# Medicare Managed Care Manual

**Department of Health & Human Services (DHHS)**

**Centers for Medicare & Medicaid Services (CMS)**

**Transmittal 5** **Date: JANUARY 2, 2002**

| CHAPTERS | REVISED SECTIONS | NEW SECTIONS | DELETED SECTIONS |
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| 3 | 30.1 | | |
| 3 | 30.3 | | |
| 3 | 40.2 | | |
| 3 | 50.1.1 | | |
| 3 | 50.4.3 | | |
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| 3 | Endnote 9 | | |
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| 5 | 30.1.2 | | |
| 5 | 30.1.5.2 | | |
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| 5 | 30.4 | | |
| 5 | 35.4 | | |

**CLARIFICATION -- EFFECTIVE DATE: Not Applicable**
**IMPLEMENTATION DATE: Not Applicable**

**Section 30.1 - Guidelines for Advertising (Pre-enrollment) Materials**, is clarified.

**Section 30.3 - "Must Use/Can't Use/Can Use" Chart**, the term "Plan Providers" is added to the chart under "Physicians and Other Health Care Providers" in the "Can Use Columns".

**Section 40.2 - Final Verification Review Process**, a reference to previously-deleted material (Category 2), and endnote 8 are removed.

**Section 50.1.1 - Nominal Gifts**, clarified policy about nominal gifts when the whole company is offering a prize to individuals well beyond only Medicare individuals.

**Section 50.4.3 - Operational Considerations Related to Value-Added Items and Services**, policy is clarified.

**Section 50.5 - Specific Guidance About the Use of Independent Insurance Agents**, sentence relating to previous policy is deleted.

**Section 50.6 - Marketing of Multiple Lines of Business Under Medicare + Choice,** policy about mail marketing is clarified.

**Endnote # 9 and # 11,** the reference to the National Marketing Guidelines is removed. The market chapter replaces the National Marketing Guidelines

**NEW/REVISED MATERIAL -- EFFECTIVE DATE: January 2, 2002**
**IMPLEMENTATION DATE: January 2, 2002**

**Section 30.1.2 - Performance Improvement Projects**, the year 2002 was changed to 2000 in the next to last paragraph to correct a typographical error.

**Section 30.1.5.2 - Non-Clinical Focus Areas - Non-Clinical Focus Areas Applicable to All Enrollees (QISMC Document Standard 1.3.5),** a note is added to the end of the section, about the deletion of interpersonal aspects of care focus area.

**Section 30.2.3 - Significant, Sustained Improvement**, added language distinguishing benchmarks from performance targets. Added 2 subtitles to subsections "Sampling" and "Interventions".

**Section 30.2.4 - Sustained Improvement Over Time,** added language explaining that once an M+CO has met the requirement for both significant and sustained improvement on any given project, they have no other CMS reporting requirements related to that project.

**Section 30.3.4 - Process for CMS Multi-Year QAPI Project Approvals**, deleted the first three sentences in the second paragraph of the subsection "When Should the Request be Submitted?".

**Section 30.4 - Evaluation of QAPI Projects**, the following changes are made:

> **Subsection "CMS Regional Office Representatives"** - Added subsection explaining the RO's responsibilities regarding QAPI projects.
>
> **Subsection "Project Completion Report"** - Added details on using the H-number as a reporting unit for the QAPI report and on using the HPMS system to file the report.
>
> **Subsection "When to Report"** - Provides deadlines on filing the "Project Completion Reports".
>
> **Subsection "Project Review Report"** - Describes information contained in this report and purpose of this report.
>
> **Subsection "Other Tools** - Describes assistance given to M+C Organizations in the implementation of the QAPI projects.

**Subsection "Corrective Action Process"** - Explains that once all corrective action plans have been executed, the M+CO would be in compliance.

**Subsection "Review of QAPI Projects"** - Deleted because it was redundant.

**35.4 - Obligations of Deemed M+C Organizations,** paragraph added which explains conditions for including costs of accreditation as an administrative cost in ACR submission.

**NOTE***:* **Red italicized font identifies new material.**

**The MMCM is an Internet document and may be accessed from the CMS Web site: http://www.hcfa.gov/pubforms/progman.htm.**

## 30.1 - Guidelines for Advertising (Pre-enrollment) Materials

**(Rev. 5, 01-02-02)**

This section provides guidance to health plans/M+C organizations regarding sales packages and language that may be used in marketing materials. Advertising/pre-enrollment material may be defined as material that is intended primarily to attract or appeal to M+C eligible non-members and to promote membership retention by providing general information to enrollees about the health plan. This includes all ads (print as well as radio TV and Internet ads) and certain other material such as sales scripts, sales presentation flyers, and direct mail pieces that contain information of interest to all potential and current enrollees of the plan. This chapter offers a general guide and a matrix describing marketing language that health plans/M+C organizations "Must Use/Can't Use/Can Use."

These guidelines were created by identifying required language frequently omitted by health plans/M+C organizations or revised by CMS. Acceptable language was created to meet both CMS requirements and the needs of the health plans/M+C organizations. Although use of suggested “Can Use” language is not required, its use will expedite the review process and achieve greater consistency among marketing materials. Please note that the specific language and format used in all standardized marketing materials like the standardized Summary of Benefits (SB) is required. Please also note that the language provided in the "Must Use" column of the "Must Use/Can’t Use/Can Use Chart" (see §30.3 of this Chapter) is required for all the marketing materials as specified in the chart.

Some phrases in this document may not apply to your health plan's/M+C organization's benefit package or marketing strategy. We caution you to apply the information contained in this document with the understanding that it must be evaluated for applicability to your health plan/M+C organization.

Listed below are items that apply to the various pre-enrollment/member retention marketing scenarios experienced by Medicare managed care contracting entities:

**Operational Items**

1. For M+C coordinated care plans, the concept of "lock-in" must be clearly explained in all materials. For marketing pieces which tend to be of short duration we suggest: "You must receive all routine care from [name of plan/M+C organization] plan providers" or "You must use [name of plan/M+C organization] plan providers except in emergent care situations or for out-of-area urgent care/renal dialysis." However, in all written materials used to make a sale, a more expanded version is suggested: "If you obtain routine care from out-of-plan providers neither Medicare nor the health plan/M+C organization will be responsible for the costs." Modify materials if the health plan has a Point-of-Service (POS) or Visitors' Program benefit or is a cost contractor or Private Fee-For-Service Plan.

2. All marketing materials must clearly explain the concept of networks and sub-networks and the process for obtaining services including referral requirements.

3. Health plans/M+C organizations must list the hours of operation for customer services and other health plan services anywhere that these phone numbers are provided. This requirement does not apply to any numbers included on advertising materials for persons to call for more information.

4. Definition of Outdoor Advertising (ODA) - ODA is marketing material intended to capture the quick attention of a mobile audience passing the outdoor display (e.g., billboards, signs attached to transportation vehicles, etc.). ODA is designed to catch the attention of a person and influence them to call for detailed information on the product being advertised. Due to the nature of ODA, CMS is willing to waive the disclaimer information required with other forms of marketing media (e.g., lock-in and premium information). [3]

5. Marketing material identification systems - Health plans/M+C organizations must use the system mandated by the reviewing RO for identifying marketing materials submitted to CMS. If the reviewing RO does not have a system, health plans/M+C organizations may use their own system for identifying marketing materials. The health plan identifier should appear on the lower left or right side of the marketing piece. After the RO approves the marketing piece, the approval date (month/year) should always be posted to the marketing piece. The approval date is the date on the CMS approval letter. *This requirement is applicable to all approved internet pages and paper advertisements (e.g. brochures, newspaper ads). Approved radio and television marketing materials need not include mention of the approval date.*

6. Where M+C organizations may file separate/distinct Adjusted Community Rate (ACR)s Proposals and the Plan Benefit Package (PBP)s covering the same service area (or portions of the same service area), there is no requirement that all plans be identified in all of the health plan's/M+C organization's marketing materials, although M+C organizations may do so at their discretion. M+C organizations must disclose whether other plans are available in their Annual Notice of Change letter.

7. M+C organizations may market plans directly to beneficiaries of former Medicare plans that have chosen not to renew their contracts as long as the following requirements are met:

    i No such marketing is permitted until after the date the beneficiary has received the plan termination letter; and

    ii In addition to the targeted message, the marketing piece must contain a statement indicating that the plan is open to all Medicare beneficiaries eligible by age or disability in the plan's service area.

8. Sales scripts, both for in-home and telephone sales use, must be reviewed by CMS prior to use. However, health plans/M+C organizations are not required to adhere to a specific format for submission (i.e. verbatim text or bullet points).

