CMS Manual System	Department of Health & Human Services (DHHS)
Pub. 100-16 Medicare Managed Care	Centers for Medicare & Medicaid Services (CMS)
Transmittal 61	Date: SEPTEMBER 3, 2004

I. SUMMARY OF CHANGES:

Chapter 4

Section 130.2 - Emergency and Urgently Needed Services - Clarified that the M+C organization is not responsible for the care provided for an unrelated non-emergency problem during treatment for an emergency situation.

NEW\REVISED - EFFECTIVE DATE: September 3, 2004

Chapter 17, Subchapter F

Sections 10 - 130 - is a new chapter describing benefits and beneficiary protections.

NEW\REVISED - -EFFECTIVE DATE: September 3, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

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

R/N/D	CHAPTER/SECTION/TITLE
R	4/130/130.2/Emergency and Urgently Needed Services
N	17/Subchapter 17F

III. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Special Notification

130.2 - Emergency and Urgently Needed Services

(Rev. 61, 09-03-04)

Definitions

An **emergency medical condition** is a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

- Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;
- Serious impairment to bodily functions; or
- Serious dysfunction of any bodily organ or part.

Emergency services are covered inpatient and outpatient services that are:

- Furnished by a provider qualified to furnish emergency services; and
- Needed to evaluate or stabilize an emergency medical condition.

Urgently needed services are covered services that are not emergency services as defined in this section, provided when an enrollee is temporarily absent from the M+C plan's service (or, if applicable, continuation) area when the services are medically necessary and immediately required:

- As a result of an unforeseen illness, injury, or condition; and
- It was not reasonable given the circumstances to obtain the services through the organization offering the M+C plan.

Note that under unusual and extraordinary circumstances, services may be considered urgently needed services when the enrollee is in the service or continuation area, but the organization's provider network is temporarily unavailable or inaccessible.

M+C organization responsibility. The M+C organization is financially responsible for emergency services and urgently needed services:

- Regardless of whether services are obtained within or outside the M+C organization;

- Regardless of whether there is prior authorization for the services. In addition:

    - No materials furnished to enrollees (including wallet card instructions) may contain instructions to seek prior authorization for emergency or urgently needed services, and enrollees must be informed of their right to call 911;

    - No materials furnished to providers, including contracts, may contain instructions to providers to seek prior authorization before the enrollee has been stabilized.

- In accordance with a prudent layperson's definition of "emergency medical condition" regardless of the final medical diagnosis;

    - The M+C organization is not responsible for the care provided for an unrelated non-emergency problem during treatment for an emergency situation. For example, the M+C organization is not responsible for any costs, such as a biopsy, associated with treatment of skin lesions performed by the attending physician who is treating a fracture.

- Whenever a plan provider or other M+C organization representative instructs an enrollee to seek emergency services within or outside the plan.

Stabilization of an Emergency Medical Condition

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 M+C organization.

Chapter 13 of this manual, "*Medicare+Choice Beneficiary Grievances, Organization Determinations, and* Appeals," addresses the enrollee's right to request a Quality Improvement Organization review for hospital discharges to a lower level of care. For transfers from one inpatient setting to another inpatient setting, an enrollee (or person authorized to act on his or her behalf) who disagrees with the decision and believes the enrollee cannot safely be transferred, can request that the organization pay for continued out-of-network services. If the M+C organization declines to pay for the services, appeal rights are available to the enrollee.

Limit on Charges for Emergency Services

Enrollees' charges for emergency services, i.e., outpatient and inpatient services until stabilized (as defined above), cannot exceed the lesser of :

- $50; or
- What the enrollee would be charged if he or she obtained the services through the M+C organization.

Medicare Managed Care Manual

Chapter 17 - Subchapter F

Benefits and Beneficiary Protections

Table of Contents

(Rev. 61, 09-03-04)

10 - General Requirements
20 - Requirements of Specific Benefits
30 - Hospice
40 - Medicare-Covered Benefits
50 - Financial Responsibility
60 - Out-of-Area, Out-of-Network and Extended Absence
70 - Cost Employer Group Health Plans (EGHP)
80 - Medicare Secondary Payer
90 - National Coverage Determinations and Legislative Changes In Benefits
100 - Discrimination Against Beneficiaries Prohibited
110 -Disclosure Requirements
120 - Confidentiality and Records
130 - Availability, Accessibility, and Continuity
140 - Information on Advance Directives

---

10 - General Requirements

(Rev. 61, 09-03-04)

(42 CFR 417.440) This section presents details and requirements on several frequently occurring situations in which an HMO or CMP provides:

- **Medicare Part A/B Services:** Each Medicare enrollee is entitled to receive all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if the enrollee

is entitled only to benefits under Part B) that are **available** to beneficiaries residing in the HMO's or CMP's **geographic area**.

