Medicare Managed Care Manual

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

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CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
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NEW/REVISED MATERIAL --EFFECTIVE DATE: Not Applicable

IMPLEMENTATION DATE: Not Applicable

Chapter 2, Medicare + Choice Enrollment and Disenrollment

Section 10 - Definitions

1. "Conversions" - opening word "When" was changed to "For".

2. "Election Form" - added text defining the acronym EGHP. In second paragraph clarified that the form is sent to the M+C Organization.

3. "M+CO Error" - added the word "one" to correct typographical error.

Section 20.2.2 -Exceptions to Eligibility Rule for Persons Who Have ESRD - corrected the last bulleted paragraph to clarify that ESRD individuals in nonrenewing/terminating plans can make election in the current nonrenewal/termination SEP.

Section 20.3 - Place of Permanent Residence - deleted the word "whether" in the last sentence of the second to last paragraph.

Section 20.10 - Eligibility Requirements for Medicare MSA Plans - within third bullet closed parenthesis sign at end of paragraph.

Section 30 - Election Periods and Effective Dates - added clarifying statement to fourth paragraph that M+C plan is not required to publish notice when re-opening enrollment periods.

Section 30.2 - Initial Coverage Election Period (ICEP) - updated dates used in bulleted example.

Section 30.3 - Open Enrollment Period (OEP)

1. Added text defining the acronyms OEPI and OEPNEW.

2. Added clarifying statement as a "Note" regarding an M+C Organization's open and closed enrollment periods for OEPI and OEPNEW.

3. In third paragraph, updated example for current year, 2002.

4. Corrected last paragraph to clarify that an individual may make only **one** election during each OEP, not including any elections made during an SEP, ICEP, OEPNEW, or OEPI

Section 30.4 - Special Election Period - (SEP) - added statement near end of section regarding SEP/guaranteed issue policy

Section 30.4.1 - SEP's for Changes in Residence - in the Example, in bullet A corrected the effective dates that a beneficiary may choose to July 1, August1, or September 1.

Section 30.4.4 - SEP's for Exceptional Conditions

1. Bullet 2 - clarified the start/length of the SEP when an enrollee disenrolls in connection with a matter that gave rise to a CMS sanction.

2. Bullets 4, 5, 6, and 9 - added closing sentence that The effective date would be dependent upon the situation.

3. Bullet 7 - revised text regarding M+C Plans which open in or expand into rural abandoned counties to apply to rural & abandoned county; established 2 new SEPs for general retro entitlement determination & zero-premium plans.

4. Bullet 8 - revised text regarding SEP for individuals with ESRD whose entitlement determination was made retroactively.

5. Bullet 10 - added text regarding SEP for individuals whose Medicare entitlement determination was made retroactively.

6. Bullet 11 - added text regarding SEP for current M+C organization members who wish to enroll in a zero-premium plan offered by the same M+C organization in 2002.

Section 30.5 - Effective Date of Coverage

1. First paragraph - added the word "generally" to the first sentence.

2. Paragraph Below Effective Dates Table - deleted text "For example, until 2001, the AEP and OEP will coincide every November if an M+C plan has open enrollment."

3. Deleted example regarding enrollment effective dates that an individual can choose.

4. Paragraph before ranking - revise hierarchy section to reflect that priority should be given in order that maximizes beneficiary options (SEP before AEP & OEP)

5. Ranking - changed the ranking of the election periods to 1 - 6, and changed example following election periods.

Section 30.6 - Effective Date of Voluntary Disenrollment

Deleted text in third paragraph - "For example, since Original Medicare is always open during the OPE, the AEP and OPE will overlap in November 2001."

Section 50.1 - Voluntary Disenrollment by Member

1. Updated text to define specifically how a member may voluntarily disenroll.

2. Added text specifically clarifying conditions to be met for receiving requests via e-mail:

3. Paragraph beginning "Request Signature and Date" to clarify this section applies to individuals providing a written request to disenroll:

4. Add text regarding certain privacy/security requirements required by CMS.

5. Subsection **"Request Signature and Date" -** Clarify that first paragraph applies when an individual provides a written request.

6. Subsection **"Notice Requirements" -** deleted the word written:

Section 50.2.1 - Members Who Change Residence - revises policy for permanent moves. The effective date is based on move AND after notice provided by member (returning to OPL 100 policy).

Section 50.3.2 - Disruptive Behavior - clarified that there is no required timeframe for M+C organization to send notice to member, but can occur upon approval from CMS and must occur before transaction submitted to CMS.

Section 50.5 - Disenrollments Not Legally Valid

1. Clarified that optional involuntary disenrollments are legally valid; therefore individual does not qualify for a reinstatement.

2. Fourth paragraph - Correct sentence to read 'CMS believes".

Section 60.5 - Retroactive Disenrollments - delete statement for retroactive disenrollments for permanent moves (based upon revised policy for permanent moves in 50.2.1).

Section 60.6.1 - EGHP Retroactive Enrollments - miscellaneous correction of dates.

Exhibit 12: Model Notice to Confirm Voluntary Disenrollment Identified through Reply Listing - substantially revised Medigap language to reflect language in Exhibit 9, 10, and 11a.

Exhibit 20: Model Notice on Failure to Pay Plan Premiums - Notification of Involuntary Disenrollment - add following language for individuals disenrolled for nonpayment of premiums, would have opportunity to make election in OEP if the individual has not already used up OEP election for that year.

Chapter 3 - Marketing

Section 20.2 - Employer Group Marketing Review Process - is added to describe changes resulting from §617 of the Benefits Improvement and Protection Act (BIPA). CMS has waived all M+C organizations from CMS pre-approval of marketing materials for members of employer groups.

Section 30.1 - Guidelines for Advertising (pre-Enrollment) Materials - in "Special Situation" subsection requirements for showing telephone numbers are clarified.

Section 30.3 - Must Use/Can't Us/Can Use Chart - is clarified

Section 40 - Guidelines for Beneficiary Notification Materials - is clarified to include newspapers within the definition of mareting materials.

Section 40.4 - Specific Guidance About Drug Formularies - changed "theregenics" to "therapeutic" and removed the reference to 2001 EOC.

Section 40.5 - Guidance to Medicare + Choice Organizations About Outreach to Its Dual Membership - the entire section was rewritten.

Sections 60 - Other Marketing Activities - is a new section describing other marketing activities.

Sections 50.4 - 50.6 have been relocated to 60.1 - 60.3

Chapter 5 - Quality Asurance

Section 10 - Introduction - changed the first instance of Centers for Medicare and Medicaid Services (CMS) to read Health Care Financing Administration (HCFA)

Section 30 - Quality Assessment and Performance Improvement Projects - changed the word "states" lowercase.

Section 30.1.2 - Performance Improvement Projects - fourth paragraph - changed the word statewide lower case.

Section 30.1.4 - Ongoing Requirements (QISMC Document Standard 1.3.3) - subsection Requirements for All Organizations (QISMC Document Standard 1.3.3.3) - Second paragraph - changed made the word "states" lowercase.

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

In the Note:

1. Corrected sentence grammar,
2. First paragraph, second sentence - "had been" was changed to "was"
3. Second paragraph, first sentence - the word "particular" was deleted

Section 30.2.1 - Selection of Topics - subsection "Sources of Information" - updated the words Peer Review Organization (PRO) to Quality Improvement Organization (QIO)

Section 30.2.2 - Quality Indicators - second to the last paragraph - edited the words local and state to lowercase.

Section 30.2.3 - Significant, Sustained Improvement

1. Subsection Benchmarks - second paragraph - changed the words "would be" to "are", and deleted the words "In addition" at the beginning of the second sentence.

2. Subsection "Sampling" - second paragraph - deleted footnote reference 1 which referred to a footnote that was previously deleted.

Section 30.2.4 - Sustained Improvement over Time - Deleted the word "internally"in last line.

Section 30.3.3 - Other Projects

1. Subsection "Collaborative Projects" - changed the words "PROs" to "QIOs"

Section 30.4 Evaluation of QAPI projects

1. Subsection "Accrediting Organizations That Are Approved for M+CO Deeming Authority" - added this section regarding review of QAPI projects and reporting to CMS by accrediting CMS Regional Office Representatives - clarification of the RO's responsibilities to the M+C organization during QAPI organizations.

2. Subsection "CMS Regional Office Representatives" - rewrote section to make it easier to understand.

3. Subsection "Reviewers" - various miscellaneous word changes.

4. Subsection "Project Completion Report" - clarified instructions on completing this report.

5. Subsection "When to Report" - various word changes to clarify instructions on completing this report. Deleted last paragraph in this subsection regarding the requirement to report within 3 years even if the organization has not achieved significant and sustained improvement.

6. Subsection "Project Review Report" - changed the text referring to "above sections"

7. Subsection "Reporting Timelines"

    a. Inserted narrative explanation of flow charts.

    b. Inserted 2 flow charts.

8. Other Tools - delete the word "also", changed words "can have" to "has".

Section 35.4 - Added paragraph regarding submitting costs of accreditation as an administrative cost in the ACR submission.

Section 35.6.4 - Reporting Requirements - added Bullet 7 regarding the requirement that accrediting organizations report their assessment of QAPI projects to CMS via HPMS.

Appendix A - National QAPI Project Operational Policy Letters -

Year 2000 Pneumonia - Subsection 'Support/Communication for Projects" - changed the words PROs are now known as QIOs.

Year 2001 Congestive Heart Failure - in second paragraph clarified the title referenced in chapter 7, and throughout section changed the words PROs are now known as QIOs.

Year 2002 Breast Cancer Screening - changed the words PROs to QIOs, changed the word "State" to lowercase state.

Appendix B - M+C Quality Glossary

Consumer Assessment of Health Plans Study (CAHPS) - abbreviated Managed Care Organization to its acronym MCO.

Coordinated Care Plan - abbreviated M+C Organization to its acronym M+CO.

M+C Plan - corrected reference section to 42 CFR. §422.4(a)(3) from 42 CFR. §422.4(a).

Preferred Provider Organization (PPO) - corrected reference section to 42 C.F.R. Section 422.4 (a)(1)(iv) from Social Security Act Section 1852(e)(2)(D), 42 U.S.C. §139w-22(e)(2)(D).

Quality - defined QIO, formerly known as PRO

Chapter 7 - Payment to Medicare + Choice (M+C) Organizations

Notes prior to table of Contents

1. Deleted note 1 and 2, Renumbered Note 3 as Note 1.
2. Within Note 3, added the word "required".

Section 20.1 - Special Rules for M+C Payments for Certain Types of Enrollees

1. Deleted listing for "Section 50.3", add a listing for "Section 55".
2. Added listing for "Section 165" after "Section 160" and before "Section 180".
3. Inserted as 1st sentence defining “ESRD beneficiaries” for purposes of this section.

Section 20.1.1 - Enrollees With End-Stage Renal Disease (ESRD) - a new sentence is added defining ESRD beneficiaries for purposes of M+C payment, an explanation of recent adjustments made to ESRD rates made by CMS is added.

Section 50.2 - Rules for Coverage and Payment of National Coverage Determinations (NCDs) - formatting at the beginning of the bulleted list is corrected to clarify the section. Also the last sentence is deleted.

Section 55 - Coverage of Clinical Trials - Is a new section on clinical trials.

Section 70 - Adjustment of Capitation Rates for Demographic Characteristics and Health Status - is clarified to show that rates discussed in this section are "for aged and disabled beneficiaries", and the cross reference to §6 is corrected to §60.

Section 70.1 - Transition to a Comprehensive Risk Adjustment Method - Corrected "Note 3" to "Note".

Section 90.1 - Demographic Factors under the PIP-DCG Risk Adjustment Method - "PIP-DCC" is changed to "PIP-DCG".

Section 90.4.2 - Method for Calculating County Rescaling Factors - a missing left parenthesis sign is added to first bullet.

Section 90.5 - Treatment of Certain demonstrations under the PIP-DCG Risk Adjustment Method - edited sentence last sentence and delete one sentence regarding payments for these demonstrations.

Section 100.1 - Extra Payment in Recognition of the Costs of Successful Outpatient CHF Care - change "who have been" to "were" and add text regarding instructions for M+C organizations to receive extra payments.

Section 100.2.5 - Extra Payment - replace entire section regarding extra payments for principal inpatient diagnosis of CHF.

Section 100.4 - Implementation of 100 Percent Risk-Adjusted Payments for Qualifying Congestive Heart Failure Enrollees in 2001 - delete entire section

Section 110.6, Table 3 - Submission Deadlines for Hospital Inpatient Encounter Data

1. Changed year in 4th row (Payment Year 2002) from July 1, 2001-June 30, 2002 to July 1, 2000 - June 30, 2001.

2. Added to 1st footnote 2 instructions regarding deadlines.

3. Subsection "Reconciliaton of Payments" - clarified deadlines for submission of data for a payment year.

Section 160 - Special Rules for M+C Payments for Beneficiaries Enrolled as Qualifiying Individuals - corrected the word "Renrolled" to "Enrolled" in section title.

Section 165 - Special Rules for M+C Payments to Department of Veterans Affairs Facilities - is a new section.

Section 170 -Clarification of the Definition of "Certified Institution" for Adjusting Payments under the Demographic-Only Method - added closing parenthesis to the word "Medicaid" at end of first bullet.

Section 170.1, Types of Certified Institutions - Add text referencing web site http://www.hcfa.gov/stats/inst.htm for files containing the names and contact information for certified institutions, which are updated quarterly.

Section 170.3 - Payment for Institutional Status - corrected second bullet from a split sentence, and various typographical errors.

Exhibit 2 & 3 - Changed HCFA to CMS throughout

Exhibit 2

1. Changed title to "Additional Information on Coverage of Clinical Trials.".

2. Replaced first paragraph; and delete sentence.

Exhibit 3

1. Changed title to "Demographic Cost Factors for Aged, Disabled, and ESRD Beneficiaries".

2. Added table "Age/Sex Demographic Factors for M+C ESRD Enrollees" after "Demographic Factors for Disabled Beneficiaries" table.

Throughout - replaced "section" with § symbol, except where "section" starts a sentence.

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/manuals

Medicare Managed Care Manual

Chapter 2 - Enrollment and Disenrollment

10 - Definitions

(Rev. 9, 04-01-02)

The following definitions relate to topics addressed in this Chapter.

Cancellation of Election - An action initiated by the beneficiary to cancel an election before the effective date of the election.

Completed Election - An election is considered complete when:

1. The form/request is signed by the beneficiary or legal representative (refer to §40.2.1 for a discussion of who is considered to be a legal representative);

2. For enrollments, evidence of entitlement to Medicare Part A and enrollment in Medicare Part B is obtained by the Medicare+Choice Organization (M+C organization) (see below for definition of "evidence of Medicare Part A and Part B coverage");

3. All necessary elements on the form are completed (for enrollments, see Exhibit 25 for a list of elements that must be completed), and, when applicable; and

4. Supporting documentation for a representative's signature is obtained.

For enrollments, an M+C organization may also choose to wait for the individual's payment of the plan premium, including any premiums due the M+C organization for a prior enrollment that ended when the beneficiary was disenrolled for nonpayment of basic and supplementary premiums, before considering an enrollment "complete."

Some States have additional requirements before an enrollment is considered complete. For example, some States require phone verification prior to enrollment. Unless otherwise directed by CMS, M+C organizations should conduct the required activities within the time frames specified by the State. If no time frame is specified, then the M+C organization should complete the required activities as quickly as possible, but within the time frames specified in §40.2.2. The election will not be considered complete until the M+C organization has completed the State-required activities.

Continuation Area/Continuation of Enrollment Option - A continuation area is an additional CMS-approved area outside the M+C plan's service area within which the M+C organization furnishes or arranges for furnishing of services to the M+C plan's continuation of enrollment members. M+C organizations have the option of establishing continuation areas.

Conversions - *For* individuals who are enrolled in a commercial health plan offered by the M+C organization the month immediately before the month of their entitlement to Medicare Parts A and B, their enrollment in an M+C plan offered by the same organization is referred to as a "conversion" from commercial status to M+C enrollee status. In order for the individual's enrollment with the organization as an M+C enrollee to take effect upon becoming eligible for Medicare, conversions must take place during the individual's Initial Coverage Election Period (ICEP), and the individual must fill out an enrollment form and meet all other applicable eligibility requirements to elect the M+C plan.

Denial of Election - Occurs when an M+C organization determines that an individual is not eligible to make an election (e.g., the individual is not entitled to Medicare Parts A or B, the individual has ESRD, the individual is not making the election during an election period, etc.), and therefore decides not to submit the election transaction to CMS.

Election - Enrollment in, or voluntary disenrollment from, an M+C plan or the traditional Medicare fee-for-service program ("Original Medicare") constitutes an election. (Disenrollment from Original Medicare would only occur when an individual enrolls in an M+C plan.) The term "election" is used to describe either an enrollment or voluntary disenrollment. If the term "enrollment" is used alone, however, then the term is used deliberately, i.e., it is being used to describe only an enrollment, and not a disenrollment. The same applies when the term "disenrollment" is used alone, i.e., the term is being used to describe only a disenrollment, and not an enrollment.

Election Form - The form used by individuals to request to enroll in, or disenroll from, M+C plans. A model individual enrollment form is provided in Exhibit 1. **An individual who is a member of an M+C plan and who wishes to elect another M+C plan, even if it is in the same M+C organization, must complete a new election form to enroll in the new M+C plan**; however, that individual may use a short enrollment form (refer to Exhibit 3 for a model short enrollment form) to make the election in place of the comprehensive individual enrollment form. In addition, M+C organizations may want to collaborate with *employer group health plans (*EGHPs*)* to use a single enrollment form for EGHP members; a model EGHP enrollment form for this purpose is provided in Exhibit 2. Beneficiaries or their authorized representatives must complete enrollment forms to enroll in M+C plans.

Beneficiaries are not required to use a specific form to disenroll from an M+C plan, but if they do not use a form they must submit a signed and written request for disenrollment *to the M+C organization*. A model disenrollment form is provided in Exhibit 10.

Election Period - The time during which an eligible individual may elect an M+C plan or Original Medicare. The type of election period determines the effective date of M+C coverage. There are several types of election periods, all of which are defined under §30.

Evidence of Medicare Part A and Part B Coverage - For the purposes of completing an enrollment form, the M+C organization must accept any of the following as acceptable evidence of entitlement to Medicare Part A and enrollment in Part B:

1. A Medicare card;

2. A Social Security Administration (SSA) award notice;

3. A Railroad Retirement Board (RRB) letter of verification;

4. A statement from SSA or RRB verifying the individual's entitlement to Medicare Part A and enrollment in Part B;

5. Verification of Medicare Part A and Part B through one of CMS's systems, including CMS data available through CMS subcontractors; or

6. For individuals enrolling in their ICEP, an SSA application for Medicare Part A and B showing the effective date for both Medicare Parts A and B.

Evidence of Permanent Residence - A permanent residence is normally the enrollee's primary residence. An M+C organization may request additional information such as voter's registration records, driver's license records, tax records, and utility bills to verify the primary residence. Such records must establish the permanent residence address, and not the mailing address, of the individual.

Institutionalized Individual - An individual who moves into, resides in, or moves out of an institution specified in §30.3.5.

Involuntary Disenrollment - Refers to when an M+C organization, as opposed to the member, initiates disenrollment from the plan. Procedures regarding involuntary disenrollment are found in §§50.2 and 50.3.

Medicare +Choice Organization (M+C organization) - Refer to Chapter 1 (General Administration of the Managed Care/Medicare+Choice Program) for a definition of a M+C organization."

M+C organization Error - An error or delay in election processing made under the full control of the M+C organization personnel and *one* that the organization could have avoided.

Medicare +Choice Plan - Refer to Chapter 1 for a definition of "M+C plan." Elections are made at the M+C **plan level**, not at the **M+C organization level**.

Out-of-Area Members - Members of an M+C plan who live outside the service area and who elected the M+C plan while residing outside the service area (as allowed in §§20.0, 20.3, 50.2.1, and 50.2.4).

Receipt of Election - According to 42 CFR §422.60(d), an election has been made when a completed election form has been received by the M+C organization. An election is considered received and must be date stamped by the M+C organization when the M+C organization (or any entity authorized by CMS to process election forms, such as SSA or the RRB) comes into possession of a **completed** election form signed by the enrollee (or as may be the situation in the case of a disenrollment, a written request or other CMS-approved method described in §50.1). A "completed election" form is defined above.

Reinstatement of Election - An action that may be taken by CMS after an individual disenrolls from an M+C plan. The reinstatement corrects an individual's records by canceling a disenrollment to reflect no gap in enrollment in an M+C plan. A reinstatement may result in retroactive disenrollment from another Medicare managed care plan.

Rejection of Election - Occurs when CMS has rejected an election submitted by the M+C organization. The rejection could be due to the M+C organization incorrectly submitting the transactions, to system error, or to an individual's ineligibility to elect the M+C plan.

System Error - A "system error" is an unintended error or delay in election processing that is clearly attributable to a specific Federal government system (e.g., the Rail Road Benefit (RRB) system), and is related to Medicare entitlement information or other information required to process an election.

20.2.2 - Exceptions to Eligibility Rule for Persons Who Have ESRD

(Rev. 9, 04-01-02)

- **Conversions upon ICEP:** Individuals who developed ESRD while a member of a health plan offered by an M+C organization and who are converting to Medicare Parts A and B, can elect an M+C plan in the same organization (within the same State, with exceptions) as their health plan during their ICEP. ("Conversion" is defined in §10 and the time frames for the ICEP are covered in §30.2). The individuals must meet all other M+C eligibility requirements and must fill out an election form to join the M+C plan.

- **Conversions other than ICEP:**

  1. If a Medicare entitlement determination is made retroactively, an individual has not been provided the opportunity to elect an M+C plan during his/her ICEP. Therefore, these individuals will be allowed to prospectively elect an M+C plan offered by the M+C organization, as long they were in a health plan offered by the same M+C organization the month before their entitlement to Parts A and B, developed ESRD while a member of that health plan, and are still enrolled in that health plan. This would also be allowed in cases when there is an administrative delay and the entitlement determination is not made timely. For example, an individual who performs self-dialysis will have his/her entitlement date adjusted to begin at the time of dialysis, rather than the customary 3 month period **after** dialysis begins.

     These individuals will be given a special election period. See §30.4.4 for additional instructions.

  2. Individuals who are members of a group health plan and are in their 30-month coordination period will have the opportunity to elect an M+C plan at any time during this 30-month period if certain conditions are met. The individual must have been a member of a health plan offered by the M+C organization the month before his/her entitlement to Parts A and B, and must continue to be enrolled in that health plan. The individual must also choose to elect an M+C plan offered by that M+C organization, and must meet all other M+C eligibility requirements.

     These individuals will be given a special election period. See §30.4.4 for additional instructions.

- An individual who elects an M+C plan and who is medically determined to first have ESRD **after** the date on which the enrollment form is signed (or receipt date stamp if no date is on the form, per §40.2), but **before** the effective date of coverage under the plan is still eligible to elect the plan.

- An individual who develops ESRD while enrolled in an M+C plan may continue to be enrolled in the M+C plan.

- Once enrolled in an M+C plan, a person who has ESRD may elect other M+C plans in the same M+C organization (and during allowable election periods, as described under §30.0). However, the member would not be eligible to elect an M+C plan in a different M+C organization or a plan in the same M+C organization in a different State (with exceptions).

- *An individual with ESRD whose enrollment in an M+C plan was terminated on or after December 31, 1998 as a result of a contract termination, non-renewal, or service area reduction can make one election into a new M+C plan. The individual must meet all other M+C eligibility requirements, and must enroll during an M+C election period described in section 3, which includes the SEP associated with that specific termination, non-renewal or service area reduction. Once an individual has exhausted his one election, he will not be permitted to join another M+C plan, unless his new plan is terminated.*

20.3 - Place of Permanent Residence

(Rev. 9, 04-01-02)

An individual is eligible to elect an M+C plan if he/she permanently resides in the service area of the M+C plan. A temporary move into the M+C plan's service area does not enable the individual to elect the M+C plan; the M+C organization must deny such an election.

EXCEPTIONS

- A member who permanently moves from the service area of the M+C plan to an approved continuation area of the M+C organization, and who chooses the continuation of enrollment option offered by the M+C organization, may continue to be enrolled in the M+C plan (refer to §60.7 for more detail on the requirements for the continuation of enrollment option.)

- Conversions: Individuals who are enrolled in a commercial health plan of the M+C organization and are converting to Medicare Parts A and B can elect an M+C plan offered by the same M+C organization during their ICEP even if they reside in the M+C organization's continuation area. ("Conversion" is defined in §10 and the time frames for the ICEP are covered in §30.2.)

- A member who was enrolled in an M+C plan covering the area in which the member permanently resides at the time the plan was terminated in that area, may remain enrolled in the M+C plan while living outside the plan's new reduced service area if:

1. There is no other M+C plan serving the area;

2. The M+C organization offers this option; and

3. The member agrees to receive services through providers in the M+C plan's service area.

- The M+C organization has the **option** to also allow individuals who are converting to Medicare Parts A and B to elect the M+C plan during their ICEP even if they reside outside the service **and** continuation area. This option may be offered provided that CMS determines that all applicable M+C access requirements in 42 CFR §422.112 are met for that individual through the M+C plan's established provider network providing services in the M+C plan service area, and the organization furnishes the same benefits to the individual as to members who reside in the service area. The organization must apply the policy consistently for all individuals. These members will be known as "out-of-area" members. This option applies both to individual members and employer group members of the M+C organization.

Individuals who do not meet the above requirements may not elect the M+C plan. The M+C organization must deny enrollment to these individuals.

A permanent residence is normally the primary residence of an individual. Proof of permanent residence is normally established by the address of an individual's residence, but an M+C organization may request additional information such as voter's registration records, driver's license records, tax records, and utility bills. Such records must establish the permanent residence address, and not the mailing address, of the individual. If an individual puts a Post Office Box as his/her place of residence on the enrollment form, the M+C organization must contact the individual to determine place of permanent residence, unless the person is homeless (see below). If there is a dispute over where the individual permanently resides, the M+C organization should determine whether, according to the law of the M+C organization's State, the person would be considered a resident of that State.

In the case of homeless individuals, a Post Office Box, an address of a shelter or clinic, or the address where the individual receives mail (e.g., social security checks) may be considered the place of permanent residence.

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30 - Election Periods and Effective Dates

(Rev. 9, 04-01-02)

In order for an M+C organization to accept an election, the individual **must** make the election during an election period (see §10 for the definition of "election"). There are four types of election periods during which individuals may make elections. They are:

- The Annual Election Period (AEP);

- The Initial Coverage Election Period (ICEP);

- All Special Election Periods (SEP); and
- The Open Enrollment Period (OEP).

During the AEP, SEP, and OEP, individuals may enroll in and disenroll from M+C plans, or may move between M+C plans, or between an M+C plan and Original Medicare. Individuals may elect to enroll in M+C plans during an ICEP.

Unless a CMS-approved capacity limit applies, all M+C organizations must accept elections into their M+C plans (with the exception of M+C MSA plans) during the AEP, an ICEP, and an SEP. (Refer to §30.7 for election periods for Medicare MSA plans.) When an M+C plan is closed due to a capacity limit, the M+C plan must remain closed to all prospective enrollees (with the exception of reserved vacancies) until the limit is lifted.

For the OEP, M+C organizations are required to process elections into any of their M+C plans that they choose to open to enrollment during an OEP. If an M+C plan is closed for enrollment, then it is closed to all individuals in the entire service area who are making OEP elections. *When an M+C organization has a plan that re-opens after being closed during an OEP or as a result of a capacity limit, there is no requirement for the M+C organization to notify the general public. However, the M+C organization should notify CMS when this occurs.*

NOTE: If an M+C plan is closed based on a capacity limit, this closure would apply to all types of enrollment. CMS may approve a partial service area closure for capacity reasons. If a plan is closed in a portion of its service area for capacity reasons, that plan may be open during the OEP in the remaining portion of the service area.

Notice to Close Enrollment - If an M+C organization has an M+C plan that is open during an OEP, and decides to change this process, it must notify CMS and the general public 30 calendar days in advance of the new limitations on the open enrollment process.

If an M+C organization has an M+C plan that is approved by CMS for a capacity limit, it should estimate when a capacity limit will be reached and notify CMS and the general public 30 calendar days in advance of the closing of the open enrollment process. If CMS approves the capacity limit for immediate closing of enrollment, the M+C organization must notify the general public within 15 calendar days of CMS approval that it has closed for enrollment.

Exhibit 23 contains three model notices that M+C organizations can use to notify the public when they are closing for enrollment.

NOTE: Public notices must receive CMS approval under the usual marketing review process.

30.2 - Initial Coverage Election Period (ICEP)

(Rev. 9, 04-01-02)

The ICEP is the three months immediately before the individual's entitlement to **both** Medicare Part A and Part B.