9. Health plans/M+C organizations may not use Medicare member lists for non-plan-specific purposes. If a health plan/M+C organization has questions regarding specific material, which it wishes to send to its Medicare members, the material should be submitted to CMS for a decision.

**Affiliation Acknowledgements**

1. All marketing materials must include a statement that the health plan/M+C organization contracts with the Federal government. One possible statement is "A Federally Qualified HMO with a Medicare contract." Cost-contractors may use "An HMO with a Medicare contract" and/or "An M+C organization with a Medicare contract" if they are State licensed as HMOs. Medicare+Choice organizations may identify Medicare products as "An HMO with an Medicare+Choice contract" if they are Federally Qualified or State licensed as HMOs. M+C organizations may also identify their Medicare plans as "An M+C plan with an Medicare+Choice contract," or "A Coordinated Care Plan with an Medicare+Choice contract," if the health plan/M+C organization meets the requirements of §1851(a)(2)(A) of the Act. In addition, an M+C organization may describe its Medicare product as a "Medicare+Choice plan offered by [name of M+C organization], a Medicare+Choice Organization".

2. A M+C organization may only identify itself as an "M+C PSO" or imply that it is one of the PSO options for Medicare beneficiaries under M+C if it has received a State licensure waiver from CMS in accordance with 42 CFR 422.370-.378. State licensed M+C organizations may identify themselves in marketing materials as a "Provider Sponsored Organization (PSO)," a "State licensed PSO with a M+C contract," or any other term generally applied to managed care organizations that are sponsored by health care providers as long as they do not use the specific term "M+C PSO" or imply that they are one of the specific PSO options for Medicare beneficiaries defined by the Balanced Budget Act of 1997 and implementing regulations at 42 CFR 422.350-.356.

3. M+C organizations are permitted to use ethnic and religious affiliation in their plan names, as long as the legal entity offering the plan has a similar proper name/affiliation. For instance, if a plan were affiliated with the Swedish Hospital of Minnesota, it would be permissible for the plan to use the tag line, "Swedish Plan, offered by Swedish Hospital System of Minnesota."

**Special Situations**

1. Beneficiaries with disabilities must be considered part of the audience that any marketing strategy is intended to reach. Specifically, and in light of the publication of the final M+C regulation, health plans/M+C organizations may not use plan names that suggest that a plan is available only to Medicare beneficiaries

age 65 or over, rather than to all beneficiaries. This prohibition generally bars plan names involving terms such as “seniors,” “65+,” etc. In fairness to M+C organizations with an existing investment in a plan name, CMS will allow the “grandfathering” of existing M+C plan names; that is, plan names established before the final rule took effect.

2. TDD/TTY numbers must appear in conjunction with any other phone numbers in the same *font size and* style, along with the hours of operation, if these are also provided with the plan phone numbers. This is required for all media *with the exception of television ads. CMS recognizes that the requirement that the TTY/TDD number be the same font and style as other numbers can result in confusion on a television ad, resulting in some prospective enrollees calling the wrong phone number. Therefore, health plans/M+C organizations are allowed to use various techniques to sharpen the differences between TTY/TDD and other phone numbers on a television ad (such as using a smaller font size for the TTY/TDD number than for the other phone numbers).* Health plans/M+C organizations can use either their own or State relay services, as long as the number is included.

3. Review of marketing materials in non-English language or Braille: For marketing with non-English or Braille materials the health plan/M+C organization must submit the non-English or Braille version of the marketing piece, an English version (translation) of the piece, and a letter of attestation from the health plan/M+C organization that both pieces convey the same information. Health plans/M+C organizations will be subject to verification monitoring review and associated penalties for violation of this CMS policy. If national health plans/M+C organizations have submitted materials in English to the lead RO and these have been approved, the same materials in other languages or Braille may be used provided that health plans/M+C organizations submit attestation letters vouching that the non-English or Braille version contains the same information as the English language version.

**Section 1876 Cost Contracts Only**

1. For §1876 of the Social Security Act, the Act, cost-contracting health plans only - In all marketing materials (e.g., brochure narratives and introductions to side-by-side comparisons) the health plan must indicate that it meets Medicare regulatory requirements for providing enrollment opportunity and benefit packages for both Part A and B and Part B-only eligible beneficiaries.[4]

2. Cost-contracting health plans must market a low option or basic benefit package that is identical to the Medicare fee-for-service benefit package (except for any additional benefits the health plan may offer at no charge, for which the health plan claims no reimbursement). Information on the availability of this package must appear in all of the health plan's marketing materials. The health plan/M+C organization may also offer additional optional enriched benefit packages for an additional charge to the extent they wish.

**Editorial Items**

1. Readability of written materials is crucial to informed choice for Medicare beneficiaries. All member materials that convey the rights and responsibilities of the health plan/M+C organization and the member must be printed with a 12-point font size or larger. Materials subject to this requirement include, but are not limited to, the Evidence of Coverage (EOC) or member brochure and contract, the enrollment and disenrollment applications, letters confirming enrollment and disenrollment, notices of non-coverage (NONC) and notices informing members of their right to an appeals process. CMS is cognizant of the fact that, when actually measured, font size 12 point may vary among different fonts with the result that some font types may be smaller than others. Times New Roman font type is the standard by which font size is measured. Therefore, if M+C organizations choose to use a different font type, it is their responsibility to ensure that the font used is equivalent to or larger than Times New Roman 12 point.

2. The 12-point font size or larger rule also applies to any footnotes or subscript annotations in notices. In all non-notice material (e.g., TV advertisements) the footnote and any text appearing in the material must be the same size font as the commercial message. The term "commercial message" refers to the material, which is designed to capture the reader's attention regarding the health plan/M+C organization. The term does not refer to the commercial membership (i.e., non Medicare/Medicaid members) of the health plan/M+C organization. All non-notice materials must have the same font size for both the commercial message and footnotes. The size is left to the discretion of the health plan/M+C organization and can be smaller than size 12 font, but the commercial message and footnotes must be the same size font.

3. Health plans/M+C organizations must adopt a standard procedure for footnote placement. Footnotes should appear either at the end of the document or the bottom of each page and in the same place throughout the document. In other words, for example, the health plan/M+C organization cannot include a footnote at the bottom of page 2 and then reference this footnote on page 8; the footnote has to also appear at the bottom of page 8.

**Other**

1. Marketing through the Internet: CMS considers the Internet as simply another vehicle for the distribution of marketing information. Therefore, all regulatory rules and requirements associated with all other marketing conveyances (e.g., newspaper, radio, TV, brochures, etc.) are applicable to health plan/M+C organization marketing activity on the Internet. CMS marketing review authority extends to all marketing activity (both advertising and beneficiary notification activity) the health plan/M+C organization pursues via the Internet.

2. Health education materials are generally not under the purview of CMS marketing review. However, if such materials are used in any way to promote the M+C organization or explain benefits, then they are considered marketing materials and

must be approved before use. If there is any "commercial message" (defined previously in this section) or beneficiary notification information in a health education piece, it must be reviewed by CMS.

3. M+C organizations may refer to results of studies or statistical data in relation to customer satisfaction, quality, etc. as long as specific study details are given (at a minimum source, dates, sample size, and number of plans surveyed). M+C organizations may not use study or statistical data to directly compare their plan to another. If M+C organizations use study data that includes information on several other M+C organizations, they will not be required to include data on all organizations. However, study details, such as the number of plans included, must be disclosed. Qualified superlatives (e.g., among the best, one of the highest ranked, etc.) may be used. Superlatives (e.g., ranked number one, etc.) may only be used if they are substantiated with supporting data.

4. CMS recognizes the difference of purpose and intent between company logos/product tag lines and other advertising marketing materials. The guidelines regarding specifically the use of unsubstantiated statements that apply to advertising materials do not apply to logos/taglines. Contracting health plans may use unsubstantiated statements in their logos and in their product tag lines (e.g., "Your health is our major concern," "Quality care is our pledge to you," "First Care means quality care," etc.). This latitude is allowed only in logo/product tag line language. Such unsubstantiated claims cannot be used in general advertising text regardless of the communication media employed to distribute the message. Not withstanding the ability to use unsubstantiated statements as indicated above, the use of superlatives is not permitted in logos/product tag lines (e.g., "First Care means the first in quality care" or "Senior's Plus means the best in managed care"). Refer to the Must Use/Can't Use/Can Use chart in §30.3 of this Chapter for full information on restrictions associated with the use of superlatives.