The services are considered **available** if either the sources of services are located in the HMO or CMP's approved geographic area or it is common practice to refer patients to sources outside that geographic area (42 CFR 417.414(b)(2)).

(42 CFR 417.401) The term **geographic area** refers to the area found by CMS to be the area within which the HMO or CMP furnishes, or arranges for furnishing, the full range of services that it offers to its Medicare enrollees.

- **Emergent and Urgent Care:** (42 CFR 417.401) Each Medicare enrollee is entitled to receive timely and reasonable payment directly (or have payment made on his or her behalf) for services he or she obtained from a provider or supplier outside the HMO or CMP if those services are:

  - Emergency services or urgently needed services as defined below. The HMO or CMP must pay for emergent and urgently needed services even from providers and suppliers outside the HMO or CMP and even in the absence of the HMO's or CMP's prior approval (42 CFR 417.414(c)); or

  - Services denied by the HMO or CMP and found upon appeal to be services the enrollee was entitled to have furnished by the HMO or CMP.

    Emergency Services means covered inpatient or outpatient services that are furnished by an appropriate source other than the HMO or CMP that:

    - Are needed immediately because of an injury or sudden illness; or

    - Are such that the time required to reach the HMO's or CMP's providers or suppliers (or alternatives authorized by the HMO or CMP) would mean risk of permanent damage to the enrollee's health.

    Once initiated, the services continue to be considered emergency services as long as transfer of the enrollee to the HMO's or CMP's source of health care or authorized alternative is precluded because of risk to the enrollee's health or because transfer would be unreasonable, given the distance and the nature of the **medical** condition; and

    Such services must be, or appear to be, needed immediately.

Urgently Needed Services means covered services that are needed by an enrollee who is temporarily absent from the HMO's or CMP's geographic area and that:

- Are required in order to prevent serious deterioration of the enrollee's health as a result of unforeseen injury or illness; and

- Cannot be delayed until the enrollee returns to the HMO's or CMP's geographic area.

The HMO or CMP need not pay for post-stabilization services offered outside of its network or not approved by the HMO or CMP if:

- These services are not emergency;

- These services are not urgently needed; and

- These services are not offered by the HMO or CMP as a basic or optional supplemental benefit.

However, medically necessary follow-up care to emergency and urgent care is covered, if the care cannot be delayed without adverse medical effects.

Routine out-of-area renal dialysis is covered only under original Medicare.

- **Optional Supplemental Benefits**: In addition to offering a basic benefit package (that is, Medicare-covered benefits), each HMO or CMP may offer (for election by the enrollee and without regard to health status) optional supplemental services or benefits - that is, services or benefits that are in addition to those included in the basic benefits. All optional supplemental benefits must be offered for a period of at least 30 consecutive days to both new plan enrollees and to all current enrollees of a plan at least once a year.

  Although an HMO or CMP may limit the availability of optional supplemental benefits to current enrollees as described above, enrollees may voluntarily drop or discontinue optional supplemental benefits any time during the contract year upon proper advance notice to the HMO or CMP.

  The HMO or CMP may not set health status standards for those enrollees whom it will accept for these optional supplemental services.

  States may mandate that non-Medicare benefits be offered to Medicare Cost enrollees as optional supplemental benefits.

- **Waiting Periods and Exclusions Not Present In Medicare:** (Chapter 4, §10.7 of the Medicare Managed Care Manual) All beneficiaries must be provided all medically necessary benefits covered in the pan in which they enroll (including supplemental benefits) at the time of their initial enrollment. Waiting periods or exclusions from coverage, due to pre-existing conditions, are not permitted. However, an HMO or CMP can deny coverage of Medicare-covered services when the services do not meet the standard of being medically necessary and appropriate. In addition, an HMO or CMP may impose limitations or exclusions on Medicare-covered benefits to the extent that such limitations or exclusions are present in the original Medicare statute or regulations.

- **Services and Supplies:** Each Medicare enrollee is entitled to receive both:

  - Health care services; and

  - Supplies;

  Either:

  - Directly from; or

  - Through arrangements made by the HMO or CMP.

20 - Requirements of Specific Benefits

(Rev. 61, 09-03-04)

Drugs That Are Covered Under Original Medicare

(Chapter 4, §10.7 of the Medicare Managed Care Manual) For this bullet, the term "drug" means "drug or biological."