EXAMPLE:

- *If an individual is entitled to Medicare Part A effective July, 2002, and enrolls in Medicare Part B effective July, 2002, then the ICEP is April, May, and June of 2002.*

- *If an individual is entitled to Medicare Part A effective November, 2002, but waits to enroll in Medicare Part B for an effective date of July, 2003, then the ICEP is April, May and June of 2003.*

Please note that the ICEP will frequently relate to either the individual's 65th birthday or the 25th month of disability, but it must **always** relate to the individual's entitlement to **both** Medicare Part A and Part B.

30.3 - Open Enrollment Period (OEP)

(Rev. 9, 04-01-02)

Individuals have an opportunity to make an election or change an election during an OEP, in addition to their opportunities during the AEP, SEP, or ICEP. M+C organizations are not required to open their plans for enrollment during an OEP or *open enrollment period for institutionalized individuals (*OEPI*)* or *open enrollment period for newly eligible individuals (*OEPNEW*)*. However, M+C organizations must accept requests for disenrollment from M+C plans during the OEP since Original Medicare is always open during an OEP. In addition, if an M+C organization has more than one M+C plan, the M+C organization is not required to open each plan for enrollment during the same time frames, nor is it required to be open for all OEP-type (i.e., OEP, OEPI, OEPNEW) elections.

NOTE: *If the M+C plan is open for the OEP, then the M+C plan is automatically open for OEPI and OEPNEW elections. When the M+C plan is closed, it is the option of the M+C plan to be open for either OEPI or OEPNEW; the M+C plan can choose to be open for OEPI and closed for OEPNEW or vice-versa.*

If an M+C organization opens a plan during part of an OEP, it is not required to open the plan for the entire OEP. For example, in 200*2* an M+C organization may open a plan only during March and April, or it may choose to open the plan only during the first 25 days of each month.

Beginning in 2002, except as described for newly eligible individuals in §30.3.4, an individual may make only **one** election during each OEP, not including any elections made during an SEP, ICEP, OEPNEW*, or OEPI.* Beginning in 2003, only the individual's first OEP election will be processed by CMS. All subsequent OEP elections made by that individual will be rejected.

30.4 - Special Election Period - (SEP)

(Rev. 9, 04-01-02)

SEPs include those situations where:

1. The individual has made a change in residence outside of the service area or continuation area or has experienced another change in circumstances as determined by CMS (other than termination for non-payment of premiums or disruptive behavior) that causes the individual to no longer be eligible to elect the M+C plan;

2. CMS or the organization has terminated the M+C organization's contract for the M+C plan in the area in which the individual resides, or the organization has notified the individual of the impending termination of the plan or the impending discontinuation of the plan in the area in which the individual resides;

3. The individual demonstrates that the M+C organization offering the M+C plan substantially violated a material provision of its contract under M+C in relation to the individual, or the M+C organization (or its agent) materially misrepresented the plan when marketing the plan; or

4. The individual meets such other exceptional conditions as CMS may provide.

During an SEP, an individual may discontinue the election of an M+C plan offered by an M+C organization and change to a different M+C plan or Original Medicare. If the individual disenrolls from (or is disenrolled from) the M+C plan and changes to Original Medicare, the individual may subsequently elect a new M+C plan within the SEP time period. Once the individual has elected the new M+C plan, the SEP ends for that individual even if the time frame for the SEP is still in effect. In other words, **the SEP for the individual ends when the individual elects a new M+C plan or when the SEP time frame ends, whichever comes first.**

Please note that the time frame of an SEP denotes the time frame during which an individual may make an election. **It does not necessarily correspond to the effective date of coverage**. For example, if an SEP exists for an individual from May - July, then an M+C organization must receive a completed election form from that individual some time between May 1 and July 31 in order to consider the election an SEP election. However, the type of SEP will dictate what the effective date of coverage may be, and that effective date of coverage may be some time after July 31. The following discussion of SEPs and their corresponding effective dates will demonstrate this concept more fully.

Individuals who disenroll from an M+C plan to Original Medicare during an SEP are provided Medigap guaranteed issue rights. These rights are not afforded to those individuals who enroll into an M+C plan during an SEP - only those who disenroll to Original Medicare. M+C organizations are required to notify members of theses guaranteed issue rights when members disenroll to Original Medicare during a SEP. See §§50.1 and 50.2 for the additional information regarding these notification requirements.

The time frame and effective dates for SEPs are discussed in the following sections.

30.4.1 - SEPs for Changes in Residence

(Rev. 9, 04-01-02)

A SEP exists for individuals who are no longer eligible to be enrolled in the M+C plan due to a change in residence outside of the plan's service or continuation area.

Permanent Move Out of the Service or Continuation Area

If the individual is no longer eligible to be a member of the plan based on a permanent move out of the service or continuation area, the SEP begins the month prior to the month of the individual's permanent move and continues during the month of the move and up to two months after the move.

Outside the Service or Continuation Area for Over Six Months

If the individual is no longer eligible to be a member of the plan based on having left the service or continuation area for over six months, this SEP begins at the beginning of the sixth month of being out of the area and continues through to the end of the eighth month.

In Either Case:

This SEP is associated with the actual **date of the permanent move** (or, in the case of an individual who has left the service or continuation area for over six months, the date the sixth month ends). Therefore, if the beneficiary notifies the M+C organization more than two months after the permanent move or the eighth month has passed, the individual is no longer eligible for an SEP. This will not impact those who have already been disenrolled to fee-for-service by any previous action.

The effective date of enrollment is associated with the **date the M+C organization receives the completed election form**. The individual may choose an effective date of up to three months after the month in which the M+C organization receives the form. However, the effective date may not be earlier than the date the individual moves to the new service area (or the end of the sixth month, as appropriate) and the M+C organization receives the completed enrollment form.

EXAMPLE:

A beneficiary is a member of an M+C plan in Florida and intends to move to Arizona on June 18. A SEP exists for this beneficiary from May 1 - August 31.

A. If an M+C organization in Arizona receives a completed enrollment form from the beneficiary in May, the beneficiary can choose an effective date of *July 1, August 1, or September 1*.

B. If the M+C organization receives the completed enrollment form from the beneficiary in June (the month of the move), the beneficiary can choose an effective date of July 1, August 1, or September 1.

C. If the M+C organization receives the completed enrollment form in July, the beneficiary could choose an effective date of August 1, September 1, or October 1.

At the time the individual makes the election into an M+C plan, the individual must provide the specific address where the individual will permanently reside upon moving into the service area, so that the M+C organization can determine that the individual meets the residency requirements for enrollment in the plan.

Disenrollment from Previous M+C Plan

Please keep in mind that a member of an M+C plan who moves permanently out of the service area must be disenrolled from the plan, unless continuation of enrollment applies. A member of an M+C plan who is out of the area for over six months must be disenrolled from the plan.

We have established an SEP that allows an individual adequate time to choose a new M+C plan, given the fact that the individual will no longer be enrolled in the original M+C plan after the month of the move or after the sixth month (whichever is appropriate). Unless an individual enrolls in a new M+C plan with an effective date of the month after the move or the beginning of the seventh month (e.g., the individual moves on June 18 and enrolls in a new plan effective July 1), he/she will be enrolled in Original Medicare until he/she elects the new M+C plan.

30.4.4 - SEPs for Exceptional Conditions

(Rev. 9, 04-01-02)

CMS has the legal authority to establish SEPs when an individual meets exceptional conditions specified by CMS. Currently CMS has established the following SEPs for exceptional conditions:

1. **SEP EGHP -** An SEP exists for individuals electing M+C plans through their employer groups; disenrolling from their employer group-sponsored M+C plan to Original Medicare; or disenrolling from their employer group-sponsored M+C plan and electing a new M+C plan.

   For elections into M+C plans, the SEP may only be used if the EGHP provides notice to the individual at the time of enrollment stating that he/she understands the network and authorization requirements of the plan - also referred to as "lock-in" language. This language is included on the model enrollment forms in Exhibits 1, 2, and 3.

   The individual may choose an effective date of up to three months after the month in which the EGHP receives the completed enrollment form or disenrollment request. However, the effective date may not be earlier than the date the EGHP receives the completed enrollment form or disenrollment request.

   NOTE: If necessary, the M+C organization may process the election with a retroactive effective date, as outlined in §60.6.

   Keep in mind that all M+C eligible individuals, including those in EGHPs, may elect M+C plans during the AEP and ICEP, during any other SEP, and during the OEP if the plan is open for enrollment. The SEP EGHP does not eliminate the right of these individuals to make elections during these time frames.

2. **SEP for Individuals Who Disenroll in Connection with a CMS Sanction -** On a case by case basis, CMS will establish an SEP if CMS sanctions an M+C organization, and an

enrollee disenrolls in connection with the matter that gave rise to that sanction. *The start/length of the SEP, as well as the effective date, are dependent upon the situation.*

3. **SEP for Individuals Enrolled in Cost Plans that are Nonrenewing their Contracts -** For calendar years through 2004 (or, if later, for so long as authority for cost contracts is extended), an SEP will be available to enrollees of HMOs or CMPs that are not renewing their §1876 of the Act cost contracts for the area in which the enrollee lives.

   This SEP is available only to Medicare beneficiaries who are enrolled with an HMO or CMP under a §1876 of the Act cost contract that will no longer be offered in the area in which the beneficiary lives. Beneficiaries electing to enroll in an M+C plan via this SEP must meet M+C eligibility requirements.

   This SEP begins 90 calendar days prior to the end of the contract year (i.e., October 1) and ends on December 31 of the same year.

   During this SEP, a beneficiary may choose an effective date of November 1, December 1, or January 1; however, the effective date may not be earlier than the date the new M+C organization receives the completed election form.

4. **SEP for Individuals in the Program of All-inclusive Care for the Elderly (PACE) - Individuals** may disenroll from an M+C plan at any time in order to enroll in PACE. In addition, individuals who disenroll from PACE have an SEP for up to two months after the effective date of PACE disenrollment to elect an M+C plan. *The effective date would be dependent upon the situation.*

5. **SEP for Dual-eligible Individuals or Individuals Who Lose Their Dual-eligibility -** There is an SEP for individuals who are entitled to Medicare Part A and Part B and receive any type of assistance from the Title XIX (Medicaid) program. This SEP lasts from the time the individual becomes dually-eligible and exists as long as they receive Medicaid benefits, provided the Medicaid program allows for a change. *The effective date would be dependent upon the situation.*

   In addition, M+C-eligible individuals who are no longer eligible for Title XIX benefits have a 3-month period after the date it is determined they are no longer eligible to make an election.

6. **SEP For Individuals Who Dropped a Medigap Policy When They Enrolled For the First Time in an M+C Plan, and Who Are Still in a "Trial Period" -** For Medicare beneficiaries who dropped a Medigap policy when they enrolled for the first time in an M+C plan, §1882(s)(3)(B)(v) of the Act provides a guaranteed right to purchase another Medigap policy if they disenroll from the M+C plan while they are still in a "trial period." In most cases, a trial period lasts for 12 months after a person enrolls in an M+C plan for the first time. Such individuals would not be eligible for the special election period provided for in the last sentence of §1851(e) of the Act, because they did not enroll in an M+C plan immediately upon becoming Medicare eligible, but instead had been in the Original Medicare Plan for some period of time. The right to "guaranteed issue" of a Medigap policy under §1882(s)(3)(B)(v) of the Act would be meaningless if

individuals covered by this provision could not disenroll from the M+C plan while they were still in a trial period.

Accordingly, there is an SEP for individuals who are eligible for "guaranteed issue" of a Medigap policy under §1882(s)(3)(B)(v) of the Act upon disenrollment from the M+C plan in which they are enrolled. This SEP allows a qualified individual to make a one-time election to disenroll from their first M+C plan to join the Original Medicare Plan at any time of the year. *The effective date would be dependent upon the situation.*

7. ***SEP for M+C Plans that Open in (or Expand into) a Rural Abandoned County*** *- This SEP permits individuals to enroll in a plan that enters a rural non-M+C area at any time during that M+C plan's first 12 months of operation. In this case, "rural" is defined in accordance with §1886(d)(2)(D)(ii) of the Social Security Act (the Act) and further defined in the regulation at 42 CFR 412.62(f). In general, any area outside a Metropolitan Statistical Area (as defined by the Office of Management and Budget) is considered rural. This SEP allows for a one-time election into the new M+C plan. The effective date is the first day of the month after the M+C plan receives the completed election form. The SEP would end if and when another M+C plan entered the area before the end of the 12-month period.*

   For example, if CMS approves a new M+C plan on May 1, 2002, for a start date of June 1, 2002, the SEP would last from June 1, 2002, through May 31, 2003. However, if another M+C plan entered that same service area before May 31, 2003 – for example, January 1, 2003 - the SEP would end.

8. ***SEP for Individuals with ESRD Whose Entitlement Determination Made Retroactively*** *- If a Medicare entitlement determination is made retroactively, an individual has not been provided the opportunity to elect an M+C plan during his/her ICEP. Therefore, these individuals will be allowed to prospectively elect an M+C plan offered by the M+C organization, provided:*

   a) *They were in a health plan offered by the same M+C organization the month before their entitlement to Parts A and B;*

   b) *Developed ESRD while a member of that health plan; and*

   c) *Are still enrolled in that health plan.*

   This would also be allowed in cases when there is an administrative delay and the entitlement determination is not made timely. For example, an individual who performs self-dialysis will have his/her entitlement date adjusted to begin at the time of dialysis, rather than the customary 3-month period AFTER dialysis begins.

   The SEP begins the month the individual receives the notice of the Medicare entitlement determination and continues for 2 additional months after the month the notice is received. The election may only be made prospectively and the effective date is the first day of the month after the M+C plan receives the completed election form.

9. **SEP for Individuals with ESRD who are Members of a Group Health Plan and in their 30-month Coordination Period -** This SEP provides certain individuals with ESRD who are in group health plans the opportunity to elect select M+C plans at any time during the 30-month period **provided**:

    a. The individual is a member of a health plan offered by the M+C organization at the time of Medicare entitlement;

    b. Continues to be enrolled in the health plan offered by the M+C organization; and

    c. Chooses to elect an M+C plan offered by that M+C organization, assuming the individual meets all other M+C eligibility requirements.

    In order to be eligible for this SEP, there must be no break in coverage between the commercial health plan offered by an M+C organization, and coverage in the M+C plan offered by the same organization. This SEP continues throughout the duration of the 30-month coordination period and allows the individual one election from the commercial health plan to the M+C product offered by the same organization. *The effective date is dependent upon the situation.*

10. *SEP for Individuals Whose Medicare Entitlement Determination Made Retroactively - If a Medicare entitlement determination is made retroactively, an individual has not been provided the opportunity to elect an M+C plan during his/her ICEP. Therefore, these individuals will be allowed to prospectively elect an M+C plan offered by the M+C organization. This would also be allowed in cases when there is an administrative delay and the entitlement determination is not made timely.*

    The SEP begins the month the individual receives the notice of the Medicare entitlement determination and continues for 2 additional months after the month the notice is received. The election may only be made prospectively and the effective date is the first day of the month after the M+C plan receives the completed election form.

11. *SEP for current M+C organization members who wish to enroll in a zero-premium plan offered by the same M+C organization in 2002 - In 2002, individuals enrolled in an M+C plan with a monthly premium will have an SEP to elect a zero premium plan in the same M+C organization, if such a plan is offered. The election is effective the first day of the month after the M+C plan receives an election form (an abbreviated election form can be used).*

30.5 - Effective Date of Coverage

(Rev. 9, 04-01-02)

With the exception of some SEPs and when election periods overlap, *generally* beneficiaries may not request their effective date. Furthermore, except for EGHP elections, the effective date can never be prior to the receipt of a complete election form by the M+C organization. Section 40.2

includes procedures for handling situations when a beneficiary chooses an enrollment effective date that is not allowable based on the requirements outlined in this section.

To determine the proper effective date, the M+C organization **must** determine which election period applies to each individual **before** the enrollment may be transmitted to CMS. The election period may be determined by reviewing information such as the individual's date of birth, Medicare card, a letter from SSA, or by the date the completed enrollment form is received by the M+C organization.

Once the election period is identified by the M+C organization, the M+C organization must determine the effective date. Refer to §60.7 to determine the effective date for a continuation of enrollment. In addition, EGHP enrollments may be retroactive. (Refer to §60.6 for more information on EGHP retroactive effective dates.)

Effective dates are as follows:

Election Period	Effective Date of Coverage	Do M+C organizations have to accept elections in this election period?
Initial Coverage Election Period	First day of the month of entitlement to Medicare Part A and Part B	Yes, unless capacity limit applies
Open Enrollment Period (including the OEPNEW, OEPI)	First day of the month after the month the M+C organization receives a completed enrollment form.	No, the M+C organization can choose to be "opened" or "closed" to accept enrollments during this period.
Annual Election Period	January 1 of the following year	Yes, unless capacity limit applies
Special Election Period	Varies, as outlined in §30.4	Yes, unless capacity limit applies

It is possible for an individual to make an enrollment election when more than one election period applies, and therefore it is possible that more than one effective date could be used. Therefore, if an individual makes an enrollment election when more than one election period applies, an M+C organization must allow the individual to choose the election period (and therefore the effective date) in which he/she is enrolling (see exception in the next paragraph regarding the ICEP).

If the individual's ICEP and another election period overlap, the individual may not choose an effective date any earlier than the month of entitlement to both Medicare Part A and Part B.

EXAMPLE:

- If an individual's ICEP is November, December and January (i.e., he will be entitled to Medicare Part A and Part B in February) and an M+C organization receives a completed enrollment form from that individual in November (the AEP), then the individual may

NOT choose a January 1 effective date for the AEP and must be given a February 1 effective date for the ICEP.

If an individual makes an enrollment election when more than one election period applies but does not indicate or select an effective date, then the M+C organization *should assign an effective date that benefits the individual and should attempt to contact the individual to determine the individual's preference. If unsuccessful, the M+C organization should use the following ranking of election periods (1 = Highest, 6 = Lowest). The election period with the highest rank generally determines the effective date.*

Ranking of Election Periods: (1 = Highest, 6 = Lowest)

1. ICEP

2. SEP

3. AEP

4. OEP

5. OEPNEW

6. OEPI

30.6 - Effective Date of Voluntary Disenrollment

(Rev. 9, 04-01-02)

With the exception of some SEPs and when election periods overlap, *generally* beneficiaries may not select their effective date. Section 50.1 includes procedures for handling situations when a beneficiary chooses a disenrollment effective date that is not allowable based on the requirements outlined in this section.

When a member disenrolls through the M+C organization, SSA, the RRB, or 1-800-MEDICAR(E), the election will return the member to Original Medicare. If a member elects a new M+C plan while still a member of a different plan, he/she will automatically be disenrolled from the old plan and enrolled in the new plan by CMS systems with no duplication or delay in coverage.

As with enrollments, it is possible for a member to make a disenrollment request when more than one election period applies. Therefore, in order to determine the proper effective date, the M+C organization **must** determine which election period applies to each member **before** the disenrollment may be transmitted to CMS.

If an M+C organization receives a completed disenrollment request when more than one election period applies, the M+C organization must allow the member to choose the effective date of disenrollment. If the member does not make a choice of effective date, then the M+C organization must give the effective date that results in the **earliest** disenrollment.

Effective dates for voluntary disenrollment are as follows. (Refer to §§50.2 and 50.3 for effective dates for involuntary disenrollment.)

Election Period	Effective Date of Disenrollment*	Do M+C organizations have to accept elections in this election period?
Open Enrollment Periods (including OEPNEW and OEPI)	First day of the month after the month the M+C organization receives a completed disenrollment request.	Yes (because Original Medicare is always open during this election period)
Annual Election Period	January 1 of the following year.	Yes
Special Election Period	Varies, as outlined in §30.4	Yes

***NOTE:** ROs may allow up to 90 days retroactive payment adjustments for EGHP disenrollments. Refer to §60.6 for more information.

50.1 - Voluntary Disenrollment by Member

(Rev. 9, 04-01-02)

A member may only disenroll from an M+C plan during one of the election periods outlined in §§30.0 and 30.7. *The member may disenroll by:*

1) *Giving or faxing a signed written notice to the M+C organization;*

2) *E-mailing the M+C organization;*

3) *Giving a signed written notice to any SSA or RRB office (refer to section 5.6 for procedures for Medicare MSA plans); or*

4) *By calling 1-800-MEDICAR(E).*

An individual who elects another Medicare managed care plan will automatically be disenrolled from his/her current plan.

If a member verbally requests disenrollment from the M+C plan*, as mentioned in #1 and #2 above*, the M+C organization must instruct the member to make the request in writing. The M+C organization may send a disenrollment form to the member upon request (see Exhibits 9 and 10).

The disenrollment request must be date stamped when it is initially received at the M+C organization's business offices.

Requests Submitted by E-mail

The M+C organization is allowed to receive requests for disenrollment from members via e-mail, however, certain conditions must be met. The M+C organization must comply with the CMS security policies – found at www.hcfa.gov/security/isecplcy.htm. These policies indicated that with regard to receiving such e-mails, an acceptable method of encryption must be utilized to provide for confidentiality and integrity of this data, and that authentication or identifcation procedures are employed to assure that both the sender and receipient of the data are known to each other and are authorized to receive and decrypt such information.

In addition, CMS policies also require M+C organizations to provide the CMS Office of Information Services with a pro forma notice of intent to use the Internet for these purposes. The notice is essentially an attestation that the M+C organization is complying with the required encryption, authentication, and identification requirements. CMS reserves the right to audit the M+C organization to ascertain whether it is in compliance with the security policy. The effective date of the disenrollment request would be based upon the date the e-mail is received by the M+C organization.

Request Signature and Date

*When providing a written request, t*he individual must sign the disenrollment request. If the individual is unable to sign, a legal representative must sign the request (refer to §40.2.1 for more detail on who may sign election forms). If a legal representative signs the request for the individual, then a copy of the proof of court-appointed legal guardian, durable power of attorney, or proof of other authorization required by State law must be attached to the request.

The individual and/or legal representative should write the date he/she signed the disenrollment request; however, if he/she inadvertently fails to include the date, then the stamped date of receipt that the M+C organization places on the request form may serve as the signature date.

Effective Dates

The election period will determine the effective date of the disenrollment; refer to §§30.6 and 30.7 for information regarding disenrollment effective dates.

With the exception of some SEPs and when election periods overlap, beneficiaries may not choose their effective date. Instead, the M+C organization is responsible for assigning the appropriate effective date based on the election period. During face-to-face disenrollments, or when a beneficiary calls about a disenrollment, the M+C organization staff are responsible for ensuring that a beneficiary does not choose an effective date that is not allowed under the requirements outlined in §§30.6 and 30.7.

If a beneficiary mails in a disenrollment request with an unallowable prospective effective date, or if the M+C organization allowed the beneficiary to choose an unallowable prospective effective date, the M+C organization must call or write the beneficiary to explain that the disenrollment must be processed with a different effective date. The organization should resolve the issue with the beneficiary as to the correct effective date, and the call must be documented. If the beneficiary refuses to have the disenrollment processed with the correct effective date, the beneficiary can cancel the election according to the procedures outlined in §60.2.2.

Notice Requirements

After the member submits a request, the M+C organization must provide the member a copy of the request for disenrollment and a disenrollment letter, and should do so within seven business days of receipt of the request to disenroll. The disenrollment letter must include an explanation of the lock-in restrictions for the period during which the member remains enrolled in the organization, and the effective date of the disenrollment (see Exhibit 11). The M+C organization may also advise the disenrolling member to hold Original Medicare claims for up to one month so that Medicare computer records can be updated to show that the person is no longer enrolled in the plan. For these types of disenrollments, i.e., disenrollments in which the member has disenrolled directly through the M+C organization, M+C organizations are encouraged, but not required, to follow up with a confirmation of disenrollment letter after receiving CMS confirmation of the disenrollment from the reply listing.

Since Medicare beneficiaries have the option of disenrolling through SSA, RRB, 1-800-MEDICAR(E), or by enrolling in another Medicare managed care plan, the M+C organization will not always receive written request for disenrollment from the member and will instead learn of the disenrollment through the CMS Reply Listing Report. If the M+C organization learns of the voluntary disenrollment from the CMS reply listing (as opposed to through written request from the member), the M+C organization must send written confirmation of the disenrollment to the member, and should do so within seven business days of the availability of the reply listing (see Exhibit 12).

Medigap Guaranteed Issue Notification Requirements for Disenrollments to Original Medicare during a SEP

M+C organizations are required to notify members of their Medigap guaranteed issue rights when members disenroll to Original Medicare during a SEP. Model language discussing these Medigap rights has been provided in Exhibit 11 and 12.

There may be cases when a Medigap issuer requires the beneficiary to provide additional documentation that they disenrolled as a result of an SEP and are eligible for such guaranteed issue rights. A beneficiary may contact you for assistance in providing such documentation. The M+C organization may provide such a notice to the beneficiary upon request (see Exhibit 26).

50.2.1 - Members Who Change Residence

(Rev. 9, 04-01-02)

General Rule

The M+C organization **must** disenroll a member if:

1. He/she permanently moves out of the service area and his/her new residence is not in a continuation area;

2. He/she permanently moves out of the continuation area and his/her new residence is not in the service area or another continuation area;

3. The member permanently moves out of the service area (or continuation area, for continuation of enrollment members) and into a continuation area, but chooses not to continue enrollment in the M+C plan (refer to §60.7 for procedures for choosing the continuation of enrollment option);

4. The member is an out-of-area member (as defined in §10), and permanently moves to an area that is not in the service area or continuation area;

5. The member's temporary absence from the service area (or continuation area, for continuation of enrollment members) exceeds six consecutive months. The M+C organization may **not** disenroll members whose absence from the service area (or continuation area, for continuation of enrollment members) lasts for six months or less; or

6. The member is an out-of-area member (as defined in §10), who leaves his/her residence for more than six months.

*Generally, d*isenrollments for reasons 1 - 4 above are effective the first day of the calendar month after the date the member begins residing outside of the M+C plan's service area (or continuation area, as appropriate) *and after the M+C organization has been notified by the member.* Disenrollment for reasons 5 and 6 above is effective the first day of the calendar month after six months have passed.

M+C organizations may consider the six months to have begun on the date given by the beneficiary as the date that he/she will be leaving the service area. If the beneficiary did not inform the M+C organization of when he/she left the service area, then the M+C organization can consider the six months to have begun on the date the change in address is identified (e.g. through the reply listing report).

NOTE: CMS is currently in the process of developing a notice of proposed rulemaking in which we expect to address the issue of "extended enrollment" or visitor/traveler programs. Directions on this matter will be available in a subsequent update to this chapter. M+C organizations that offer a visitor/traveler benefit allowing out of area enrollment for up to 12 months at this time should contact their plan manager for further guidance.

Unless the member elects another Medicare managed care plan during an applicable election period, any disenrollment processed under these provisions will result in a change of election to Original Medicare.

A SEP, as defined in §30.4.1, applies to members who are disenrolled due to a change in residence. A member may choose another M+C plan, or Original Medicare, during this SEP. The rules for this SEP will determine the effective date in the new M+C plan or Original Medicare.

Researching and Acting on a Change of Address

M+C organizations may receive a notice of a change of address from the member, the member's representative, a CMS reply listing, or another source. M+C organizations may require members to provide written verification of changes in address, but they may also choose to allow verbal verification, as long as the M+C organization applies the policy consistently among all members.

If the M+C organization receives notice of a permanent change in address from the member or the member's representative, and that address is outside the M+C plan's service area (or continuation area, for continuation of enrollment members), then the M+C organization must disenroll the member and provide proper notification. The only exception is if the member has permanently moved into the continuation area and chosen the continuation of enrollment option (procedures for electing a continuation of enrollment option are outlined in §60.7). If the change in address is temporary (i.e., not expected to exceed six months), then the M+C organization may not initiate disenrollment. The M+C organization must retain documentation from the member or member's representative of the notice of the change in address.

If the M+C organization receives notice of a new address from a source other than the member or the member's representative, and that address is outside the M+C plan's service area (or continuation area, for continuation of enrollment members), then the M+C organization may **not** assume the move is permanent until it has received confirmation from the member or member's representative. CMS suggests that the M+C organization contact the member directly or in writing to verify address information in order to determine whether disenrollment is appropriate. The M+C organization must give the member at least 20 calendar days to respond to the verification request. The M+C organization must retain documentation from the member or member's representative of the notice of the change in address, including the determination of whether the move is temporary or permanent.

- If, based on this verification, the M+C organization determines a member's move **is** permanent, then the M+C organization must disenroll the member and provide written notice of disenrollment to the member. The only exception is if the member has moved into and chosen the continuation of enrollment option (procedures for electing a continuation of enrollment option are outlined in §60.7).

- If the M+C organization determines the change in address is temporary, then the M+C organization may not initiate disenrollment until six months have passed from the date the M+C organization learned of the change in address (or from the date the member states that his address changed, if that date is earlier).