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## 30.3 - "Must Use/Can't Use/Can Use" Chart

**(Rev. 5, 01-02-02)**

The following chart provides guidance on language that M+C organizations must use, can't use, and can use in pre-enrollment advertising. The following items: Lock-in, Eligibility, and Contract with the Government are required items in advertising. The use of any language found in the “Can Use” column is discretionary

| Subject | Must Use | Can't Use | Can Use | Reason |
|---|---|---|---|---|
| Lock-In | - Enrolled members "must use (name of health plan/M+C organization) (contracting, affiliated, or name of health plan/M+C organization participating) providers for routine care"<br><br>- "Health plan/M+C organization available to all Medicare beneficiaries"<br><br>MEDIA: All except outdoor advertising<br><br>*Outdoor advertising has the option of excluding this topic:<br><br>* See definition of outdoor advertising in §10 of this Chapter.<br><br>This information may be either in the text of the piece or in a disclosure paragraph at the end/bottom of the piece | - The term “Participating Providers” | | CMS requires lock-in for all media to inform beneficiaries of managed care requirement.<br><br>Because of the messages and the nature of outdoor advertising, this topic does not apply to outdoor advertising |
| Descriptions of the M+C organization's Quality[6] | | - Superlatives (e.g., highest, best)[7]<br><br>- Unsubstantiated comparisons with other M+C organizations<br><br>- Direct negative statements about other M+C organizations including individual statements from members or former members | - Qualified superlatives (e.g., among the best, some of the highest)<br><br>- Superlatives (e.g., ranked number 1, if they can be substantiated by ratings, studies or statistics(Source must be identified in the advertising piece.) See §30.1 for more information.<br><br>- "Health plan/M+C organization delivers (adjective) quality of care"<br><br>- Can use satisfaction survey results. E.g., "The (name of specific study) indicated we rated highest in member satisfaction." (Must disclose year and source.) See §30.3 for more information.<br><br>- M+C organizations may use CAHPS survey data regarding their own organization but may not use it to make specific comparisons to other M+C | |

| Subject | Must Use | Can't Use | Can Use | Reason |
|---|---|---|---|---|
| | | | organizations.<br><br>MEDIA: All | |
| Premium Costs | - If a health plan/M+C organization premium is mentioned, it must be accompanied by a statement that beneficiaries must continue to pay Part B premium or Medicare premium.<br><br>- If an annual dollar amount/limit is mentioned, quarterly or monthly limits must also be mentioned as well as any ability to carry over any remaining benefit from quarter to quarter.<br><br>Because of the length of the messages and the nature of outdoor advertising, this topic does not apply to outdoor advertising.<br><br>MEDIA: All except outdoor advertising<br><br>- TV-Part B caveat must be flashed in TV safe range or mentioned in narration.[13] | - "No premium"<br><br>- "No premium or deductible"<br><br>- "Free" | The following may be used:<br><br>- "No health plan/M+C organization premium"<br><br>- "Health plan/M+C organization premium equals _____"<br><br>- "$0 health plan/M+C organization premium"<br><br>- At no extra cost to you" but only if referring to a specific benefit<br><br>- "No health plan/M+C organization premium or deductibles"<br><br>- "No premium or deductibles (you must continue to pay the Medicare Part B premium"<br><br>- "No premium beyond your monthly Medicare payment"<br><br>- "No premium other than what you currently pay for Medicare"<br><br>MEDIA: All except outdoor advertising, which has the option of excluding this topic. | Materials must disclose that beneficiaries must continue to pay the Part B premium and continue their Medicare Part B coverage while enrolled in the HMO. |
| Testimonials | - Content must comply with CMS marketing guidelines, including statements by members<br><br>- Speaker must identify specific health plan/M+C organization membership<br><br>- Ads must include a verbal statement by member indicating that she/he is a member of a specific plan or a "banner" at the bottom of the screen indicating the same or a voice over identifying the | - Cannot have non-members say he/she belongs. (Can use actors, but they cannot say they belong to the health plan/M+C organization.) | | |

| Subject | Must Use | Can't Use | Can Use | Reason |
|---|---|---|---|---|
| | member as an enrollee of the specific plan.<br><br>MEDIA: All | | | |
| Contract with the Government | - Must include one of the phrases from the "Can se" column<br><br>MEDIA: All except outdoor. Outdoor advertising, which has the option of excluding this topic.<br><br>This information may be either in the text of the piece or in a disclosure paragraph at the end/bottom of the piece. | - "Recommended or endorsed by Medicare"<br><br>- Cannot imply that health plan/M+C organization has a unique or custom arrangement with the government, e.g.:<br><br>-- "Special contract with Medicare"<br><br>--"Special health plan/M+C organization for Medicare beneficiaries" | - "An HMO with a Medicare contract"<br><br>- "An M+C organization with a Medicare contract"<br><br>- "A Federally Qualified HMO with a Medicare contract"<br><br>- "A Federally Qualified Medicare contracting HMO"<br><br>- "Medicare approved HMO"<br><br>- "A Coordinated Care Plan with an Medicare+Choice contract"<br><br>- "M+C PSO"<br><br>MEDIA: All | Because of the length of the messages and the nature of outdoor advertising, this topic does not apply to outdoor advertising. |
| Physicians and Other Health Care Providers | - If the number of physicians and other health care providers is used, it must include only those available to Medicare beneficiaries<br><br>MEDIA: TV, radio, outdoor<br><br>- If the number of physicians and other health care providers is used, it must include only providers available to Medicare beneficiaries. If a total number is used it must separately delineate the number of primary care providers and specialists included.<br><br>MEDIA: Print and direct mail<br><br>- If the M+C organization uses the name and/or picture of providers and/or facilities to market itself, the provider information may only be used within the context of informing beneficiaries of | - Implication that providers are available exclusively through the particular HMO unless such a statement is true<br><br>- "Participating providers" unless you use health plan/M+C organization name<br><br>- The M+C organization may not identify itself by the name of a participating provider or provider group, with the exception of a PSO. | - "(Health plan/M+C organization's name) participating providers"<br><br>- *"Plan" providers*<br><br>- "Network" providers<br><br>- "Contracting" providers<br><br>- "Affiliated" providers<br><br>- Number of providers should be same total number of Medicare providers<br><br>MEDIA: All | Do not use the word "participating" when referring to health plan/M+C organization providers (unless you use health plan/M+C organization name), since it could be confused with a participation agreement with Medicare. Health plan/M+C organizations should either use "contracting" or "health plan/M+C organization name" when referring to health plan/M+C organization providers.<br><br>It must be clear to the beneficiary with whom the M+C contract with CMS is held. |

| Subject | Must Use | Can't Use | Can Use | Reason |
|---|---|---|---|---|
| | providers that are associated with the M+C organization's delivery system.<br><br>MEDIA: Print and direct mail | | | |
| Eligibility | - Must indicate that beneficiaries must be entitled to Part A and enrolled in B<br><br>- For M+C plans<br><br>-- Must indicate that all Medicare beneficiaries with Parts A and B of Medicare may apply<br><br>-For §1876 cost contracting health plans:<br><br>-- Must indicate that all Medicare beneficiaries may apply<br><br>This information may be either in the text of the piece or in a disclosure paragraph at the end/bottom of the piece. | "No health screening" unless specific mention is made of ESRD<br><br>"Seniors" unless term appears with "and all other Medicare eligibles"<br><br>"Health plan/M+C organization designed especially for seniors"<br><br>"Senior health plan/M+C organization" unless part of health plan/M+C organization name<br><br>"Individuals age 65 and over" | - "Anyone with Medicare may apply"<br><br>- "Medicare entitled by age or disability"<br><br>- "Individuals eligible for Medicare by age or disability"<br><br>- "Individuals on or entitled to Medicare by age or disability"<br><br>- "Medicare beneficiaries"<br><br>- "Medicare enrollees"<br><br>- "People with or on Medicare"<br><br>- "No physicals requirefd"<br><br>- "No health screening" if a caveat is included for ESRD<br><br>- “Grandfathered enrollees”<br><br>MEDIA: ALL | Since all Medicare beneficiaries may enroll in Medicare-contracting HMOs, you may not refer to your health plan/M+C organization as a "senior health plan/M+C organization" (unless you refer to it as part of the health plan/M+C organization name). The term "senior health plan/M+C organization" implies that disabled beneficiaries may not enroll.<br><br>Medicare Part A is not a requirement for enrollment in Medicare-cost contracting HMOs. M+C organizations may only enroll individuals with both Parts A and B of Medicare, with the exception of "grandfathered" members. |
| Claims Forms / Paperwork | | "No paperwork"<br><br>"No claims or paperwork/complicated paperwork"<br><br>No claims forms" | "Virtually no paperwork"<br><br>"No paperwork when using health plan/M+C organization providers"<br><br>"Hardly any paperwork"<br><br>MEDIA: All | Members may be required to submit bills or claims documentation when using out-of-plan providers. |
| Benefits:<br><br>a) Comparison | - If premiums and benefits vary by geographic area, must clearly state this or must clearly state geographic area in which differing premiums and benefits are applicable.<br><br>- If only benefits vary, clearly state | - Minimal co-pays may vary by county<br><br>- Minimal co-pays may apply | - "Premiums and benefits may vary by county" or "These benefits apply to the following counties"*<br><br>- "Except for _____ county"*<br><br>MEDIA: All | Premiums, benefits, and/or copayment amounts may vary by county within a given service area. This must be clearly conveyed in all marketing materials. |

