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

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CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
3	40		
	40.1.2		
	40.3		
	40.4		
		40.4.1	
	60.1.2		

Red italicized font identifies new material.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 1, 2003
IMPLEMENTATION DATE: January 1, 2003

Section 40, Guidelines for Beneficiary Notification Materials, deletes sentence that stated that all beneficiary notification material are subject to final review.

Section 40.1.2, Use of Standardized Beneficiary Notification Materials, is modified to reflect that CMS is no longer standardizing additional beneficiary notification materials. Use of material already standardized is mandatory.

Section 40.2, **Specific Guidelines About Provider Directories,** renumbered to §40.2, was §40.3.

Section 40.3 - Specific Guidelines About Drug Formularies, renumbered to §40.3, was §40.4. Also changed "theregentic" to "therapeutic."

Section 40.4, **Conducting Outreach to Dual Eligible Membership,** renumbered to §40.4, was §40.5.

Section 40.4.1, **General Guidance on Dual Eligibility,** renumbered to §40.4.1, was §40.5.1.

Section 40.4.2, **Guidelines for Outreach Program,** renumbered to §40.4.2, was §40.5.2.

Section 40.4.3, Submission Requirements, renumbered to §40.4.3, was §40.5.3.

Section 40.4.4 CMS Review/Approval Process, renumbered to §40.4.4, was §40.5.4. under **"**Reviewing Previously Approved Outreach Programs", changed §40.5.3 to §40.4.4 in the first sentence.

Section 60.1.2, - Relationship of Value-Added Items and Services (VAIS) to Benefits and Other Operational Considerations, deleted the last paragraph labeled as note discussing VAIS.

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40 - Guidelines for Beneficiary Notification Materials - (Rev. 15, 09-27-02)

The definition of marketing materials includes all notification forms and letters and sections of newsletters that are used to enroll, disenroll, and communicate with the member on many different membership operational policies and procedures. These materials are also described as beneficiary notification materials and subject to specific CMS requirements. Section 40.1 of this chapter provides general guidance with respect to beneficiary notification materials, including the review process. Section 40.2 provides specific guidance with respect to provider directories. Section 40.3 provides specific guidance about the use of drug formularies.

40.1.2 - Use of Standardized Beneficiary Notification Materials – (Rev. 15, 09-27-02)

The CMS has implemented certain standardized beneficiary notification marketing materials for health plan participants in Medicare managed care. In particular, all M+C organizations are required to use a standardized Summary of Benefits (SB). Use of standardized materials by health plans/M+C organizations is mandatory.

Employer group health plans (EGHPs) were granted an exemption from this requirement to use the standardized Summary of Benefits while CMS conducted a review to determine whether EGHPs should receive a permanent exemption. After discussions with various interested parties, including employer groups, consulting firms, beneficiary advocacy groups, and employer unions, CMS has decided to exempt EGHPs from the requirement to use CMS's standardized summary of benefits.

40.2 - Specific Guidance About Provider Directories - (Rev. 15, 09-27-02)

Regulations at 42 CFR 422.111(b) require that M+C organizations disclose the following information to each enrollee electing an M+C plan offered by the M+C organization:

1. The number, mix, and distribution, including addresses of providers from whom enrollees may obtain services, as well as any out-of-network coverage or point-of-service option;

2. Information regarding out-of-area coverage and emergency coverage, including the process and procedures for obtaining emergency services, and the location where emergency care can be obtained, as well as other locations where contracting physicians and hospitals provide emergency services, and post-stabilization care included in the M+C plan;

3. Prior authorization rules and other review requirements that must be met in order to ensure payment for the services; and

4. Instructions to enrollees that, in cases where noncontracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the M+C organization for processing and determination of enrollee liability, if any.