- Injectable drugs have been determined by Medicare carriers (and in some cases Fiscal Intermediaries) to be "usually not self-administered" and that are administered incident to physician services. For further information, see Program Memorandum AB-02-072 (May 15, 2002) and Program Memorandum AB-02-139 (October 11, 2002), found at CMS 2002 Program Memos:

  - Drugs that the M+C enrollee takes while using durable medical equipment (such as nebulizers) that were authorized by the enrollee's M+C plan;

  - Clotting factors if the enrollee is diagnosed with specific clotting disorders;

  - Immunosuppressive drugs, if the enrollee had an organ transplant that was covered by Medicare;

  - Injectable osteoporosis drugs, if the enrollee is homebound, has a bone fracture that a doctor certifies was related to post-menopausal osteoporosis, and cannot self-administer the drug;

- Antigens;

- Certain oral anti-cancer drugs and anti-nausea drugs; and

- Erythropoietin by injection if the member has end-stage renal disease and needs this drug to treat anemia.

Effective August 1, 2002, if an M+C enrollee wishes to receive a "not usually self-administered" drug in a physician's office, then the M+C organization must cover the drug and the service of administering the drug. That is, M+C organizations may not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered incident to physician services. (M+C organizations can continue to make determinations concerning the appropriateness of a drug to treat a patient's condition, and the appropriateness of the intravenous or injection form as opposed to the oral form of the drug.)

HMO or CMPs can choose to cover, as an additional benefit, injectable drugs that the local carrier has determined are not usually self-administered, but that members purchase at a pharmacy and administer at home. However, HMO or CMP enrollees always have the option of receiving the Medicare-covered benefit, i.e., administration of the covered drug in a physician's office.

A list of drugs excluded from coverage, by carrier, is available on the HPMS Web site.

Drug Benefit Caps

(Chapter 4, §10.7 of the Medicare Managed Care Manual) HMO and CMPs frequently design M+C plans in which a beneficiary receives coverage for outpatient prescription drugs that would not normally be covered under the Medicare program. The CMS has approved non-Medicare prescription drug benefits that provide for annual, quarterly and monthly caps on the dollar amount of benefits available to enrolled members. An HMO or CMP may also pro-rate an annual drug benefit that has an annual cap. Pro-rating of the annual cap is permitted according to the member's enrollment date, since this would be similar to, but more generous than, a quarterly or monthly cap. (42 CFR 417.104(a)(4)(ii)) The tracking of out of pocket maximums is the responsibility of the enrollee, not the plan. As indicated in §110 of this subchapter, the HMO or CMP must clearly notify the beneficiary of this limitation.

Mid-year Drug Benefit Changes

(Chapter 4, §10.7 of the Medicare Managed Care Manual) The CMS is providing HMOs and CMPs the opportunity to change their drug formulary during the contract year. Plans may:

- Add drugs to their formulary;
- Remove drugs from their formulary; and
- Move drugs to different tier levels.

Plans that wish to remove a drug from their formulary during the contract year are required to establish an exceptions process. This exceptions process will provide physicians a mechanism to continue prescribing drugs that are determined to be medically necessary and that were on the formulary when the Medicare beneficiary enrolled. The HMO or CMP will determine how the exceptions process will work and can include reviewers who determine whether or not the request for an exception is medically appropriate and/or whether or not an exception will be granted.

An HMO or CMP that changes their formulary must notify beneficiaries as discussed in §110 of this subchapter.

Items and Services That Are Not Considered Benefits

(Chapter 4, §10.7 of the Medicare Managed Care Manual) An HMO or CMP is allowed to list their Medicare endorsed discount drug card in their Plan Benefit Package (PBP). However, Pharmacy discount programs or benefits (offered as a Value Added Item and Service - (VAIS)), although they may be listed in the PBP, are not considered benefits. All other VAIS are not considered benefits and may not be listed in the PBP. Examples of value-added items and services are discussed more fully in Chapter 3 of the Medicare Managed Care Manual, "Marketing."

Authorization and Cost-Sharing

HMOs or CMPs:

- Must permit in-network direct access to influenza vaccines;
- May not impose cost sharing for influenza vaccines;
- Must permit in-network direct access to screening mammographies; and
- Non-emergent non-urgent-care services that HMO or CMP enrollees obtain from non-network providers, when not referred, are covered under Original

Medicare and subject to Medicare Fee-for-Service coinsurance and deductible requirements.

30 - Hospice

(Rev. 61, 09-03-04)

An HMO or CMP is not reimbursed through the Section 1876 Cost Program for the provision of Hospice care. Medicare-covered Hospice care may only be furnished by a Medicare Certified Hospice. An enrollee may elect hospice care if they are entitled to Part A Medicare benefits and if a physician certifies the enrollee as terminally ill.

(42 CFR 417.423(2)(b)) Individuals who have already made a hospice election may not enroll in an HMO or CMP. However an individual who makes a hospice election while enrolled in an HMO or CMP may remain with the HMO or CMP during the hospice election.

(42 CFR 417.414(b)(3)) Each HMO or CMP must inform their Medicare enrollees about the availability of hospice care if:

- A hospice participating in Medicare is located within the HMO's or CMP's geographic area; or

- It is common practice to refer patients to hospices outside the geographic area.