| Subject | Must Use | Can't Use | Can Use | Reason |
|---|---|---|---|---|
| | geographic area in which benefits are applicable.<br><br>MEDIA: All | | - M+C organizations may compare benefits to Medigap plans as long as information is provided accurately and in detail. | |
| Benefits:<br><br>b) Limitations | | - "At no extra cost to you" or "free" if co-pays apply | - State exact dollar amount limit on any benefit<br><br>- "Limitations and restrictions may apply"<br><br>- "Minimal copayments will apply"<br><br>- "Minimal copayments vary by county"*<br><br>- State which benefits are subject to limitations<br><br>MEDIA: All | If benefits are specified within the piece, any applicable copayment should be stated or you may include the general statement as shown. |
| Benefits:<br><br>c) Prescription Drugs | - If prescription drugs are mentioned and have limitations, must say:<br><br>- Limited outpatient drug coverage; or,<br><br>- Drug coverage benefits subject to limitations; or<br><br>- Up to xxx annual/quarterly/monthly limit or xxx limit per year/quarter/month and other limits and restrictions may apply.<br><br>- Copayment amounts and indicate for a xx number of days supply<br><br>- If benefits are restricted to a formulary, this must be clearly stated. - In addition, must state:<br><br>- that formulary contents are subject to change within a contract year without advance notice<br><br>- health plan/M+C organization should be | - "We cover prescription drugs" unless accompanied by reference to limitation<br><br>- "Prescription drug coverage" unless accompanied by reference to limitation | - Fully disclose dollar amount of copayments and annual/quarterly/monthly limit<br><br>- If limited, you must say so<br><br>- Limited outpatient drug coverage with xx copayments for xx number of days supply and xxx annual/quarterly/monthly limit<br><br>- "Prescriptions must be filled at contracting or health plan/M+C organization affiliated pharmacies."<br><br>MEDIA: All | Prescription drugs are an important benefit that must be adequately described. Any dollar limits must be clearly conveyed. |

| Subject | Must Use | Can't Use | Can Use | Reason |
|---|---|---|---|---|
| | contacted for additional details.<br><br>MEDIA: All | | | |
| Benefits:<br><br>d) Multi-Year Benefits | - Whenever multi-year benefits are discussed, M+C organizations are required to make appropriate disclosure that the benefit may not be available in subsequent years.<br><br>MEDIA: All, where multi-year benefit(s) are mentioned | | - "[benefit] may not be available in subsequent years" OR<br><br>- "[name of M+C organization] contracts with Medicare each year, this benefit may not may not be available next year"<br><br>MEDIA: All, where multi-year benefit(s) are mentioned | Potential applicants and members must be informed in marketing materials that multi-year benefits in current year benefit packages are not guaranteed in future contract years. |
| Definitions - Emergency and Urgently Needed Care | | - "Life threatening"<br><br>- "True emergency" | - Emergency - definition as stated in current CMS policy.<br><br>- Urgent - definition as stated in current CMS policy.<br><br>MEDIA: All | Emergency and urgent care criteria should be explained per Medicare guidelines rather than in the commercial context. |
| Drawings / Prizes | | - "Eligible for free drawing and prizes"<br><br>MEDIA: Direct mail, flyers, print advertising | - "Eligible for a free drawing and prizes with no obligation"<br><br>- "Free drawing without obligation"<br><br>MEDIA: Direct mail, flyers, print advertising. | It is a prohibited marketing practice to use free gifts and prizes as an inducement to enroll. Any gratuity must be made available to all participants regardless of enrollment. The value of any gift must be less than the nominal amount of $15. |
| Sales presentations | - "A sales representative will be present with information and applications."<br><br>MEDIA: Flyers and invitations to sales presentations<br><br>- "A sales representative may call."<br><br>MEDIA: Response card where the beneficiary's phone number is requested<br><br>- "A telecommunications device for the deaf (TDD) is available to get additional information or set up a meeting with a sales representative." | - "A health plan representative will be available to answer questions." | | This phrase must be used whenever beneficiaries are invited to attend a group session with the intent of enrolling those individuals attending.<br><br>This phrase must be included on any response card in which the beneficiary is asked to provide a telephone number.<br><br>All Health plans must indicate in all advertising that a telecommunication device for the deaf (TDD/TTY) is available to get additional information or to set up a meeting with a sales |

| Subject | Must Use | Can't Use | Can Use | Reason |
|---|---|---|---|---|
| | MEDIA: All<br><br>- "For accommodation of persons with special needs at sales meetings, call (Health Plan Phone Number)."<br><br>MEDIA: Flyers and invitations to sales meetings | | | representative. |

*NOTE: Flexible benefits are not permitted under the M+C program. Therefore, premiums, co-pays and benefits may not vary by county for the same M+C plan.

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## 40.2 - Final Verification Review Process

**(Rev. 5, 01-02-02)**

Beneficiary notification materials described in *section 40* above are subject to CMS's final verification review process, in which the materials are reviewed at the final proof stage. This final proof is usually the printed document or electronic file that is sent to the health plan/M+C organization by the printer prior to printing. When approval is given by the organization based on review of the final proof, the electronic file is transmitted to the printer for execution of the print job. Under special circumstances when final proof copy is not available, blue-line or camera ready copy may be substituted for final proof copy in the final verification review procedure.

When the final text or script version of the beneficiary notification material is satisfactory and the final proof needs to be submitted to CMS for approval, the material is designated by CMS as "acceptable." Approval stamps should not be affixed to documents in this stage of the review process. The RO should indicate that material is not yet the final-proof version by appending the suffix "txt" to the file. Once the final proof is approved by CMS and the marketing material can be published and distributed by the health plan/M+C organization, the material is considered, "approved" and approval stamps (or other methods of indicating approval) should be fixed to the documents at this stage in the process. The RO should indicate that the material is a final proof version by appending the suffix "fv" to the file.

CMS marketing reviewers will stress detection of errors during the initial text review(s) of the material. This effort will, to the extent possible, avoid costly revisions at the "camera ready" or "final proof" review stage. The final verification review is conducted to confirm that the final proof version contains no changes from the initial text version that was approved by CMS.

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## 50.1.1 - Nominal Gifts

**(Rev. 5, 01-02-02)**

Many health plans/M+C organizations offer gifts to potential enrollees if they attend a marketing presentation. This is permitted as long as such gifts are of nominal value and are provided whether or not the individual enrolls in the health plan/M+C organization. Nominal value is defined as an item worth $15 or less, based upon the retail purchase price of the item. Local Medicare fee-for-service fiscal intermediary and/or carrier charge listings can be used to determine the value of medical services, examinations, laboratory tests, etc., associated with nominal value determinations in marketing scenarios. Cash gifts are prohibited including charitable contributions made on behalf of people attending a marketing presentation, and including gift certificates that can be readily converted to cash, regardless of dollar amount. The dollar amount associated with the definition will be periodically reassessed by CMS. *An organization may offer a prize of over $15 to the general public (for example, a $1,000 sweepstakes on its corporate web site) as long as*

*the prize is offered to the general public and not just to Medicare beneficiaries. When the whole company is offering a prize to individuals well beyond only Medicare individuals, and that prize does not relate to a specific inducement to enroll in company products, the company should not exclude anyone with Medicare from being able to win the prize.*

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## 50.4.3 - Operational Considerations Related to Value-Added Items and Services

**(Rev. 5, 01-02-02)**

M+C organizations can market, either through oral presentations or written materials, Value-Added Items and Services (VAIS). *Organizations can include a page on VAIS along with their ANOC and Summary of Benefits 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. Organizations can also mention VAIS in their newsletters.*

CMS will not require prior approval of materials describing VAIS, since VAIS are not benefits as described within CMS regulations. CMS will review these materials on monitoring visits to ensure compliance with these requirements. 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. CMS will also investigate complaints by beneficiaries regarding VAIS, just as it would other possible violations of CMS requirements.