Section 422.111(a) requires that this information be disclosed in clear, accurate, and standardized form at the time of enrollment and at least annually thereafter.[9] M+C organizations generally include this information in their provider directory and distribute the directory to new members upon enrollment and existing members on an annual basis. [10] In addition to the information provided above, provider directories should also contain the following:

1. Names, complete addresses, and phone numbers of the primary care physicians;

2. Names and addresses (city or town) of specialists, skilled nursing facilities, hospitals, outpatient mental health providers, and pharmacies, where outpatient prescription drugs are offered by the M+C plan;

3. General information regarding lock-in, including the role of the primary care physician (PCP) as well as the process for selecting a new PCP and any specific requirements for referrals to specialists and ancillary providers;

4. A description of the plan's service area, including a list of cities and towns;

5. Telephone numbers for customer service or appropriate contact information (including the hours of service) for members who have questions or require assistance in selecting a PCP;[11] and

6. A general disclaimer that indicates that the directory is current as of a particular date and that a provider's listing in the directory does not guarantee that the provider is still in the network or accepting new members.

The M+C organizations may publish separate PCP and Specialty directories provided that both directories must be given to enrollees at the time of enrollment and at least annually thereafter. M+C organizations that use sub-networks of providers must clearly delineate these sub-networks (preferably by listing the providers as a separate sub-network) and describe any restrictions imposed on members that use these sub-networks. This is particularly important since beneficiaries could choose their primary care physician without realizing that this choice restricts them to a specified group of specialists, ancillary providers, and hospitals. M+C organizations must also clearly describe the process for obtaining services in these networks and sub-networks, including any referral requirements, as well as any out-of-network coverage or point-of-service option.

The M+C organizations may find it more economical to print a separate directory for each sub-network and disseminate this information to members in a particular sub-network. This practice is permissible, provided that the directory clearly states that a directory that lists providers for other networks is available and provides this information to members upon request.

40.3 - Specific Guidance About Drug Formularies - (Rev. 15, 09-27-02)

In providing a prescription drug benefit, a health plan/M+C organization may rely on a formulary. A formulary is a list of prescription drugs, grouped by therapeutic drug class. There are three categories of formularies: open, preferred, and closed. Open formularies list all drugs and drug products that are covered and do not place restrictions on coverage of drugs within each *therapeutic* class (i.e., the physician can order any one in the class). Preferred formularies are similar to open formularies, but also use incentives and interventions to encourage use of certain preferred drugs. Closed formularies use limited lists of drugs; enrollees pay penalties (sometimes the entire cost) for drugs not on the formulary.

Many health plans/M+C organizations make periodic changes to formularies or the items on preferred lists, often convening meetings of their pharmacy and therapeutics committees several times a year to add and remove items from the formulary or preferred list. When they enroll in a M+C plan, beneficiaries may not be aware that changes to formularies or preferred lists are likely to occur during the contract year.

Every health plan/M+C organization that covers outpatient prescription drug benefits (those not covered under the original Medicare fee-for-service program) must provide notice in its Evidence of Coverage (EOC) whether it uses a formulary or preferred list. If it uses formularies or preferred lists, the notice shall include:

- An explanation of what a formulary is;
- A statement that the formulary (or drugs on the preferred list) may change during the contract year;
- An estimate of how often the health plan/M+C organization reviews the contents of the formulary and makes changes based upon that review;
- A description of any process by which a prescribing provider may obtain authorization for a nonformulary or non-preferred list drug to be furnished under the same terms and conditions as drugs on the formulary or preferred list; and
- A statement that members may use health plan/M+C organization grievance and appeals process if they have complaints about the formulary or its administration.

In addition, health plans/M+C organizations that use formularies or preferred lists must disclose whether specific drugs are on the health plan/M+C organizations' formularies or preferred lists when enrollees or potential enrollees make telephone or other inquiries.

With respect to pre-enrollment marketing materials that describe plan benefits, health plans/M+C organizations must disclose whether a formulary or preferred list is used and that the formulary or list may change during the contract year and provide a contact number that the beneficiary can call for more information. This policy will be effective beginning in contract year 2001 and will be incorporated into the Model EOC for 2001.

