to determine whether or not a provider termination without cause is significant. CMS considers significant changes to provider networks to be those that go beyond individual or limited provider terminations that occur during the routine course of plan operations and affect, or have the potential to affect, a large number of the MAO's enrollees.

Please note: *Significant network changes could result from any no-cause provider termination, whether it is initiated by the MAO or the provider. In addition, significant network changes could result from no-cause provider terminations that are effective at any point during the contract year, whether it is mid-year or on January 1.*

110.1.2.2 – Notification to CMS

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

An MAO must notify its CMS Account Manager of any no-cause provider termination that the MAO deems to be significant, at least 90 days prior to the effective date of the termination. To the extent possible, CMS would like to ensure that appropriate contingency planning is in place prior to an MAO making any significant network change. For example, an MAO should notify its Account Manager if it is in current contract negotiations with a provider group that would have a significant impact on the network if the negotiations were not successfully concluded.

CMS expects MAOs to take a conservative approach in determining whether a network change is significant by notifying CMS if there is any doubt as to whether the no-cause provider termination represents significant change to the network. This prior notification facilitates CMS oversight and verification of MAO compliance with current CMS network adequacy standards. An MAO that does not notify CMS of network changes that are ultimately deemed significant will be subject to appropriate compliance actions.

Upon CMS notification, CMS may ask the MAO to provide additional information about the network change, and CMS will verify whether the network change is indeed significant. If CMS deems the MAO's network change to be significant, then CMS may ask the MAO to demonstrate its continued compliance with current CMS network adequacy standards through the submission of HSD tables to the NMM.

CMS may also ask the MAO to submit 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, CMS may require the MAO to augment its network by contracting with additional providers to meet network adequacy standards 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.

110.1.2.3 – Notification to Enrollees

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Pursuant to 42 CFR § 422.111(e), when an MAO makes changes to its provider network, the MAO must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is

terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

Please note that CMS considers “enrollees who are patients seen on a regular basis by the provider whose contract is terminating” to be “affected enrollees.” An “affected enrollee” as an enrollee who is assigned to, currently receiving care from, or has received care within the past three months from a provider or facility being terminated.

When an MAO makes significant network changes, at any point during the contract year, the MAO must also follow the requirements at 42 CFR § 422.111(e). CMS recommends that as a best practice, MAOs making significant no-cause network changes should provide affected enrollees more than the required 30 days advance notice. A longer notification period is important, not only to address enrollee concerns, furnish enrollees with needed assistance in selecting new providers, and manage the continuity of care for those undergoing medical treatment, but also for maintaining enrollee satisfaction. If enrollees are notified sooner than 30 days prior to a significant provider termination, then they will be afforded additional time to transition to a new provider.

CMS expects that when an MAO has 60 days advance notice that a contract with a provider will be terminated (as discussed in section 110.1.2.4 below), the MAO should notify affected enrollees at least 30 days in advance of the contract termination but preferably more than 30 days in advance. For those MAOs that do not have the 60 days advance notice of a contract termination, they must make a good faith effort to notify affected enrollees as soon as possible and at least 30 days before termination.

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.

110.1.2.4 – MAO/Provider Notification

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

In accordance with 42 CFR § 422.202(d)(4), an MAO and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

110.1.2.5 – Significant Network Change Special Election Period (SEP)

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Pursuant to 42 CFR § 422.62(b)(4), enrollees who meet the exceptional conditions of being substantially affected by a significant no-cause provider network termination may be afforded a special election period (SEP).

If CMS determines that an MAO's network change is significant with substantial enrollee impact, then a "significant network change SEP" may be warranted. CMS will use a variety of criteria for making this determination, such as: (1) the number of enrollees affected; (2) the size of the service area affected; (3) the timing of the termination; (4) whether adequate and timely notice is provided to enrollees, (5) and any other information that may be relevant to the particular circumstance(s).

The MAO will be required to notify eligible enrollees of the significant network change SEP if the SEP is granted by CMS. SEPs will not be granted when MAOs make changes to their network that are effective on January 1 of the following contract year, as long as affected enrollees are notified of the changes prior to the AEP.

For more information regarding the significant network change SEP, please see the Medicare Advantage Enrollment and Disenrollment Guidance at:

<https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html>.

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

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

All MAOs 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 he/*she* 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, 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 170* 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 chapter 6, "Relationships with Providers," of the MMCM. 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 160* below.