- If the member does not respond to the request for verification within the time frame given by the M+C organization, then the M+C organization must assume the move is not permanent and may not disenroll the member. The M+C organization may continue its attempts to verify address information with the member, but may not initiate disenrollment unless it verifies a move is permanent or until the member has been out of the service area (or continuation area, for continuation of enrollment members) for over six months from the date the M+C organization learned of the change in address.

Notice Requirements

The M+C organization is strongly encouraged to contact a member directly or in writing when it learns of a change of address from a source other than the member or the member's representative, in order to verify the change of address and determine whether disenrollment is necessary. The M+C organization must give the member at least 20 calendar days to respond to the request for verification.

The M+C organization must provide written notification of disenrollment to the member upon the M+C organization's learning through the member or a member's representative of the permanent move. This notice must be sent within seven business days of the M+C organization's learning of the permanent move before the disenrollment transaction is submitted to CMS.

In the notice, the M+C organization is encouraged to inform the member who moves out of the service area that he/she may have certain Medigap enrollment opportunities available to them. These opportunities end 63 days after coverage with the M+C organization ends. The M+C organization can direct the beneficiary to contact the State Health Insurance Assistance Program (SHIP) for additional information on Medigap insurance.

If the member has left the service area (without having chosen a continuation area) or continuation area (for continuation of enrollment members) for six months after the date the M+C organization learned of the change in address (or the date the member stated that his address changed, if that date is earlier), the M+C organization must provide written notification of the upcoming disenrollment to the member. This written notice must also be sent to out-of-area members (as defined in §10) who leave their residence for a location outside the service area, and that absence exceeds six months. The notice must be sent some time during the sixth month, or no later than seven business days after the sixth month as long as the notice is sent before the disenrollment transaction is submitted to CMS. The notice must advise the member to notify the M+C organization within 20 calendar days of the date of the notice if the information is incorrect. The notice must also state that if the member has not responded after the 20 days have passed, or if the member indicates that he/she will not be returning to the service/continuation area before the six months have passed, the M+C organization must disenroll the member effective with the first day of the month following the 20-day notice. CMS strongly encourages that M+C organizations send final confirmation of disenrollment to the member to ensure the individual does not continue to use M+C organization services.

50.3.2 - Disruptive Behavior

(Rev. 9, 04-01-02)

The M+C organization **may** disenroll a member if the member's behavior is disruptive, unruly, abusive, or uncooperative to the extent that his/her continued enrollment in the plan seriously impairs the M+C organization's ability to furnish services to either the particular member or other members enrolled in the plan. However, the M+C organization may only disenroll a member for disruptive behavior upon approval from CMS. The M+C organization may not disenroll a member because the member exercises the option to make treatment decisions with

which the M+C organization disagrees, including the option of no treatment and/or no diagnostic testing. The M+C organization may not disenroll a member who chooses not to comply with any treatment regimen developed by the M+C organization or any health care professionals associated with the M+C organization.

Before beginning the disenrollment for cause process, the M+C organization must make a serious effort to resolve the problems presented by the member. This includes making an effort to provide reasonable accommodations for individuals with disabilities, in accordance with the Americans with Disabilities Act. It must inform the member, in writing, that his/her continued behavior may result in termination of membership in the plan. Such efforts must include the use (or attempted use) of the organization's grievance procedures. In this process, the member has a right to submit any information or explanation that he/she may wish to the M+C organization.

If the problem cannot be resolved, the M+C organization must give the member written notice of the M+C organization's intent to request, from CMS, permission to disenroll for cause.

The M+C organization must establish that the member's behavior is not related to the use, or lack of use, of medical services or to diminished mental capacity. The organization must document the member's behavior, the efforts it has taken to resolve any problems, and any extenuating circumstances cited under 42 CFR §422.74(d)(2)(iii) and (iv). In addition to a summary of the case and a reason for the disenrollment request, the M+C organization must submit to the CMS RO a description of the member's age, diagnosis, mental status, functional status, and social support systems, as well as statements from primary providers describing their experiences with the member.

After a review of this documentation, the CMS RO will decide whether the organization may disenroll the member on this basis. Such review will include any documentation or information provided either by the organization or the member (information provided by the member must be forwarded by the organization to the CMS RO) and CMS will make the decision within 20 calendar days after receipt of this information. The M+C organization will be notified within seven business days after CMS's decision. The disenrollment is effective the first day of the calendar month after the month in which the organization gives the member a written notice of the disenrollment. Any disenrollment processed under these provisions will always result in a change of election to Original Medicare.

Notice Requirements

The M+C organization must inform the member, in writing, that his/her continued behavior may result in termination of membership in the plan. If the problem cannot be resolved, the M+C organization must give the member written notice of the M+C organization's intent to request disenrollment for cause. This notice must include an explanation of the organization's grievance procedures. In this process, the member has a right to submit any information or explanation that he/she may wish to the organization. Refer to Chapter 13 (Grievances, Organizations Determinations, and Appeals) for the appropriate procedures for grievances.

If CMS permits an M+C organization to disenroll a member for disruptive behavior, the M+C organization must provide the member with a written notice that contains, in addition to the notice requirements outlined in §50.3, a statement that this action was approved by CMS and

meets the requirements for disenrollment due to disruptive behavior described above. *While there is no required timeframe in which the M+C organization must provide notice to the member, the M+C organization may provide the member the required notice as soon as CMS notifies the M+C organization of the approved disenrollment. The M+C organization can only submit the transaction to CMS after it has provided the notice of disenrollment to the individual. The disenrollment is effective the first day of the calendar month after the month in which the organization gives the member a written notice of the disenrollment.*

50.5 - Disenrollments Not Legally Valid

(Rev. 9, 04-01-02)

When a disenrollment is not legally valid, a reinstatement action may be necessary (refer to §60.3 for more information on reinstatements). In addition, the reinstatement may result in a retroactive disenrollment from another plan. *Since optional involuntary disenrollments (as stated in §50.3) are considered legal and valid disenrollments, individuals would not qualify for reinstatements in these cases.*

A voluntary disenrollment that is not complete, as defined in §10, is not legally valid. In addition, there are instances in which a disenrollment that appears to be complete can turn out to be legally invalid. For example, automatic disenrollments due to an erroneous death indicator or an erroneous loss of Medicare Part A or Part B indicator are not legally valid.

CMS also does not regard a voluntary disenrollment as actually complete if the member or his/her representative did not intend to disenroll from the M+C organization. If there is evidence that the member did not intend to disenroll from the M+C organization, the M+C organization should submit a reinstatement request to the CMS RO. Evidence that a member did not intend to disenroll may include:

- A disenrollment request signed by the member when a legal representative should be signing for the member; or
- Request by the member for cancellation of disenrollment before the effective date (refer to §60.2 for procedures for processing cancellations).

Discontinuation of payment of premiums does not necessarily indicate that the member has made an informed decision to disenroll.

In contrast, *CMS* believe*s* that a member's deliberate attempt to disenroll from a plan (e.g., filing a CMS-566 with SSA, sending a written request for disenrollment to the M+C organization, or calling 1-800-MEDICAR(E)) implies intent to disenroll. Therefore, unless other factors indicate that this disenrollment is not valid, what appears to be a deliberate, member-initiated disenrollment should be considered valid.

60.5 - Retroactive Disenrollments

(Rev. 9, 04-01-02)

CMS may grant a retroactive disenrollment if an enrollment was never legally valid (§40.6) or if a valid request for disenrollment was properly made, but not processed or acted upon (as outlined in the following paragraph), which includes not only system error, but plan error (see §10 for a definition of "system error" and "plan error"). CMS may also grant a retroactive disenrollment if the reason for the disenrollment is related to a contract violation (as outlined in 42 CFR §422.62(b)(3)). Retroactive disenrollments can be submitted to CMS by the beneficiary or an M+C organization. Requests from an M+C organization must include supporting evidence justifying a late disenrollment. M+C organizations must submit retroactive disenrollment requests to CMS RO as soon as possible. If CMS approves a request for retroactive disenrollment, the M+C organization must return any premium paid by the member for any month for which CMS processed a retroactive disenrollment. In addition, CMS will retrieve any capitation payment for the retroactive period.

A retroactive request must be submitted by the M+C organization to CMS by the member in cases in which the M+C organization has not properly processed or acted upon the member's request for disenrollment as required in §50.4.1 of these instructions. A disenrollment request would be considered not properly acted upon or processed if the effective date is a date other than as required in §30.6.

If an M+C organization is making a retroactive request that is a result of M+C organization error or system problems (as defined in §10) in which the disenrollment is not recorded on a timely basis by the M+C organization or in CMS records, the M+C organization must submit the request to:

- CMS central office, for a CMS or SSA computer system problem involving multiple members, or
- CMS RO, for individual cases or situations when the organization is experiencing internal problems.

If the CMS RO is not able to resolve system errors, the recommendation is submitted to CMS central office for correction.

The M+C organization should submit a retroactive disenrollment request to the CMS RO for errors made by SSA in submitting plan disenrollments. CMS makes an adjustment of the dates. If the M+C organization is uncertain which CMS office should process the request, the M+C organization should contact the CMS RO.

60.6.1 - EGHP Retroactive Enrollments

(Rev. 9, 04-01-02)

CMS will allow the M+C organization to submit the EGHP enrollment to CMS with retroactive enrollment dates. However, the effective date cannot be prior to the signature date on the election form. The effective date may be adjusted to reflect a retroactive adjustment in payment of up to, but not exceeding, 90 days **payment** adjustment, to conform with the adjustments in payment described under §422.250(b).

EXAMPLE:

In March *2002*, the CMS system processing date was March *13, 2002*. Elections processed by CMS for the March 13, *2002* due date were for the prospective April 1, *2002* payment. For EGHPs, an effective date of March 1, February 1, or January 1 would reflect 30-, 60-, and 90-days of retroactive payment adjustment, respectively. Therefore, if a completed EGHP election were to be received on *3/5/02*, the retroactive effective date could be January 1, February 1, or March 1.

NOTE: Keep in mind that unless a capacity limit applies, all M+C plans are open for ICEP, AEP, and SEP elections. Therefore, all M+C plans are open for retroactive enrollments for these type of elections

No retroactive enrollments may be made unless the individual certifies that the M+C organization (or EGHP) provided him/her with the explanation of enrollee rights (including the lock-in requirement) at the time of enrollment. The M+C organization should submit such enrollments using a number 60 enrollment code. Refer to Chapter 19 (Managed Care and M+C Systems Requirements) and the Enrollment and Payment User's Guide for more detail on the use of code 60.

Exhibit 12: Model Notice to Confirm Voluntary Disenrollment Identified Through Reply Listing

Referenced in section(s): 50.1, 50.4.1, 60.3.2

Dear <Name of Beneficiary>:

This is to confirm your disenrollment from <M+C Plan.> This disenrollment began <effective date,> and <M+C Plan> will not cover any health care you receive after that date. Please note that you may want to tell your doctors that if they need to send Medicare claims, you just disenrolled from <M+C Plan> and there may be a short delay in having your records updated. If you want to change your enrollment status again this year, you will have to wait until the Annual Election period in November, unless there are special circumstances.

IMPORTANT NOTE ABOUT MEDIGAP RIGHTS

If you return to Original Medicare, and any of the following situations apply to you, you might have a guaranteed right to buy a Medicare supplement (Medigap) insurance policy, even if you have health problems.

- **Trial Periods -** If you are in a trial period and you disenroll from <M+C Plan> before the trial period ends.
- **Moving -** If you move out of the <M+C Plan>'s service area.
- **Medigap Open Enrollment -** If you are age 65 or older and you enrolled in Part B within the past 6 months, Federal law guarantees your right to purchase any Medigap policy sold in your State.
- **Medicaid -** If you are receiving financial assistance from the State (Medicaid) to pay for your Medicare premiums.
- Other special circumstances defined by Medicare.

You might be in a trial period if you have been enrolled in <M+C Plan> less than 12 months and you have never before been enrolled in another Medicare+Choice plan, OR you enrolled in <M+C plan> immediately after losing coverage under another health plan, and you were still in a trial period under the other plan when you lost coverage. Call 1-800-MEDICARE (TTY/TDD: 1-877-486-2048 for the hearing and speech impaired) for more information about trial periods.

Under Federal law, if you are in a trial period or you move out of the service area, you will need to apply for a Medigap policy no later than 63 days after you disenroll from <M+C Plan>. If

you are still within your six-month open enrollment period, you must apply before the period ends.

Your State may have laws that provide additional Medigap protections. Contact your State Health Insurance Program <insert name of SHIP > to get more information about open enrollment and trial periods; the availability of Medigap insurance in your State; which policies you have the right to buy; the rules you must follow when applying for a policy; and any more generous protections that may apply under State law.

Your enrollment in a Medigap policy is not automatic. You must contact an insurance company that sells Medigap insurance and request an application.

If you think you did not disenroll from <M+C Plan>, and you want to keep being a member of our plan, please call us right away at <phone number> or, for the hearing impaired, at <TDD/TTY number> so we can make sure you stay a member of our plan. We are open <insert days and hours of operation>. Thank you.

Exhibit 20: Model Notice on Failure to Pay Plan Premiums - Notification of Involuntary Disenrollment

Referenced in section(s): 50.3.1

Dear <Name of Member>:

We recently sent you a letter dated <date> that said your plan premium was overdue. The letter said that if we did not get payment from you, we would disenroll you from <M+C Plan>. Unfortunately, since we did not receive that payment, we have asked the Center for Medicare and Medicaid Services to disenroll you from <M+C Plan> beginning <date>.

Due to your disenrollment from <M+C Plan>, you are now covered by the Original Medicare plan. If you have not already done so, you may elect another M+C plan in your area during the months of {insert applicable language – if 2002, insert "January through June, 2002." Or if 2003, insert "January through March, 2003." If you have already elected to enroll in a plan during that timeframe or if that timeframe has passed, you must wait until the Annual Election Period in November to select another Medicare+Choice Plan, unless there are special circumstances. Any enrollment changes made during the Annual Election period will be effective January 1, <insert year>.

You have the right to ask us to re-think this decision through the grievance procedure written in your Member Handbook.

Please note that until <disenrollment effective date>, you must keep using <M+C Plan> doctors except for emergency or urgently needed care or out-of-area dialysis services. After that date, you can see any doctor through the Original Medicare Plan, unless you join another Medicare managed care plan.

If you think that we have made a mistake or if you have any questions, please call us at <phone number> or, for the hearing impaired, at <TDD/TTY number> between <days and hours of operation>.

Medicare Managed Care Manual

Chapter 3 - Marketing

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20.2 - Employer Group Marketing Review Process

(Rev. 9, 04-01-02)

Under the authority granted in §617 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, CMS has waived all M+C organizations from having to follow the requirements under 42 CFR 422.80(a) for employer group members. This means that M+C organizations need not have CMS pre-approve marketing materials prepared by M+C organizations designed for members of employer groups. (The waiver does ***not*** *include waiving the requirements at 42 CFR 422.111, which outline what information must be provided to*

members annually and at the time of enrollment. We believe this information is critical for members to completely understand the benefits in a plan, rules for obtaining covered services, and the rights they have as members of the plan.)

CMS will assume that M+C organizations have chosen to use this waiver unless we hear otherwise from the M+C organization. All M+C organizations will be required to send informational copies of employer group-specific marketing materials to the Regional Office/lead region within 14 days of their release/use. (Regional Offices will not be reviewing these materials; instead, they will keep them on file in the event any inquiries are received about them.)

The M+C organization assumes responsibility for the accuracy of the employer group marketing materials, including making any corrections to those materials when necessary. The M+C organization is expected to continue to follow the guidelines within this chapter when preparing its marketing materials. In the unusual circumstance of an organization knowingly releasing/distributing incorrect or false marketing materials, sanctions and or/fines may be imposed on that organization.

30.1 - Guidelines for Advertising (Pre-enrollment) Materials

(Rev. 9, 04-01-02)

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) 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 *as the other phone numbers. The TDD/TTY number must also appear along with the hours of operation, if the inclusion of hours of operation are required (as outlined under "Operational Items," item #3). The font size/style rule 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 plan/M+C organization member ID cards must contain the customer service phone number as well as inform the member that they may call “911” in emergency situations. For all member ID cards with an effective date of January 1, 2003, or thereafter, the customer service phone number and any instructions for the beneficiary must be in 10 point font or larger.

4. 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.

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

(Rev. 9, 04-01-02)

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" - "Health plan/M+C organization available to all Medicare beneficiaries" MEDIA: All except outdoor advertising *Outdoor advertising has the option of excluding this topic: * See definition of outdoor advertising in §10 of this Chapter. 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. 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] - Unsubstantiated comparisons with other M+C organizations - 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) - 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. - "Health plan/M+C organization delivers (adjective) quality of care" - 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. - 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 organizations. 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. - 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. Because of the length of the messages and the nature of outdoor advertising, this topic does not apply to outdoor advertising. MEDIA: All except outdoor advertising - TV-Part B caveat must be flashed in TV safe range or mentioned in narration.[13]	- "No premium" - "No premium or deductible" - "Free"	The following may be used: - "No health plan/M+C organization premium" - "Health plan/M+C organization premium equals _____" - "$0 health plan/M+C organization premium" - At no extra cost to you" but only if referring to a specific benefit - "No health plan/M+C organization premium or deductibles" - "No premium or deductibles (you must continue to pay the Medicare Part B premium" - "No premium beyond your monthly Medicare payment" - "No premium other than what you currently pay for Medicare" 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	- Cannot have non-members say he/she belongs. (Can use actors, but		

	statements by members - Speaker must identify specific health plan/M+C organization membership - 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 member as an enrollee of the specific plan. MEDIA: All	they cannot say they belong to the health plan/M+C organization.) *- "Health plans/M + C organizations cannot use negative testimonials about other plans from members or ex-members."*		
Contract with the Government	- Must include one of the phrases from the “Can se” column MEDIA: All except outdoor. Outdoor advertising, which has the option of excluding this topic. 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" - Cannot imply that health plan/M+C organization has a unique or custom arrangement with the government, e.g.: -- "Special contract with Medicare" --"Special health plan/M+C organization for Medicare beneficiaries"	- "An HMO with a Medicare contract" - "An M+C organization with a Medicare contract" - "A Federally Qualified HMO with a Medicare contract" - "A Federally Qualified Medicare contracting HMO" - "Medicare approved HMO" - "A Coordinated Care Plan with an Medicare+Choice contract" - "M+C PSO" 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 MEDIA: TV, radio, outdoor - If the number of physicians and other health care providers is used, it must include only providers available	- Implication that providers are available exclusively through the particular HMO unless such a statement is true - "Participating providers" unless you use health plan/M+C organization name - The M+C organization may not	- "(Health plan/M+C organization's name) participating providers" - “Plan” providers - "Network" providers - "Contracting" providers - "Affiliated" providers	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 Medicare beneficiaries. If a total number is used it must separately delineate the number of primary care providers and specialists included. MEDIA: Print and direct mail - 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 providers that are associated with the M+C organization's delivery system. MEDIA: Print and direct mail	identify itself by the name of a participating provider or provider group, with the exception of a PSO.	- Number of providers should be same total number of Medicare providers MEDIA: All	to health plan/M+C organization providers. It must be clear to the beneficiary with whom the M+C contract with CMS is held.
Eligibility	- Must indicate that beneficiaries must be entitled to Part A and enrolled in B - For M+C plans -- Must indicate that all Medicare beneficiaries with Parts A and B of Medicare may apply -For §1876 cost contracting health plans: -- Must indicate that all Medicare beneficiaries may apply 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 "Seniors" unless term appears with "and all other Medicare eligibles" "Health plan/M+C organization designed especially for seniors" "Senior health plan/M+C organization" unless part of health plan/M+C organization name "Individuals age 65 and over"	- "Anyone with Medicare may apply" - "Medicare entitled by age or disability" - "Individuals eligible for Medicare by age or disability" - "Individuals on or entitled to Medicare by age or disability" - "Medicare beneficiaries" - "Medicare enrollees" - "People with or on Medicare" - "No physicals required" - "No health screening" if a caveat is included for ESRD - “Grandfathered enrollees” 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. 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" "No claims or	"Virtually no paperwork" "No paperwork when using health	Members may be required to submit bills or claims documentation when

		paperwork/complicated paperwork" No claims forms"	plan/M+C organization providers" "Hardly any paperwork" MEDIA: All	using out-of-plan providers.
Benefits: 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. - If only benefits vary, clearly state geographic area in which benefits are applicable. MEDIA: All	- Minimal co-pays may vary by county - Minimal co-pays may apply	- "Premiums and benefits may vary by county" or "These benefits apply to the following counties"* - "Except for _____ county"* MEDIA: All - M+C organizations may compare benefits to Medigap plans as long as information is provided accurately and in detail.	Premiums, benefits, and/or copayment amounts may vary by county within a given service area. This must be clearly conveyed in all marketing materials.
Benefits: b) Limitations		- "At no extra cost to you" or "free" if co-pays apply	- State exact dollar amount limit on any benefit - "Limitations and restrictions may apply" - "Minimal copayments will apply" - "Minimal copayments vary by county"* - State which benefits are subject to limitations 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: c) Prescription Drugs	- If prescription drugs are mentioned and have limitations, must say: - Limited outpatient drug coverage; or, - Drug coverage benefits subject to limitations; or - Up to xxx annual/quarterly/monthly limit or xxx limit per year/quarter/month and other limits and restrictions may apply.	- "We cover prescription drugs" unless accompanied by reference to limitation - "Prescription drug coverage" unless accompanied by reference to limitation	- Fully disclose dollar amount of copayments and annual/quarterly/monthly limit - If limited, you must say so - Limited outpatient drug coverage with xx copayments for xx number of days supply and xxx annual/quarterly/monthly limit - "Prescriptions must be filled at contracting or health plan/M+C	Prescription drugs are an important benefit that must be adequately described. Any dollar limits must be clearly conveyed.

	- Copayment amounts and indicate for a xx number of days supply - If benefits are restricted to a formulary, this must be clearly stated. - In addition, must state: - that formulary contents are subject to change within a contract year without advance notice - health plan/M+C organization should be contacted for additional details. MEDIA: All		organization affiliated pharmacies." MEDIA: All	
Benefits: 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. MEDIA: All, where multi-year benefit(s) are mentioned		- "[benefit] may not be available in subsequent years" OR - "[name of M+C organization] contracts with Medicare each year, this benefit may not may not be available next year" 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" - "True emergency"	- Emergency - definition as stated in current CMS policy. - Urgent - definition as stated in current CMS policy. 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" MEDIA: Direct mail, flyers, print advertising	- "Eligible for a free drawing and prizes with no obligation" - "Free drawing without obligation" 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	- "A health plan representative will be available to answer questions."		This phrase must be used whenever beneficiaries are invited to attend a

	applications." MEDIA: Flyers and invitations to sales presentations - "A sales representative may call." MEDIA: Response card where the beneficiary's phone number is requested - "A telecommunications device for the deaf (TDD) is available to get additional information or set up a meeting with a sales representative." MEDIA: All - "For accommodation of persons with special needs at sales meetings, call (Health Plan Phone Number)." MEDIA: Flyers and invitations to sales meetings			group session with the intent of enrolling those individuals attending. This phrase must be included on any response card in which the beneficiary is asked to provide a telephone number. 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 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 - Guidelines for Beneficiary Notification Materials

(Rev. 9, 04-01-02)

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. All beneficiary notification materials are subject to Final Verification Review, a process that is described in §40.2 of this chapter. Section 40.3 provides specific guidance with respect to provider directories. Section 40.4 provides specific guidance about the use of drug formularies.

40.4 - Specific Guidance about Drug Formularies

(Rev. 9, 04-01-02)

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 Medicare+Choice plan, beneficiaries may not be aware that changes to formularies or preferred lists are likely to occur during the contract year.

Every health plan/ Medicare+Choice 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 non-formulary 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.

40.5 - Conducting Outreach to Dual Eligible Membership

(Rev. 9, 04-01-02)

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*

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[12] *The CMS's monthly capitation rate to an M+C Organization for an M+C member is higher for an enrollee who is a Medicaid recipient because, statistically, the Organization incurs higher medical costs due to higher utilization than that of a non-Medicaid recipient. However, CMS does not pay the Medicaid adjustment factor for QI-1s or QI-*

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.

40.5.1 - General Guidance on Dual Eligibility

(Rev. 9, 04-01-02)

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:*	*Medicare premiums, deductibles, and coinsurance.* *Medicaid services.*	*Medicare* *Medicaid*	*QMB rates for Medicare deductibles and coinsurance* *Medicaid rates for Medicaid services only.*

2s because CMS created those categories of Medicaid recipients after it established the standard monthly payment upon which it bases all capitation payments.

	$870 – individual *$1,165 – couple*			
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*			

40.5.2 - Guidelines for Outreach Programs

(Rev. 9, 04-01-02)

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.

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 §40.5.5 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.*

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[13] Because CMS holds the M+C organization ultimately responsible for all outreach functions, CMS directs these Guidelines to the M+C organization. However, if the M+C organization contracts with another entity for any part of this outreach, the contracting entity must abide by these Guidelines as well.

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. *Submit all outreach procedures and materials to CMS's Central and Regional Office Plan Managers and await approval before initiating any outreach actions. [See Section 40.5.3 for more information on submission requirements.]*

11. *Work closely with CMS's Regional Office staff during the outreach 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.*

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.*

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.*

40.5.3 - Submission Requirements

(Rev. 4, 04-01-02)

To facilitate CMS's review of outreach programs, an M+C organization must submit one copy of the material listed below to its Central Office Plan Manager and one copy to the Regional Office Plan Manager.

1. *Detailed description of each step in the outreach process and the entity responsible for each step. (CMS recommends a flow-chart showing the result of each action.)*
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).*
3. *Contracts with all external entities involved in the outreach process. This includes contracts with any subcontractors taking part in the activities.*
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 - 6) in addition to the following:

8. *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 40.5.4 contains a description of CMS's review process and time frames for both initial and previously approved proposals.

40.5.4 - CMS Review / Approval Process

(Rev. 9, 04-01-02)

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[14] CMS considers the following to be examples of substantive changes to an outreach program that would make the proposal and/or attached member materials an "initial" proposal: changes to the steps involved in the outreach process, changes to the language in the outreach letters, revisions to the telephone scripts, changes to the network of subcontractors participating in the outreach efforts, etc. CMS considers the following to be examples of changes allowable without designating the proposal as "initial": contact telephone numbers, letterhead, mailing dates and targeted member numbers, updates to income and resource criteria and benefit levels as updated by the State.

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

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.

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.

As noted in §40.5.3, M+C organizations must submit one complete copy of the materials listed in §40.5.3 to the CMS Central Office Plan Manager. The M+C organization must submit a second copy of the same materials to the CMS Regional Office Plan Manager.

Until otherwise instructed, within one week of receiving the proposal, the CMS Central Office Plan Manager will provide a copy of the outreach proposal and materials to the Dual Eligibility Product Consistency Team (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.*

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.

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

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

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[15] As of July 2001, outreach proposals should go to the PCT Lead, Ann Knievel, CMS San Francisco Regional Office, 75 Hawthorne Street, Suite 401, San Francisco, CA 94105, phone: 415-744-3625, fax: 415-744-3761, aknievel@cms.hhs.gov. After the PCT provides staff with training on proposal requirements, each Central Office and Regional Office Plan Manager will be responsible for reviewing the outreach proposal and member materials. The PCT will, at that point, relinquish its role in the review process.

If an M+C organization submits an outreach proposal that CMS has already approved and that does not contain substantive changes (outlined in §40.5.3), 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. CMS will respond to the M+C organization within the 10-day time frame CMS has established for reviewing standardized marketing materials. 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 3), 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.

40.5.5 - Model Direct Mail Letter

(data valid for 2001)

August 25, 2001

Mr. Frank Smith
123 Maple Lane
Anywhere, USA 12345

Dear Mr. Smith,

Did you know you may be able to save up to $600 a year on Medicare expenses?

There are programs that save millions of people $50.00 to $600 in their Social Security checks, each year! If you answer "yes" to ALL three of these questions, then you may qualify for Savings for Medicare Beneficiaries.

- *Do you have Medicare Part A, also known as hospital insurance? If you are eligible for Medicare Part A, but do not have it because you cannot afford it, you may still qualify because there is a program that will pay the Medicare Part A premium.*

- *Are you an individual with a monthly income of less than $1,273 or a couple with a monthly income of less than $1,714?*

- *Are you an individual with savings of $4,000 or less or a couple with savings of $6,000 or less? Savings include things like money in a checking account or savings account, stocks, or bonds. When you are figuring out your savings, do not include your home, a car, burial plots, up to $1,500 for burial expenses, furniture, or $1,500 worth of life insurance.*

Enclosed is a brochure that gives you more information about the programs that can help you save on your medical expenses, information on who qualifies, and how to apply for the programs.