40.4 - Conducting Outreach to Dual Eligible Membership - (Rev. 15, 09-27-02)

A number of M+C plan members are, due to financial status, eligible for State financial assistance through State Medicaid Programs. This assistance provides them an array of financial savings ranging from partial payment of Medicare Part B premiums to full payment of Medicare premiums and other plan cost sharing. Historically, some of those eligible do not apply for these State savings programs because:

1. The individuals equate Medicaid with Welfare and associate a social stigma to the terms;
2. They are not aware of the savings that are available;
3. They do not understand the eligibility requirements; or
4. They find the process sometimes complex and difficult to understand.

Some M+C organizations choose to conduct outreach to their M+C members to educate them and to assist them in applying for these savings programs. This may be especially true because CMS capitates M+C organizations at a higher rate for some dual eligible members. [12] The CMS encourages but does not require M+C organizations to assist their members with applying for State financial assistance because of the potential benefits to both the members and to the M+C organizations.

This section instructs M+C organizations in outreach program requirements and the process for submitting those programs and member materials (e.g., letters, call scripts, etc.) to CMS for approval. It also provides CMS staff with operating procedures for reviewing and approving the outreach programs.

40.4.1 - General Guidance on Dual Eligibility - (Rev. 15, 09-27-02)

There are several categories of dual eligibility, each having specific income requirements and providing different levels of financial assistance to those who qualify at that level. The categories are outlined in the following chart:

Data valid for year 2002 can be found at www.hcfa.gov/medicaid/dualelig/4732rate.htm. Income Requirements for Hawaii and Alaska specifically noted. Resource and Income Limits shown below may vary by state; contact the state for specific resource amounts.

Eligibility Category	Monthly Income Requirements	Medicaid Benefits	Provider	Medicaid Liability for Services
QMB only Qualified Medicare Beneficiary without other Medicaid	$759 – individual $1,015 – couple Alaska: $944 – individual $1,265 – couple Hawaii: $870 – individual $1,165 – couple	Medicare premiums, deductibles, and coinsurance. No Medicaid services.	Medicare	QMB rates for Medicare deductibles and coinsurance

QMB Plus Qualified Medicare Beneficiary with Full Medicaid	$759 – individual $1,015 – couple Alaska: $944 – individual $1,265– couple Hawaii: $870 – individual $1,165 – couple	Medicare premiums, deductibles, and coinsurance. Medicaid services.	Medicare Medicaid	QMB rates for Medicare deductibles and coinsurance Medicaid rates for Medicaid services only.
SLMB only Specified Low-Income Medicare Beneficiary without other Medicaid	$906 – individual $1,214 – couple Alaska: $1,128 – individual $1,513 – couple Hawaii: $1,040 – individual $1,394 – couple	Medicare Part B premiums. No Medicaid services.	Medicare	No liability for Medicare deductibles and coinsurance.
SLMB Plus Specified Low-Income Medicare Beneficiary with Full Medicaid	$906 – individual $1,124 – couple Alaska: $1,128 – individual $1,513 – couple Hawaii: $1,040 – individual $1,394 – couple	Medicare Part B premiums. Medicaid services.	Medicare Medicaid	No liability for Medicare deductibles and coinsurance. Difference between Medicare payment and Medicaid rates for Medicaid services.
QI-1 Qualifying Individuals - 1	$1,017 – individual $1,364 – couple Alaska: $1,267 – individual $1,700 – couple Hawaii: $1,168 – individual $1,566 – couple	Medicare Part B premium.	Medicare	No liability for Medicare deductibles and coinsurance.
QI-2 Qualifying Individuals - 2	$1,313 – individual $1,762 – couple Alaska: $1,636 – individual $2,198 – couple Hawaii: $1,508 – individual $2,024 – couple	All or part of Medicare Part B premium.	Medicare	No liability for Medicare deductibles and coinsurance.
QDWI Qualified Disabled and Working	$3,039 – individual $4,065 – couple Alaska: $3,779 – individual	Medicare Part A premium.	Medicare	No liability for Medicare deductibles and coinsurance.