(42 CFR 417.440(c)) An individual enrolled in an HMO or CMP who elects to receive hospice care waives the right to receive from the HMO or CMP any Medicare services that:

- Are equivalent to hospice care; or

- Are related to the terminal condition for which the enrollee elected hospice care or to a related condition.

However, since HMOs or CMPs continue to receive interim payments during the period of hospice election, they must also continue to provide and pay for all non-hospice related care that the Medicare member seeks from the HMO or CMP provided that:

- His or her attending physician is an employee or contractor of the HMO or CMP;

- His or her attending physician is not an employee of the Hospice; and

- His or her attending physician does not receive compensation from the hospice for these activities.

In the event an enrollee elects hospice care the relevant start and termination dates of coverage are discussed in the subpart of this cost chapter dealing with enrollment.

40 - Medicare-Covered Benefits

(Rev. 61, 09-03-04)

(From Section 4.30 of the Medicare Managed Care Manual) As indicated in §10 of this subchapter, HMOs or CMPs must generally provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if the enrollee is entitled only to benefits under Part B) that are available to beneficiaries residing in the plan's geographic area.

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

The scope of the benefits under Part A and Part B is defined in the Act. The scopes of Part A and Part B are discussed in §1812 and §1832 of the Act respectively, while §1861 of the Act lays out the definition of medical and other health services. Each HMO or CMP must offer at least all Part A benefits (other than hospice care) and all Part B benefits (or all Part B benefits to those entitled to only Part B) to all individuals residing in the area served by the plan in all benefit packages in its authorized geographic area Some benefit categories are defined more broadly than others. Specific health care services must fit into one of these benefit categories, and not be otherwise excluded for coverage under the Medicare program.

The Act does not contain a comprehensive list of specific items or services eligible for Medicare coverage. Rather, it lists categories of items and services, and vests in the Secretary the authority to make determinations about which specific items and services within these categories can be covered under the Medicare program. That is, the Act allows Medicare to cover medical devices, surgical procedures and diagnostic services, but generally does not identify specific covered or excluded items or services. Further guidance is presented in the Code of Federal Regulations and CMS interpretations. Medicare payment is contingent upon a determination that:

- A service meets a benefit category;
- Is not specifically excluded from coverage; and
- The item or service is "reasonable and necessary."

Section 1862(a)(1)(A) of the Act states that, subject to certain limited exceptions, no payment may be made for any expenses incurred for items or services that are not "reasonable and necessary" for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member. These authorities are exercised to make coverage determinations regarding whether a specific item or service meets one of the broadly defined benefit categories and can be covered under the Medicare program. National coverage decisions are published on the National Coverage Web site - for further information please see §90 of this subchapter.

In the absence of a specific National Coverage Decision, coverage decisions are made, at the discretion of local contractors. An HMO or CMP is required to follow any local medical review policies (LMRP) issued by the fiscal intermediaries and carriers in its geographic area.

50 - Financial Responsibility

(Rev. 61, 09-03-04)

Financial Responsibility

(42 CFR 417.414(c)) The HMO or CMP assumes financial responsibility to provide reasonable reimbursement to its enrollees for:

- Emergency services; and
- Urgently needed services (as defined above);

Even:

- From providers and suppliers outside the HMO or CMP;

And even:

- In the absence of the HMO's or CMP's prior approval.

The HMO or CMP also assumes financial responsibility for:

- Services that were initially denied, but later granted, due to an appeal by the enrollee.

(42 CFR 417.452) An HMO or CMP may impose:

- Deductibles;
- Coinsurance; or

- Copays;

for any of the services which it provides except for influenza vaccines for which no copays may be charged)

An HMO or CMP may impose annual, semi-annual, quarterly, monthly or any other periodic limits on the Optional Supplemental Benefits it offers its enrollees provided these limits are not prohibited by State law.

The HMO or CMP may not impose caps on any Medicare covered benefit unless original Medicare also imposes a cap (for example, the 100-day limit on SNF benefits).

The deductibles and coinsurances may be paid by or on behalf of the enrollee in the form of a:

- Premium;
- Membership fee;
- Charge per unit; or
- Other similar charge.

(42 CFR 417.454) The HMO or CMP must agree to charge its Medicare enrollees only for the:

- Deductible and coinsurance amounts applicable to furnished Medicare covered services;
- Premium and cost-sharing charges for services offered as supplemental benefits provided that the sum of the amounts an HMO or CMP charges its Medicare enrollees for these services does not exceed the actuarial value for those services (42 CFR 417.452(d)(3));
- Charges for services not covered under the plan; and
- Services for which Medicare is not the primary payer if payment for the services has been made to the enrollee (42 CFR 417.528(b)(2)).