I hope you will call me between 9 a.m. and 5 p.m. Monday through Friday at (your phone number here) for more information or for help joining one of these programs. All information that you share will only be used to determine if you may be able to get help with your medical expenses. I will not share the information with anyone else. I encourage you to call to see if you can receive help with your medical expenses, but the choice is yours. You are not required to call. If you like, you can also receive information about the programs by calling a representative of the State Health Insurance Assistance Program at XXX or a State representative at XXXX. Deaf or hearing-impaired people who use a TTY/TDD can call Medicare's national help line at 1-800-486-2048. When you call, ask about programs that can help with Medicare expenses.

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60 - Other Marketing Activities

(Rev. 9, 04-01-02)

60.1 - Specific Guidance about Value-Added Items and Services

(Rev. 9, 04-01-02)

Value-Added Items and Services (VAIS) are items and services offered to M+C plan enrollees, by an M+C organization, that do not meet the definition of "benefits" under the M+C program and may not be funded by Medicare program dollars. Nonetheless, VAIS may be of value to some beneficiaries, and we do not wish to deprive Medicare enrollees of access to items and services commonly available to commercial enrollees. Examples of VAIS may include, but are not limited to discounts in restaurants, stores, entertainment, and travel or discounts on health club memberships and on insurance policy premiums. CMS permits VAIS to be offered to M+C enrollees under the rules outlined below.

VAIS are partly defined by what they are not - they are not benefits under the M+C program. The M+C regulations at §42 CFR 422.2 define benefits using a three-prong test:

1. *Health care items or services that are intended to maintain or improve the health status of enrollees;*

2. *The M+C organization must incur a cost or liability related to the item or service and not just an administrative cost; and*

3. *The item or service is submitted and approved through the Adjusted Community Rate (ACR) process.*

All three parts of the definition must be met for an item or service to be considered a benefit under M+C. If an item or service fails to meet one or more of these parts, it is not a benefit. However, it may be offered to M+C enrollees as a VAIS, subject to the restrictions that follow.

The following examples demonstrate the application of the three-prong test:

Example 1:

An M+C organization arranges for its enrollees a discount on all daily supplements purchased from a health food chain. The health food chain does not charge the M+C organization for this discount, and requires the M+C organization to develop a verification system so the health food chain can identify the organization's enrollees. The M+C organization incurs an administrative cost to develop the verification system, but does not incur a cost of providing or furnishing the daily supplement. Therefore, the discount on daily supplements would be considered a VAIS. The ACR submitted by the M+C organization may not reflect (as a Medicare enrollee benefit cost) the administrative cost.

Example 2:

An M+C organization arranges for its enrollees a 10 percent discount on eyeglasses purchased from a group of eye doctors. The physician group charges the M+C organization for the group's cost to administer the program, and requires the M+C organization to develop a verification system to identify the organization's enrollees. The M+C organization incurs two costs:

1. *The M+C organization pays the physician group's administrative cost of administering the program; and*

2. *The M+C organization incurs the administrative cost for developing and providing the verification system.*

Both of these costs are administrative in nature, and the M+C organization does not incur a cost of providing or furnishing the eyeglasses. Therefore, the discount on eyeglasses is considered a VAIS. The ACR submitted by the M+C organization should not reflect (as a Medicare enrollee benefit cost) either of the two administrative costs.

Example 2a:

Given the same circumstances outlined in Example 2 above, except, the amount paid to the physician group by the M+C organization includes an amount for the cost of the eyeglasses. In this case, the M+C organization does incur a cost of providing or furnishing the eyeglasses. Therefore, the 10 percent discount on eyeglasses is not considered a VAIS. The ACR submitted by the M+C organization should reflect the administrative costs it incurs and the amount paid to

the physician group. The marketing materials should describe the eyeglass benefit with a 90 percent coinsurance. As with all benefits offered as part of an M+C plan, the Medicare enrollee must be afforded appeal rights for this benefit.

60.1.1 - Restrictions on Value-Added Items and Services

(Rev. 9, 04-01-02)

M+C organizations may make VAIS available to Medicare enrollees in accordance with the following guidelines:

- *VAIS must be offered uniformly to all M+C plan enrollees and potential enrollees.*
- *M+C organizations may not describe VAIS as benefits. In accordance with 42 CFR 422.80(e)(iv), which states that M+C organizations may not engage in activities that could mislead or confuse Medicare beneficiaries, the M+C organization may not claim or imply that the VAIS are recommended by or endorsed by CMS or Medicare.*
- *The M+C organization must maintain confidentiality of enrollee records in accordance with §42 CFR 422.118 and other applicable statutes and regulations. The use or distribution of information about enrollees for non-plan purposes is prohibited. The M+C organization is thus prohibited from selling names, addresses, or information about the individual enrollees for commercial purposes. If the M+C organization uses a third party to administer VAIS, the M+C organization is ultimately responsible for adhering to and complying with confidentiality requirements.*

60.1.2 - Relationship of Value-Added Items and Services to Benefits and Other Operational Considerations

(Rev. 9, 04-01-02)

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:

- *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].*

- *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.*

- *Should a problem arise with any Value-Added Item or Service, please 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.

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.

60.1.3 - Value Added Items and Services Provided to Employer Groups

(Rev. 9, 04-01-02)

Value-added items and services may be offered to employer groups. Value-added items and services are offered outside the core benefit package, thus they are outside of CMS's purview.

60.1.4 - Application to §1876 of the Social Security Act (the Act) Cost Plans

(Rev. 9, 04-01-02)

Value-added items and services may be offered by §1876 cost plans. However, VAIS are non-covered services for which §1876 cost plans are not reimbursed.

60.1.5 - Specific Guidance About the Use of Independent Insurance Agents

(Rev. 9, 04-01-02)

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.

60.2 - Marketing of Multiple Lines of Business Under Medicare + Choice

(Rev. 9, 04-01-02)

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 (ACR) 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 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.

Managed Care Manual

Chapter 5 - Quality Assurance

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10 - Introduction

(Rev. 9, 04-01-02)

In June, 1998, *Health Care Financing Administration (HCFA)* now the Centers for Medicare and Medicaid Services (CMS) issued an interim final rule implementing the Medicare+Choice program (Part C of Title XVIII of the Social Security Act) as established by the Balanced Budget Act (BBA) of 1997 (P.L. 105-33). The final rule was published June 29, 2000. These regulations, contained in Part 422 of Chapter 42 of the Code of Federal Regulations, build upon requirements in the Section 1876 risk-contracting program by clarifying previous requirements and introducing certain new provisions required by law.

Subpart D 42 CFR Part 422 establishes the quality assurance and performance improvement (QAPI) requirements that Medicare+Choice Organizations (M+C organizations) must meet under the BBA. These requirements do not apply to §1876 cost plans or §1833 Health Care Prepayment Plans. M+C network MSA plans and coordinated care plans other than Preferred Provider Organizations (PPO) plans are required to achieve compliance with these requirements through the use of CMS's Quality Improvement System for Managed Care, documented in the Interim QISMC Standards and Guidelines hereafter referred to as the "QISMC document" in this Manual. However, the requirements of §30.1.1 regarding minimum performance levels (QISMC document standard 1.1.1) do not apply to Network Medical Savings Accounts (MSA) plans.

The QISMC document is equivalent to an interim program manual and is integrated into this Chapter and several other Chapters of the Medicare Managed Care Program Manual. It represents CMS's implementation of the Medicare+Choice requirements for an organization's operation and performance in the areas of quality measurement and improvement. As the QISMC document is incorporated into the Medicare Managed Care Program Manual, at least initially, the QISMC numbering system will be retained to assist users in adapting to the new format. The various standards will be placed into the appropriate chapters of the manual and will not continue to be classified by domain.

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30 - Quality Assessment and Performance Improvement Projects

(Rev. 9, 04-01-02)

These standards direct an M+C organization to operate an internal program of quality assessment and performance improvement that achieves significant improvements sustained over time in enrollee health, functional status and satisfaction across a broad spectrum of care and services. M+C organizations will have considerable discretion to select focus areas addressing specific

health care and service needs of their populations. The M+C organization must collect and report data reflecting performance on standardized measures of health outcomes and enrollee satisfaction as appropriate, and meet such minimum performance levels on these measures as may be established under its contract with CMS or states. The M+C organization must also demonstrate compliance with basic requirements for administrative structures and processes that promote quality of care and beneficiary protection.

30.1.2 - Performance Improvement Projects

(Rev. 9, 04-01-02)

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.

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

(Rev. 9, 04-01-02)

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 *was* eliminated as a requirement.

If a project for year 1999, 2000, or 2001 has already been implemented using that 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+C organization 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.

30.2.1 - Selection of Topics

(Rev. 9, 04-01-02)

Within each focus area, the organization selects a specific topic or topics to be addressed by a project. (QISMC document standard 1.4.1)

Topics are identified through continuous data collection and analysis of comprehensive aspects of patient care and member services by the organization. (QISMC document standard 1.4.1.1)

Topics are systematically selected and prioritized to achieve the greatest practical benefit for enrollees. (QISMC document standard 1.4.1.2)

Selection of topics takes into account: the prevalence of a condition among, or need for a specific service by, the organization's enrollees; enrollee demographic characteristics and health risks; and the interest of consumers in the aspect of care or services to be addressed. (QISMC document standard 1.4.1.3)

These standards relate to focus areas for projects selected by the organization itself. Projects conducted at the specific direction of CMS will be deemed to have met this standard.

Documentation of completed projects must show the basis on which the organization selected project topics; i.e., continuing monitoring of population needs and preferences and organizational performance; identification of areas of concern; and clear criteria, identified by the organization, for prioritizing the areas to be addressed.

As §§30.2.1 and 20.1 (QISMC document standards 1.4.1.4 and 1.6.1.3) indicate, the organization's affiliated providers and enrollees must have opportunities to participate in the selection and prioritization of QAPI projects.

Sources of Information

The QAPI program must routinely collect and interpret information from all parts of the organization, to identify areas of clinical concern, health delivery system issues, and issues in member services. Types of information to be reviewed include:

- Population Information - Data on enrollee characteristics relevant to health risks or utilization of clinical and non-clinical services, including age, sex, race/ethnicity/language, and disability or functional status.

- Performance Measures - Data on the organization's performance as reflected in standardized measures, including, when possible: Local, State, or national information on performance of comparable organizations.

- Other Utilization, Diagnostic, and Outcome Information - Data on utilization of services, procedures, medications and devices; admitting and encounter diagnoses; adverse incidents (such as deaths, avoidable admissions, or readmissions); and patterns of referrals or authorization requests.

- External Data Sources - Data from outside organizations, including Medicare or Medicaid fee-for-service data, data from other managed care organizations, and local or national public health reports on conditions or risks for specified populations. (In newly formed organizations, or organizations serving a new population, external data may be the major source of potential project topics.

- Enrollee Information on Their Experiences With Care - Data from surveys (such as the Consumer Assessment of Health Plans Study, or CAHPS), information from the grievance and appeals processes, and information on disenrollments and requests to change providers. (Note that general population surveys may under-represent populations who may have special needs, such as linguistic minorities or the disabled. Assessment of satisfaction for these groups may require over sampling or other methods, such as focus groups or enrollee interviews.) The QAPI program should assess, in

addition to information generated within the organization, information supplied by purchasers, such as data on complaints.

The QAPI program's project selection process must explicitly take into account quality of care concerns identified by a *Quality Improvement Organization, (QIO) formerly known as a P*eer Review Organization (PRO) and, for M+C organizations contracting with both Medicare and Medicaid, an external quality review organization (EQRO). While it is not expected that each concern will be addressed through a formal QAPI project meeting the requirements of these standards, the organization should be able to show that issues raised by these organizations were considered in the formulation of its QAPI program agenda, and that alternative remedial action is taken in cases for which a QAPI project is not initiated.

Prioritizing topics

A clinical or non-clinical issue selected for study should affect a significant portion of the organization's Medicare enrollees (or a specified sub-population of enrollees) and have a potentially significant impact on enrollee health, functional status, or satisfaction. There may be instances in which infrequent conditions or services warrant study, as when data show a pattern of unexpected adverse outcomes; however, the prevalence of a condition or volume of services involved must be sufficient to permit meaningful study.

A project topic may be suggested by patterns of inappropriate utilization, for example, frequent use of the emergency room by enrollees with a specific diagnosis. However, the project must be clearly focused on identifying and correcting deficiencies in care or services that might have led to this pattern, such as inadequate access to primary care, rather than on utilization and cost issues alone. This is not to say that the organization may not make efforts to address over-utilization, but only that such efforts might not be considered QAPI activities for the purpose of assessing compliance with these standards, unless the primary objective is to improve health outcomes. Thus it would be acceptable for a project to focus on patterns of over-utilization that present a clear threat to health or functional status, for example because of a high risk of iatrogenic problems or other adverse outcomes.

Because the achievement of significant and sustained improvement is a central criterion in the evaluation of QAPI projects, projects must necessarily focus on areas in which significant improvement can be effected through system interventions by the organization. Most organizations are likely to give priority to areas in which there is significant variation in practice and resulting outcomes within the organization, or in which the organization's performance as a whole falls below acceptable benchmarks or norms.

It is recognized that the requirement for significant and sustained improvement creates incentives for organizations to focus their QAPI activities on aspects of care in which rapid and measurable improvement is possible through simple interventions. It is not the intention of these standards to discourage organizations from undertaking more complex projects or innovative projects that have a high risk of failure, but that offer some offsetting potential for making a significant difference in the health or functional status of enrollees. Organizations considering such projects should develop long-range goals for projects and establish criteria for evaluation of the organization's progress in implementing its project.

Organizations Using Physician Incentive Plans

An organization that adopts a physician incentive plan that places physicians at substantial financial risk (as defined at 42 CFR §422.208(d)) for the care of Medicare or Medicaid enrollees, must include in its QAPI program continuous monitoring of the potential effects of the incentive plan on access or quality of care. This monitoring should include assessment of the results of surveys of enrollees and former enrollees required under 42 CFR §422.479(h). In addition, the organization should review utilization data to identify patterns of possible under-utilization of services that may be related to the incentive plan (such as low rates of referral services ordered by physicians at risk for the cost of such services). Concerns identified as a result of this monitoring should be considered in development of the organization's focus areas for QAPI projects.

The QAPI program provides opportunities for enrollees to participate in the selection of project topics and the formulation of project goals. (QISMC document standard 1.4.1.4)

The organization must establish some mechanism for obtaining enrollee input into the priorities for its QAPI program. Possibilities could include enrollee representation on a quality assurance committee or subcommittees or routine inclusion of QAPI issues on the agenda for a general enrollee advisory committee. To the extent feasible, input should be obtained from enrollees who are users of or concerned with specific focus areas. For example, priorities in the area of mental health or substance abuse services should be developed in consultation with users of these services or their families.

30.2.2 - Quality Indicators.

(Rev. 9, 04-01-02)

Assessment of the organization’s performance for each selected topic is measured using one or more quality indicators. (QISMC document standard 1.4.2)

Quality indicators are objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research. When indicators exist that are generally used within the public health community or the managed care industry and are applicable to the topic, use of those measures is preferred. (QISMC document standard 1.4.2.1)

Each QAPI project must establish one or more quality indicators that will be used to track performance and improvement over time. An indicator is a variable reflecting either a discrete event (an older adult has/has not received a flu shot in the last 12 months) or a status (an enrollee’s hypertension is/is not under control). In either case, an indicator must be clearly defined and subject to objective measurement.

An organization may adopt standard indicators from outside sources, such as the National Committee for Quality Assurance (NCQA)’s Healthplan Employer Data and Information Set (HEDIS) or the Foundation for Accountability's (FACCT) measures, or develop its own indicators on the basis of clinical literature or findings of expert consensus panels. When the organization develops its own indicators, it must be able to document the basis on which it adopted an indicator. It also should be able to show that the process included consultation with

affiliated providers and enrollees to assure that measures are meaningful, relevant to the organization's enrolled population, and reflective of accepted standards of practice.

An organization is not required to select specific indicators at the outset of a QAPI project. There may be instances in which a project would begin with more general collection and analysis of baseline data on a topic, and then narrow its focus to more specific indicators for measurement, intervention, and reevaluation. The success of the project will be assessed in terms of the indicators ultimately selected.

All clinical indicators measure changes in health status, functional status, or enrollee satisfaction, or valid proxies of these outcomes. Measures of processes are used as a proxy for outcomes only when those processes have been established through published studies or a consensus of relevant practitioners to be significantly related to outcomes. (QISMC document standard 1.4.2.2)

The object of the QAPI program is to improve outcomes, defined as objective measures of patient health, functional status, or satisfaction following the receipt of care or services. Under this definition, measures of costs, or other administrative results do not constitute outcomes. It is recognized, however, that relatively few standardized performance measures actually address outcomes. Even when outcome measures are available, their utility as quality indicators for QAPI projects may be limited because outcomes can be significantly influenced by factors outside the organization's control; e.g., poverty, genetics, environment. In other instances, improvement is possible, but the resources and sophistication needed to analyze the complex factors involved in the outcome and to develop meaningful interventions might be beyond the reach of many organizations.

This standard therefore does not require that quality indicators be outcome measures. Process measures are acceptable so long as the organization can show that there is strong clinical evidence that the process being measured is meaningfully associated with outcomes. To the extent possible, this determination should be based on published guidelines that support the association and that cite evidence from randomized clinical trials, case control studies, or cohort studies. A plan may furnish its own similar evidence of association between a process and an outcome so long as this association is not actually contradicted by a published guideline. Although published evidence is generally required, there may be certain areas of practice for which empirical evidence of process/outcome linkage is limited. At a minimum, the organization must be able to demonstrate that there is a consensus among relevant practitioners with expertise in the defined area as to the importance of a given process. Structural measures are acceptable for non-clinical focus areas such as Culturally and Linguistically Appropriate Services (CLAS.)

Indicators selected for a topic in a clinical focus area (§30.1.5.1, QISMC document standard 1.3.4) include at least some measure of change in health status or functional status or process of care proxies for these outcomes. Indicators may also include measures of the enrollee's experience of and satisfaction with care. (QISMC document standard 1.4.2.3)

While organizations are encouraged to consider enrollee satisfaction as an important aspect of care in any of the clinical areas listed in the QISMC document standard 1.3.4 (§30.1.5.1), improvement in satisfaction must not be the sole demonstrable outcome of a project in any of these areas. Some improvement in health or functional status must also be measured. (Note that

this measurement can rely on enrollee surveys that address topics in addition to satisfaction. For example, self-reported health status may be an acceptable indicator). For projects in the non-clinical areas, use of health or functional status indicators is generally preferred, particularly for projects addressing access and availability. However, there may be some non-clinical projects for which enrollee satisfaction or structural indicators alone are sufficient.

The organization selects some indicators for which data are available that allow comparison of the organization's performance to that of similar organizations or to *l*ocal, *s*tate, or national benchmarks. (QISMC document 1.4.2.4)

Significant and sustained improvement may be defined either as reaching a prospectively set benchmark or as improving performance and sustaining that improvement. While the latter form of improvement is acceptable, an organization that works only towards incremental improvements relative to its own past performance can never determine that its performance is optimal or even minimally acceptable relative to prevailing standards in the community. Whenever possible then, an organization should select indicators for which data are available on the performance of other comparable organizations (or other components of the same organization), or for which there exist local or national data for a similar population in the fee-for-service sector. Because the availability of such data will vary by topic and by population, this standard does not set a fixed number of focus areas for which benchmarks must be adopted. However, every organization should be able to establish benchmarks for at least some project topics (e.g., immunizations or diabetic care).

Data Collection and Methodology

Assessment of the organization's performance on the selected indicators is based on systematic, ongoing collection and analysis of valid and reliable data. (QISMC document standard 1.4.3).

Assessment of compliance with this standard will be coordinated with review of the organization's information systems under §20.2 and the QISMC document standard 1.5.

The organization establishes a baseline measure of its performance on each indicator, measures changes in performance, and continues measurement for at least one year after a desired level of performance is achieved. (QISMC document standard 1.4.3.1)

Documentation of completed QAPI projects must include a detailed account of the data collection methodology used, and the procedures through which the organization has assured that the data are valid and reliable.

Methodology

Most quality indicators are reported in terms of percentages or ratios; for example, the percentage of diabetic members who have a hemoglobin A1C test in the year 2000. An organization adopting this measure must show that it can accurately compute the relevant denominator or population at risk (all diabetic members) and the numerator or indicator (diabetic members who have a hemoglobin A1C test in the specified year).

Identification of the population at risk requires particular scrutiny. For some indicators, the population can be identified in readily available administrative data (all women over 65, or all

inpatient discharges with a diagnosis of heart attack). For others, needed data may be more difficult to obtain. For example, even in an organization that collects individual encounter data, this data might not be able to identify all enrollees with diabetes, because physicians may not report ongoing conditions at every encounter. Instead, the organization must identify the population at risk through a valid data source such as a patient disease registry, if present, or through a pharmacy database.

The organization must clearly specify what data are used to identify the population at risk and show that these data can reliably and validly capture the entire population; i.e., without systematically excluding a subset or subsets of the population. The organization may study a sample of the relevant population. If so, it must show that the sample size is sufficient to achieve an appropriate level of confidence in the estimates of the incidence of the indicator under study (see the QISMC document standard 1.4.4.2). The organization also must show that the sampling method is such that all members of the population are equally likely to be selected. (This will generally mean random sampling, although stratified random sampling may be appropriate when the intent is to compare care by different practitioners or at a different site.)

In addition to assuring that data collection is complete and free from bias, the study methodology may need to address other issues in the computation of the indicator. For example, when an indicator relates to receipt of a specific service, the denominator may need to be adjusted to reflect instances in which the patient refuses the service or the service is contraindicated. Similar problems may affect the numerator. For example, in a study of adult immunization rates, the organization would need to establish how it would detect and account for instances in which immunizations were received at a senior center or at a health department, rather than through the primary care practitioner.

Validation

Data will commonly be derived from administrative data generated by the organization's health information system or from review of medical records. In assessing non-clinical services, other sources such as enrollee or provider surveys may be appropriate. When data are derived from the health information system, their reliability is obviously a function of the general integrity of the system. In this case, assessment of compliance with this standard will be coordinated with review of compliance with the information system requirements in §20.2 and the QISMC document standard 1.5.

When data are derived from direct review of medical records or other primary source documents, steps must be taken to assure that the data are uniformly extracted and recorded. Appropriately qualified personnel must be used; this will vary with the nature of the data being collected and the degree of professional judgment required. There must be clear guidelines or protocols for obtaining and entering the data; this is especially important if multiple reviewers are used or if data is collected by multiple subcontractors. Inter-reviewer reliability should be assured through, for example, repeat reviews of a sample of records.

NOTE: If the indicator selected for a QAPI project is a performance measure that the organization is required to report routinely to CMS, review of compliance in this area

might be coordinated with whatever validation process CMS establishes for such reporting. CMS may conduct random reviews on a percentage of QAPI projects to assess the integrity of the data.

All data collection for QAPI projects is subject to the confidentiality requirements of the QISMC document standard 2.2.1.

When sampling is used, sampling methodology for assessment of the organization's performance shall be such as to ensure that the data collected validly reflect: (QISMC Document Standard 1.4.3.2)

- The performance of all practitioners and providers who serve Medicare or Medicaid enrollees and whose activities are the subject of the indicator (QISMC document standard 1.4.3.2.1):

  Once a topic has been selected, the organization must assure that its measurement and improvement efforts are system-wide. Each project must, to the extent feasible, reach all providers in its network who are involved in the aspect of care or services to be studied. This standard does not establish a requirement that an organization review the performance of each and every provider who furnishes the services that are the subject of the project. Sampling is acceptable so long as the organization assures that its samples are genuinely random. The organization must be able to show that:

  - Each relevant provider has a chance of being selected; no provider is systematically excluded from the sampling;

  - Each provider serving a given number of enrollees has the same probability of being selected as any other provider serving the same number of enrollees; and

  - Providers who were not included in the sample for the baseline measurement have the same chance of being selected for the follow-up measurement as providers who were included in the baseline.

  This is, of course, easier to meet if the organization selects for study a condition that affects relatively few of its enrollees or is treated by a limited number of providers. However, the organization might then be unable to show that its selection of topics meets the criteria in §30.2.1 and the QISMC document standard 1.4.1, including the core requirement that topics be selected so as to achieve the greatest practical benefit for enrollees.

  An M+C organization may use a single sample that combines Medicare members with other members. This does not eliminate the requirement for reporting of HEDIS, CAHPS and HOS separately for Medicare. For example, if elements of HEDIS, CAHPS or HOS are used as an indicator for a QAPI project, Medicare must be reported separately. If the QAPI project is non-clinical or does not use HEDIS, HOS or CAHPS elements, it is not necessary to break out the Medicare members as long as the project is relevant to Medicare enrollees and Medicare enrollees are included in the sample.

- The care given to the entire population (including populations with special health care needs and populations with serious and complex health care needs) to which the indicator is relevant. (QISMC Document Standard 4.3.2.2):

    - Similar to the equal treatment of all providers and practitioners by the sampling methodology, a sampling methodology should not exclude any population subgroups to which the topic area and indicators are applicable. For example, when studying use of preventive services an organization needs to design its study to include all persons who are in need of the service (e.g., routine health screening) as opposed to including only those individuals who have already made a visit to a managed care organization's providers.

30.2.3 - Significant, Sustained Improvement

(Rev. 9, 04-01-02)

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 *are* appropriate for use. *I*f 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+C organization may create an internal performance target based on a clear rationale. The target should be something that a M+C organization strives for, but may not necessarily reach. If a M+C organization 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 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.

30.2.4 - Sustained Improvement over Time

(Rev. 9, 04-01-02)

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+C organization 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+C organization may choose to continue the project or to go onto another topic.

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30.3.3 - Other Projects

(Rev. 9, 04-01-02)

The projects described below are subsets of the national and M+C organization selected projects.

Special Projects

CMS (for Medicare) or the State Medicaid agency for M+C organizations contracting with Medicaid, may require an organization to conduct particular projects that are specific to the organization and that relate to topics and involve quality indicators of CMS or the State Medicaid agency's choosing. (QISMC document 1.3.6.1)

The focus areas specified in §§30.1.5.1 and 30.1.5.2 and in the QISMC document standards 1.3.4, 1.3.5.1 and 1.3.5.3, are intended to highlight key components of care and services for organizations serving typical Medicare and Medicaid populations. There may be instances in which CMS or the State Medicaid agency believes that some aspects of care require greater emphasis, either because of the organization's relationship to populations with special health care needs or because the organization's performance is in need of greater improvement in some areas than in others. In such an instance, CMS (for Medicare) or the State Medicaid agency (for Medicaid) may require the organization to conduct a particular project.

An M+C organization will be informed by CMS if it will be required to conduct a special project.

Collaborative Projects

Organizations may satisfy the requirements of the QISMC document standards 1.3.2 and 1.3.3 by collaborating with one another. (QISMC document 1.3.6.2)

CMS and some State Medicaid agencies have encouraged collaborative efforts, under which several contracting organizations undertake a joint quality improvement project addressing a common topic. For Medicare, *QIOs* are not only a convening structure for national performance improvement projects, but they are also a regional presence for convening local collaborative performance improvement projects. These standards would not preclude such collaborative efforts for M+C organizations contracting with Medicare and Medicaid .

Multi-Year Projects

If a project is conducted over a period of more than one review year (QISMC document standard 1.3.7), the project will be considered as achieving significant and sustained improvement in each year for which it achieves an improvement meeting the requirements specified in this manual chapter.

An organization may continue a project that has already been determined to have achieved significant and sustained improvement. If further improvement occurs, the project may again be considered to have achieved significant and sustained improvement. However, the improvement will not be measured relative to the original baseline, but relative to the improved performance level previously scored.

A project may be considered as achieving improvement in each year for which it achieves an improvement that constitutes an intermediate target specified in a project work plan developed in consultation with CMS and the State Medicaid agency for M+C organizations contracting with both Medicare and Medicaid. (QISMC document 1.3.7.2)

An organization may undertake a particularly complex or difficult project that is not expected to achieve significant and sustained improvement for several years (i.e., more than three years). This might occur because:

- Improvement in the targeted outcome cannot be measured for a long period; for example, the organization wishes to improve 5-year survival rates for breast cancer.

- Improvement in outcomes can come only after process improvements that are not closely enough related to outcomes to meet the requirement of the QISMC document standard 1.4.3.2; and

- Improvement will require multiple system interventions that cannot be implemented over a short period.

Such a project would not ordinarily be counted as achieving improvement until an improvement meeting the requirement for significant and sustained over time was documented. The organization must conduct other projects that achieve improvement more rapidly, because of the requirement that improvement be achieved in two areas during each 12 month review period after the initial 2-year phase-in period. This standard creates an exception for certain multi - year projects (more than three years) with measurable interim goals.