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## 50.5 - Specific Guidance About the Use of Independent Insurance Agents

**(Rev. 5, 01-02-02)**

CMS recognizes that independent insurance agents can provide a necessary service to Medicare beneficiaries and potential enrollees. They can also be a valuable resource in helping to reach low-income and rural populations, persons with disabilities, and other special populations. Therefore, CMS urges M+C organizations to consider requiring specific M+C training for their contracted agents. This will ensure that appropriate information is being delivered to Medicare beneficiaries and potential enrollees.

Please note that CMS is aware that sales by independent insurance agents are typically tied to compensation and that agents are often given incentives to steer enrollees towards the carrier offering the most compensation. Further, independent insurance agents may be in a unique position to "cherry pick," given their often longstanding relationships with clients. Additional operational guidelines to address these concerns will be forthcoming.

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## 50.6 - Marketing of Multiple Lines of Business Under Medicare + Choice

**(Rev. 5, 01-02-02)**

M+C organizations may market multiple lines of business in accordance with the following.

Direct mail M+C marketing materials sent to current members describing other lines of business should contain instructions describing how individuals may opt out of receiving such communications. M+C organizations may apply this opt-out provision on an annual basis. The M+C organizations should make reasonable efforts to ensure that all individuals (including non-members) who ask to opt out of receiving future marketing communications, are not sent such communications.

*With one exception (mentioned below), M+C organizations may advertise multiple lines of business in direct mail marketing materials within the same document as the one that is advertising the M+C product, as long as the non-M+C lines of business are clearly and understandably distinct from the M+C product. For example, the document might highlight the name of the M+C product in bold and underlined font and then include a paragraph to describe the product in "regular" font, then it would go on to highlight the name of a Medigap product in bold and underlined font followed by a paragraph describing the Medigap product in "regular" font. Please keep in mind that the direct mail materials advertising multiple lines of business still should allow the beneficiary the choice of opting out of receiving future notices about non-M+C products. Also, if an M+C organization advertises non-M+C products with an M+C product, it must pro-rate any costs so that costs of marketing non-M+C products are not included as "M+C plan-related" costs on Adjusted Community Rate proposal submissions.*

***Exception:*** *While M+C organizations may mention non-M+C lines of business at the time they send a plan nonrenewal notice, they may only do so using separate enclosures in the same envelope. M+COs may not include mention of the non-M+C lines of business within the actual nonrenewal notice. The purpose of this exception is to ensure that the nonrenewal notice gives beneficiaries focused information only about the M+C nonrenewal.*

M+C organizations should not include enrollment forms for non-M+C lines of business in any package marketing its M+C products, as beneficiaries might mistakenly enroll in the other option thinking they are enrolling in an M+C plan. Also, if information regarding M+C products and non-M+C lines of business are included in the same package, postage costs must be prorated so that costs of marketing non-M+C products are not included as "M+C plan-related" costs on Adjusted Community Rate (ACR) proposal submissions.

M+C organizations may market other lines of business concurrently with M+C products on the Internet, though to avoid beneficiary confusion, M+C organizations must continue to maintain a separate and distinct section of their Web site for M+C plan information only.

CMS will review the M+C organization's Web pages to ensure that M+C organizations are maintaining the separation between M+C plan information and information on other lines of business.

## Endnotes

[1] The primary CMS/health plan contractual frame of reference in the Guide is a coordinated care plan contracting under the Medicare + Choice program. Where applicable, alternative language is provided for cost contractors as well as scenarios involving the point-of-service (POS) and Visitor Program features which may be applicable for M+C an/or cost contractors. **Back to Text**

[2] The guidelines throughout this document apply to Medicare + Choice Organizations (M+Cos) as well as Section 1876 of the Act cost contractors unless stated otherwise. Therefore, for ease of review and reference, the term "health plan" is used throughout the document to include requirements specific to both Medicare + Choice Organizations and §1876 cost contractors. **Back to Text**

[3] See §30 of the Chapter for specific application requirements for Outdoor Advertising (ODA.) **Back to Text**.

[4] Under M + C, individuals who are not already member - those that are grandfathered in - must have both Parts A and B of Medicare in order to eligible for enrollment. **Back to Text**.

[5] The health plan/M+C organization must be sure to offer adequate explanation of Medicare card use with out-of-plan utilization that is not an emergency or an urgently-needed service. **Back to Text**

[6] Note to health plan/M+C organization - CMS has the discretion to disapprove language based on site visit reviews identifying substantial deficiencies in health plan/M+C organization operations. **Back to text**.

[7] Note to health plan/M+C organization - A member of the health plan/M+C organization may use a superlative in relating their personal experience with the health plan/M+C organization so long as the testimonial is preceded with the phrase "in my opinion" (e.g., "I have been with the health plan/M+C organization for 10 years and in my opinion they have given me the best care possible.") If the member does not preface the superlative statement with the "in my opinion" phrase, the member must substantiate the statement with an acceptable qualifying information source. **Back to text**.

Note 8 has been deleted.

[9] This information should be provided in at least 12-point font size. **Back to text**.

[10] M+C organizations may choose to disseminate an errata sheet or addendum during the year to update members with respect to changes in provider's addresses and phone numbers. However, in accordance with 42 CFR 422.111(c), M+C organizations must make a good faith effort to disclose any changes to the provider information upon request and, under 422.111(e), must make a good faith effort to provide written notice at least 30

calendar days before the termination effective date. M+C organizations should consult the M+C regulations for further information. **Back to Text**.

[11] The applicable TDD/TTY number must also be provided, including the hours of operation. **Back to text**.

[12] The monthly capitation rate for an M+C enrollee that CMS pays to the M+C organization is higher for an enrollee who is a Medicaid recipient because this beneficiary tends to have higher medical costs than a Medicare beneficiary who is not a Medicaid recipient. CMS does not pay the Medicaid adjustment factor for Qualified Individuals-2 or Qualified Individuals-1. **Back to text**.

[13] The Organization is ultimately responsible for outreach even if the task is delegated to another entity. See section on Delegation. **Back to text.**

[14] Section 1851(e)(3) of the Act and 42 CFR 422.10(b). **Back to text**.

[15] An Enrollment by Mail Forms (EBMF) may be either:

1) A specifically designed enrollment application form which is attached to health plan/M+C organization marketing materials; or

2) A standard health plan/M+C organization enrollment application form with instructions that the form must be mailed back to the health plan M+C organization.

The key feature of the EBMF is that it must be completed by the beneficiary in the absence of health plan/M+C organization marketing influences and returned to the health plan/M+C organization by mail. (Self-addressed, postage paid, return envelopes may be provided by the health plan/M+C organization.). **Back to text**.

[16] This "no" statement also applies to "zero" premium plans that might want to award a nominal value gift as a reward for longevity of enrollment. **Back to text**.

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## Chapter 5

## 30.1.2 - Performance Improvement Projects

**(Rev. 5, 01-02-02)**

Performance improvement projects are projects conducted under the organization's QAPI program address that achieve demonstrable improvement in major focus areas of clinical care and non-clinical services (QISMC document standard 1.3). Demonstrable improvement is defined for QAPI projects as significant improvement sustained over time. Significant does not mean statistically significant, but rather that improvement is shown.

Definition: A project is an initiative by the organization to measure its own performance in one or more of the focus areas described in the QISMC document standards 1.3.4, 1.3.5.1 and 1.3.5.3, undertake system interventions to improve its performance, and follow-up on the effectiveness of those interventions. (QISMC document standard 1.3.1.1)

Assessment of the effectiveness of an organization's QAPI program will include review of individual performance improvement projects. In the first two years, review will focus on whether an organization has initiated performance improvement projects. In all subsequent years, reviews will focus on whether or not projects have achieved significant, sustained improvement in quality indicators. For each project, the organization will be required to supply documentation sufficient to assess the extent to which the project has met all relevant standards.

Project topics and the quality indicators used to assess each project are chosen either by the organization itself, by CMS (for Medicare) or by the State Medicaid agency (for M+C Organizations contracting with Medicaid) either for an individual organization or on a national or Statewide basis. (QISMC document standard 1.3.1.2.)

The organization will be required to conduct projects relating to certain topics selected by CMS or, if the M+C Organization has a contract for Medicaid, by the State Medicaid agency, as well as projects relating to topics of its own choosing, as outlined in the QISMC document standards 1.3.2 and 1.3.3.

A project will be considered to have achieved significant improvement in a focus area during any project year in which an improvement meeting the minimum thresholds of this manual is attained. The use of the term "significant improvement" does not mean that "statistically significant" improvement is required.