110.2 – Provider Directories

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

110.2.1 – General

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Pursuant to 42 CFR §422.111(b)(3) MAOs must provide the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services.

If an MAO chooses to develop a non-model provider directory for either hardcopy or online provider directories, the directory must contain all information and follow all instructions within the CMS model provider directory located at: <http://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketingModelsStandardDocumentsandEducationalMaterial.html>. This includes the introductory language and disclaimers.

MAOs can find complete website and electronic media related requirements at section 100 of the Medicare Marketing Guidelines.

MAOs must include information regarding all contracted network providers in directories at the time of enrollment. Directories must include information about the number, mix, and distribution of all network providers. MAOs may have separate directories for each geographic area they serve, (e.g., metropolitan areas, surrounding county areas), provided that all directories together cover the entire service area.

MAOs may print a separate directory for each sub-network and disseminate that information to enrollees residing in that particular geographic sub-network. To ensure that enrollees are fully aware of their overall network provider options, plans that furnish their enrollees with directories containing a sub-network of plan providers must also advise enrollees that the complete directory of network providers is available online and that it will be furnished in hard copy upon request in plans that have sub-networks.

MAOs also may publish separate primary care physician (PCP) and specialty physician directories provided both directories are available, online and hard copy, to enrollees at the time of enrollment and throughout the contract year.

MAOs' MA-PD plans may combine the model provider and model pharmacy directories in one document. The guidance in this section, combined with the specific guidance on pharmacy directories, should be followed when creating a combined provider/pharmacy directory.

110.2.2 – Provider Directory Updates

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

MAOs are expected to update directory information any time they become aware of changes. All updates to the online provider directories are expected to be completed within 30 days of receiving information. Updates to hardcopy provider directories must be completed within 30 days, however, hardcopy directories that include separate updates via addenda are considered up-to-date.

MAOs should contact their network/contracted providers on a quarterly basis to update the following information in provider directories:

- Ability to accept new patients;*
- Street address;*
- Phone number; and*
- Any other changes that affect availability to patients.*

MAOs should contact providers using a method that is likely to achieve the highest response rate. It is not sufficient to determine that a group practice is accepting new patients. Outreach does not apply to entities such as hospitals.

All providers listed in hard copy or online directories must have current contracts to participate in the MA plan network. Directories provided during the AEP for the upcoming plan year are expected to fairly represent the network for the upcoming plan year.

Note: Employer/Union-only Group Waiver Plans (EGWP) may direct enrollees to their employer for information on the available providers. Employer/Union-only Group Waiver Plans (EGWP) must comply with the same requirements that are applicable to all MA and PDP plans regarding the provision of hard copy and online directories.

110.2.3 – Provider Directory Dissemination and Timing

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

MAOs must make the provider directory available to all enrollees at the time of enrollment, and at least annually thereafter by September 30.

MAOs have some flexibility in how they provide access to their provider directories. MAOs must send all enrollees either the provider directory in hard copy, or a distinct and separate notice (in hard copy) describing where enrollees can find the provider directories online and how enrollees can request a hard copy. This notice must be a stand-alone document (i.e., not bound with other materials) and may be included in the

same mailing envelope as the Annual Notice of Change/Evidence of Coverage (ANOC/EOC).

To take advantage of this flexibility under § 422.11 to provide a notice of on-line availability instead of providing a hard copy, an MAO must include in the notice the following to ensure that enrollees may access a hard copy:

- If the MAO will not allow requests for a hard copy by email: “If you need help finding a network provider, please call [customer service phone #] or visit [URL] to access our online [searchable, if applicable] directory. If you would like a provider directory mailed to you, you may call the number above, or request one at the website link provided above.”;*
- If the MAO will allow requests for a hard copy by email: “If you need help finding a network provider, please call [customer service phone #] or visit [URL] to access our online [searchable, if applicable] directory. If you would like a provider directory mailed to you, you may call the number above, request one at the website link provided above, or email [MAO email address].”*

110.2.4 – Online Provider Directory Requirements

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

MAOs must post a provider directory for all products offered by service areas or by general geographic area. The provision of accurate provider information and ensuring adequate access to covered services are essential protections for enrollees. Accurate provider directories are critical to helping enrollees make educated decisions about their MA plan choices.