Prior approval by the M+C organization's CMS RO Representative is required prior to the implementation of a multi-year project. If the M+C organization collaborates with a PRO in the development and implementation of a QAPI project, then CMS approval is not required. An organization that anticipates that it will meet the minimum requirements of this standard for a review year only if a multi-year project is counted, must request advance review of the project plan at the time the project is initiated. A multi-year project may be approved under the following circumstances:

- The timetable for the project is reasonably related to the complexity of the project or the length of time that must elapse before the outcomes of the project can be assessed. There must be a clear and defensible reason for defining a project as a multi-year project.

- There must be significant ongoing activity related to the project during each of the review years for which the project is to be counted. For example, while a project that involves a one-time system change that is expected to affect 5-year survival rates cannot measure its success until five years have elapsed, it will not necessarily be considered as an ongoing project during each of the intervening years. It would be treated as ongoing only if it provided for continuous data collection throughout the project period, along with ongoing efforts to identify and implement system changes aimed at improving the long-term outcome.

- The project must specify some form of quantifiable interim goals or intermediate outcomes for each project year, so that it is possible to monitor the continuing progress of

the project. For example, an organization conducting a project on breast cancer survival rates might track a process of care (such as mammography screening rates) or an intermediate outcome (such as stage of breast cancer at detection) and set goals for each year of the project.

The national projects and M+C organization selected projects are not considered multi-year projects, in this context, even though they are conducted over several years. A "regular" national or M+C organization selected project cannot be converted into a multi-year project without prior approval.

30.3.4 - Process for CMS Multi-Year QAPI Project Approvals

(Rev. 9, 04-01-02)

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.

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.

30.4 - Evaluation of QAPI projects

(Rev. 9, 04-01-02)

Accrediting Organizations That Are Approved for M+C organization Deeming Authority

Accrediting organizations that are approved for M+C organization deeming authority will review QAPI projects for those M+C organizations that have selected deemed status via

accreditation. The accrediting organizations are required to assess the M+C organizations QAPI projects and report the results of their evaluation to CMS. M+C organizations are encouraged to contact their accrediting organizations for further instructions.

CMS Regional Office Representatives

The CMS Regional Office staff will continue to be *available to* M+C organizations when questions arise regarding their QAPI projects. M+C organizations may share their project information with their RO Representative *to inform them about the* projects and interventions that are being developed and *discuss CMS QAPI requirements.* However, the responsibility for the final review of the projects is solely that of the M+CQRO teams. CMS regional and central office staff *will make the final approval decision.*

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 conduct monitoring reviews. It is not expected that the reporting of projects must coincide with CMS monitoring. RO staff will be able to review all previous QAPI project submissions in preparation for monitoring.

Reviewers

The QAPI evaluations *are conducted* by four contractors, known as the Medicare+Choice Quality Review Organizations (M+CQRO). The M+CQRO are four *QIOs*, - 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.

QIOs may provide technical assistance and expertise to M+C organizations in their *s*tate 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. *However,* 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 *contract* H-number into smaller units (subunits), but not to report on a unit larger than the H-number. Each segment will 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 *contract* H-number. *T*hese organizations will then report on several projects as to ensure that all counties within their H-number are *covered by a QAPI project*.

M+C organizations which have consolidated their contract H numbers over the course of the project will report on their current H-number as recognized by CMS. M+C organizations will report significant improvement on the end of the project contract H numbers, but make note of any change in service areas which might have 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.

The Project Completion Report is in a password protected web-based format. The report information will be directly submitted into the CMS Health Plan Management System (HPMS) database where the web-based project completion report is housed. Each M+C organization has limited access to the HPMS database. This web-based system was available for use in mid-January, 2002.

Each person who is a contact for QAPI reports and is responsible for filling out the report must have their own individual password and access. The user's computer must be able to access the AT&T Global Network. 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. The instructions are also available to complete this form.

Please submit the original completed forms 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 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 *set* any specific deadlines for the submission of the project completion reports. CMS considers the type of data the M+C organizations are using (i.e. HEDIS, CAHPS, etc) and any *additional* factors that may affect when the M+C organization can complete and report their projects. If a M+C organization knows that there will be a significant delay in the reporting of their project beyond the 3-year cycle 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 use*d*, such as HEDIS)). "Sustained improvement" would then be reported one year later in 2002/2003. *A*lthough a 3-year cycle is assumed, a M+C organization 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.

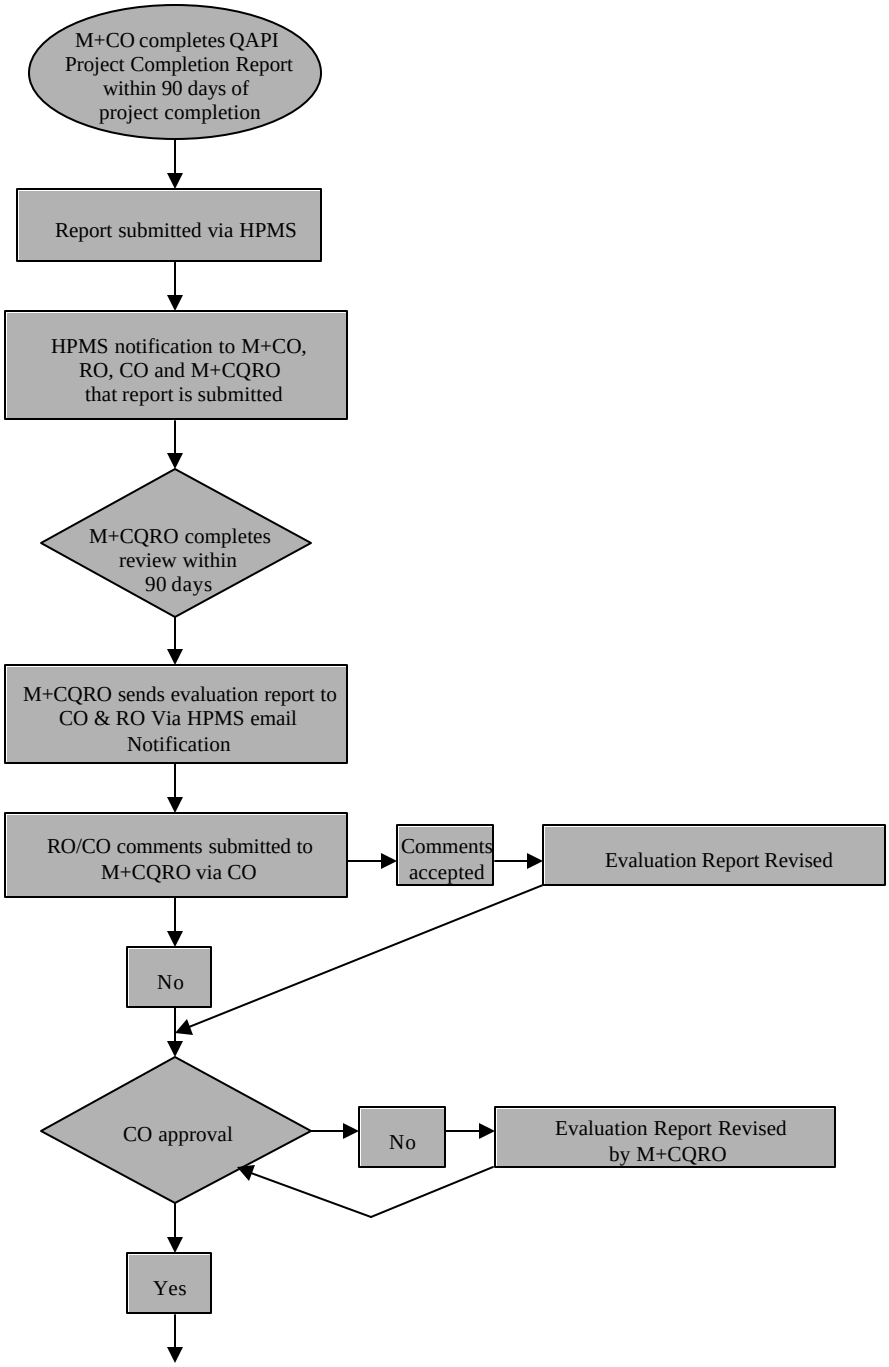
Project Review Report

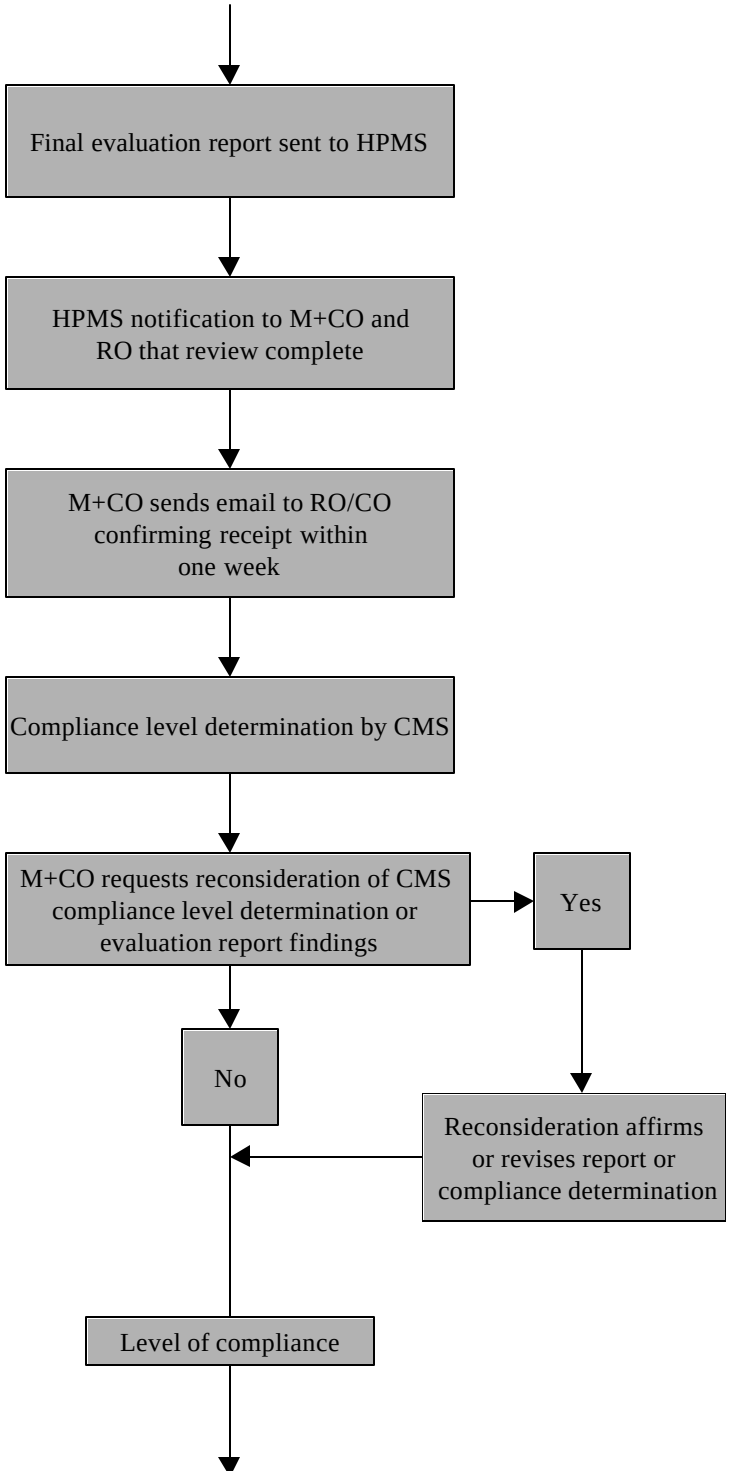
The Project Review Report will be sent to CMS via the HPMS system from the M+CQRO reviewers. This report will highlight the strengths and weaknesses of each project. The M+CQROs will list general recommendations for consideration in the development and execution of future QAPI projects. The report will 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.

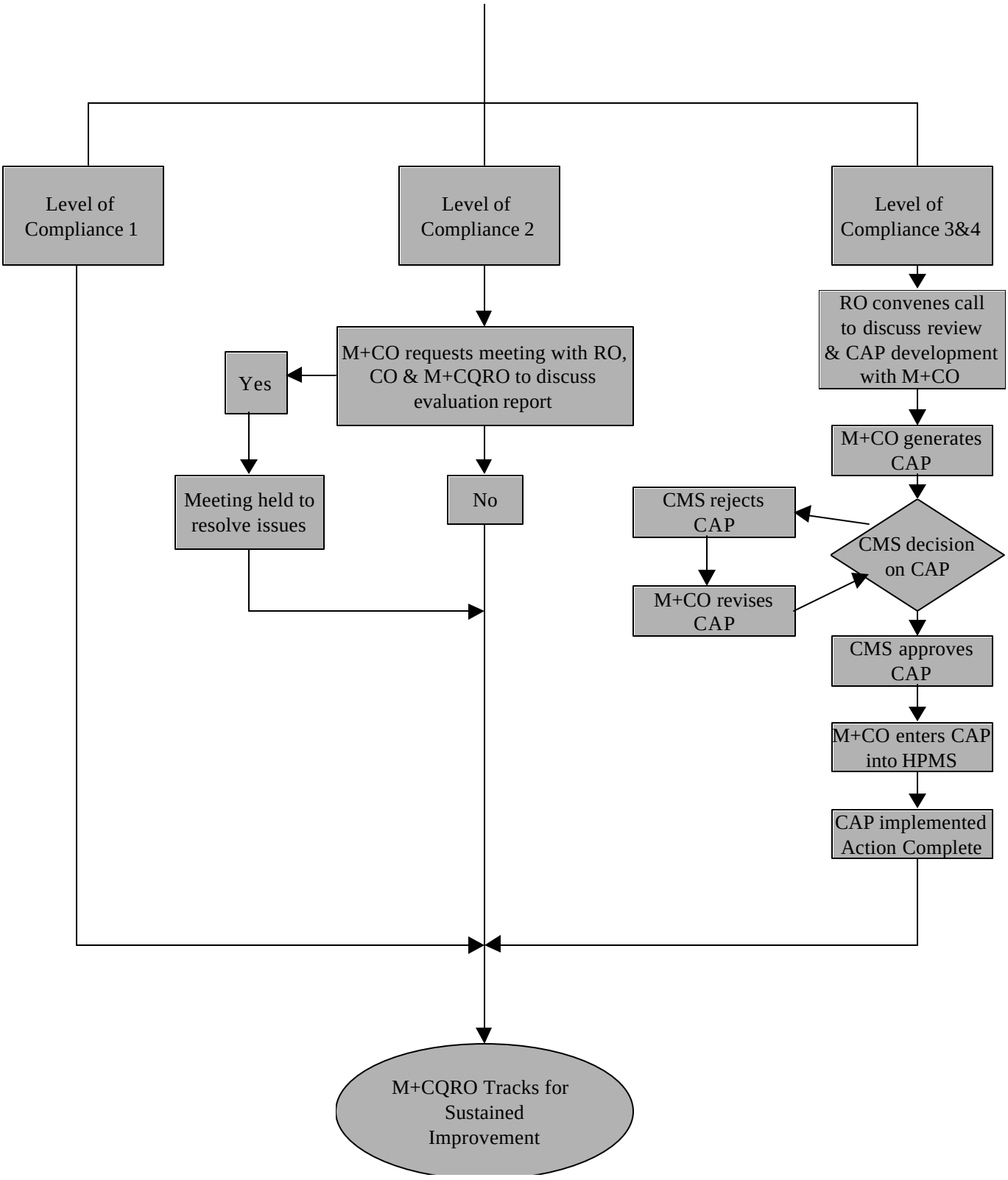
In cases where a CAP has been required, *the process described in the above sections will be followed*. If the M+C organization wishes to discuss the findings from the project or the CAP, it must contact theCMS RO representative, not the M+CQRO reviewer. All interactions with the M+CQROs will be through 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*n immediate* resolution cannot be achieved, the issue will be reviewed further and a final decision reached.

Reporting Timelines

This process will take place via the HPMS system and e-mail. It is essential that each M+C organization provides accurate, up to date contact information to ensure timely communication in this process. The following flowcharts (numbered 1 through 5) depict the exchange of information and communication processes. A brief narrative explaining the flowcharts is at the end of this section.




Final evaluation report sent to HPMS
HPMS notification to M+CO and RO that review complete
M+CO sends email to RO/CO confirming receipt within one week
Compliance level determination by CMS
M+CO requests reconsideration of CMS compliance level determination or evaluation report findings
Yes
No
Reconsideration affirms or revises report or compliance determination
Level of compliance


Level of Compliance 1
Level of Compliance 2
Level of Compliance 3&4
M+CO requests meeting with RO, CO & M+CQRO to discuss evaluation report
Yes
No
Meeting held to resolve issues
RO convenes call to discuss review & CAP development with M+CO
M+CO generates CAP
CMS decision on CAP
CMS rejects CAP
M+CO revises CAP
CMS approves CAP
M+CO enters CAP into HPMS
CAP implemented Action Complete
M+CQRO Tracks for Sustained Improvement

M+C organization submits project for evaluation within 90 days of project completion.

1. *M+CQROs will have 90-days to review and evaluate projects. M+CQRO may contact the M+C organization once for clarification/ additional information. The M+C organization is not required to provide any additional information.*

2. *M+CQRO submits final report to CMS RO and CO for approval.*

4. *CMS considers any comments from the CMS RO and approves or disapproves the report. If approved, it will then be sent to the M+C organization. If CMS does not approve, the report will be returned to the M+CQRO for revisions.*

5. *Within one week of receipt of the final evaluation, the M+C organization will confirm to CMS RO and CO staff that they have received their evaluation via HPMS*

6. *Reconsideration: If the M+C organization does not agree with their evaluation, they may contact their CMS RO representative for a reconsideration of the project evaluation. CMS CO and the MCQRO will participate in the reconsideration.*

7a. Level of compliance 1: (Compliant) M+C organization continues with their project and goal of attaining sustained improvement.

7b. Level of compliance 2: (Compliant with minor deficiencies) M+C organization may request a conference call with CMS RO, CO, and M+CQRO to clarify and discuss project results or any issues with the evaluation. The M+C organization should contact their CMS RO representative to facilitate this call. This session is informational and serves as a learning discussion for future projects. The M+C organization then continues with their project and goal of attaining sustained improvement.

7c. Compliance levels 3 and 4: (Compliance requires a corrective action plan)

Step 1: After the M+C organization has confirmed receipt of their evaluation, they must then contact their CMS RO representative to convene a conference call with CMS CO and M+CQROs to discuss the completed project review. Typically, dates and times are based upon when the M+C organization will be ready to discuss their project. CMS expects that this call will occur within a few weeks of the M+C organizations' receipt of their project review.

Step 2: M+C organization generates the corrective action plan (CAP) within 45 days from receipt of final evaluation report and sends it to CMS. CMS approves an acceptable corrective action plan. This will typically be the CAP that is suggested in the project review report but may be a plan that the M+C organization negotiates with CMS. The M+C organization has 45-days from initial receipt of the project review to submit a CAP for CMS approval.

Step 3: CMS will either accept or reject the CAP proposal. If rejected, the M+C organization will be required to resubmit another CAP proposal for consideration. However, CMS does not expect CAP proposals to be rejected if they have been previously agreed upon.

Step 4: Once accepted, the M+C organization will enter the CAP information into the designated location within the QAPI/ HPMS database. Once the CAP has been entered into the database, it cannot be altered. CMS and the M+CQROs will monitor the CAP based on the information in the database.

Step 5: The M+C organization implements the CAP in the specified timeframes. CMS and the M+CQRO will re-evaluate the CAP for compliance. Once the CAP has been resolved, the M+C organization will then continue with the project for sustained improvement.

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 divided into a section for significant improvement, which *has* a maximum of 80 points, and sustained improvement, which *has* 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+C organizations significant improvement score to a total value of 50 points out of a possible 80 points. This increase brings the M+C organization 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.

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.

35.4 - Obligations of Deemed M+C Organizations

(Rev. 9, 04-01-02)

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+C organizations 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+C organizations Medicare and non-Medicare line of business.

35.6.4 - Reporting Requirements

(Rev. 9, 04-01-02)

1. Accrediting organizations that have been approved for deeming authority must provide to CMS in written form and on a monthly basis all of the following:

    a. Copies of all accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of unmet CMS requirements);

    b. Notice of all accreditation decisions;

    c. Notice of all complaints related to deemed M+C organizations;

    d. Information about any M+C organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal or revision of the M+C organization's accreditation, within 30 days of taking the action;

e. Notice of any proposed changes to their accreditation standards or requirements or survey process. If an accrediting organization implements any changes before or without CMS approval, we may withdraw our approval.

2. If an accrediting organization finds a deficiency in an M+C organization that poses an immediate jeopardy to the organization's enrollees or to the general public, they must give CMS written notice of the deficiency within three days of identifying the deficiency.

3. When CMS gives notice that we are withdrawing our approval for deeming authority, the accrediting organization must notify all their accredited M+C organizations within 10 days.

4. Accrediting organizations must provide, on an annual basis, summary data that will be specified by CMS that relate to the past year's accreditation activities and trends.

5. Within 30 days after CMS changes a Medicare M+C organization requirement, the accrediting organization must:

   a. Send a written acknowledgement of CMS's notice of the change,

   b. Submit a new cross-walk reflecting the new requirement; and

   c. Send a written explanation how they plan to alter, within a timeframe that CMS will specify in the notice of change, their standards and review process to conform to CMS's new requirement.

6. Accrediting organizations must have a mechanism for publicly disclosing the results of an M+C organizations accreditation survey.

7. Accrediting organizations must report their assessment of M+C organizations QAPI projects to CMS via HPMS.

Appendix A - National QAPI Project Operational Policy Letters

1999 - Diabetes

Diabetes is a major health problem which is becoming more prevalent in all age groups. The increasing prevalence is attributed both to higher detection and to poorer health habits.

Adult onset diabetes is highly prevalent in the Medicare population and over 150,000 Americans die each year from diabetes and its complications. Complications of the disease include blindness, kidney failure, nerve damage, and cardiovascular disease. For most persons with diabetes, many of these complications can be prevented or delayed with appropriate monitoring and treatment. However, studies in both fee-for-service and managed care settings indicate that care is suboptimal. The Diabetes National Project focuses on improving monitoring in the outpatient setting.

Overview of Diabetes Project

The CMS-sponsored national project for 1999 focused on diabetes mellitus, using a standardized measurement set for diabetic processes of care and suggested interventions. M+C organizations with existing diabetes mellitus projects were allowed to substitute their own studies in place of CMS's project. However, those who participated in CMS's study had the benefit of participation in a national standardized measurement system. CMS did not require pre-approval of such projects.

One of the main objectives of this project is to reduce rates of blindness, amputations, kidney failure and the rate of diabetes-associated cardiovascular disease that is the major cause of death for the elderly population with diabetes. Diabetes and the complications of the disease can be prevented or delayed by management of blood glucose through diet, exercise and medication, by management of other risk factors such as lipids, blood pressure, smoking and by appropriate and timely examinations and treatment (e.g., eyes and feet).

The performance measures that were used for this project were the Diabetes Quality Improvement Project (DQIP) Measures. The finalized set of DQIP measures were released in August, 1998. Adoption of the DQIP measures was the result of a collaborative effort among several organizations, including CMS, the American Diabetes Association (ADA) and the National Committee for Quality Assurance (NCQA) Council on Performance Measures, which adopted six of the eight DQIP measures for its Health Employer Data Information Set (HEDIS) for the year 2000.

2000 - Pneumonia

According to the Centers for Disease Control and Prevention, pneumonia and influenza are the sixth leading causes of death in the United States. The incidence of pneumonia increases with age and approximately 90 percent of deaths attributed to this condition are in the population age 65 and older. Medicare patients with pneumonia are being hospitalized at the rate of approximately 600,000 per year, utilize over 4.2 million inpatient days, and account for more than 500,000 emergency department visits each year.

Overview of Pneumonia Project

The main objective of this project is to decrease the morbidity and mortality associated with community-acquired pneumonia in Medicare beneficiaries enrolled in M+C organizations. In order to accomplish this goal, a series of process objectives have been developed which include:

- Increase immunization rates for pneumococcal and influenza vaccines;
- Increase the number of inpatients receiving timely antibiotic administration;
- Increase the use of initial antibiotic therapy consistent with current guidelines;
- For inpatients, increase the collection of blood cultures prior to the initial antibiotic dose; and
- Increase the number of hospitalized patients screened for or given pneumococcal or influenza vaccines.

National Pneumonia Project Quality Indicators

The Centers for Medicare & Medicaid Services (CMS) worked with a Pneumonia technical expert panel whose members included representatives from the American Thoracic Society, the Infectious Disease Society of America, the Pneumonia Patient Outcomes Research Team, the American Pharmacy Association, the Institute of HealthCare Improvement, and other influenza/pneumococcal experts. This panel guided the writing of the final pneumonia indicators based upon a combination of both ambulatory and hospital-based data.

Medicare+Choice organizations could choose one or more of the national pneumonia indicator(s) from the list below. In addition to the seven defined quality indicators, CMS was also interested in exploring alternative options with M+C organizations (as described below). The seven national pneumonia indicators were:

- Influenza vaccination rates;
- Pneumococcal vaccination rates;
- Proportion of patients given an initial antibiotic consistent with current recommendations;
- Proportion of inpatients who have blood cultures collected before antibiotics administered;
- Proportion of inpatients with pneumonia screened for or given influenza vaccination;
- Proportion of inpatients with pneumonia screened for or given pneumococcal vaccination; and
- Proportion of patients who receive the initial antibiotic dose within eight hours of hospital arrival.

Alternative M+C organization 8th Indicator

CMS was aware of M+C organization expertise and creativity in the development of ambulatory quality indicators, as well as their participation in collaborative, community-based projects working to reduce the development of antibiotic resistant bacteria. If a QAPI project based on these activities required a quality indicator different from the above seven, M+C organizations were allowed to submit those indicators for CMS comment. This alternative quality indicator had to meet the following requirements:

- Indicator should affect the M+C organization's Medicare enrollees;
- Indicator should be measurable; and
- Indicator should reflect the national pneumonia project goal of reducing morbidity and mortality associated with pneumonia.

Organizations interested in pursuing this eighth option were required to work through their CMS RO representative.

Support/Communication for Projects

CMS encourages M+C organizations to work in collaboration with their local *Quality Improvement Organization (QIO) formerly known as* Peer Review Organization (PRO), as they proceed with the conduct of the pneumonia project. Under the PRO Sixth Scope of Work, PROs *were* required to conduct a pneumonia project using the indicators described above. It is to the mutual advantage of the *QIO/*PRO and the M+C organization to work collaboratively on their respective projects to promote efficiency, administrative simplification and reduction of resource burden. The Oklahoma Foundation for Medical Quality has been identified as the Pneumonia Clinical Area Support PRO, or "CASPRO", and will serve as a resource to other *QIO/*PROs in maintaining project staff lists, pneumonia literature and pneumonia intervention data on their web page (www.nationalpneumonia.org). Pneumonia data entry and analysis provider software were available on the web site in March of 2000. In addition to *QIO/*PRO support, CMS and the Centers for Disease Control and Prevention (CDC) have collaborated on an immunization intervention project using standing orders programs to increase adult immunization rates. An evidence-based standing orders program and intervention materials have been developed and CMS and CDC are available to representatives from M+C organizations to discuss implementing this program in M+C organization settings. If an M+C organization chooses not to utilize *QIO* support, questions regarding design and implementation should be directed to their CMS RO representative.

2001 - Congestive Heart Failure

Year 2001 National Project on Congestive Heart Failure (CHF) for Medicare + Choice Organizations (M+C organization).

Note that a related *activity*, Extra Payment in Recognition of the Costs of Successful *O*utpatient CHF *Care in 2002 and 2003* is included in Chapter 7 of this *m*anual.

For the year 2001, the national project must address congestive heart failure (CHF). According to the American Heart Association, approximately 3,000,000 Americans are currently diagnosed with CHF. Of these, over 80 percent (2,400,000) are over the age of 65, most being Medicare enrollees. The one-year mortality rate for CHF is between 20 - 30 percent in the elderly. CHF patients also experience significant functional limitations. Recent studies suggest effective clinical treatments and disease management strategies which may be effective in improving patient function, reducing mortality rates, decreasing hospital admissions and improving overall patient quality of life.

The National CHF QAPI project is similar in many ways to the previous diabetes and pneumonia national efforts. M+C organizations will identify the relevant patient population, perform baseline data collection and calculate the baseline values for the selected quality indicators. They will then design and implement improvement strategies, and perform follow-up indicator data collection and measurement.

However, there are aspects to this National CHF QAPI project which differ from previous projects. This project requires M+C organizations to measure and report performance on two specified quality indicators instead of one, and CMS will review the outcome on each indicator. M+C organizations will be expected to achieve significant and sustained improvement on the second indicator (QAPI #2).

As with the 1999 and 2000 national quality projects, some organizations may have existing projects that could be modified to meet the requirements of the national CHF project. Those organizations wishing to utilize projects currently underway may do so if:

- They follow the requirements of this Manual chapter;
- Utilize the CHF quality indicators as described herein, and
- Conduct a re-measurement in 2001 to establish a new baseline against which to assess their improvement.