Individuals	$5,062 – couple Hawaii: $3,485 – individual $4,665 – couple			

40.4.2 - Guidelines for Outreach Program - (Rev. 15, 09-27-02)

In order to assure CMS that M+C organizations' outreach programs effectively assist members while protecting them from undue pressures or privacy violations, M+C organizations[13] must adhere to the following guidance.

The M+C Organizations MUST:

1. Provide outreach to all levels of dual eligibles, including those levels that do not provide M+C organizations with additional capitation amounts from CMS. All outreach materials (e.g., member letters (see §40.4.5 for a model Direct Mail Letter), telephone scripts) must include eligibility information that includes QI-1 and QI-2 levels. [See footnote 12 for clarification.]

2. Clarify in outreach materials that the member may voluntarily offer information, including financial information, but that the member is not obligated to provide this information.

3. Clarify in outreach materials and discussions with members that the member's failure to provide information will in no way adversely affect the beneficiary's membership in his or her health plan.

4. State in materials and discussions with members that the M+C organization will not share the information with any other entity not directly associated with determining eligibility or under contract to participate in the outreach process.

5. Clarify in outreach materials that the M+C organization is only providing an initial eligibility screening and that only the appropriate State Agency can make a final eligibility determination.

6. Provide guidance to a member on how to proceed with the application process even if the M+C organization's screening process indicates that the member is probably not eligible for assistance under any of the dual eligibility programs.

7. Provide adequate training to staff conducting the outreach. If the M+C organization subcontracts this effort to another entity, it must ensure that the subcontractor's staff is adequately trained to provide outreach.

8. Include alternate sources of information in outreach materials. Member letters and/or brochures that contain outreach information telephone numbers must also include the telephone number for the State Health Insurance Assistance Program (SHIP) and the

appropriate State Agency. Outreach materials may also include the telephone number for the Medicare Service Center (1-800-MEDICARE).

9. Include privacy guidelines in outreach materials, telephone scripts, and internal processes and/or contracts with entities performing outreach for the M+C organization. Contractual privacy guidelines must clearly state that all financial information collected from members of the M+C organization will not be used for any other purpose by the entity collecting the data. Privacy guidelines must also state that entities involved in the outreach will not share member information with anyone not involved in the outreach process.

10. Ensure that contracts with entities taking part in some aspect of outreach activities meet M+C Administrative Contracting requirements listed in the Medicare Managed Care Manual Chapter 11, §100.5.

11. Work closely with CMS's regional office staff during the outreach submission and review process so that CMS can work cooperatively with stakeholders (e.g., SHIPs, State Agency) to ensure better education and preparation prior to the outreach process initiation.

The M+C Organizations MAY:

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

2. Provide hands-on assistance to the member in completing all necessary applications for financial assistance including submitting the paperwork to the appropriate State office. This assistance can be in the member's home only if the member requests such a visit.

3. Use the "Authorization to Represent" limited to the specific purposes of completing and submitting paperwork on behalf of the member, discussing the member's case with case workers, representing the member in cases of appeal, and gather information from and on behalf of the Plan member. The "Authorization to Represent" form must specify that the authorization is limited to securing benefits under "the Medicare savings program" or "the Medicaid Program" and cannot extend to other programs unless agreed upon and noted by the member. "Authorization to Represent" shall not give the outreach specialist the authority to sign any documents on behalf of the member nor make any enrollment decisions for the member.

4. Follow-up with members who do not respond to the initial member letter. This follow-up may be in the form of a second and/or third letter or telephone calls. If the member does not respond to the third effort, the M+C organization refrain from contacting the member for at least six months following the last outreach attempt.

5. Provide assistance to members reapplying for financial benefits if and when required to do so by the state agency.

6. Subcontract all outreach efforts to another entity or entities. In such cases, while the M+C organization retains all responsibility for meeting CMS's requirements, it must still submit all documentation to CMS for approval including contracts held by the subcontractor with all entities related to the program. The M+C organization must also coordinate changes and revisions between the subcontractor and CMS.