It is not expected that a project initiated in a given year will necessarily achieve improvement in that same year. For example, a project focusing on improving health outcomes for patients with a given condition might continue for several years before it would be possible to measure the effect of the organization's interventions. Such a project would not be counted as achieving improvement until the year in which the improvement is demonstrated. (An exception for certain multi-year projects is provided under the QISMC document standard 1.3.7.2.)

The first project year begins on a date established by CMS (for Medicare). (QISMC document standard 1.3.1.4)

Each newly contracting M+C Organization is expected to have initiated a national and M+C Organization selected project before the end of their second contract year. For example, organization A signs a contract with CMS on January 1, 2000, and organization B signs a contract August 1, 2000. For both organizations, the second contract year will be 2001, initiation of a project is not required in year *2000,* the first year of the contract.

This extended time frame allows new M+C Organizations to enroll beneficiaries, and accumulate data prior to the initiation of a project, and is similar to HEDIS requirements.

All subsequent project years begin on the anniversary of the beginning of the first project year. Note that project years are independent of the CMS review cycle and there may be instances where a M+C Organization completes a project after the end of a project year, but before the CMS review for that year is conducted. Upon request by the M+C Organization, the project may be included in the review for the preceding year if all necessary documentation is available for the CMS review.

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## 30.1.5.2 - Non-Clinical Focus Areas - Non-Clinical Focus Areas Applicable to All Enrollees (QISMC Document Standard 1.3.5)

**(Rev. 5, 01-02-02 )**

**Availability, Accessibility and Cultural Competency of Services (QISMC Document Standard 1.3.5.1)**

Projects in this area should focus on assessing and improving the accessibility of specific services or services for specific conditions, including reducing disparities between services to minorities and services to other members (see also QISMC document standard 1.4.4.1.4), as well as addressing barriers due to low health literacy. Projects may also focus on improving the effectiveness of communications with enrollees, and targeting areas of improvement identified as a result of the evaluation conducted under QISMC document standard 2.3.4.

This standard works in conjunction with QISMC document standard 3.1.7.1 which requires the organization to develop and monitor its own standards of timely access to all services and continuously monitor its own compliance with these standards. This standard requires that the plan go beyond examining how it evaluates compliance with its own standards, but requires the plan to identify ways to exceed its own standards and continue to identify ways to improve the ability of consumers to receive the services that they need in a timely manner. For example, a project might focus on reduction of inpatient admissions for ambulatory sensitive conditions (those for which timely ambulatory care may prevent inpatient admissions). A project might address the promptness with which referral services are furnished in response to a positive result on a given diagnostic test.

For detailed guidance regarding definition and implementation of cultural competency requirements, see QISMC document standard 3.1.5 and Manual Section 2.3.1.5, National Project on Clinical Health Care Disparities or Cultural and Linguistically Appropriate Services .

**Appeals, Grievances and Other Complaints (QISMC Document Standard 1.3.5.3 )**

Projects related to the grievance and coverage determination processes may aim either to improve the processes themselves or to address an underlying issue in care or services identified through analysis of grievances or appeals. For example, an organization with a high rate of grievances not resolved until the third or fourth step in its grievance procedure, might focus on how grievances are addressed in the initial phases of the process. An organization with a high rate of grievances related to one particular type of service might instead focus on improvements in access to or delivery of that service. Similarly, an organization with a high rate of adverse determinations overturned by the Medicare independent reconsideration contractor might aim to reduce this rate by improving its procedures for initial review of authorization requests. An organization with a high rate of sustained adverse determinations (for example, denials of inappropriate emergency room care) might instead focus on measures to improve provider and enrollee understanding of its procedures for obtaining covered services.

***NOTE**: In the review of the QAPI requirements, nine of the ten focus areas found in the QISMC document were specifically stated in regulation. The focus area "interpersonal aspects of care" was not. Therefore in early 2001, that focus area had been eliminated as a requirement.*

*If a project for year 1999, 2000, or 2001 has already been implemented using that particular focus area, CMS will continue to consider that focus area valid. CMS will accept projects done under "interpersonal aspects of care" through 2001. If a M+CO has implemented a project using the non-clinical focus area "interpersonal aspects of care", for reporting purposes, your project may be placed into the "availability, accessibility and cultural competency of services" focus area category with a note that the project focus is on interpersonal aspects of care in the project completion report.*

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## 30.2.3 - Significant, Sustained Improvement

**(Rev. 5, 01-02-02)**

The organization's interventions result in significant and sustained improvement in its performance as evidenced in repeat measurements of the quality indicators specified for each performance improvement project undertaken by the organization. (QISMC document standard 1.4.4)

The organization must demonstrate, through repeated measurement of the quality indicators selected for the project, significant change in performance relative to the performance observed during baseline measurement. This significant change does not require statistical significance although statistical significance may be used by the M+C Organization to satisfy this standard. In documenting significant improvement, the M+C

Organization must provide evidence demonstrating that change occurred and that the improvement is meaningful for the organization's Medicare population. In evaluating the projects, CMS will consider such aspects of the project as study design and whether the improvement can be attributed to actions taken by the M+C Organization.

The repeat measurement should use the same methodology as the baseline measurement, except that, when baseline data was collected for the entire population at risk, the repeat measurement may use a reliable sample instead. When an organization measures its performance using the identified indicators, it can do so by collecting information on all individuals, encounters or episodes of care to which the indicator is applicable (a census) or by collecting information on a representative subset of individuals, encounters, providers of care, etc.

When a project measures performance on quality indicators by collecting data on all units of analysis in the population to be studied (i.e., a census), significant improvement is demonstrated by achieving (QISMC document standard 1.4.4.1):

- In the case of a national Medicare project, a benchmark level of performance defined in advance by CMS or significant improvement sustained over time (QISMC document standard 1.4.4.1.1); and
- In the case of a project developed by the organization itself, a local, State or national benchmark level of performance that is defined in advance by the organization or significant improvement sustained over time (QISMC document standard 1.4.4.1.3).

**Benchmarks**

Benchmarks may be established by CMS for national QAPI projects. When the project is one determined by the managed care organization, the benchmarks must reflect performance in other organizations, local, State or national norms as established through comparative data, or reasonable expectations of optimum performance. The organization must be able to document the basis on which its benchmark was determined.

*Some benchmarks for the Medicare population such as HEDIS results are available as public use files on the CMS.gov web-site and would be appropriate for use. In addition, if Medicare specific data is not available, commercial measures may be appropriate to use.*

**NOTE:** As of 2001, CMS has not determined benchmarks for national QAPI projects.

*Performance Target*

*The terms benchmark and performance targets are not necessarily one and the same. CMS is looking for a recognized benchmark as a performance target, but realize that sometimes there is not an established or available benchmark for a particular indicator.*

*If this is the case, a M+CO may create an internal performance target based on clear rationale. The target should be something that a M+CO strives for, but may not necessarily reach. If a M+CO does not attain their stated performance target for a given QAPI project, it will not be counted against them in the evaluation of their project as long as they are moving towards improvement.*

***Sampling***

When a project measures performance on quality indicators by collecting data on a subset (sample) of the units of analysis in the population to be studied, significant improvement is demonstrated by achieving the specifications stated under QISMC1.4.4.1, using a sample that is sufficiently large to detect the targeted amount of improvement. (QISMC document standard. 1.4.4.2)

Managed care organizations must provide documentation that the sampling procedure actually implemented was random, valid, and unbiased. Organizations should be aware that using a sample creates a risk of underestimating actual improvement because of a statistical phenomenon called sampling error. If an organization demonstrates an inadequate amount of improvement based on an estimate that is derived from a sample, CMS will not assume that the inadequate amount of improvement is attributable to sampling error. Organizations therefore face a tradeoff between the cost of using a larger sample to minimize the sampling error and the risk that their actual improvement will be underestimated if they use a smaller sample. If an organization is experiencing difficulty in determining sample size or methodology, they should contact a statistician about this trade-off before making the decision regarding sample size.

From the perspective of the purchaser, the risk is one of overestimating actual improvement. CMS notes, however, that a chosen sample size that protects organizations against underestimation can be reasonably expected to protect purchasers from overestimation.

The sample or subset of the study population shall be obtained through random sampling. (QISMC document standard 1.4.4.2.1)
The samples used for the baseline and repeat measurements of the performance indicators shall be chosen using the same sampling frame and methodology. (QISMC document standard 1.4.4.2.2)

*Interventions*

It is essential that the measures of performance before and after the organization's interventions be comparable in order to measure improvement accurately. The same methods for identifying the target population and for selecting individual cases for review must be used for both measurements. For example, in a project to improve care of diabetes, it would not be acceptable to draw the baseline sample from a population identified on the basis of diagnoses reported in ambulatory encounter data, and draw the

follow-up sample from a population identified on the basis of pharmacy data. In a project to address follow-up after hospitalization for mental illness, it would not be acceptable to shift from a sampling method under which an individual with multiple admissions could be chosen more than once to a method under which the individual could be chosen only once.