National CHF QAPI Quality Indicators

CMS has developed the quality indicators based on evaluation and treatment recommendations contained in the Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guideline Number 11, Heart Failure: Evaluation and Care of Patients with Left-Ventricular Systolic Dysfunction (AHCPR Publication No. 94-0612, June 1994), the American College of Cardiology/American Heart Association Task Force Report Guidelines for the Evaluation and Management of Heart Failure ("JACC' 1995;26:1376-98), and the Heart Failure Society of America Guidelines for Management of Patients with Heart Failure Caused by Left Ventricular Systolic Dysfunction-Pharmacological Approaches ("J Cardiac Failure" 1999;5:357-82).

The indicators are also based on experience gained from the design and implementation of quality indicators for CMS's Inpatient National Heart Failure Project and the pilot outpatient Heart Failure Performance Improvement Effort, which utilized expert input from an American Heart Association Work Group. Additionally, CMS utilized the principles and recommendations contained in the report of an American Heart Association/American College of Cardiology work group "Evaluating quality of care for patients with heart failure. A summary from the First

Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke." "Circulation" 2000;101: e122-e140. The indicators have been previously tested by CMS for feasibility of data collection in the outpatient setting, reliability, and acceptability of the measure to providers. M+C organizations, physicians and trade associations provided input throughout this process to help refine the design and selection of the quality indicators.

The two National project CHF QAPI quality indicators are:

- QAPI #1 = Proportion of CHF patients with assessment of left ventricular function;
- QAPI #2 = Proportion of CHF patients with left ventricular systolic dysfunction (LVSD) who
    - Have been prescribed an angiotensin-converting enzyme inhibitor (ACEI); *or*
    - Have documentation of a reason why ACEI was not prescribed.

Appendix I contains more detailed measurement specifications for the CHF indicators.

Use of Alternative CHF Indicators

At their option, if a M+C organization has a baseline level above 75 percent for QAPI indicator #1 and 80 percent for QAPI indicator #2, it may design and use an alternative quality indicator. Prior to proceeding to use an alternative indicator, however, M+C organizations must provide information to CMS RO (RO) managed care staff demonstrating that they have met the required baseline levels. RO staff will in turn work with the CMS Office of Clinical Standards and Quality in assisting the M+C organization in the design of the alternative indicator. M+C organizations are encouraged, although not required, to also work with their *s*tate *QIO*.

Regardless of the choice of alternative indicator, the selected measure must meet the following requirements:

- Indicator should affect the M+C organizations Medicare enrollees;
- Indicator should be measurable; and
- Indicator should reflect the *National CHF QAPI* goal of reducing morbidity and mortality associated with congestive heart failure.

Technical Support for the National CHF QAPI Project

CMS encourages M+C organizations to work in collaboration with their *s*tate *QIO* in the design and implementation of their QAPI CHF projects. In the event that the M+C organization chooses not to utilize the *QIO*, questions regarding design and implementation should be directed to the CMS RO managed care staff.

If the M+C organization works cooperatively with the *QIO* on quality improvement projects, CMS will pay the *QIO* and/or Clinical Data Abstraction Centers (CDACs) the costs of abstracting information from the M+C organization medical records, as in prior years. In

addition, if the medical records need to be photocopied prior to abstraction by the PRO/CDAC, the M+C organization's cost of such photocopying will be reimbursed by CMS through the *QIO*.

CMS is developing an optional data collection instrument for use in data abstraction. This will include data specifications, e.g., words and phrases that indicate LVEF assessment and LV systolic dysfunction. It will also include lists of ICD-9-CM and CPT codes likely to indicate that LVF was assessed. These optional tools will be available to all M+C organizations regardless of who performs data abstraction. They will be posted to our web page at www.cms.hhs.gov.

QAPI Quality Indicators for Heart Failure

NB: Both quality indicators must be measured and reported to CMS.

Quality Indicator QAPI 1:

Proportion of heart failure patients with assessment of left ventricular function:

Population:	M+C organization enrollees with a continuous enrollment of at least 180 days prior to the date of data collection, who have encounter/billing diagnoses of heart failure in the inpatient or outpatient settings, including: (a) Those enrollees discharged alive from an acute care hospital with a principal discharge diagnosis of heart failure[1] in the one year prior to the date of data collection; as well as: (b) Those enrollees without a hospital principal discharge diagnosis of CHF, but with three or more physician encounters with a diagnosis of CHF[2], in the one year prior to the date of data collection.
Denominator:	A census or random sample of M+C organization enrollees from the 'Population' as (LVF) have been evaluated. Documentation of LVF evaluation consists of a billing record indicating that LVF evaluation has been performed, defined above.
Numerator:	Those in denominator with documentation that left ventricular function quantitative or qualitative lab report of LVF evaluation results, clinician notation that LVF evaluation has been performed, clinician notation of LVF results, or any other chart or administrative evidence that LVF evaluation has been performed.
Data Sources:	Enrollees with heart failure: Enrollment data, billing data, encounter data, hospital discharge data, any other reviewable source.
LVF evaluation:	Billing data, radiology or laboratory data, medical records, physician

[1] ICD-9-CM codes: 402.01, 402.11, 402.91, 404.01, 404.11, 404.91, 428.x

[2] See footnote 1.

summary, any other reviewable source.

Quality Indicator QAPI 2:

Proportion of heart failure patients with left ventricular systolic dysfunction (LVSD) who:

- Are prescribed angiotensin converting enzyme inhibitors (ACEI); OR
- Have documented reason for not being on ACEI

Population: Those in numerator of QAPI Quality Indicator 1 with left ventricular systolic dysfunction (LVSD). LVSD is defined as an ejection fraction less than 40 percent or equivalent narrative description[3]

Denominator: A census or random sample of M+C organization members from the 'Population' defined above.

Numerator: Those in denominator who have:

1. Been prescribed ACEI; OR
2. Chart documentation of one or more of the following contraindications to ACEI use:
    - Moderate or severe aortic stenosis, OR
    - History of angioedema, hives, or severe rash with ACEI use; OR
    - Bilateral renal artery stenosis; OR
3. Chart documentation of any specific reason why ACEI is not used (e.g., cough, hyperkalemia, hypotension, renal insufficiency/failure, other physician-noted reason); OR
4. Chart documentation of participation in a clinical trial testing alternatives to ACEIs as first-line heart failure therapy.

Data Sources: LVF evaluation results (quantitative or qualitative): Radiology or laboratory test results, medical record, physician summary, any other reviewable source.

Prescription of ACEI: Pharmacy data, medical records, physician summary, any other reviewable source.

Reason for not prescribing ACEI: Inpatient or outpatient diagnosis codes, medical record, any other reviewable source.

Participation in a clinical trial testing ACEI alternatives: any reviewable source

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[3] A list of qualitative descriptions from laboratory reports or clinician notes considered consistent with LVSD will be provided.

2002 - Breast Cancer Screening

Overview of the Breast Cancer Screening (BCS) Project

The main objective of this project is to decrease the morbidity and mortality associated with breast cancer in female Medicare beneficiaries enrolled in M+C organizations. In order to accomplish this goal, it is important to increase the level of early detection of the disease by encouraging optimal use of mammography.

National BCS QAPI Project Specifications

This project will involve the use of the HEDIS® breast cancer screening measure as described by the NCQA in Volume 2 of its HEDIS 2002 Technical Specifications. Briefly, this measure considers the percentage of women age 52 through 69 years who were continuously enrolled during the measurement year and the preceding year, and who had a mammogram during the measurement year or the preceding year.

Baseline data for the project will use the Medicare HEDIS 2002 (measurement year 2001) reported rate filed through NCQA by June 28, 2002. M+C organizations that do not report HEDIS 2002 because they do not meet minimum enrollment or contract effective date requirements will not have to participate in the 2002 BCS project since it is not likely they will have sufficient incidence to develop a baseline due to low enrollment.

Re-measurement, after interventions, will use the HEDIS specifications in effect at that time. If the BCS measure has been rotated or if HEDIS is no longer being used at the point of re-measurement then HEDIS 2002 specifications will be used.

Rewarding High Performance

We recognize that some organizations have already achieved a high rate on screening by mammography and that opportunity for additional improvement would be difficult and costly to achieve. Therefore, CMS has decided that MCOs that have a reported rate at or above 80 percent for HEDIS 2001 (measurement year 2000) will be excused from performing the national BCS project and will have to perform only the M+C organization selected project for this year. For HEDIS 2000 there were 61 HEDIS submissions which met or exceeded the 80 percent rate. Additionally, organizations that report a rate below 80 percent for HEDIS 2001, but report a rate at or above 80 percent for HEDIS 2002 (measurement year 2001) will be exempt from the 2002 national project. Organizations that did not report HEDIS 2001, but report a rate at or above 80 percent for HEDIS 2002, will also be exempt from the 2002 national project.

Although CMS does not receive the annual HEDIS report from NCQA until approximately August 1, organizations are aware of their own rates several months earlier. Additionally, most M+C organizations are aware of their previous BCS rates and are in a position to judge the effectiveness of previous interventions so they can determine the level of effort that will be required to achieve demonstrable improvement in the future. Therefore, using HEDIS 2002 for

the baseline should not cause a problem for initiating the 2002 national project. Also, it will permit the use of data from the previous year, consistent with QAPI project provisions.

Organizations that do not have to perform the national project will be notified by CMS, about October 1st of 2001 and 2002, that they are exempt based on data from HEDIS 2001 (measurement year 2000) or HEDIS 2002 (measurement year 2001) reporting years, respectively. CMS will input the exemption into the M+C Quality Review Organization QAPI database.

Project Initiation and Implementation

CMS requires that the organization achieve demonstrable and sustained improvement in clinical care as a result of performing this project. Therefore, interventions must achieve improvement that is significant and sustained over time.

Organizations that are currently engaged in a similar BCS project as their internally selected project will need to follow guidance in section 1.3.3.3 of the QISMC document. This requires drawing a new baseline based on HEDIS 2002 (measurement year 2001) from which a re-measurement will be made while completing the previously initiated M+C organization selected project. The national QAPI project will not affect the cycle of internal optional projects.

Support/Communication for Projects

We encourage M+C organizations to work in collaboration with their local *QIO* as they seek appropriate interventions to improve mammography rates and reduce burden on providers of services. In addition to *QIO* support, we would like to alert MCOs about the Centers for Disease Control and Prevention's information resources on the web at http://www.cdc.gov/cancer/nbccedp/. Another helpful site is located at http://cis.nci.nih.gov.

Please send any questions regarding this OPL/BCS project to your RO managed care staff, or to: Richard Malsbary, (410) 786-1132 in the Center for Beneficiary Choices.

∗Kerlikowske, et al. JAMA 1993; 270(20): 2444-2450

∗∗http://www.cancer.org/NBCAM_fastfacts.html (cited 2001 January 4)

2003 - Clinical Health Care Disparities or Culturally and Linguistically Appropriate Services

Reducing clinical health care disparities (CHCD) is one of the major challenges facing the entire health care industry. Compelling evidence exists that race and ethnicity correlate with persistent, and often increasing, health disparities. Since 1993, key indicators have shown that our nation's health has greatly improved. However, this good news does not apply to all Americans, a fact that has been recognized by leading organizations and health care researchers across the United States.[4, 5, 6, 7, 8, 9] Achieving new health care goals will require a national commitment to identify

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4 Mandelblatt JS, Gold K, O'Malley AS, et al: Breast and Cervix Cancer Screening Among Multiethnic Women: Role of Age, Health and Source of Care: *Preventive Medicine* 418-425. 1999.

and address the causes underlying higher levels of disease and disability in certain racial and ethnic groups. The urgent need for this commitment is further emphasized by the fact that the overall population is expected to grow dramatically, especially in the number of Hispanics, Asians and the minority elderly over age 85.

An increasing body of health services research also indicates that the provision of culturally and linguistically appropriate services (CLAS) leads to improved health outcomes, increased patient or beneficiary satisfaction, and organizational efficiencies that result in decreased expenditures. Many of the critical interventions that support the provision of culturally and linguistically appropriate services occur at the clinical encounter between health care providers and patients, but it is not the only locus of concern. A health care organization must also think about how it provides support for its customers in terms of customer service relations and communications, compliance with plan operating procedures, addressing grievances and appeals, etc.

Overview of 2003 National QAPI Projects

For the year 2003 national QAPI project, an M+C organization will have a choice between initiating a project that addresses clinical health care disparities (CHCD) or culturally and linguistically appropriate services (CLAS). M+C organizations that select a project that addresses CHCD must focus on one of four clinical areas - diabetes, pneumonia, congestive heart failure, or mammography. They must also use previous guidelines issued by CMS in the form of OPLs to determine appropriate quality indicators and implementation strategies.[10] [11] [12] M+C organizations that select a project that addresses CLAS must focus on language access or organizational support for CLAS. M+C organizations that wish to initiate a CHCD or CLAS project in 2002 (begin baseline data collection in 2001), may do so and receive credit for the year 2003 national QAPI project.

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5 Gornick ME, Eggers PW, Reilly TW, et al. Effects of Race and Income on Mortality and Use of Services Among Medicare Beneficiaries; *New England Journal of Medicine* 335:791-799, September 12, 1996.

6 Tortolero-Luna G, Glober GA, Villarreal R, Palos G, Linares A Screening Practices and Knowledge, Attitudes, and Beliefs about Cancer among Hispanic and Non-Hispanic White Women 35 Years Old or Older in Nueces County, Texas: *Journal of the National Cancer Institute Monograph* 49-56, 1995.

7 Center for Health Quality, Outcomes, and Economic Research: *Quarterly 2*, Spring 1999.

8 Racial and Ethnic Disparities in Access to Health Insurance and Health Care: UCLA Center for Health Policy Research and The Henry J. Kaiser Family Foundation 1, October 1999.

9 Influenza and Pneumococcal Vaccination Levels Among Adults Aged Greater Than or Equal to 65 Years: United States 47(38): 797-802, October 2, 1998.

10 http://www.cms.hhs.gov/medicare/mgdqual.htm. OPL #129 (1) The Year 2001 National Project on Congestive Heart Failure (CHF) for Medicare+Choice Organizations (M+C Organization); and (2) Extra Payment in Recognition of the Costs of Successful Outpatient CHF Care. OPL #116 Quality Improvement System for Managed Care (QISMC) Year 2000 National Project on Community-Acquired Pneumonia.

11 http://www.cms.hhs.gov/quality/3l.htm Diabetes Quality Improvement Project (DQIP).

12 Breast Cancer Screening OPL.

Clinical Health Care Disparities

CHCD projects must measure and improve care for individuals enrolled in the M+C organization from any, all, or a subset of the following populations:

- American Indian/Alaskan Native;
- Asian;
- Black/African American;
- Native Hawaiian/Pacific Islander, and
- Hispanic/Latino.

CHCD projects should demonstrate improvement for the selected population(s) in the quality indicators set forth in the OPL for the chosen clinical area. M+C organizations may measure the disparity between the rate for the selected population(s) and the overall enrolled population, but a reduction in the amount of disparity is not required.

The M+C organization should identify enrollees in the selected population(s) using an appropriate data source, such as plan data collected at the time of, or subsequent to, enrollment, or the data supplied by CMS that is collected by SSA at the time of original enrollment in Medicare. Other data sources, such as zip-code/census data, may be used to target interventions to appropriate individuals. For M+C organizations selecting pneumonia as a clinical topic, CAHPS data, which includes the race/ethnicity of respondents, may be used to determine rates. Plans wishing to use CAHPS for this purpose must notify CMS by July 1st of the year of the CAHPS survey; an additional sample of enrollees from the selected population(s), or a subset of the selected population, will be drawn to increase the sample size used in determining the rate.

Examples of two CHCD projects follow. M+C organizations may find these examples useful in developing their own project plans.

Culturally and Linguistically Appropriate Services (CLSA)

M+C organizations that select CLAS must conduct a project that addresses one of two broad categories - language access and organizational support. Projects that address language access should focus on limited English proficiency (LEP) managed care enrollees.[13] Projects that focus on organizational support should be built on the understanding of, and in response to specific, cultural and linguistic needs of beneficiaries enrolled in a managed care plan. Examples of CLAS projects that address language access and organizational support are provided in Appendix A, '2003 - Clinical Health Care Disparities or Culturally and Linguistically Appropriate Services" of this chapter. M+C organizations may find these examples useful in

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13 LEP individuals are those who "…cannot speak, read, write, or understand the English language at a level that permits them to interact effectively with health care providers and social service agencies." DHHS Office for Civil Rights. *Policy Guidance on the Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency*. 65 FR 52763. August 30, 2000 at www.hhs.gov/ocr/lep.

developing their own project plans. M+C organizations that decide to use one of the example projects provided in this appendix may decide, however, to implement an intervention that is not addressed by the example. This is acceptable, as long as the intervention can be linked to the topic and outcome of the project.

CLAS projects should use the following framework:

- Identify an opportunity for improvement;
- Develop and/or conduct meaningful intervention(s);
- Determine if the opportunity for improvement or goal has been achieved; and
- Review one year later to ensure improvement has been sustained.

Project Support and Evaluation

We encourage M+C organizations to collaborate on or develop a community-wide approach for conducting QAPI projects that focus on CHCD or CLAS. Interventions, for example, may be implemented on a community-wide or regional basis. Each M+C organization, however, will be assessed individually on the success of their project. M+C organizations may have their QAPI projects evaluated at a level less than the contract (H-number), but may not have their QAPI projects evaluated at a level greater than the contract (H-number). For example, an M+C organization may not request an evaluation of QAPI projects for a multi-*s*tate area, unless CMS has a contract (H-number) for the multi-*s*tate unit.[14]

We also encourage M+C organizations to work with their *local Quality Improvement Organization (QIO) formerly known as* Peer Review Organization (PRO) to identify interventions that will decrease health care disparities and/or provide culturally and linguistically appropriate services. In addition, to assist M+C organizations that focus on CLAS for their project, CMS is working with the Agency for Healthcare Quality and Research (AHRQ) and one of their contractors to develop detailed specifications and interventions for two of the example projects.

M+C organizations that meet the following conditions may receive an automatic pass for the 2003 national project by providing CMS the report (analysis) from the *s*tate Medicaid agency or accrediting organizations that verifies the satisfactory completion of the QAPI project and results.

- M+C organizations that have conducted a CLAS project for a *s*tate Medicaid program and have met the *s*tate's requirement for demonstrable improvement during the project period (projects must be completed or reviewed between 2001 through 2003).

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14 HCFA has a contract with Kaiser Mid-Atlantic that serves several states and the District of Columbia.

- M+C organizations that have conducted a CLAS project for private accreditation that meets the accreditation organization's requirement for improvement during the project period (projects must be completed or reviewed between 2001 through 2003).

For M+C organizations that complete a project after 2003 that is determined to meet an accrediting organization's or *s*tate Medicaid agency's requirements, CMS will also accept that determination, as long as the determination is made prior to the measurement reporting year, which is 2005. If the project does not meet the accrediting organizations or *s*tate Medicaid agency's requirements, however, it must be reported to and reviewed by CMS.

For QAPI projects, CMS requires demonstrable improvement. For non-clinical CLAS projects, CMS will allow an M+C organization to demonstrate improvement by using structural measures that show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Additional Resources

M+C organizations seeking guidance on developing QAPI projects that address CHCD or CLAS may use the following sources:

- U.S. Department of Health and Human Services Office for Civil Rights. Title VI of the Civil Rights Act of 1964: Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency. "Federal Register", August 30, 2000. 2000;65(169):52762-74; and

- U.S. Department of Health and Human Services Office of the Secretary. National Standards on Culturally and Linguistically Appropriate Services (CLAS) in Health Care. "Federal Register", December 22, 2000. 2000;65(247):80865-80879.

Please send any questions regarding this OPL or CHCD/CLAS projects to your RO managed care staff, or to: Trisha Kurtz, (410) 786-4670 in the Medicare Managed Care Group.

Clinical Health Care Disparities Sample QAPI Projects

These sample projects are not required. M+C organizations may, however, find these sample projects useful in developing their own QAPI project plans

Example 1 - Mammography

This project seeks to increase the use of mammography screening with a focus on clinical health care disparities. The M+C organization with a Medicare enrollment of 10,000 decides to aggregate all of the potential categories to create a selected population. The M+C organization uses race and ethnicity that is collected at the time an individual enrolls in the plan to identify the population, and determines that in 2001 about 10 percent of its enrollment were in a population that the M+C organization selected for their QAPI project, about 200 of whom were women of appropriate age. Beginning in 2003, the M+C organization uses claims alone to determine the rate. For the baseline year (2002), the rate for the selected population is 50 percent (performance gap of 50 percent), and for the overall enrolled population the rate is 55 percent (performance gap of 45 percent), so - although the existence of a disparity in this example, it is not necessary

to conduct the project. For this M+C organization the apparent disparity is 5 percent. The M+C organization uses this same methodology to determine the rates for the years 2003, 2004, and 2005.

In 2003, the M+C organization does a mailing to a sample of the selected and the overall enrolled populations to determine if there are any special barriers to mammographic screening among the selected population. It finds that there are two notable barriers - availability of screening centers on evenings and weekends, and the disbelief among the selected population that screening is of benefit. It does a special mailing to enrollees identifying screening centers with extended hours, and making the case for benefits of screening, and makes this mailing available to it PCPs.

For the 2003 reporting period there is no improvement in rates, but in 2004 the rate for the selected population is 56 percent. Compared to baseline this means that the performance gap has been reduced from 50 percent to 44 percent, which is a 12 percent improvement in gap. In 2005 the rate for the selected population is 55 percent, which demonstrates that improvement has been sustained.

Example 2 - Pneumonia

This project seeks to increase flu/pneumonia vaccine rates for a selected population(s). The M+C organization with Medicare enrollment of 5000 decides to aggregate all of the potential categories to create a selected population. In June of 2002 it informs CMS of its need for CAHPS results for the selected population. During the Fall of 2002, CMS augments the usual CAHPS sample with an additional sample of 100 enrollees from the selected population. In the spring of 2003, the M+C organization receives CAHPS results for 2002 by racial/ethnic category. For this year, for the 500 respondents, the rates of flu and pneumococcal vaccination were 30 percent and 20 percent. For the selected population, there were a total of 125 respondents, and the rates were 30 percent and 25 percent.

Although there is no disparity between the selected and the overall enrolled population, the MCO proceeds with the project, focusing on interventions specific to the selected population. The M+C organization requests similar breakdowns of CAHPS results for the reporting years 2003, 2004, and 2005.

In 2003, the M+C organization does a mailing to a sample of the selected and the enrolled populations to determine if there are any special barriers to flu and pneumococcal vaccination among the selected population. It finds that there are no special barriers. It does a mailing to all enrollees in the Fall reminding them of the benefits of screening. Using census data to identify zip codes with higher proportions of residents from the selected population, the M+C organization works with the State health department to publicize the importance of immunization, and available sources of it, in those areas.

Using CAHPS data, in the 2003 reporting year there is improvement in rates for the selected population, to 35 percent (flu) and 30 percent (pneumococcal). Compared to baseline this means that the initial gap of 70 percent has been reduced to 65 percent, which represents a 7 percent improvement in gap. For the 2004 reporting period, the rates for the selected population are 40 percent and 35 percent. This represents a 14 percent improvement in the gap. For the 2005

reporting period the rates for the selected population are unchanged from those of the prior year, which demonstrates that improvement has been sustained.

Culturally and Linguistically Appropriate Services Sample QAPI Projects

These sample projects are not required. M+C organizations may, however, find these sample projects useful in developing their own QAPI projects plans.

Language Access

Language access is critical for minority individuals who have "limited English proficiency" (LEP). Research shows that language barriers have a negative impact on utilization, satisfaction, and possibly adherence to treatment regimens [15]. LEP has been linked to fewer physician visits, reduced receipt of preventive services, and higher rates of missed appointments and medication noncompliance among LEP patients[16]. Included among the negative effects of language barriers are higher rates of diagnostic testing, omission of vital information, misdiagnoses, inappropriate treatment and misunderstanding[17.]

Incentives for M+C organizations to undertake efforts directed at ensuring access to services for LEP enrollees through the provision of required language access services include:

- More accurate medical histories and clearer descriptions of symptoms leading to fewer diagnostic errors;
- More appropriate testing and screening yielding fewer missed opportunities for early detection and treatment;
- More successful patient education resulting in reduced behaviors constituting risk factors for disease and exposure to risk;
- Clearer communication between physicians and patients concerning treatment options leading to more appropriate treatment and improved compliance with treatment regimens; and

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[15] Brach, C., and Fraser, I. 2000. Can Cultural Competency Reduce Racial and Ethnic Health Disparites? A Review and Conceptual Model. "Medical Care Research and Review" 57(1): 181-217

[16] Derose, K.P., and Baker, W.D. 2000. Limited English Proficiency and Latinos' Use of Physician Services. "medical Care Research and Review" 57(1): 76-91

Commonwealth Fund. 1995. "National Comparative Survey of Minority Health Care". NewYork: Commonwealth Fund.

Eraker, S.A., Kirscht, J.P., and Becker M.H. 1984. Understanding and Improving Patient Compliance. Annals of Internal Medicine 100(2): 258-268

[17] David, R.A., and Rhee, M. 1998. The Impact of Language as a Barrier to Effective Health Care in an Underserved Urgan Hispanic Community. "Mount Sinai Journal of Medicine 65". (5,6): 393-397

- Better protection for the M+C organization against tort liability, malpractice lawsuits, and charges of negligence.

M+C organizations are also required, as are all recipients of Federal financial assistance, to take steps to ensure LEP persons have meaningful access to the health services they provide.

Example 1 - Compile or Enhance and Make Available a Practitioner Directory Identifying Bilingual/Multi-Lingual Practitioners

Identify an Opportunity for Improvement

- Identify the languages likely to be encountered by appropriate M+C organization practitioners;
- Use these data to assess the need to identify plan practitioners who are bilingual/multi-lingual;

Intervention

- Survey M+C organization practitioners to request the voluntary identification of those who are bilingual/multilingual;
- Compile or enhance and publish a directory identifying the bilingual/multi-lingual practitioners and the language(s) in which they are competent;
- Make the directory available to all enrollees through normal channels;
- Include notice of the availability of the directory in outreach materials to M+C organization LEP populations.

Benchmark/Goal

- Make the directory that identifies bilingual/multilingual practitioners, and/or notice of that directory, available to M+C organization enrollees by completion of the project.

Outcome

For improvement, M+C organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 2 - Establish a System to Identify M+C organization LEP Beneficiaries and Access and Use This Information

Identify an Opportunity for Improvement

Assess the adequacy of any existing system(s) for identifying M+C organization LEP enrollees and for accessing and using this information.

Intervention

Identify enrollees written/oral language needs for a medical encounter. (Identification methods include survey, enrollment application, etc.) Incorporate and record this information in the plan data (e.g., plan enrollment database) so that it is accessible to staff and/or providers.

Benchmark/Goal

The M+C organization identifies its LEP enrollees and provides for the access and use of this information by providers and staff. A new or significantly improved system exists to identify M+C organization LEP enrollees and to access and use this information.

Outcome

For improvement, M+C organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 3 - Acquainting M+C organization LEP Enrollees of Their Right to Language Services

Identify an Opportunity for Improvement

Evaluate the plan's current process for acquainting M+C organization LEP enrollees of their right to language access services.

Intervention

Develop or enhance the process for acquainting M+C organization LEP enrollees of their right to language access services.

Benchmark/Goal

New or enhanced procedures exist and are operational to acquaint M+C organization LEP enrollees of their right to receive language assistance services. Procedures include processes for both verbal offers and written notices in the enrollee's preferred language.

Outcome

For improvement M+C organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 4 - Provide Oral Language Interpretation Assistance to M+C organization LEP Enrollees

Identify an Opportunity for Improvement

Identify the languages likely to be encountered in the M+C organization service area and enrollee population by reviewing census data, CMS-provided race and ethnicity data for M+C organization's enrollees and/or data from school systems and community agencies and organizations.

- Select one or more of the most dominant LEP groups in the service area.
- Evaluate the adequacy of any existing process (es) to provide oral language interpretation services to enrollees in the selected LEP groups.
- Identify the points of contact in the M+C organization where language assistance is likely to be needed (e.g., beneficiary services).
- Define the resources that will be needed to provide effective language assistance to M+C organization enrollees in the selected LEP groups, and identify the location and availability of these resources.

Intervention

Expand existing capacity as necessary to address unmet need by hiring bilingual staff or paid interpreters, contracting with interpreters, engaging community volunteers, and/or arranging for telephone interpreter services.

Benchmark/Goal

The M+C organization offers and provides oral language assistance including bilingual staff and interpreter services to M+C organization LEP beneficiaries in the selected groups at points of contact in a timely manner during hours of operation. A new or significantly improved system for providing oral language services to individuals with limited English proficiency in the selected groups who seek services from the M+C organization is implemented and fully operational.

