DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417 and 422

CMS–4069–F

RIN 0938–AN06

Medicare Program; Establishment of the Medicare Advantage Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements provisions of the Social Security Act (the Act) establishing and regulating the Medicare Advantage (MA) program. The MA program was enacted in Title II of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) on December 8, 2003. The MA program replaces the Medicare+Choice (M+C) program established under Part C of title XVIII of the Act, while retaining most key features of the M+C program.

The MA program attempts to broadly reform and expand the availability of private health plan options to Medicare beneficiaries.

This final rule responds to public comments on a proposed rule published on August 3, 2004 (FR 69 46866).

EFFECTIVE DATE: These regulations are effective March 22, 2005 except for the following changes which will become effective on January 1, 2006: amendment of § 417.600(b); removal of § 417.602 through § 417.638; and amendments to § 417.832(d); and § 417.840.

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Regulations Text

Acronyms

Because of the many terms to which we refer by acronym in this final rule, we are listing the acronyms used and their corresponding terms in alphabetical order below:

ABN	Advance beneficiary notice
ACR	Adjusted Community Rate
ACRP	Adjusted Community Rate Proposal
ADL	Activities of Daily Living
AHRQ	Agency for Healthcare Research and Quality
AI/AN	American Indian and Alaska Native
ALJ	Administrative law judge
APA	Administrative Procedure Act
BBA	Balanced Budget Act of 1997
BBRA	Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, (Pub. L. 106–113)
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub L. 105–33)
CAH	Critical Access Hospitals
CCPs	Coordinated Care Plans
CMPs	Competitive Medical Plans
CORF	Comprehensive outpatient rehabilitation facility
DSH	Disproportionate Share Hospital
EGPH	Employer and Union Group Health Plans
EOC	Evidence of coverage
ESRD	End-Sage Renal Disease
FEHB	Federal Employees Health Benefits
FFS	Fee-for-Service plans
FI	Fiscal Intermediaries
HCPP	Health care prepayment plan
HHA	Home health agency
HMO	Health Maintenance Organizations
HOS	Health Outcomes Survey
ICF/MR	Intermediate Care Facilities for Mentally Retarded
IHS	Indian Health Service
IPA	Independent Physician Association
ISAR	Intra-Service Area Rate
I/T/U	Indian Health Service, Tribal and Urban Health Program
LEP	Limited English Proficiency
LMRP	Local Medical Review Policy
M+C	Medicare+Choice
MA	Medicare Advantage
MA-PD	Medicare Advantage Prescription Drug
MAC	Medicare Appeals Council
MCOs	Managed Care Organizations
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSA	Medical Savings Account
MYBE	Mid-year Benefit Enhancement
OACT	Office of the Actuary
OPM	Office of Personnel Management
PACE	Program All-Inclusive Care for the Elderly
P4P	Pay for Performance
PCP	Primary Care Physician
PDP	Prescription Drug Plan
PFFS	Private Fee-For-Service
POS	Point of Service
PPOs	Preferred Provider Organizations
PSOs	Provider Sponsored Organizations
QI	Quality Improvement
QIO	Quality Improvement Organization
RFB	Religious Fraternal Benefit
SAE	Service Area Expansion
SEP	Special Election Period
SHIP	State Health Insurance Programs

SNF	Skilled Nursing Facility
SNPs	Special Needs Plans

I. Background

A. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. Title II of the MMA makes important changes to the current Medicare+Choice (M+C) program by replacing it with a new Medicare Advantage (MA) program under Part C of Medicare. On August 3, 2004, we published a proposed rule in the **Federal Register** (69 FR 46866) that set forth the provisions that would implement Title II of the MMA. Beginning in 2006, the MA program is designed to:

- Provide for regional plans that may make private plan options available to many more beneficiaries, especially those in rural areas.
- Expand the number and type of plans provided for, so that beneficiaries can choose from Health Maintenance Organizations (HMOs), Preferred Provider Organization (PPO) plans (the most popular type of employer-sponsored plan), Fee-for-Service (FFS) plans, and Medical Savings Account (MSA) plans, if available where the beneficiary lives.
- Enrich the range of benefit choices available to enrollees including improved prescription drug benefits, other benefits not covered by original Medicare, and the opportunity to share in savings where MA plans can deliver benefits at lower costs.
- Provide incentives to plans, and add specialized plans to coordinate and manage care in ways that comprehensively serve those with complex and disabling diseases and conditions.
- Use open season competition among MA plans to improve service, improve benefits, invest in preventive care, and hold costs down in ways that attract enrollees.
- Enhance and stabilize payments to organizations, improve program design, introduce new flexibility for plans, and reduce impediments to plan participation.
- Advance the goal of improving quality and increasing efficiency in the overall health care system. Medicare is the largest payer of health care in the world. Medicare can drive changes in the entire health care system.