The improvement is reasonably attributable to interventions undertaken by the organization (i.e., a project and its results have face validity). (QISMC document standard 1.4.4.3)

It is expected that interventions associated with improvements on quality indicators will be system interventions; i.e., educational efforts, changes in policies, targeting of additional resources, or other organization-wide initiatives to improve performance. Interventions that might have some short-term effect but that are unlikely to induce permanent change (such as a one-time reminder letter to physicians or beneficiaries) are insufficient.

The organization is not required to demonstrate conclusively (for example, through controlled studies) that a change in an indicator is the effect of its intervention; it is sufficient to show that an intervention occurred that might be reasonably be expected to affect the results. Nor is the organization required to undertake data analysis to correct for secular trends (changes that reflect continuing growth or decline in a measure as a result of external forces over an extended period of time). To the extent feasible, however, the organization should be able to demonstrate that its data have been corrected for any major confounding variables with an obvious impact on the outcomes. (For example, an organization should not use a baseline measure of asthma admissions during pollen season and then measure an improvement during another season.)

To the extent feasible, interventions should be designed to address underlying system problems uncovered in the analysis, rather than simply to improve performance on a specific indicator. For example, the organization might determine that one factor in poor outcomes for a given condition was an access problem: too few providers in a given specialty or in a given part of the service area. While the immediate intervention might be to recruit additional providers, the finding should also trigger a review of the organization's policies and procedures for ongoing monitoring of network adequacy.

The expectation of system-level intervention is in contrast to that expressed in some earlier Medicare guidelines on quality assurance activities, that intervention would occur at a provider-specific or patient-specific level. This does not mean that individual instances of substandard care observed in the course of QAPI projects should merely be recorded for statistical purposes and then forgotten. For example, if reviewers identify a specific case in which an enrollee's health is in jeopardy because there has never been follow-up on a given test result, there is clearly an ethical and professional responsibility to assure that the specific needs of that enrollee are promptly addressed. In other instances, findings of QAPI studies may trigger intensive review of the practice patterns

of an individual provider, leading to interventions in the form of counseling, possible contract sanctions, or reporting to appropriate professional disciplinary bodies.

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## 30.2.4 - Sustained Improvement Over Time

**(Rev. 5, 01-02-02)**

The organization sustains the improvements in performance described in QISMC document standard 1.4.4 for at least one year after the improvement in performance is first achieved. Sustained improvement is documented through the continued measurement of quality indicators for at least one year after the performance improvement project described in QISMC document standard 1.4.4 is completed. (QISMC document standard 1.4.5)

The organization must repeat measurement of the indicators one year after the initial indicator measurement on the basis of which demonstrable improvement was achieved. This is necessary in order to demonstrate that the improvement that was achieved has been sustained. After a M+C Organization has achieved sustained improvement for a project, CMS will not require any further documentation on that project. A M+C Organization may then continue or discontinue that project.

A project that has achieved improvement, and under which no further system interventions are undertaken by the organization, will not be regarded as an ongoing project for the purposes of the QISMC document standard 1.3.3 during the period that elapses between the measurement of improvement and the repeat measurement. The organization must carefully distinguish between active projects and projects that have been concluded but for which the repeat measurement has not yet been conducted.

*After a M+CO has met the requirement for both significant and sustained improvement on any given project, they have no other CMS reporting requirements related to that project. The M+CO may internally choose to continue the project or to go onto another topic.*

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## 30.3.4 - Process for CMS Multi-Year QAPI Project Approvals

**(Rev. 5, 01-02-02)**

### How to Make a Request for Approval

A standardized request form will be available on the CMS.hhs.gov web site. The M+C Organization will download this document, fill it out, and send it electronically to the designated address with a copy to their CMS RO representative. An acknowledgement of

receipt of the request will be sent to the M+C Organization from the recipient of the request.

**Who Reviews the Request?**

A CMS standing committee will address these requests. This group will consist of representatives from the Medicare+Choice Quality Review Organization, and CMS CO and RO.

**When Should the Request be Submitted?**

The M+C Organization should identify its intention to do a multi-year project significantly in advance of the proposed implementation date. The committee will address all proposals received subsequent to their last meeting.

*Text deleted.*

A M+C Organization may choose to change the topic of its selected project provided that the new project topic meets all of the requirements of this manual. The baseline of the new project topic must also be from the appropriate year. CMS does not require that a M+C Organization notify the agency of this type of change. However, a M+C Organization may choose to notify their CMS RO representative of the change.

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## 30.4 - Evaluation of QAPI Projects

**(Rev. 5, 01-02-02)**

***CMS Regional Office Representatives***

*The CMS Regional Office staff will **continue** to be a good resource for M+COs to utilize when questions arise regarding their QAPI projects. Although the M+CQROs will be reviewing the QAPI projects, the CMS RO staff will continue to monitor the other aspects of the QAPI Program and Health Information System when they come on-site for monitoring reviews. M+COs may share their project information with their RO Representative to let them know about what projects and interventions are being developed and ask for guidance. However, the responsibility for the final review of the projects will be solely that of the M+CQRO teams with final approval from both CMS regional and central office staff. It is not expected that the reporting of projects coincide with a CMS site visit. However, RO staff will be able to access all previous QAPI project submissions for review in preparation for a site visit.*

**Reviewers**

The QAPI evaluations will be completed by four contractors, known as the Medicare+Choice Quality Review Organizations (M+CQRO). The M+CQRO are four

PROs - California Medical Review, Inc., Colorado Foundation for Medical Care, Delmarva Foundation for Medical Care and Island Peer Review Organization. The contract period began in February, 2000, and will be completed in February, 2003. The four contractors have developed the training and implementation materials and manuals that are used to provide technical assistance to M+C Organizations and CMS in the design, development, implementation and evaluation of their quality assessment and performance improvement programs.

PROs may provide technical assistance *and expertise* to M+C Organizations in their State in the development and implementation of QAPI projects. To prevent potential conflict of interest, the M+CQRO's will not review QAPI projects within their own states. Thus, the four contractors listed above will provide technical assistance to M+C Organizations in their own respective states.

**Project Completion Report**

The Project Completion Report will provide the M+C Organization with an effective reporting tool for QAPI projects. The reporting unit will be the H-number *(CMS contract identification number)* level or less. The M+C Organization will be allowed to segment their single H-number into smaller units *(subunits)*, but not to report on a unit larger than the H-number. Each segment will then have its own unique password and code for access into the CMS database. *This issue is especially relevant for those large organizations that conduct their businesses in a geographically defined manner within their larger H-number. In essence, these organizations will then report on several projects as to ensure that all counties within their H-number are accounted for.*

*For those M+COs who have consolidated H numbers over the course of the project, they report on their current H-number as recognized by CMS. For significant improvement, the M+COs should report with the numbers they are ending the project with, but make note if there has been a significant consolidation that has affected the study outcomes. In some instances units for baseline measurement may not be exactly the same as units used in re-measurement. If unsure of how to proceed, please contact your RO representative for consideration of your issue.*

The *project completion* report will be in a web-based format, which will be password protected. The information will be directly submitted into the CMS Health Plan Management System (HPMS) database *where the web-based project completion report is housed. This web-based system will be available for use in mid-January, 2002*

*Each M+C organization has limited access to the HPMS database. However, each organization must ensure that the person or persons who will be the contact for each QAPI report and will be responsible for filling out the report have their own individual passwords and access. To obtain access to the project completion report (which is also called the QAPI module in HPMS), an individual must apply for HPMS access codes. In order to get access to HPMS, individuals must fill out a form called "APPLICATION*

*FOR ACCESS TO CMS COMPUTER SYSTEMS" which is located at URL: www.hcfa.gov/mdcn/access.pdf. In addition, the user's computer must be able to access the AT&T Global Network.*

*The instructions are also available to complete this form. The original completed forms can be submitted to :*

*Centers for Medicare & Medicaid Services*
*Attention: Don Freeburger*
*7500 Security Boulevard*
*Mailstop Central 4-14-21*
*Baltimore, Maryland 21244-1850*

*Please contact Don Freeburger at DFreeburger@cms.hhs.gov with questions on this process.*

The report format is designed to be user-friendly through the inclusion of informational cues and text fields allowing for broad responses. An M+C Organization may report any information regarding the project that it feels will describe and support understanding of the project by the reviewer. **The M+C Organization will be able to determine what information they consider proprietary and CMS will not release any proprietary information**. Only one indicator and intervention is required in this report. If a M+C Organization chooses to report more than one, it will be evaluated only on the indicator(s) for which it achieves significant improvement.