Refunds and Recoupment

(42 CFR 417.456(b)) An HMO or CMP must agree to refund all amounts **incorrectly collected** from its Medicare enrollees, or from others on behalf of the enrollees, and any **other amounts due** the enrollees or others on their behalf.

(42 CFR 417.456(a)) **Amounts incorrectly collected** means amounts collected that are in excess of those due to:

- Deductibles;
- Coinsurances;
- Non-covered Medicare services (which are not supplemental benefits);
- Services for which Medicare is not the primary payer; or
- Supplemental benefit premiums and copays**.**

Amounts incorrectly collected include amounts collected when the enrollee was believed not entitled to Medicare benefits if the enrollee is later determined, upon appeal, to have been entitled to Medicare benefits and CMS is liable for these payments.

Other amounts due means amounts due a Medicare enrollee for services obtained outside the HMO or CMP if they were:

- Emergency services;
- Urgently needed services for which the HMO or CMP has assumed financial responsibility; or
- On appeal, found to be services the enrollee was entitled to have furnished by the HMO or CMP.

In general an HMO or CMP may make payments to enrollees either in the form of lump sum payments, premium adjustment, or both.

Refunds by Lump Sum Payments

(42 CFR 417.456(c)) An HMO or CMP must make refunds to its current and former Medicare enrollees, or to others who have made payments on behalf of enrollees, by lump sum payment for the following:

- Incorrectly collected amounts that were not collected as premiums;
- Other amounts due; and
- All amounts due, if the HMO or CMP is going out of business.

Refund by Premium Adjustment or Lump Sum Payment or Both

An HMO or CMP may make refund by adjustment of future premiums, by lump sum payment, or by a combination of both methods, for:

- Amounts that were incorrectly collected in the form of premiums; or

- For amounts that were incorrectly collected through a combination of premium payments and other charges.

If an enrollee has died or cannot be located after reasonable effort by the HMO or CMP, the HMO or CMP must make the refund in accordance with State law.

If the HMO or CMP does not make refund in accordance with the above payment methods by the end of the contract period following the contract period during which an amount was determined to be due an enrollee, CMS reduces its payment to the HMO or CMP by the amounts incorrectly collected or otherwise due, and arranges for those amounts to be paid to the Medicare enrollee.

Recoupment

(42 CFR 417.458) An HMO or CMP agrees not to recoup deductible and coinsurance amounts for which Medicare enrollees were liable in a previous contract period except in the following circumstances:

- The HMO or CMP failed to collect the deductible and coinsurance amounts during the contract period in which they were due because of:

    - Underestimation of the actuarial value of the deductible and coinsurance amounts; or

    - A billing error;

- The HMO or CMP has identified the amounts and obtained advance CMS approval of the recoupment and the method and timing of recoupment;

- The HMO or CMP collects these amounts no later than the end of the contract period following the contract period during which they were found to be due.

60 - Out-of-Area, Out-of-Network and Extended Absence

(Rev. 61, 09-03-04)

Services obtained from non-network providers (when not referred) are covered under the Fee-For-Service program (and thus subject to Medicare Fee-For-Service coinsurance and deductible requirements), unless they are emergency or urgently needed services. For

emergency or urgently needed services the HMO or CMP is liable for reimbursement and the contracted member cost sharing applies. Emergency and urgently needed services are defined in §10 of this subpart.

As discussed in further detail in the enrollment section of this chapter an HMO or CMP must disenroll an individual if that individual has **permanently moved** from the HMO's or CMP's geographic area. An uninterrupted absence of 90 days is deemed to be a **permanent move** and the individual must be disenrolled unless the HMO offers an **extended absence option** (42 CFR 417.460).

An HMO or CMP that chooses to offer an **extended absence option** may retain members who temporarily (more than 90 days but less than one year) leave the geographic area but remain in the United States either:

- By paying for all covered services for such members based on mutually agreeable restrictions; or

- By providing services through an affiliated organization (42 CFR 417.460(f)(2)).

(42 CFR 417.460(f)(2)(ii)-(iii)) An HMO or CMP that chooses to exercise this exception must make the option available to all Medicare enrollees who are absent for an extended period from their geographic areas. However an HMO or CMP may limit this option to enrollees who go to a geographic area served by an affiliated HMO or CMP.

When an HMO or CMP offers an extended absence option it must provide all Part A and Part B services ; however supplemental benefits for which the member is paying a premium may be discontinued on leaving the geographic area as long as the member is not required to continue paying the premium or portion of a premium that corresponds to these services.