The following formats for the online provider directory are acceptable:

- A searchable “master” provider directory that represents the complete network for the MAO;*
- Individual provider directories by plan product and/or service area (e.g., mirroring those that will be printed for the MAO membership); and*
- A search engine. If an MAO uses only a search engine on its website, it must meet all the requirements for the model Directory.*

MAOs must also provide the option on their websites for users to request a hard copy provider directory, as applicable. MAOs are expected to mail the requested hard copy directory within three (3) business days of the request.

110.2.5 – Provider Directory Disclaimers

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

The following is expected to be included in hardcopy and online provider directories if a directory is for a subset of a service area, Plans must advise members that: “This directory is for <geographic area>.”

110.2.6 – Provider Directory Submissions to CMS

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

MAOs must submit their hardcopy directories to CMS on a yearly basis. All hardcopy directories must be uploaded into HPMS as a non-marketing material under the XXX submission code. All hardcopy directories must be uploaded prior to making the directory available by September 30.

Note that updates and/or addenda pages are not to be uploaded. Because provider directories are considered non-marketing, MAOs should not include a status after the material ID. To distinguish the provider directories as non-marketing, the following material ID should be used: MAO’s contract number, followed by an underscore, followed by a series of alpha numeric characters chosen at the discretion of the MAO, followed by an underscore, followed by the letters “NM” (for example, H1234_ABC123_NM).

110.3 – Health Maintenance Organization (HMO) and HMO Point of Service (POS) Coverage and Access

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

HMOs restrict the network of providers from which a beneficiary can receive non-urgent/emergent covered services. HMOs furnish in-network services only.

To ease restrictions on access to out-of-network providers, however, an HMO may offer a point of service (POS) benefit option. The following rules apply to an HMOPOS:

- *Enrollees are allowed the option of receiving specified services outside of the plan's provider network;*
- *An HMOPOS may require enrollees to incur increased cost-sharing for POS services;*
- *An HMOPOS benefit option may limit out-of-network coverage to a specific service or services, and may also limit the dollar amount of coverage that will be provided; and*
- *The HMOPOS option may be offered as a mandatory supplemental benefit or as an optional supplemental benefit.*

For more information about the POS benefit option for an HMO, see section 30.3 above.

110.4 – Preferred Provider Organization (PPO) Coverage and Access

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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;*
- PPO plans 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 that 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.*

110.5 – Special Rules for RPPOs

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

110.5.1 -- Access through Non-contracted Providers

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Situations may arise where an MA plan cannot establish contracts with providers that meet Medicare access requirements in portions of an RPPO's defined service area. In such cases, RPPOs may meet Medicare access requirements by demonstrating to CMS' satisfaction that there is adequate access to all plan-covered services through arrangements other than through contracted provider (42 CFR §422.112(a)(1)(ii)). Enrollees who receive plan-covered services in non-network areas of an RPPO must be covered at in-network cost-sharing levels for the enrollee.

110.5.2 – Essential Hospitals

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 at §422.112(c) 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.

110.6 – Ensuring Coordination of Care

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 risk assessment (HRA) 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 its best effort to conduct an HRA annually and follows up on unsuccessful attempts to contact an enrollee.*

- *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.*

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

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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

<i>Plan Type</i>	<i>Is a gatekeeper¹ allowed?</i>	<i>Is a network required?</i>	<i>Must benefits be provided In-network and OON?</i>	<i>May Cost-sharing requirements differ In-network/OON</i>
<i>HMO</i>	<i>Optional</i>	<i>Must contract</i>	<i>Must provide In-network only</i>	<i>Not applicable</i>
<i>HMOPOS</i>	<i>Optional</i>	<i>Must contract</i>	<i>Must provide in-network; must provide specific OON</i>	<i>May have higher cost-sharing OON</i>
<i>PPO, RPPO</i>	<i>Optional, In-network; Prohibited Out-of-network (OON)</i>	<i>Must contract²</i>	<i>Must provide both in-network/OON</i>	<i>May have higher cost-sharing OON</i>
<i>MSA and PFFS</i>	<i>Prohibited</i>	<i>May use full, partial, or non-network model</i>	<i>Must provide both in-network/OON</i>	<i>May have higher cost-sharing OON</i>

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 RPP0 must contract with a network, it may, upon obtaining a waiver from CMS, only contract with a network in part of its service area (42 CFR § 422.112(a)(1)(ii)).