The M+CQROs will evaluate the QAPI projects. This review will include (but not be limited to) analysis of the choice of focus area, patient population and eligibility criteria, selection of intervention and methodological integrity as required in the QISMC document standards. The review will be done solely from the data contained in the QAPI Project Completion Report; no on-site review will be done

The M+CQROs will provide their CMS with a report on each QAPI project *via the secure HPMS system.* The report will include the final score of the project based on CMS scoring methodology, recommendations as to whether the project met the required goals and recommendations for improvement. The report will also recommend a corrective action plan in the event that the M+C Organization did not satisfy all of the requirements.

**When to Report**

The M+C Organization will have 90 days from the completion of their project to submit its Project Completion Report electronically, *via the HPMS system,* to the M+CQRO. The completion date of a project is usually close to the end of the 3-year project cycle, and is the date on which the last data run of the project was completed. This data run demonstrates the required significant and sustained improvement. The M+C Organization determines the actual date of project completion. *CMS has not determined any specific deadlines for the submission of the project completion reports. Remaining flexible, CMS*

*considers the type of data the M+COs are using (i.e. HEDIS, CAHPS, etc) and any other factors that may affect when the M+CO can complete and report their projects. If a M+CO knows that there will be a significant delay in the reporting of their project (beyond the assumed 3-year cycle, specifically using HEDIS), they should notify their CMS Regional Office representative. For example, if a project was initiated in 1999, one could report "significant improvement" in 2001/2002 (depending upon the type of data or indicators that you use, such as HEDIS) ). "Sustained improvement" would then be reported one year later in 2002/2003. Additionally, although a 3-year cycle is assumed, a M+CO may report on demonstrable improvement prior to the end of 3-years, if they have met the QAPI project requirements. The reporting date is also affected by the time period of the baseline data. For example, a 1999 project may use data from either 1998 or 1999.*

For those organizations that are using CMS standardized measurements, such as HEDIS, CAHPS, or HOS, allowances will be made to accommodate these predetermined reporting timeframes. For instance, if an organization used HEDIS measurements in their 2000 project, CMS will expect that the project is completed by the end of 2003. However, because of the HEDIS predetemined reporting timeframes, CMS will accept the Project Completion Report after the audited HEDIS results were announced in June of 2004. It will be assumed that during year 2004, the M+C Organization is working on sustaining its improvement for reporting in 2005. If this is the case for your organization, notify your CMS RO Representative.

Even if the organization has not achieved significant and sustained improvement, it must report by the end of the 3-year cycle. The M+CQROs will evaluate the project and make recommendations as to how the M+C Organization can best achieve the required significant improvement (see CAP example #2).

***Project Review Report***

*The Project Review Report will be sent to CMS via the HPMS system from the M+CQRO reviewers. This report will highlight the strengths and weaknesses of each project. The M+CQROs will list general recommendations for consideration in the development and execution of future QAPI projects. The report will include the final score of the project based on the scoring methodology. For significant improvement, if a project scores 50 or higher, a corrective action will not be required. If the project scores a 49 or less, CMS will require a corrective action plan.*

*In cases where a CAP has been required, please refer to the above sections that address the corrective action process. If the M+C Organization wishes to discuss the findings from the project or the CAP, it must contact their CMS RO representative, not the M+CQRO reviewer. All interactions with the M+CQROs will be through the CMS RO. They will facilitate all communication between M+C Organization and M+CQRO either via e-mail, telephonically, or through conference calls. If a resolution cannot be achieved, the issue will be reviewed further and a final decision reached.*

**Other Tools**

In addition to the Project Completion Report *and Project Review Report*, other tools have been developed to assist M+C Organizations in the implementation of the QAPI projects. An instructional guide and a reviewer guide provide clarification of the elements requested in the report. The guides include definitions as well as examples of appropriate answers to ensure that both the M+C Organization staff and reviewer have the same understanding of the requirements.

The scoring methodology was created using the framework of the QISMC document standards. All aspects of the QISMC standards are important, however, some areas such as *significant* (demonstrable) and sustained improvement were determined to be the most significant. The scoring is weighted based on the significance placed on particular elements. *Scoring is also divided into a section for significant improvement, which can have a maximum of 80 points, and sustained improvement, which can have a maximum of 20 points. The maximum point value assigned to a completed project is 100 points.*

All tools *are* available on cms.hhs.gov, the CMS web site.

**Validation**

CMS will determine the frequency and type of independent validation and in-depth reviews. These will be done either on site or by having all materials sent to the reviewer. Either the M+CQRO or another CMS contractor may perform these reviews. It is expected that selection for independent validation will be done in a random manner. The CMS ROs will not be evaluating QAPI projects during their monitoring site visits to a M+C Organization. They will continue to review and evaluate the administration of the M+C Organization QAPI program and the health information system.
Of the independent validations and audits performed, the evaluation may include but not be limited to:

- Validation/reliability edits/measures for individual records;
- Cross tabulations among comparable data in different files or databases;
- Conducting validity and accuracy checks on data samples;
- Patient selection criteria and applying statistical algorithms that relate sample error rates to population error rates;
- Development and/or implementation of comparability measures using either similar data for other sources or demonstrably valid surrogates;
- Development of data reliability measures and statistical quality controls; and

- Conversion of these statistics into program management report and evaluation analyses.

**Corrective Action Process**

In the event that a M+C Organization does not meet the set requirements in the standards and guidelines determined by CMS, a Corrective Action Plan (CAP) will be required. The CAP is meant to bring the M+C Organization into compliance with the QAPI requirements *Once all CAPs have been resolved, CMS will automatically increase the M+COs significant improvement score to a total value of 50 points out of a possible 80 points. This increase brings the M+CO into a compliance level of 2, which does not requires corrective action. This increase will positively affect the total project score after sustained improvement is evaluated in the following year.*

*Text deleted*

**Possible Examples of CAP Elements**

- Sampling methodology is inappropriate - The M+C Organization will have to re-sample and re-calculate final figures for the project under review. The M+C Organization may be required to collaborate with the PRO for future sampling efforts.

- Methodology is appropriate and study is sound, but did not achieve significant and sustained improvement - The M+C Organization may be required to add or strengthen interventions. If appropriate, it may also be allowed to have a specific extension of time if the reviewers believe that more time would show the improvement.

- Interventions do not support indicators - The M+C Organization may be required to implement new interventions or collaborate with its PRO on future projects.

- Conducts a project, but has poor planning, methodology, indicators, interventions, etc - The M+C Organization may be instructed to collaborate with its PRO in future projects and repeat the project as its next M+C Organization selected study.

- Failure to conduct a QAPI project - The M+C Organization may be required to conduct a CMS-directed special project with significant increased oversight.

The examples of CAPs listed above are not exhaustive. The type of CAP imposed will depend on the quality of the QAPI project and the M+C Organization's performance in conducting its QAPI projects.

The requirement for conducting a special project may be imposed for a variety of reasons besides total non-compliance (see §30.3.2). CMS has not yet required any M+C Organizations to do a CMS-directed special project.

It is unlikely that an M+C Organization's contract will be terminated solely based on poor performance in a QAPI project. However, if an M+C Organization was consistently a poor performer on QAPI projects, it would raise questions about its other QAPI projects as well as its performance in other required areas as laid out in this Manual Chapter and the QISMC document standards.

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## 35.4 - Obligations of Deemed M+C Organizations

**(Rev. 5, 01-02-02)**

As noted above, to be granted deemed status an M+C Organization must be fully accredited and periodically re-accredited by a CMS-approved accrediting organization. In addition, an M+C Organization deemed to meet Medicare requirements must submit to surveys to validate its accrediting organization's accreditation process. There are two types of validation surveys:

1. Observational (commonly referred to as concurrent); and
2. Retrospective (or look behind) surveys.

An M+C Organization that seeks deemed status must also agree to authorize its accreditation organization to release to CMS a copy of its most current accreditation survey, as well as any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements).

*M+COs who seek deemed status via accreditation by a CMS-approved accrediting organization can submit the cost of accreditation as an administrative cost in their ACR submission. Administrative costs that bear a significant relationship to the M+C plan being priced are allowed to be included in the ACR. However, the cost for the accreditation should be equally allocated between the M+COs Medicare and non-Medicare line of business.*