Outcome

For improvement M+C organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 5 - Provide Written and Oral (Sight) Translations of Vital Documents and Information to M+C organization LEP Enrollees

Identify an Opportunity for Improvement

Identify the non-English languages that are likely to be encountered in the M+C organization's service area by reviewing census data, CMS-provided race and ethnicity data for M+C organization enrollees and/or data from school systems and community agencies and organizations.

Identify one or more of the most dominant LEP language groups in the service area.

Evaluate the adequacy of available translated materials to meet the needs of language group(s).

Intervention(s)

One or more of the following:

- Secure written translations into the selected LEP language(s) of vital documents and information. Translated materials should be responsive to the culture as well as the levels of literacy of M+C organization LEP enrollees in these language groups;

- Provide/post signs in public areas (e.g., waiting rooms) in the selected LEP language(s) notifying LEP enrollees of a variety of patient rights, availability of conflict and grievance resolution, and directions to service locations;

- Provide/post way-finding signs to identify or label the location of specific services (e.g., registration, examining rooms);

- Make available translated written documents to LEP enrollees in the selected language group(s).

Benchmark/Goal

A new or significantly improved system for improving access for LEP beneficiaries to easily understood patient-related materials and/or posted signage is implemented and fully operational. The M+C organization makes available translations of, at a minimum, vital documents and information for the selected one or more most dominant LEP language groups in the service area. For other language groups, the M+C organization provides written notice in the primary language of the LEP beneficiary of the right to receive oral translation of written materials.

Outcome

For improvement M+C organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Potential Organizational Support Class QAPI Projects

For purposes of the QAPI project, the premise for the organizational support for CLAS is built on understanding and responding to specific cultural and language needs of Medicare and Medicaid beneficiaries enrolled in the managed care plan. Health journal literature indicates that the provision of culturally and linguistically appropriate services leads to better health outcomes, increased customer satisfaction, and organizational efficiencies that result in decreased expenditures.

Many of the critical interventions that support the provision of culturally and linguistically appropriate services occur at the clinical encounter between health care providers and patients. But that is not the only locus of concern. A health care organization must carefully think about how it provides support for its customers in terms of customer service relations and communications, compliance with plan operating procedures, negotiating complaints and grievance and appeals processes, etc.

Example 1 - Establish and Implement a Plan to Recruit and Retain Bi/Multi-Cultural and Bi/Multi-Lingual Minority Employees Who Reflect the Dominant Racial, Ethnic and Linguistic Minorities Served

Rationale

There are distinct communication and service advantages to recruiting and retaining employees within the M+C organization who reflect the demographics of the enrolled population. This is especially true at key points of beneficiary encounters, such as customer service, including navigating the complaints and appeals processes. Also, the customer service representative provides a wide array of information across all aspects of plan services and refers beneficiaries to other parts of the organization to obtain information, assistance and services.

Initial Assessment

Identify dominant cultural and linguistic minority groups enrolled in the M+C organization; assess whether M+C organization employees at key points of beneficiary encounters have the capacity to understand and meet cultural and language needs of enrollees.

Interventions (Steps in Completing the Project)

- Assess the diversity of populations served with regard to culture and language.
- Review employee recruitment and retention practices; do these practices reflect sensitivity to the linguistic and cultural needs of communities served?
- Develop a written plan with regard to recruiting and retaining employees who reflect sensitivity to the linguistic and cultural needs of communities served.
- Acquire board sign-off to implement the plan with an effective date within the next year and has a budget to support the plan.

Benchmark/Goal

The M+C organization has a written plan for recruiting and retaining employees who reflect sensitivity to the linguistic and cultural needs of the communities served. The organization is better able to meet the needs of linguistic and cultural minorities by systematically attempting to recruit and retain employees who reflect the cultural and linguistic minority communities served.

NOTE: This does not require a particular ratio be met with regard to so many employees per so many beneficiaries.

Outcome

For improvement M+C organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 2 - Establish and Implement a Plan to Recruit and Retain Bi/Multi-Cultural and Bi/Multi-Lingual Minority Practitioners Who Reflect the Dominant Racial, Ethnic and Linguistic Minorities Served

Rationale

There are distinct communication and service advantages to recruiting and retaining practitioners who reflect the demographics of the enrolled population. This is especially true at key points of

beneficiary encounters, such as the clinical setting, where the practitioner provides a wide array of direct services.

Initial Assessment

Identify dominant cultural and linguistic minority groups enrolled in the M+C organization; assess whether M+C organization practitioners have the capacity to understand and meet cultural and language needs of enrollees.

Interventions - (Steps in Completing the Project)

- Assess the diversity of populations served with regard to culture and language.
- Review practitioner recruitment and retention practices to ensure that these practices reflect sensitivity to the linguistic and cultural needs of communities served.
- Develop a written plan with regard to recruiting and retaining practitioners that reflect sensitivity to the linguistic and cultural needs of communities served.
- Acquire board sign-off to implement the plan with an effective date within the next year and has a budget to support the plan.

Benchmark/Goal

The M+C organization has a written plan for recruiting and retaining practitioners who reflect sensitivity to the linguistic and cultural needs of the communities served. The organization is better able to meet the needs of linguistic and cultural minorities by systematically attempting to recruit and retain practitioners who reflect the cultural and linguistic minority communities served.

NOTE: This does not require a particular ratio be met with regard to so many practitioners per so many beneficiaries.

Outcome

For improvement M+C organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 3 - Develop or Provide Access to *Culturally Linguistic Appropriate Services (***CLAS***)* **Training Programs for Employees and Practitioners**

Rationale

CLAS training programs increase cultural awareness, knowledge, and skills, leading to changes in clinical and administrative understanding of patients. CLAS training provides a way to introduce staff to interaction issues that have previously gone unnoticed or misinterpreted. Therefore, a critical part of organizational support for CLAS is ensuring that employees and practitioners receive ongoing generalized training and education in delivery of CLAS. Further, at the clinical level in particular, continuing medical education related to specific disease incidence and prevalence and treatment efficacy and outcomes is critical.

Initial Assessment

Review current capabilities for developing or providing CLAS training either through internal or external sources.

Interventions - (Steps in Completing the Project)

- Assess the diversity of populations served with regard to culture and language.
- Establish and/or identify CLAS training that addresses the needs of the enrolled population. (CMS will provide technical assistance regarding CLAS training sources for optional use by M+C organizations.)
- Assist employees and practitioners in attending CLAS training.
- Establish a mechanism to record that employees and practitioners have attended CLAS training.

Benchmark/Goal

Employees and/or practitioners have received CLAS training. If CLAS training is already underway, then the M+C organization shall increase the number attending the training. If the program is new, then the M+C organization shall demonstrate that the program is initiated and that there is participation with significant attendance by employees and practitioners.

Outcome

For improvement M+C organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Example 4 - Conduct an Organizational Assessment to Identify Opportunities for Improvement and Develop a Multi-Year Plan for Improving Provision of CLAS

Rationale

An organizational assessment to identify opportunities for improvement is essential for creating an incremental, coherent effort in the provision of CLAS. An assessment provides a status check on where the M+C organization is in the provision of CLAS, and a gap analysis between where the organization is now and where it wants to be at a future point in time.

Initial Assessment

Review current activities relating to conducting an organizational assessment of the provision of CLAS.

Interventions

- Assess the diversity of populations served with regard to culture and language.
- Assess organizational capacity for providing CLAS.

- Use the organizational assessment to build a multi-year plan for providing CLAS.
- Put into place the necessary organizational structure needed to execute the multi-year plan.

Benchmark/Goal

M+C organization conducts an organizational assessment to identify opportunities for improvement in the provision of CLAS. Based on the assessment, M+C organization puts into place the necessary organizational structure needed to execute the multi-year plan.

Outcome

For improvement M+C organizations will need to show what was in place prior to the quality improvement effort and what is operational at the end of the project.

Appendix B - M+C Quality Glossary

Accreditation

An evaluative process in which a healthcare organization undergoes an examination of its policies, procedures and performance by an external organization ("accrediting body") to ensure that it is meeting predetermined criteria. It usually involves both on- and off-site surveys.

Fully Accredited

Designation that all the elements within the accreditation standards for which the accreditation organization has been approved by CMS have been surveyed and fully met or have otherwise been determined to be acceptable without significant adverse findings, recommendations, required actions or corrective actions.

Accreditation Cycle for M+C Deeming

The duration of CMS's recognition of the validity of an accrediting organization's determination that a Medicare+Choice organization (M+C organization) is “fully accredited.”

Baseline Data

Initial data gathered before improvements or interventions are made that will be compared with data collected later to determine whether changes have been effective.

Benchmarking

The process of measuring products, services, strategies, processes, and practices against known leaders/best-in-class companies.

Consumer Assessment of Health Plans Study (CAHPS)

An annual satisfaction survey, administered by CMS, in which a sample of members from each Medicare managed care organization are asked for their opinions relating to clinical and administrative services provided by the MCO.

Continuous Quality Improvement (CQI)

An integrated, comprehensive approach to continuously examine, refine, and revise organizational processes to meet and exceed customers’ expectations. Integrates fundamental management approaches, improvement efforts, tools, and training.

Coordinated Care Plan

A plan that includes a CMS-approved network of providers that are under contract or arrangement with the M+C organization to deliver the benefit package approved by CMS. Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), preferred provider organizations (PPOs), as well as other types of network plans (except network MSA plans. See 42 CFR. §422.4(a)(1.)

Cost Benefit Analysis

Weighing known costs against probable benefits; objective is to have potential benefits to exceed (additional) costs.

Customer

Anyone who receives a service or product; can be internal and/or external to the organization.

Deemed Status

Designation that an M+C organization has been reviewed and determined "fully accredited" by a CMS-approved accrediting organization for those standards within the deeming categories that the accrediting organization has the authority to deem.

Deeming Authority

The authority granted by CMS to accrediting organizations to determine, on CMS's behalf, whether a M+C organization evaluated by the accrediting organization is in compliance with corresponding Medicare regulations.

Equivalency Review

The process CMS employs to compare an accreditation organization's standards, processes and enforcement activities to the comparable CMS requirements, processes and enforcement activities.

Expected variation

A change or measurement observed in a step of the process which one could predict would occur because of natural causes; data points are within the upper and lower control limits

Goal

The measurable outcome of the process under study, as defined by the improvement team.

Health Outcomes Survey (HOS)

The first outcomes measure used in the Medicare program. It is a longitudinal, self-administered survey that uses a health status measure, the SF 36, to assess both physical and mental functioning. A sample of members from each Medicare+Choice health plan is surveyed. Two years later these same members are surveyed again in order to evaluate changes in health status.

Health Plan Employer Data and Information Set (HEDIS â)

A widely used set of health plan performance measures utilized by both private and public health care purchasers to promote accountability and assess the quality of care provided by managed care organizations. HEDIS® is developed and maintained by the National Committee on Quality Assurance (NCQA) in collaboration with CMS and other entities. HEDIS® 2002 contains over 50 measures across 8 domains of care. Annual HEDIS reporting has been required of Medicare managed care organizations since January 1997.

Improvement

Planned, fundamental changes which result in unprecedented levels of performance. It is not the "removal of an irritant," solving a particular problem, or "fire fighting."

Licensed by the State as a Risk-Bearing Entity

An entity that is licensed or otherwise authorized by the State to assume risk for offering health insurance or health benefits coverage. The entity is authorized to accept prepaid capitation for providing, arranging, or paying for comprehensive health services under an M+C contract.

Measures of Performance

Characteristics of what is done and how well it is done.

M+C organization

A public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider sponsored organization receiving waivers) that is certified by CMS as meeting the M+C contract requirements. See 42 CFR §422.2.

M+C Plan

Health benefits coverage offered under a policy or contract offered by a Medicare+Choice Organization under which a specific set of health benefits are offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan. See 42 CFR §422.2. An M+C plan may be a coordinated care plan (with or without point of service options), a combination of an M+C medical savings account (MSA) plan and a contribution into an M+C MSA established in accordance with 42 CFR §422.262, or an M+C private fee-for-service plan. See 42 CFR §422.4(a)(3).

Operational Definition

A description in quantifiable terms of what to measure and the steps to follow to measure it consistently (e.g., the operational definition of a report handed in on time is one that is put in the correct mailbox within 10 minutes of the stated deadline).

Physician Incentive Plan (PIP)

Any compensation arrangement to pay a physician or physician group that may directly or indirectly have the effect of reducing or limiting the services provided to a plan's enrollees. See 42 CFR §422.208(a).

Population

The total number of individual units for a defined area.

Preferred Provider Organization (PPO)

An M+C organization coordinated care plan that: (a) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the

plan; (b) provides for reimbursement for all covered benefits regardless of whether the benefits are provided with the network of providers; and (c) is offered by an organization that is not licensed or organized under State law as an HMO. See *42 CFR §422.4 (a)(1)(iv).*

Quality

Meeting and exceeding customer expectations, doing the right things right, and making continuous improvements. Is defined by the customer.

Quality Improvement Organization (QIO)

CMS contracts with a QIO, formerly known as Peer Review Organization, in each state to fulfill provisions in Title XI of the Social Security Act as amended by the Peer Review Improvement Act of 1982. These provisions relate to improving the quality of care for Medicare beneficiaries, protecting the integrity of the Medicare Trust Fund by ensuring that payments for services are reasonable and medically necessary and protecting beneficiaries by addressing care related complaints and other beneficiary issues.

Sample

A subgroup of units chosen from a diffuse group of units or population.

Standard Deviation

A measure of variability exhibited by the distance from the mean that a typical data point is expected to fall.

Subgroup

A sample selected from a large population

Variation

The inevitable differences in measurements observed in a given step of a process.

Medicare Managed Care Manual

Chapter 7 - Payment to Medicare + Choice (M+C) Organizations

NOTE *1:* On May 25, 2001, the Secretary announced that CMS has suspended through July 1, 2002 the required filing by M+C organizations of physician and hospital outpatient encounter data. For this reason, discussions of CMS policy related to these types of encounter data have been deleted from this release.

Table of Contents

Tables

Exhibits

20.1 - Special Rules for M+C Payments for Certain Types of Enrollees

(Rev. 9, 04-01-02)

Exceptions to the general rule for payments are explained in the section below. See the following sections for explanations of additional special rules:

Section 50.2, Rules for coverage and payment of National Coverage Determinations (NCDs);

Section 55, Coverage of Clinical Trials

Section 130, Special rules for beneficiaries enrolled in M+C Medical Savings Account (MSA) plans;

Section 140, Special rules for coverage that begins or ends during an inpatient hospital stay;

Section 150, Special rules for payments to M+C organizations for their beneficiaries enrolled in Hospice;

Section 160, Special rules for M+C payments for beneficiaries enrolled as Qualifying Individuals;

Section 165, Special Rules for M+C Payments to Department of Veterans Affairs Facilities; and

Section 180 Special rules for new entry bonus payments to M+C organizations.

20.1.1 - Enrollees With End-Stage Renal Disease (ESRD)

(Rev. 9, 04-01-02)

For the purpose of M+C payment, "ESRD beneficiaries" includes beneficiaries with ESRD, whether entitled to Medicare because of ESRD, disability, or age. For enrollees diagnosed with ESRD, CMS establishes special rates at the State-level. The per capita Part A and Part B rates for each State are based on all fee-for-service ESRD expenditures in that State. Thus, costs related to dialysis, transplantation, and post-transplant drug therapy are included in the M+C rates. Services and supplies that are billable outside of the composite rate under fee-for-service Medicare are included in the M+C capitation rate. In short, all claims for ESRD beneficiaries under original Medicare are included in this tabulation, including claims for treatments not related to ESRD (such as a broken arm). *Also, M+C ESRD rates include the costs of beneficiaries with Medicare as Secondary Payer (MSP) and the costs of beneficiaries who have functioning grafts 3 years or less from date of transplant*.

In addition, CMS subtracts from the State capitation rate the actuarial value of the amount that the Secretary is authorized to subtract from each composite rate payment for each renal dialysis treatment under original Medicare, as set forth in §1881 (b) (7) of the Act. These funds are to be

used to help pay for the ESRD network program in the same manner as similar reductions are used in original Medicare.

Prior to the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), ESRD base rates were built on a base year (1997) amount representing 95 percent of projected State average fee-for-service costs, as determined at the time. The State-level rates were not risk-adjusted. The BIPA required the Secretary to increase M+C ESRD payment rates, using appropriate adjustments, to reflect the rates paid under the ESRD Demonstration (including the risk adjustment methodology associated with those rates) of the social health maintenance organization (SHMO) ESRD capitation demonstrations. The new payment ESRD payment methodology, per the BIPA, is effective January 1, 2002, and involves two basic changes:

- *CMS increased the base year rates by 3.0 percent to reach 100 percent of fee-for-service costs as estimated for the base year for M+C purposes (this adopts the approach used under the ESRD SHMO demonstration); and*

- *CMS tabulated age and sex factors for adjusting the State per capita rates, in order to pay more accurately due to differences in costs among ESRD patients. (See Table 1.)*

See Exhibit 3 for the age and sex factors for M+C ESRD enrollees. To calculate the payment for a given ESRD enrollee, multiply the appropriate age/sex factors by the statewide M+C ESRD payment rates, and then sum the adjusted Part A and B amounts. The ESRD payment rates can be found on the CMS web site at http://www.hcfa.gov/stats/hmorates/aapccpg.htm.

50.2 - Rules for Coverage and Payment of NCDs

(Rev. 9, 04-01-02)

The M+C organization must furnish, arrange, or pay for an NCD "significant cost" service prior to the adjustment of the annual M+C capitation rate. The following rules apply to such services.

In affected coverage areas, Medicare payment for the service is:

- In addition to the capitation payment to the M+C organization; and

- Made directly by the fiscal intermediary and carrier to the M+C organization (or its designee, which may be the provider) in accordance with original Medicare payment rules, methods, and requirements.

NCD costs for which CMS intermediaries and carriers will not make payment and are the responsibility of the M+C organization are:

- Services necessary to diagnose a condition covered by the NCD;

- Most services furnished as follow-up care to the NCD service;

- Any service that is already a Medicare-covered service and included in the annual M+C capitation rate; and

- Any service, including the costs of the NCD service itself, to the extent the M+C organization is already obligated to cover it as an additional or supplemental benefit.

NCD costs for which CMS intermediaries and carriers make payment are:

- Costs relating directly to the provision of services related to the NCD that were non-covered by original Medicare prior to the issuance of the NCD; and

- A service that is not included in the M+C per capita payment rate.

If the M+C organization does not provide or arrange for the service consistent with CMS's NCD, enrollees may obtain the services through qualified providers not under contract to the M+C organization, and the M+C organization must pay for the services. Beneficiaries are liable for Part A deductible and any applicable coinsurance amounts.

See Chapter 4 of the M+C Manual for additional information on NCDs.

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55 - Coverage of Clinical Trials

(Rev. 9, 04-01-02)

For Calendar Years (CY) 2002 and 2003, CMS will continue the CY 2001 policy of making fee-for-service payments for covered clinical trial costs.

On September 19, 2000, the Centers for Medicare & Medicaid Services (CMS) published a National Coverage Determination (NCD) regarding coverage of certain benefits related to clinical trials that were not covered by Medicare prior to that date. (See §30.1 of the Coverage Issues Manual at http://www.hcfa.gov/pubforms/06_cim/ci00.htm.) Since the cost of covering these new benefits was not included in the 2001 M+C capitated payment rates, and since this cost met the threshold for "significant cost" under 42 CFR 422.109(c), Medicare paid for covered clinical trial services outside of the M+C capitated payment rate through CY 2001. Medicare intermediaries and carriers made payments on behalf of M+C organizations directly to providers of covered clinical trial services, on a fee-for-service basis.

We reviewed the M+C payment rates for CY 2002, which were published on March 1, 2001, and determined that these rates do not reflect any adjustment for this significant cost NCD. We have determined, therefore, that the published CY 2002 rates do not adjust appropriately for the costs of this NCD, as required under §1853(c)(7) of the Act. As a result, for CY 2002 CMS will continue the CY 2001 policy of making payments on a fee-for-service basis for covered clinical trial costs. Medicare intermediaries and carriers will make payments on behalf of M+C organizations directly to providers of covered clinical trial services, on a fee-for-service basis.

For CY 2003, we will continue paying M+C organizations on a fee-for-service basis for covered clinical trial items and services provided to their members.

As in CY 2001, payment for clinical trial services furnished to beneficiaries enrolled in M+C plans will be determined according to the applicable fee-for-service rules. M+C organizations may continue operating under the rules and procedures they have in place for CY 2001 clinical trial benefits, including beneficiary cost-sharing, coverage of complications, and any prior notification rules in effect. In addition, M+C organizations may continue to use their CY 2001 Explanation of Coverage (EOC) language on clinical trials.

In CY 2001, original Medicare cost-sharing amounts applied automatically to clinical trial services covered by the NCD because they were covered "outside" the M+C contract. For CY 2002 and CY2003, however, these services are now considered part of the M+C plan, even though CMS is continuing to pay for them on a fee-for-service basis. Thus, while M+C organizations may retain the existing cost-sharing structure for these services, they also have the flexibility to adopt their own cost-sharing structures for these services (even though CMS's payment will be based on the original Medicare rules). Because benefits and cost-sharing for CY 2002 have already been established, this could only be done for 2002 as a "mid-year benefit enhancement." M+C organizations also could make changes in beneficiary liability for these services in the ACRs they submit for 2003.

Program Memorandum AB-01-103 available at http://www.hcfa.gov/pubforms/transmit/AB01130.pdf gives instructions to providers and suppliers on billing intermediaries and carriers for clinical trial services. Beginning January 1, 2002 M+C organizations should continue operating under the procedures in this PM until further notice (extension of this PM or release of a new one.)

Under Original Medicare, providers and suppliers must include ICD-9 code V70.7 (Examination of Participation in Clinical Trial) as the second or subsequent diagnosis code on the UB-92 submitted to intermediarie. In addition they must include the "QV" procedure code modifier on the line item of all clinical trial services submitted to carriers. Starting April 1, 2001, they also must use condition code 30 on UB-92 claim forms. Providers and suppliers may resubmit rejected claims with the clinical trial codes if they were inadvertently omitted. These codes must be present in order for the claims to be resubmitted or otherwise brought to the attention of the M+C organization.

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70 - Adjustment of Capitation Rates for Demographic Characteristics and Health Status

(Rev. 9, 04-01-02)

Prior to the BBA, county-wide payment rates *for aged and disabled beneficiaries* were adjusted based on the following factors, which were called "demographic" factors: Age, gender, Medicaid eligibility, and institutional status. (*Aged r*ates were also adjusted for working aged status; see Section *60*.) Under the BBA (§1853(a)(3) of the Act), the Secretary is required to develop and implement a risk adjustment method to better reflect the expected relative health status of each enrollee.

The purpose of adding health status to demographic factors is to consider the unique cost implications of characteristics related to diagnoses, and to increase the accuracy of the payment estimates for subgroups of the Medicare population. Thus, the goal of the new methodology is to pay M+C organizations based on better estimates of their enrollees' health care utilization, relative to the fee-for-service (FFS) population. Under the new risk adjustment method, capitation payments are adjusted for demographic factors and health status as captured by diagnoses.

NOTE: In this chapter the term **"demographic only method"** is used to indicate the method that does not include diagnostic data, while **"risk adjustment method"** refers to the new method where encounter data are incorporated.

70.1 - Transition to a Comprehensive Risk Adjustment Method

(Rev. 2, 10-01-01)

The BBA specifically requires implementation of a risk adjustment method no later than January 1, 2000. Under §1853(a)(3)(B), the BBA also requires "Medicare+Choice organizations (and eligible organizations with risk-sharing contracts under §1876) to submit data regarding inpatient hospital services for periods beginning on or after July 1, 1997, and data regarding other services and other information as the Secretary deems necessary for periods beginning on or after July 1, 1998."

The timing of this data collection authority indicated that the initial risk adjustment method should be based only on data from inpatient hospital stays, with later implementation of a method based on data from additional sites of care. Thus, CMS selected the Principal Inpatient Diagnostic Cost Group (PIP-DCG) model as the risk adjustment method under which payments are made, beginning January 1, 2000. In this model, diagnoses from hospitalizations are used to identify a particularly ill and high cost subset of beneficiaries for whom higher payments will be made in the next year. The system recognizes hospital discharges for which inpatient care is most frequently appropriate and which are predictive of higher future costs.

BIPA Section 603 amended §1853(a)(3)(C) of the Act by extending until 2007 the phase-in of risk adjustment. Between 2000 and 2007, the PIP-DCG-based risk adjustment method is used to adjust a portion of payment, and the demographic-only method is used to adjust the other portion. At the conclusion of the transition schedule described below in Table 2, a risk adjustment method centered on health status is scheduled to replace the demographic-only method.

Thus, under the current schedule, there are two methods comprising the M+C payment system until 2007. The demographic-only method is described in Section 80 and the PIP-DCG risk adjustment method is described in Section 90.

NOTE: On May 25, 2001, the Secretary announced that CMS has suspended through July 1, 2002, the required filing by M+C organizations of physician and hospital outpatient encounter data. For this reason, discussions of policy related to these types of encounter data have been deleted from this release.

90.1 - Demographic Factors Under the PIP-DC*G* Risk Adjustment Method

(Rev. 9, 04-01-02)

Note that institutional status is not a factor in the risk adjustment method for several reasons, including the fact that the PIP-DCG model accurately predicts average costs for institutionalized beneficiaries.

90.4.2 - Method for Calculating County Rescaling Factors

(Rev. 9, 04-01-02)

First, average county risk factors are computed for each county, using the PIP-DCG risk adjustment payment model. The average county risk factors replace the average county demographic factors applied under the demographic-only methodology.

CMS's Office of the Actuary (OACT) calculates combined aged, disabled, Parts A, and Part B per capita costs. These combined county costs then are divided by the average county risk factors, creating new area-specific standardized rates. OACT applies the mandated calculations to these new area-specific rates, e.g., the "greater of three" approach (blends, floors, and two percent increase), budget neutrality, medical education carve outs, etc.

This process generates a risk rate book. To determine the rescaling factor for a county, the per capita risk county rate is divided by the demographic-only county rate. Technically there are two rescaling factors for each county: one to rescale payments for aged enrollees, and the other for disabled enrollees.

In a given county, the rescaling factor used in payments for an aged beneficiary is defined as:

- (Risk County Rate) / (Aged Demographic-only County Rate) = County Aged Rescaling Factor

For disabled beneficiaries, the rescaling factor is defined as:

- (Risk County Rate) / (Disabled Demographic County Rate) = County Disabled Rescaling Factor

Additional information on average county risk factors is available at CMS's website hcfa.gov/stats/hmorates/aapccpg.htm. A file containing estimated county risk factors used to create the risk rate book is posted here.

90.5 - Treatment of Certain Demonstrations Under the PIP-DCG Risk Adjustment Method

(Rev. 9, 04-01-02)

Certain demonstration projects involve the provision of care to special populations, such as the frail elderly. These projects include Evercare, the Program of All-inclusive Care for the Elderly (PACE), the Social Health Maintenance Organization (SHMO) demonstration, the Minnesota Senior Care Project, and the Wisconsin Partnership Demonstration. These projects currently provide enhanced benefit packages and are paid based on adjustments to M+C capitation rates that are specific to each demonstration model. Given the unique features of these demonstration projects, CMS will *not apply* the new M+C payment system for these organizations *until further notice.*

100.1 - Extra Payment In Recognition of the Costs of Successful Outpatient CHF Care

(Rev. 9, 04-01-02)

The current M+C organization risk adjustment payment methodology for CHF, the Principal Inpatient Diagnostic Cost Group (PIP-DCG) model, is based upon inpatient hospitalization discharge diagnoses. Recent studies strongly suggest that excellent outpatient management of CHF may decrease hospitalization rates and improve quality of life for CHF patients. In response to industry concerns, and specifically trying to work within current data constraints, CMS has developed a payment mechanism for recognizing and paying for the costs of this successful outpatient CHF care. To qualify for extra payment in 2002, M+C organizations will identify enrollees *were* hospitalized for CHF during a prior two-year period. *To qualify for extra payment in 2003, M+C organizations will identify enrollees who were hospitalized for CHF during a prior three-year period. M+C organizations will* measure the success in treating these enrollees via two designated quality indicators. M+C organizations achieving threshold levels on both quality indicators will receive extra payment. *See Section 100.2.5 for details on the extra payments.*

100.2.5 - Extra Payment

(Rev. 9, 04-01-02)

Consistent with the risk adjustment payment methodology, extra payment will only be made for those enrollees in a qualifying M+C organization who are identified in CMS's records as having had the required principal inpatient discharge diagnosis of CHF and who are enrolled in the M+C organization at the beginning of each payment month in 2002 (for payments in CY 2002) or who are enrolled in the M+C organization at the beginning of each payment month in 2003 (for payments in CY 2003).