The M+C Organizations Shall NOT:

1. Conduct door-to-door solicitation or outreach prior to receiving an invitation from the member to provide assistance in his or her home.

2. Share any member information, financial or otherwise, with any entity not directly involved in the outreach process.

3. Store or use member financial information for any purpose other than the initial screening eligibility, the submission and follow-up of an application for benefits, for recertification purposes, and as required by law.

4. Contact any member who has refused outreach assistance or who has not responded to the telephone call or follow-up letter until at least six months following the last outreach attempt.

5. Infer in any written materials or other contact with the member that the organization has the authority to determine the member's eligibility for state assistance programs.

40.4.3 - Submission Requirements - (Rev. 15, 09-27-02)

To facilitate CMS's review of outreach programs, an M+C organization must submit *one copy*) of the *materials* listed below to its Central Office Plan Manager, one *copy* to *the* Regional Office Plan Manager, *and one electronic copy to the Dual Eligibility Outreach Product Consistency Team (PCT)*[15]*.*

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

2. Timeline showing the proposed dates of outreach activities, the number of members involved in each activity, and the service area (e.g., county) included in the activities.

This is to allow CMS to more accurately coordinate outreach activities with its partners (e.g., SHIP, State Agencies).

Contracts with all external entities involved in the outreach process. This includes contracts with any subcontractors taking part in the activities.

3. *Supporting documentation from the appropriate State agency providing specific state income requirements for each savings program level.*

4. Outreach letters and other materials (e.g., brochures) going to plan members.

5. Internal training programs the organization is using to educate staff involved in outreach.

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

7. Internal plan for protecting the confidentiality of the member's financial or other personal information gathered in the outreach process.

In some instances, an M+C organization may chose to submit an outreach proposal that CMS has already approved for use by another M+C organization. This is common when an M+C organization is part of a national organization with multiple contracts, each of which is conducting its own outreach. This is also common when a subcontracting entity designs and conducts the outreach. These subcontractors often seek to contract with multiple M+C organizations and conduct the same outreach programs for each of their clients.

If an M+C organization submits an outreach proposal that (a) CMS previously approved on or after April 1, 2002; (b) That CMS approved within the twelve months prior to the submission; and (c) That does not contain substantive changes [14] to qualify it as an "initial" proposal, the M+C organization must submit the items listed above (1 - *7*) in addition to the following:

An attestation from either the M+C organization or its contracted outreach vendor stating (a) That the proposal has been approved by CMS, (b) The date of that approval, and (c) That the new submission does not contain substantive changes to the approved program.

Section *40.4.4* contains a description of CMS's review process and time frames for both initial and previously approved proposals.

40.4.4 - CMS Review/Approval Process- (Rev. 15, 09-27-02)

NOTE: The CMS review process for new outreach proposals differs from the review process or previously approved outreach proposals. The processes for both submissions are stated below.

Reviewing New Outreach Programs

1 The M+C organization is responsible for submitting the outreach proposal to CMS and working with CMS through the review and approval process even if a subcontractor developed the proposal. The CMS will hold the M+C organization fully responsible for all the provisions of the outreach program and for assuring the members of their rights and protections outlined in the M+C program regulations.

2 In that CMS considers outreach materials to be a form of marketing, CMS will review outreach proposals according to current time frames for reviewing marketing material. The agency will conduct its initial review and provide comments to the M+C organization within 45 days of receipt of a new (not previously approved) proposal.

3 As noted in §*40.4.3* M+C organizations must submit one complete copy of the materials listed in §*40.4.3* to the CMS Central Office Plan Manager, second copy of the same materials to the CMS Regional Office Plan Manager, *and an electronic copy of the materials to the Dual Eligibility Outreach (PCT)*[15].

The Dual Eligibility *PCT* will review all the enclosed documentation in conjunction with the Plan Managers and will provide comments to the Central and Regional Office Plan Managers. The Regional Office Plan Manager will relay CMS comments back to the M+C organization will gather revisions (when necessary) and will finish the review and approval process based upon the M+C Organization's revisions.