120.1 – General Rule

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 (*see 42 CFR §422.106(a)(2)*). 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 *MMCM*, for further information.

120.2 – Requirements, Rights, and Beneficiary Protections

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 Medicare Marketing Guidelines for further discussion at:

<https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2016-Medicare-Marketing-Guidelines-Updated.pdf>.)

Medicaid benefits provided through a contract with an *MAO* 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

For more details on employer/union coverage see *chapter 9* of the *MMCM*, “Employer/Union-Sponsored Group Health Plans.”

130.1 – Basic Rule

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 chapter 9 of the MMCM* “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.

130.3 – Medicare Benefits Secondary to Group Health Plans (GHPs) and Large Group Health Plans (LGHPs) and in Settlements

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

Secondary payer status can arise from legal settlements, as well as other insurance plans. *MAOs* 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 *may* 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

130.7 – Medicare as Secondary Payer (MSP) Rules and State Laws

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *MMCM*, "Payments to Medicare Advantage Organizations" for further discussion of Medicare Secondary Payer and Coordination of Benefits.)

140.1 – Service Area Defined

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *MAO*. 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 *MAO* 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 *MAO* 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 *MMCM*, "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 *MAO* must cover urgently needed services.

140.2 – Factors That Influence Service Area Approvals

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *MMCM*, "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" *that a service area generally consists of a full county or counties as* described in § 422.2 (definition of service area) and below in *section 140.3; and*
- 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.

140.3 – Partial County Service Areas

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 *MAO and whether there are other MA plans serving the entire county*.

140.3.1 – Necessity

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

For CMS to determine that a partial county is **necessary**, an *MAO* must be able to demonstrate *that* the MAO cannot establish a provider network to make health care services available and accessible to beneficiaries residing in the portion of the county to be excluded from the service area.

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 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.

140.3.2 – Non-Discriminatory

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

For CMS to determine if a partial county is **non-discriminatory**, an **MAO** 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 **MAO** is requesting a service area reduction (creating a new partial county) the **MAO** 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 **MAO** 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.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

In order for CMS to determine whether a partial county is in the **best interest of beneficiaries**, an **MAO** must provide reasonable documentation to support their request. *As previously noted, CMS will generally only approve partial counties when it is not possible for an MAO to serve an entire county.*

An **MAO** 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 portions of the county *to be excluded from the service area.*

150 – Benefits during Disasters and Catastrophic Events

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 must:

- *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.

MAOs must disclose their policies about providing benefits during disasters on their plan websites.

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.

160 – Beneficiary Protections Related to Plan-Directed Care

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 MMCM 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.

170 – Balance Billing

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

170.1– Definitions

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

170.2 – Balance Billing by Provider Type

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 MMCM, “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.

180 – Information on Advance Directives

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

180.1 – Definition

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

180.2 – Basic Rule

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 MAO 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 180.4.

180.3 – State Law Primary

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

180.4 – Content of Enrollee Information and Other MA Obligations

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 MAO 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 MAO'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 180.3 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.*

180.5 – Incapacitated Enrollees

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

180.6 – Community Education Requirements

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

180.7 – MAO Rights

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

180.8 – Anti-discrimination Rights

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

190 – Part C Explanation of Benefits (EOB)

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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>.

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

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

200.1 – Defining Guidance

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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.

200.2 – Relationship to D-SNP Eligibility/Enrollment

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 MMCM chapter 2 for guidance on D-SNP eligibility and enrollment.

200.3 – Relationship to Dual Eligible Demonstration Programs

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

MAOs should be aware of how an enrollee's eligibility for Medicaid might affect their enrollees' continued plan enrollment in those states or counties where Financial Alignment Initiative demonstrations with passive enrollment exist. More information, including state-specific names for the Financial Alignment Initiative, is available at <https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/FinancialModelstoSupportStatesEffortsinCareCoordination.html>.

200.4 – Scope of Financial Assistance Programs

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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)*

200.5 – Targeting Membership

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 MAO must provide outreach to all enrollees within those pre-identified population segments. Additionally, if the MAO 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.

200.6 – Required Elements of Education/Enrollment Assistance Programs

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

In its education and enrollment assistance programs, the MAO 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 MAO’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 MAO 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 MAO's efforts.

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

200.7 – CMS Oversight

(Rev.121, Issued: 04-22-16, Effective: 04-22-16, Implementation: 04-22-16)

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 MAO 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.*