70 - Cost Employer Group Health Plans (EGHP)

(Rev. 61, 09-03-04)

(42 CFR.440(b)) In general, since enrollment in a Cost HMO/CMP is at the organizational (not the plan) level, therefore, all enrollees of an HMO/CMP must receive the same basic package for the same cost-sharing or copayment amounts. However, employer groups can negotiate privately an EGHP on behalf of employer group members. An EGHP:

- May elect only some, but not all of the optional supplemental benefits offered by an HMO/CMP for its members;

- May "buy-down" premium and cost-sharing for its members; and

- May negotiate for benefits not covered by Medicare. Such privately negotiated non-Medicare benefits (with their associated premiums and copays) are deemed "outside" the CMS Medicare contract.

80 - Medicare Secondary Payer

(Rev. 61, 09-03-04)

Basic Rule

The rules for Medicare Secondary payer are covered with computational detail in Chapter 17B of the Medicare Managed Care Manual. We add the following two comments:

Collection From GHPs and LGHPs

When an HMO or CMP is the secondary payer to an employer group health plan, the coordination of benefits occurs in the aggregate through the cost report process. This process results in a copayment as part of the HMO or CMP benefit package for which every enrollee is liable. Therefore, there is no coordination of benefits on a beneficiary-specific basis that would relieve an enrollee with employer group health plan coverage of his or her cost sharing obligation under the HMO or CMP. As a result, the enrollee remains liable for payment of the HMO's or CMP's cost sharing regardless of whether Medicare is primary or secondary. However, under 42 CFR 417.454, which addresses beneficiary financial protection contained in the contract between the HMO or CMP and CMS, the HMO or CMP is responsible for relieving the beneficiary of responsibility for payment of health care costs other than cost sharing, and therefore, the HMO or CMP must relieve the enrollee of his or her liability under the terms of the employer group health plan.

For example, if the employer group health plan (the primary payer) has a copayment of $20 and the HMO or CMP has a copayment of $10 for the service the beneficiary received, the beneficiary cannot be liable to pay more than the plan copayment of $10. The HMO or CMP must absolve the beneficiary of the liability for any amount in excess of the plan copayment of $10.

MSP Rules and State Laws

Consistent with Federal preemption of state law the rules established in this chapter supersede any state laws, regulations, contract requirements, or other standards that would otherwise apply to HMO or CMP plans only to the extent that those state laws are inconsistent with the standards established for the HMO/CMP program. Thus, HMOs or CMPs could pursue their federally authorized claims under the remedies provided under state law as a state licensed insurer or health care plan. Federal preemption of state laws in the MSP context would occur only to the extent a state law would prohibit an HMO or CMP from complying with what the Federal rules authorize (that is, from billing and

recovering from specified third parties, and from beneficiaries to the extent they have received third party payments that are primary to Medicare under MSP rules). State law could modify an HMO's or CMP's rights as to the amount of recovery, but could not deny them entirely.

90 - National Coverage Determinations and Legislative Changes In Benefits

(Rev. 61, 09-03-04)

Definitions

(Chapter 4, §90 of the Medicare Managed Care Manual) 1A National Coverage determination (NCD) is a determination by CMS about whether or not a particular item or service is covered nationally under Medicare. The HMOs or CMPs must comply with all NCDs.

A legislative change in benefits refers to new Medicare coverage of an item or service mandated by the Congress.

General Rules

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

1. National coverage determinations made by CMS;

2. Other coverage guidelines and instructions issued by CMS (e.g., Program Memoranda and Program Transmittals);

3. Legislative changes in benefits; and

4. Local medical review policies established by Medicare contractors for local areas.

As indicated in §10 of this subchapter HMOs or CMPs must provide all Medicare-covered benefits. Consequently HMOs and CMPs must furnish, arrange, or pay for all new NCDs and legislative changes as soon as they take effect. This is true independent of whether the NCD or legislative change meets a criterion for **significant cost**. A determination of **significant cost** has no relevance to the HMO/CMP program. For these services or benefits, the Medicare enrollee will be responsible for HMO or CMP cost sharing as approved by CMS. The costs incurred by the HMO or CMP for furnishing of these benefits may be included on their annual cost report.

Sources for Obtaining Information

In an effort to make the coverage process more open, understandable, and predictable, CMS has redesigned its Medicare coverage process. Part of the redesign includes using the Internet to inform interested parties about how national coverage determinations are made and the progress of each issue under coverage review. The Web page on NCDs which is hyperlinked to the coverage page found at http://www.cms.hhs.gov/coverage/, lists both pending and closed coverage determinations. For each coverage topic on the NCD Web page, CMS provides a staff name and e-mail link so interested parties can use the Internet to send questions and to provide feedback.

The Medicare National Coverage Determinations Manual, Publication 100-3, is the primary record of Medicare national coverage policies, and includes a discussion of the circumstances under which items and services are covered. This manual may be accessed at http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp.

Additional information on new coverage can be found in the Program Memoranda and Program Transmittals that transmit CMS' new policies and procedures. These may be found at http://www.cms.hhs.gov/manuals/.