Note that if an enrollee with a CHF hospitalization disenrolls from an M+C organization that qualified for extra payment and then enrolls in an M+C organization that does not qualify for extra payment, the new M+C organization would not receive the extra payment for that enrollee.

Assuming the M+C organization's report on quality indicators shows attainment of the required threshold levels for both quality indicators, extra payments will be made to the M+C organization as follows.

CMS takes two reporting years into account when assessing whether an M+C organization qualifies for an extra payment in 2002: July 1, 1999, to June 30, 2000; and July 1, 2000, to June 30, 2001. CMS takes three reporting years into account when assessing whether an M+C organization qualifies for an extra payment for CHF enrollees in 2003: July 1, 1999, to June 30, 2000; July 1, 2000, to June 30, 2001; and July 1, 2001, to June 30, 2002. M+C organizations are paid for a qualifying CHF diagnosis under several scenarios, which are listed below. Scenario 1 describes the "normal" payment CMS makes under the PIP-DCG methodology for a principal inpatient diagnosis of CHF during the reporting year. Scenarios 2 and 3 describe special conditions under which M+C organizations may qualify for the CHF extra payment.

Scenario 1.

> *In 2002, M+C organizations with enrollees hospitalized with a greater than one-day stay for a principal diagnosis of CHF between July 1, 2000, and June 30, 2001, will receive the regular PIP-DCG-16 amount, at the phased-in level of 10 percent under the risk adjustment payment methodology.*
>
> *In 2003, M+C organizations with enrollees hospitalized with a greater than one-day stay for a principal diagnosis of CHF between July 1, 2001, and June 30, 2002, will receive the regular PIP-DCG-16 amount, at the phased-in level of 10 percent under the risk adjustment payment methodology.*

Scenario 2.

> *Under the extra payment provision for 2002, qualifying M+C organizations with an enrollee hospitalized with a qualifying CHF diagnosis between July 1, 1999, and June 30, 2000, who did not have a hospital stay during the July 1, 2000, to June 30, 2001, period will receive an extra payment for the CHF hospitalization incurred during the first reporting year (July 1, 1999, to June 30, 2000), based on the CHF extra payment formula described below, at the phased-in level of 10 percent under the risk adjustment payment methodology.*
>
> *Under the extra payment provision for 2003, qualifying M+C organizations with an enrollee hospitalized with a qualifying CHF diagnosis between July 1, 1999, and June 30, 2000, or July 1, 2000, and June 30, 2001, who did not have a hospital stay during the July 1, 2001, to June 30, 2002, period will receive an extra payment for the CHF hospitalization incurred during either July 1, 1999, to June 30, 2000, or July 1, 2000, to June 30, 2001, based on the CHF extra payment formula described below, at the phased-in level of 10 percent under the risk adjustment payment methodology.*

Scenario 3

> *Under the extra payment provision for 2002, qualifying M+C organizations with an enrollee hospitalized with a qualifying CHF diagnosis between July 1, 1999, and June*

30, 2000, who also had a discharge for another diagnosis during the period July 1, 2000, to June 30, 2001, will receive the greater of the two possible payments.

Under the extra payment provision for 2003, qualifying M+C organizations with an enrollee hospitalized with a qualifying CHF diagnosis between July 1, 1999, and June 30, 2000, or July 1, 2000, to June 30, 2001, who also had a discharge for another diagnosis during the period July 1, 2001, to June 30, 2002, will receive the ***greater of the two possible payments****.*

Two examples are provided below:

Example 1.

For 2002. If an enrollee had a qualifying discharge for CHF between July 1, 1999, and June 30, 2000, and also had a discharge during the period July 1, 2000 to June 30, 2001, that fell into PIP-DCG 8 or higher (which would also include a diagnosis of CHF), the M+C organization will receive payment for the qualifying diagnosis incurred during the second reporting year (July 1, 2000, to June 30, 2001), because that payment would be greater than the payment for the CHF diagnosis that occurred during the July 1, 1999, and June 30, 2000, period.

For 2003. If an enrollee had a qualifying discharge for CHF between July 1, 1999, and June 30, 2000, or between July 1, 2000, and June 30, 2001, and also had a discharge during the period July 1, 2001, to June 30, 2002, that fell into PIP-DCG 8 or higher (which would also include a diagnosis of CHF), the M+C organization will receive payment for the qualifying diagnosis incurred during July 1, 2001, to June 30, 2002, because that payment would be greater than the payment for the CHF diagnosis that occurred during the July 1, 1999, and June 30, 2000, or July 1, 2000, to June 30, 2001, period.

Example 2.

For 2002. If an enrollee had a qualifying discharge for CHF between July 1, 1999, and June 30, 2000, and also had a discharge during the period July 1, 2000, to June 30, 2001, that fell into PIP-DCG 7 or below, the M+C organization will receive payment for the CHF diagnosis incurred during the first reporting year (July 1, 1999, to June 30, 2000), because that payment would be greater than the payment for the diagnosis that occurred during the July 1, 2000, to June 30, 2001, period.

For 2003. If an enrollee had a qualifying discharge for CHF between July 1, 1999, and June 30, 2000, or between July 1, 2000, and June 30, 2001, and also had a discharge during the period July 1, 2001, to June 30, 2002, that fell into PIP-DCG 7 or below, the M+C organization will receive payment for the CHF diagnosis incurred during either July 1, 1999, to June 30, 2000, or July 1, 2000, to June 30, 2001, because that payment would be greater than the payment for the diagnosis that occurred during the July 1, 2001, to June 30, 2002, period.

Payment formula

For CY 2002, the extra payments made to qualifying M+C organizations for CHF discharges between July 1, 1999, and June 30, 2000, will be based on approximately one-third of the full PIP-DCG-16 amount, subject to the 10 percent risk adjustment transition schedule. For CY 2003, the extra payments made to qualifying M+C organizations for CHF discharges between July 1, 1999, and June 30, 2000, or between July 1, 2000, and June 30, 2001, will be based minimally on approximately one-third of the full PIP-DCG-16 amount, subject to the 10 percent risk adjustment transition schedule.

Given the payment blend of 90 percent demographic payment and 10 percent risk-adjusted payment for 2002 and 2003, the additional payments to qualifying M+C organizations would be based approximately on the following ***formula:*** *0.33 (representing one-third of PIP-DCG 16 amount) X 2.438 (representing the PIP-DCG-16 risk factor) X 0.10 (representing the risk adjustment transition schedule).* ***(NOTE: In addition to this PIP-DCG risk factor calculation for extra payment, the enrollee's risk score also would include the appropriate base factor and, if relevant, Medicaid and previously disabled factors.)***

Table 3 in section 110.6 presents the deadlines for receipt of inpatient encounter data between July 1, 2001, and June 30, 2002. For 2002, encounters for CHF discharges from July 1, 1999, to June 30, 2000, that are received by CMS after September 30, 2001, ("late encounter data") will be incorporated into a reconciliation conducted during 2003 for payments made to M+C organizations in 2002. For 2003, encounters for CHF discharges from July 1, 2001, to June 30, 2002, that are received by CMS after September 27, 2002, will be incorporated into a reconciliation conducted during 2004 for payments made to M+C organizations in 2003.

110.6 - Deadlines for Submission of Encounter Data

(Rev. 9, 04-01-02)

NOTE: On May 25, 2001, the Secretary announced that CMS has suspended through July 1, 2002, the required filing by M+C organizations of physician and hospital outpatient encounter data. For this reason, discussions of policy related to these types of encounter data have been deleted from this release.

The BBA requires that M+C organizations submit data regarding inpatient hospital services for all enrollee discharges that occur on or after July 1, 1997. Table 3 presents the submission schedule.

TABLE 3. Submission Deadlines for Hospital Inpatient Encounter Data

Data Collection Year (Service Dates)	Payment Year (CY)	Deadline for Submission*	Late Encounter Data Deadline**
July 1, 1997 – June 30, 1998	start-up year; not used for payment	NA	NA

July 1, 1998 – June 30, 1999	2000	Sept. 10, 1999	Sept. 30, 2000
July 1, 1999 – June 30, 2000	2001	Sept. 8, 2000	Dec. 31, 2001***
July 1, 200*0* - June 30, 200*1*	2002	Sept. 7, 2001	Sept. 30, 2002
July 1, 2001 - June 30, 2002	2003	Sept. 6, 2002	Sept. 30, 2003
July 1, 2002 - June 30, 2003	2004	Sept. 5, 2003	Sept. 30, 2004
July 1, 2003 - June 30, 2004	2005	Sept. 3, 2004	Sept. 30, 2005

* *Deadline for submission of data.* Any data received by CMS after September 30 will be processed as late encounter data. *For payment year 2003, CMS must receive the data by September 27, 2002*.

** Data used for reconciliation; also see Section 21*0* on the reconciliation process.

***Extended 3 months

Risk adjustment factors for each payment year are based on encounter data submitted for services furnished during the 12-month period ending 6 months before to the payment year. (For example, risk adjustment factors for CY 2000 were based on data for services furnished during the period July 1, 1998 through June 30, 1999).

Reconciliation of Payments - Monthly payments during a payment year are based on the encounter data received by CMS by the annual deadlines for the data collection periods listed in Table 3.CMS conducts a reconciliation process to take into account late encounter data submissions, so that total payment for a year will reflect these late submissions. *Under the reconciliation process, the deadline for receipt by CMS of all data for a payment year will be September 30 of that payment year for the period ending the previous June 30.*

See §210 for further detail on reconciliation.

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160 - Special Rules for M+C Payments for Beneficiaries Enrolled as Qualifying Individuals

(Rev. 9, 04-01-02)

The BBA established "Qualified Individuals" (QIs) for CY 1998 through 2002. Qualified Individuals are low-income Medicare beneficiaries for whom State Medicaid programs cover all or a portion of Medicare Part B premiums. Qualified Individuals, by definition, have higher incomes than other groups for whom Medicaid pays Medicare cost sharing and premiums.

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165 – Special Rules for M+C Payments to Department of Veterans Affairs Facilities

(Rev. 9, 04-01-02)

Medicare law prohibits CMS from paying a Federal provider of services (see §1814(c) and §1835(d) of the Social Security, (the Act). However, the statute provides two exceptions at §1814(d) and §1814(h) of the Act.

- *The §1814(d) exception allows Medicare to pay a Federal provider of services (such as a Department of Veterans Affairs (VA) hospital) for emergency services furnished to a beneficiary who is not entitled to have services furnished at public expense.*

- *The §1814(h) exception allows for Medicare payment to a VA hospital for care furnished to an individual who is admitted to a VA hospital under the belief by the individual and the VA that the individual is entitled to free health care when in fact they are not.*

Under Medicare law, then, M+C organizations cannot reimburse the VA for care furnished in its facilities to veterans because the VA is obligated to furnish care to veterans whom it admits. With respect to the §1814(d) exception, an M+C organization is only required to pay a VA hospital when a M+C plan member who is a non-veteran receives emergency health care services at a VA hospital. The §1814(h) exception only applies to the unusual situation where an M+C enrollee who is a non-veteran is mistakenly admitted to a VA hospital for a service that does not require pre-authorization by their M+C plan. CMS expects that this situation would be very rare.

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170 - Clarification of the Definition of "Certified Institution" for Adjusting Payments *u*nder the Demographic-Only Method

(Rev. 9, 04-01-02)

One of the categories for which payment adjustments are made under the demographic-only method is institutional status, referring to Medicare beneficiaries who are under care or custody in institutions. To be considered institutionalized, an enrolled member must:

- Be a resident in an institution, or distinct part of an institution, that is one of the seven following types of institutions certified under Title XVIII (Medicare) or Title XIX (Medicaid*)*; and

- Satisfy the qualifying period of residency in a certified institution (or distinct part of an institution) that is Title XVIII or Title XIX certified.

170.1 - Types of Certified Institutions

(Rev. 9, 04-01-02)

Medicare and Medicaid certified institutions are:

- **Skilled Nursing Facility (SNF)**, as defined at §1819(a) of the Act, is an institution, or distinct part of an institution, primarily engaged in providing skilled nursing care or rehabilitative services to residents which has in effect an agreement with a hospital that ensures transfer of patients will be affected between the two whenever such transfer is medically appropriate.

- **Nursing Facility (NF),** as defined at §1919(a) of the Act, is the same as a SNF but also includes institutions that provide health-related care and services to residents who because of their mental or physical condition require care and services, which can be made available to them only through institutional facilities.

- **Intermediate Care Facility for the mentally retarded (ICF/MR**), as defined at §1905(d) of the Act, is an institution that provides health or rehabilitative services for mentally retarded residents receiving active treatment under Medicaid.

- **Psychiatric Hospital or Unit,** as defined at §1886(d)(1)(B) of the Act, is an institution, or distinct part of an institution, primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons.

- **Rehabilitation Hospital or Unit,** as defined at §1886(d)(1)(B) of the Act, is an institution that serves an inpatient population of whom the vast majority require intensive rehabilitative services for the treatment of certain conditions, e.g., stroke, amputation, brain or spinal cord injuries, and neurological disorders.

- **Long-term Care Hospital**, as defined at §1886(d)(1)(B) of the Act) is a hospital, which has an average inpatient length of stay of greater than 25 days.

- **Swing-bed Hospital,** as defined under §1883 of the Act, is a hospital, which has entered into an agreement whereby its inpatient hospital facilities may be used for the furnishing of services of the type which, if furnished by a SNF, would constitute extended care service.

In the case of an enrolled member in a swing-bed hospital, the enrolled member must be receiving post-hospital extended care services or SNF services.

See http://www.hcfa.gov/stats/inst.htm for files containing the names and contact information for certified institutions, which are updated quarterly.

170.3 - Payment for Institutional Status

(Rev. 9, 04-01-02)

CMS determines whether an M+C organization should be paid at the institutional rate for an enrollee by asking two questions:

- Did the enrollee fulfill the 30-day residency requirement in a certified institution (where the 30th day is the last day of the month)?
- *Is the* M+C organization entitled to payment based on this qualifying residency?

Conceptually, the institutional payment is prospective. Generally, for example, when an enrollee satisfies the residency requirement in April, the M+C organization is entitled to an institutional payment in May. In practice, however, the payment mechanism is retroactive. Given the residency requirement, where the 30th day must be the last day of the month, our payment system could not receive and process monthly status information in time to use a prospective payment system As a result CMS makes a retroactive payment adjustment two months after the month where an enrollee satisfies the residency requirement. for example, when an enrollee satisfies the residency requirement in April, the June 1 capitation payment for this enrollee is adjusted to bring the May 1 payment retroactively up to the full amount owed the M+C Corporation in May because of the enrollee's qualifying residency.

Death or discharge on the last day of the month - If an M+C enrollee is discharged or dies on the last day of the month (and this is the 30th consecutive day of residency in a certified institution), then the beneficiary has satisfied the residency requirement.

Original Medicare does not count the day of discharge towards residency requirements. However, capitated payments made to the M+C organizations are not for units of service or treatment, as in original Medicare. Under the M+C program, institutional status is a proxy for health status, not a unit of service. In this context, it is appropriate to count the day of discharge towards residency requirement.

The next step is to determine whether the M+C organization is entitled to a prospective payment at the institutional rate for the qualifying residency. The M+C plan elected by the beneficiary for the month subsequent to the qualifying period of residency is entitled to receive the institutional amount.

This is not necessarily the same as M+C plan elected by the beneficiary while a resident of the institution. For example (assuming the beneficiary has satisfied the residency requirement):

- If the beneficiary is discharged on the last day of the month of the qualifying period of residency and the beneficiary is enrolled in *the* same plan of the subsequent month, payment would be made to that plan
- If the beneficiary is discharged on the last day of the month of the qualifying period of residency and the beneficiary is enrolled in a new plan on the first day of the subsequent month, payment would be made to the new plan.

- However, if the beneficiary dies on the last day of the qualifying period of residency, that beneficiary would not be enrolled in any plan on the first day of the subsequent month. Therefore, payment would not be made to any M+C plan.

Payment examples - Below are examples clarifying when M+C organizations are entitled to payment at the institutional status rate:

1. On March 2, a member of an M+C organization enters a certified institution. On March 20, the individual is hospitalized for a surgical procedure. On April 2, the individual is discharged from the hospital, re-enters the institution, and remains there continuously through April 15. The individual does meet the residency requirement (March 2 through March 31) and has remained in the same plan for the subsequent month. The M+C organization is paid the institutional rate for the month of April through a retroactive adjustment to the capitated payment for May.

2. Mr. X, whose M+C enrollment is effective April 1, enters a certified institution on April 15 and remains there continuously until his discharge on May 25. He does not meet the criteria for reporting institutionalized status for May or June. *A*lthough he was institutionalized for at *least* 30 days in May, his residency did not include the last day of the month as the 30th day. His stay would have had to continue through May 31 in order to be reported for an institutional payment for the month of June. If Mr.. X had been discharged on May 31, his M+C organization would be entitled to payment at the institutional rate in June.

3. Ms. Y, whose M+C enrollment is effective April 1, enters a certified institution on February 28 and remains there continuously until her discharge on April 25th. She does meet the qualifying period of residency for reporting institutionalized status for April (March 2 through March 31) but not for May. *T*he qualifying period of residency for a payment in May at the institutional rate is April 1 through April 30. Note that Ms. Y was not a member of the M+C organization during the qualifying period of residency (March 2 through March 31). I*t* is not required that Ms. Y be a member of M+C organization during the qualifying period of residency. Thus, the M+C organization in which she is enrolled on April 1 is paid the institutional rate in April for her qualifying period of residency in March. The M+C organization would not be paid the institutional rate for the month of May because the qualifying period of residency (April 1 through April 30) was not satisfied.

Changes in Exhibits 2 and 3

Exhibit 2 - *Additional Information* on C*overage of* Clinical Trials

Effective September 19, 2000, Medicare initiated coverage of certain benefits related to Medicare-covered clinical trials. See §30.1 of the Coverage Issues Manual at http://www.hcfa.gov/pubforms/06_cim/ci00.htm. Since the cost of covering these new benefits was not included in the 2001 M+C capitated payment rates, and since CMS determined that covered clinical trial costs are high enough to meet the threshold for "significant cost, "

Medicare paid for covered clinical trial services outside of the M+C capitated payment rate through CY 2001. Medicare intermediaries and carriers made payments on behalf of M+C organizations directly to providers of covered clinical trial services, on a fee-for-service basis.

Medicare will be paying for these services outside of the M+C capitated payment rate on behalf of M+C organizations until the M+C payment rates are appropriately adjusted to reflect the cost of this NCD. While these payments were made outside the scope of M+C contracts through the end of CY 2001, beginning in CY 2002, these services are officially covered under M+C plans. However, as discussed in section 55 of this chapter, the "adjustment" to M+C payments that CMS is making to cover the costs of these new plan services in CYs 2002 and 2003 is in the form of continued fee-for-service payments. Medicare intermediaries and carriers will be making these payments directly to providers of clinical trials services on behalf of M+C organizations.

Medicare intermediaries and carriers will be making payments directly to providers of clinical trials services.

Below is additional information *CMS* provided in November 2000 on coverage of routine costs of clinical trials by M+C organizations and original Medicare. The information, presented in question and answer format, also can be found at http://www.hcfa.gov/medicare/ctqa.htm.

See Chapter 4 of the manual for general information on NCDs.

Q1. Do Medicare+Choice organizations need to cover the routine costs of clinical trials described in the National Coverage Determination (NCD)?

A1. Medicare rules provide that if an NCD meets a threshold for "significant cost," Medicare will pay for these services outside of the capitated payments until the next payment rate announcement after the NCD takes effect. In the case of the clinical trials NCD, the new coverage was determined to meet the significant cost threshold, and Medicare is paying on a fee-for-service basis for these services in 2001.

Q2. May an M+C enrollee participate in clinical trials even when the providers in the trial are not in the M+C organization's network?

A2. Yes. Medicare regulations require that NCD services be furnished to M+C enrollees even when these services cannot be furnished though an M+C organization network. The nature of clinical trials is such that many of these services only will be available and accessible to M+C enrollees when furnished by out-of-network providers. For this reason, coverage cannot be limited to trials in which the M+C organization itself may participate or to trials in which M+C organization network providers may participate.

Q3. Does the fact that Medicare will be paying for the routine costs of clinical trials on a fee-for-service basis mean that all services for M+C enrollees in clinical trials may be billed in this way?

A3. No. There is no change in M+C organizations' obligation to provide all other benefits that are covered under the contract to beneficiaries who participate in these clinical trials.

Q4. Medicare+Choice organizations are concerned about losing track of the services and care being provided to members who participate in clinical trials when the organizations do not pay for the services. What can Medicare+Choice organizations do to follow these M+C members?

A4. *CMS*'s payments for clinical trial services directly to providers in the short term may make it hard for M+C organizations to track and coordinate the care for these beneficiaries. M+C organizations may set up a notification process to collect information about which members are in a clinical trial, and which clinical trial they are in. This notification process may not be used in any way as a pre-authorization mechanism, however.

In addition, the Agency for Health Research and Quality will be developing a registry of approved clinical trials. Once this is developed, M+C organizations and others will be able to use this registry to contact the trial sponsors in the clinical trial to learn more about the nature of the trial, the services that will be furnished, and the providers who are participating.

Q5. M+C organizations are very concerned about how they are going to cover these services once they are included in capitation payments. How are M+C organizations' questions going to be resolved?

A5. M+C organizations and their representatives have raised many important questions about how this will work, and *CMS* will continue ongoing discussions with industry representatives to resolve operational issues. *CMS* will be developing answers to questions of this nature that were submitted as a part of the comment process for the NCD and publishing them on an ongoing basis on the hcfa.gov web site.

Q6. How will payments to providers be calculated?

A6. Payment for clinical trial services furnished to beneficiaries enrolled in Medicare managed care plans is determined according to the applicable fee-for-service rules, except that M+C enrollees are not responsible for meeting either the Part A or Part B deductible (i.e., the deductible is waived). M+C enrollees are liable for the coinsurance amounts applicable to services paid under Medicare fee for service rules.

Q7. How will intermediaries and carriers recognize bills for the routine costs of clinical trials?

A7. Please refer to the procedures described in the program memorandum describing implementation of clinical trials coverage. This is available at http://www.hcfa.gov/quality/8d3.htm.

Q8. What happens if providers forget to put these codes on their bills?

A8. Bills/services that are not coded accordingly will not be paid; however providers may resubmit the claims with the clinical trials codes if they were inadvertently omitted.

Q9. What should M+C organizations do if clinical trial providers send them bills?

A9. If a provider sends a bill with the clinical trial codes on it to an M+C organization, the M+C organization should not pay it. Instead, the organization should inform the provider that the bill should be submitted to the appropriate intermediary or carrier. Of course, M+C

organizations continue to be responsible for all other benefits that are covered under the contract to beneficiaries who participate in the clinical trials.

Q10. Some of the providers in an M+C organization network are involved in clinical trials but are not enrolled as Medicare providers. What do they need to do to enroll?

A10. Providers serving managed care enrollees receiving clinical trial services must be enrolled with Medicare in order to bill on a fee-for-service basis for those services. Providers that wish to bill but that have not yet enrolled with Medicare should contact their local carrier, intermediary, or National Supplier Clearinghouse, as appropriate, to obtain an enrollment application.

Q11. What should M+C organizations tell beneficiaries about this new coverage?

A11. In their next regularly scheduled communication with members, M+C organizations must inform that Medicare is now covering certain services related to clinical trials. M+C organizations should also inform their Medicare members that beneficiaries are responsible for paying the coinsurance that applies for fee-for-service benefits when those benefits are provided as part of a clinical trial. In other words, any plan-defined cost sharing would not apply.

M+C organizations are not responsible for making up the difference between the Medicare fee-for-service cost sharing and any plan cost sharing that would apply to that type of service. *CMS* will be collaborating with M+C organizations, clinical trial sponsors, and groups that work with beneficiaries to educate beneficiaries about their financial liabilities when they enter a clinical trial.

If M+C members ask their organizations for information on Medicare coverage of these clinical trials services, the organizations may wish to direct them to 1-800-MEDICARE for more information.

Q12. Do M+C organizations need to furnish non-Medicare benefits as part of the routine costs of clinical trials?

A12. No. Until the costs of clinical trials' services are factored into M+C capitated payment rates, M+C organizations are not obligated to furnish any additional or supplemental benefits as routine costs of clinical trials.

Q13. Are M+C organizations responsible for submitting encounter data for these services?

A13. No. M+C organizations are not responsible for submitting encounter data from clinical trial providers. Because *CMS* will be making fee-for-service payments directly to providers for clinical trials services, the information needed for risk adjustment (diagnoses and other data elements) will already be present in *CMS'*s systems.

Q14. Where can M+C organizations go to get more information on clinical trials?

A14. If M+C organizations or other entities have further questions regarding the coverage of clinical trials and their responsibilities regarding this coverage they may send an e-mail to clinicaltrials@hcfa.gov or contact their plan manager.

Exhibit 3 - Demographic Cost Factors *for* Aged, Disabled, *and ESRD* Beneficiaries

Demographic Factors for Aged Beneficiaries, CY 2000

Part	Sex	Age	Institutionalized	Non-Institutionalized		
				Medicaid	Non-Medicaid	Working Aged
A	Male	65-69	1.75	1.15	0.65	0.4
		70-74	2.25	1.5	0.85	0.45
		75-79	2.25	1.95	1.05	0.7
		80-84	2.25	2.35	1.2	0.8
		85+	2.25	2.6	1.35	0.9
	Female	65-69	1.45	0.8	0.55	0.35
		70-74	1.8	1.05	0.7	0.45
		75-79	2.1	1.45	0.85	0.55
		80-84	2.1	1.7	1.05	0.7
		85+	2.1	2.1	1.2	0.8
B	Male	65-69	1.6	1.1	0.8	0.45
		70-74	1.8	1.35	0.95	0.65
		75-79	1.95	1.55	1.1	0.8
		80-84	1.95	1.7	1.15	0.9
		85+	1.95	1.7	1.15	1
	Female	65-69	1.5	1.05	0.7	0.4
		70-74	1.65	1.15	0.85	0.55
		75-79	1.65	1.25	0.95	0.7
		80-84	1.65	1.25	0.95	0.75
		85+	1.65	1.25	1	0.85

Demographic Factors for Disabled Beneficiaries

Part	Sex	Age	Institutionalized	Non-institutionalized		
				Medicaid	Non-Medicaid	Working Aged
A	Male	<35	1.8	1.1	0.6	N/A
		35-44	1.45	1.2	0.7	N/A
		45-54	1.1	1.3	0.65	N/A
		55-59	0.9	1.6	0.85	N/A
		60-64	0.6	1.85	1	N/A
	Female	<35	1.8	1.2	0.55	N/A
		35-44	1.4	1.2	0.6	N/A
		45-54	1.15	1.2	0.75	N/A
		55-59	0.95	1.35	0.95	N/A
		60-64	0.7	1.55	1.3	N/A
B	Male	<35	1.7	1.1	0.45	N/A
		35-44	1.5	1.15	0.55	N/A
		45-54	1.25	1.15	0.6	N/A
		55-59	1.1	1.3	0.75	N/A
		60-64	0.95	1.45	0.95	N/A

Female	<35	1.95	1.05	0.75	N/A
	35-44	1.85	1.15	0.85	N/A
	45-54	1.6	1.25	0.95	N/A
	55-59	1.35	1.35	1.05	N/A
	60-64	1.15	1.55	1.2	N/A

NOTE: Since the BBA stipulated that the base year for the new M+C payment method would be 1997 (the last year of the AAPCC method) and since the BBA did not stipulate any adjustments to these 1997 AAPCC standardized county rates (other than to "carve out" a specified portion of the rates representing medical education expenses), *CMS* cannot restandardize the 1997 ratebook with new demographic factors. Thus, the above national demographic factors have been used since 1997.

County average demographic factors (ADFs), however, are calculated every year, using updated information on the number of beneficiaries in each county and the average demographic factor for these beneficiaries. The county ADFs are used to calculate the national average input-price adjusted capitation rate, which is then used in combination with area-specific rates to calculate blended rates.

Age/Sex Demographic Factors for M+C ESRD Enrollees

Age	***Part A***		***Part B***	
	Male	***Female***	***Male***	***Female***
0-34	*.55*	*.70*	*.70*	*.75*
35-44	*.65*	*.70*	*.80*	*.80*
45-54	*.70*	*.85*	*.85*	*.90*
55-59	*.80*	*.95*	*.90*	*1.00*
60-64	*.90*	*1.10*	*.90*	*1.10*
65-69	*1.15*	*1.35*	*1.10*	*1.20*
70-74	*1.25*	*1.45*	*1.15*	*1.25*
75-79	*1.30*	*1.55*	*1.20*	*1.25*
80-84	*1.40*	*1.60*	*1.20*	*1.25*
85+	*1.45*	*1.60*	*1.20*	*1.25*