4 The Regional Office Plan Manager will share outreach materials with the appropriate State agency as a way to verify the accuracy of the information contained in the proposal and to receive input from state partners.

5 Upon final approval of the proposal and outreach materials, the Regional Office Plan Manager will send an approval letter to the M+C Organization.

6 The regional office will then contact its partners (SHIPs, State Medicaid Offices, etc.) to notify them of the outreach effort and possible increase in beneficiary inquiries. The regional office will share copies of outreach letters with the State Agencies to prepare them for incoming questions.

Reviewing Previously Approved Outreach Programs

If an M+C organization submits an outreach proposal that CMS has already approved and that does not contain substantive changes (outlined in §*40.4.3*), then the CMS Regional Plan Manager will only review the targeted membership information (audience number and outreach dates), the contract(s) between the M+C organization and its outreach subcontractor(s), the updates to benefit levels and income and resource criteria, and the attestation. The CMS will respond to the M+C organization within the 10-day time frame CMS has established for reviewing standardized marketing materials. The CMS's regional office will file the outreach proposal for future reference.

The CMS recognizes that the M+C organization will have to make simple periodic changes to their outreach programs in order to update minimum income levels, etc. As stated previously (*in footnote 14*), CMS does not consider these updates to be "substantive changes" in that they do not prompt a full review of an outreach proposal. However, the M+C organization is still responsible for submitting such changes to the appropriate CMS regional office for marketing review to ensure accuracy of such changes.

If the M+C organization wishes to make substantive changes to the outreach process, it must submit those changes to the appropriate CMS Central Office and Regional Office Plan Managers for review through the PCT according to the review process above.

60.1.2 - Relationship of Value-Added Items and Services (VAIS) to Benefits and Other Operational Considerations - (Rev. 15, 09-27-02)

The M+C organizations can market, either through oral presentations or written materials, Value-Added Items and Services (VAIS). Organizations can also mention VAIS in their newsletters. VAIS may not appear in the Plan Benefit Package (PBP) or the Standardized Summary of Benefits (SB) (including in the M+C organization special features §30 at the end). However, organizations will be permitted to reference their pharmacy discount program in Section 3 of their SB, provided they also include the disclaimers included in this section. In addition, the SB must clearly state (in the location that the program is described) that the discount drug program will be available for the entire contract year.

Any description of VAIS must be preceded by the following prominently displayed language:

1. The products and services described on this page are neither offered nor guaranteed under the M+C organization's contract with the Medicare program, but are made available to all enrollees who are members of [Name of M+C organization].

2. These products and services are not subject to the Medicare appeals process. Any disputes regarding these products and services may be subject to the [Name of M+C organization] grievance process.

3. Should a problem arise with any Value-Added Item or Service, call [Name of M+C organization] for assistance at [M+C organization customer service number]. Our customer service hours are [Enter hours].

Organizations may include VAIS along with their Annual Notice of Change (ANOC) and Summary of Benefits (SB) in one bound brochure as long as the value-added services are clearly distinct from the ANOC and SB (such as on a different color piece of paper), and the information on value-added services includes all the disclaimers required in this chapter.

Because VAIS does not meet the definition of a benefit under the M+C program, neither the actual costs of the VAIS nor associated administrative costs may appear in the ACR.

Furthermore, because they are not contained within the contracted health benefits package, these services are not subject to the Medicare appeals process. VAIS may not be described in Medicare Compare or the "Medicare and You" handbook.

The CMS will not require prior approval of materials describing VAIS, since VAIS are not benefits as described within CMS regulations. The CMS will review these materials on monitoring visits to ensure compliance with these requirements. The CMS may initiate a monitoring visit if it becomes aware that materials have been distributed describing VAIS without the appropriate disclaimers or in violation of the requirements stated herein. The CMS will also investigate complaints by beneficiaries regarding VAIS, just as it would other possible violations of CMS requirements.