100 - Discrimination Against Beneficiaries Prohibited

(Rev. 61, 09-03-04)

General Prohibition

(Chapter 4, §100 of the Medicare Managed Care Manual) Except for not enrolling most individuals who have been medically determined to have end-stage renal disease, and except for not enrolling enrollees who have already elected hospice, an HMO or CMP may not deny, limit, or condition the coverage or furnishing of benefits to individuals eligible to enroll in an HMO or CMP on the basis of any factor that is related to health status, including, but not limited to the following:

- Medical condition, including mental, as well as physical illness;
- Claims experience;
- Receipt of health care;
- Medical history;
- Genetic information;
- Evidence of insurability, including conditions arising out of acts of domestic violence; and

- Disability.

An HMO or CMP may not disenroll an HMO or CMP member just because they develop end-stage renal disease while **enrolled** in the HMO or CMP. An individual who is an enrollee of a particular HMO or CMP, and resides in the HMO or CMP plan geographic area at the time he or she first becomes HMO or CMP eligible, is considered to be **enrolled** in the HMO or CMP for purposes of the preceding sentence.

Additional Requirements: An HMO or CMP is also required to observe the provisions of the Civil Rights Act, Age Discrimination Act, Rehabilitation Act of 1973, and Americans with Disabilities Act.

AN HMO's or CMP's Responsibility

An HMO or CMP must ensure that they have procedures in place to ensure that members are not discriminated against in the delivery of health care services consistent with the benefits covered in their policy based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

110 -Disclosure Requirements

(Rev. 61, 09-03-04)

(42 CFR 417.436) An HMO or CMP must offer its plan to Medicare beneficiaries and provide to those interested in enrolling, adequate written descriptions of the HMO's or CMP's rules, procedures, benefits, fees and other charges, services, and other information necessary for beneficiaries to make an informed decision about enrollment. The HMO or CMP must furnish a copy of the rules to each Medicare enrollee at the time of enrollment and at least annually thereafter. If an HMO or CMP changes its rules, it must submit the changes to CMS in accordance with proper procedure and notify its Medicare enrollees of the changes at least 30 days before the effective date of the changes.

An HMO or CMP must maintain written rules that deal with, but need not be limited to the following:

- All benefits provided under the contract;

- How and where to obtain services from or through the HMO or CMP;

- The restrictions on coverage for services furnished from sources outside an HMO or CMP, other than emergency services and urgently needed services;

- The obligation of the HMO or CMP to assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services;

- Any services other than the emergency or urgently needed services that the HMO or CMP chooses to provide from sources outside the HMO or CMP;

- The fact that the enrollee may receive services through any Medicare provider and supplier at Medicare cost-sharing levels;

- Premium information, including the amount (or if the amount cannot be included, the telephone number of the source from which this information may be obtained) and the procedures for paying premiums and other charges for which enrollees may be liable;

- Grievance and appeal procedures;

- Disenrollment rights;

- The obligation of an enrollee who is leaving the HMO's or CMP's geographic area for more than 90 days to notify the HMO or CMP of the move or extended absence and the HMO's or CMP's policies concerning retention of enrollees who leave the geographic area for more than 90 days;

- The expiration date of the Medicare contract with CMS and notice that both CMS and the HMO or CMP are authorized by law to terminate or refuse to renew the contract, and that termination or nonrenewal of the contract may result in termination of the individual's enrollment in the HMO or CMP;

- Advance directives (see §140 below); and

- Any other matters that CMS may prescribe.

For further information on disclosure see the subpart of this chapter that deals with Marketing materials.

120 - Confidentiality and Records

(Rev. 61, 09-03-04)

General Rule

For any medical records or other health and enrollment information it maintains with respect to enrollees, an HMO or CMP must establish procedures to do the following:

- Abide by all Federal and state laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The HMO or CMP must safeguard the privacy of any information that identifies a particular enrollee and have procedures that specify:

    - For what purposes the information will be used within the organization and

    - To whom and for what purposes it will disclose the information outside the organization;

- Ensure that medical information is released only in accordance with applicable Federal or state law, or pursuant to court orders or subpoenas;

- Maintain the records and information in an accurate and timely manner; and

- Ensure timely access by enrollees to the records and information that pertains to them.

130 - Availability, Accessibility, and Continuity

(Rev. 61, 09-03-04)

The Basic Rule

(42 CFR 417.416 supplemented with material from the HMO/CMP manual)

The HMO or CMP must ensure that the:

- Basic required services; and
- Any other optional supplemental services;

for which the Medicare enrollee has contracted are:

- Available;
- Accessible; and
- Furnished in a manner that ensures continuity.

Certification

The HMO or CMP must furnish the required services to its Medicare enrollees through providers and suppliers that meet applicable Medicare statutory definitions and implementing regulations.

- Hospitals, SNFs, HHAs, CORFs, and providers of outpatient physical therapy or speech-language pathology services must meet the applicable conditions of participation in Medicare;
- Suppliers must meet the conditions for coverage or conditions for certification of their services;
- If more than one type of practitioner is qualified to furnish a particular service, the HMO or CMP may select the type of practitioner to be used.

Provider Adequacy

The provider networks for Medicare enrollees must be sufficient to deliver both:

- Inpatient; and
- Outpatient services;

for both:

- Primary; and
- Specialty services;

to both:

- Current; and
- Expected Medicare members.

The obligation on the HMO or CMP to provide services remains even if there is a loss of providers in a portion of the geographic area. HMOs and CMPs must inform members, in writing, 30 days before a physician or supplier terminates affiliation.

Availability

Generally, an HMO or CMP is obligated to provide all Medicare Covered services, even if Medicare Certified facilities are not available in the geographic area. For example, if Fee-For-Service beneficiaries commonly seek services in another town outside the geographic area then the HMO or CMP must provide these services to its enrollees in a similar manner.

Accessibility

The HMO or CMP must ensure that the required services and any other services for which Medicare enrollees have contracted are accessible, with reasonable promptness, to the enrollees with respect to:

- Geographic location;
- Hours of operation;
- Provision of after hours service; and
- Medically necessary emergency services must be available twenty-four hours a day, seven days a week.

A general rule of thumb is the 30-30 rule that asserts that services must be available either within 30 miles of an enrollee's residence or within 30 minutes travel time. Exceptions however may be made if usual travel patterns for Fee-For-Service beneficiaries in parts of the geographic area exceed these amounts (as happens for example, in rural areas).

The HMO or CMP must have systems in place to collect data and evaluate the availability and accessibility of services provided or arranged for by the HMO or CMP. Some typical factors that are evaluated are:

- Waiting times;
- Member complaints;
- Emergency and urgent care;
- Requests for changes of primary care physicians;
- Physician requests to close their practice to new patients;
- Referrals; and
- Back-up arrangements.

Continuity of Care

Continuity of care refers to the continuous flow of care in a timely and appropriate manner. Continuity includes:

- Linkages between primary and specialty care;
- Coordination among specialists;
- Appropriate combinations of prescribed medications;
- Coordinated use of ancillary services;
- Appropriate discharge planning; and
- Timely placement at different levels of care including hospital, skilled nursing and home health care.

(42 CFR 417.407(f), 42 CFR 417.122(b)) In the case of insolvency the HMO must continue to provide benefits to all enrollees for the duration of the contract period for which payment was made.

Recordkeeping

The HMO or CMP must maintain a health (including medical) recordkeeping system through which pertinent information relating to the health care of its Medicare enrollees is accumulated and is readily available to appropriate professionals.

140 - Information on Advance Directives

(Rev. 61, 09-03-04)

(Chapter 4, §160 of the Medicare Managed Care Manual)

Definition

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.

The Basic Rule

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

State Law Primary

The HMO or CMP program's advance directive requirements, which Fee-For-Service providers have been following for some years, are guidelines, which refer to state law, whether statutory or recognized by the courts of the state. Therefore, HMO or CMPs must comply with the advance directive requirements of the states in which they provide services. The CMS cannot give detailed guidelines as to what constitutes best efforts in

each state. Medicare regulations give HMOs and CMPs and states a great deal of flexibility, and CMS is prepared to work with the HMO and CMP (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 HMOs and CMPs 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.

Content of Enrollee Information and Other HMO/CMP Obligations

The written information provided to enrollees must, at a minimum, include a description of the HMO's and CMP's written policies on advance directives including an explanation of the following:

- That the organization cannot refuse care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

- The right to file a complaint about an organization's noncompliance with advance directive requirements, and where to file the complaint;

- That the plan must document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive;

- That the HMO or CMP is required to comply with state law;

- That the HMO or CMP must educate its staff about its policies and procedures for advance directives; and

- That the HMO or CMP must provide for community education regarding advance directives.

If the HMO or CMP 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.

Incapacitated Enrollees

If an enrollee is incapacitated at the time of initial enrollment and is unable to receive information due to an incapacitating condition, the HMO or CMP may give advance directive information to the enrollee's family or surrogate.

The HMO or CMP is not relieved of its obligation to provide this information to the enrollee once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to ensure that the information is given to the individual directly at the appropriate time.

Community Education Requirements

The HMO or CMP 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 HMO or CMP, 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 HMO or CMP must be able to document its community education efforts.

HMO/CMP Organization Rights

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

Appeal and Anti-Discrimination Rights

An HMO or CMP 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 HMO or CMP must inform individuals that complaints concerning noncompliance with the advance directive requirements may be filed with the State Survey and Certification Agency.