With these new and improved choices, Medicare beneficiaries, like Federal employees and retirees in the Federal Employees Health Benefits (FEHB) Program, will have the opportunity to obtain improved benefits, improved services, and reduced costs. However, beneficiaries will still be able to remain in traditional Medicare (referred to throughout as ''original'' Medicare), enhanced by the new Part D drug benefit. All will have the opportunity to switch among plans, or to or from original Medicare, during the annual election period (or ''open season'') in November and December.

Over time, participating plans will be under continued competitive pressure to improve their benefits, reduce their premiums and cost sharing, and improve their networks and services, in order to gain or retain enrollees. In addition, we expect plans to use integrated health plan approaches such as disease prevention, disease management, and other care coordination techniques. In doing so, integrated plans that combine the original Parts A and B of Medicare and the new Part D drug benefit and apply these innovative techniques must pass on savings that may result from these care coordination techniques to the enrollee through reduced premiums or additional benefits.

Beginning in 2006, payments for local and regional MA plans will be based on competitive bids rather than administered pricing. MA organizations will submit an annual aggregate bid amount for each MA plan. An aggregate plan bid is based upon the MA organization's determination of expected costs in the plan's service area for the national average beneficiary for providing non-drug benefits (that is, original Medicare (Part A and Part B) benefits), Part D basic prescription drugs, and supplemental benefits if any (including reductions in cost sharing). Our payment to an MA organization for an MA plan's coverage of original Medicare benefits depends on the relationship of the plan's basic A/B bid to the plan benchmark. For a plan with a basic A/B bid below its benchmark, we will pay the MA organization the basic A/B bid amount, adjusted by the individual enrollee's risk factor, plus the rebate amount. (The rebate is 75 percent of the difference between the plan bid and benchmark, and is used to provide mandatory supplemental benefits or reductions in Part B or Part D premiums. The government retains the other 25 percent.) For a plan with a bid equal to or above its benchmark, we will pay the MA organization the plan benchmark, adjusted by the individual enrollee's risk factor. In addition, we would pay the bid amount, if any, for Part D basic coverage. The MMA also requires other adjustments to payments. See the subpart G preamble for a discussion of the geographic Intra-Service Area Rate (ISAR) adjustment and the government premium adjustment (referred to in the MMA as the ''adjustment relating to risk adjustment'').

We will be able to negotiate bid amounts with plans in a manner similar to negotiations conducted by the Office of Personnel Management(OPM) with FEHB plans. We will work with plans to ensure benefit packages meet the needs of our population and that information is made available to beneficiaries so that they can make decisions about which plans best meet their needs.

Finally, in conjunction with the new drug benefit required under Title I of MMA, which is addressed in separate rulemaking found in part 423, changes made in the MMA to the M+C program (now called the MA program) are intended to bring about broad-based improvements to the Medicare program's benefit structure, including improved prescription drug coverage under the MA program. Organizations offering local and regional coordinated care MA plans must offer at least one plan with the Medicare prescription drug benefit or an actuarially equivalent drug benefit.

In addition to the changes because of the MMA, we identified many areas in the proposed rule where we believed we could prevent or reduce unnecessary burden, duplication, or complexity either in interpreting the new MMA provisions or in modifying existing rules to accommodate MA reforms.

B. Relevant Legislation

1. Balanced Budget Act of 1997

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added sections 1851 through 1859 to the Social Security Act (the Act) establishing a new Part C of the Medicare program, known as the Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Act, every individual entitled to Medicare Part A and enrolled under Medicare Part B, except for individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where he or she lived.

The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices through which to obtain their Medicare benefits. The BBA authorized

us to contract with private organizations offering a variety of private health plan options for beneficiaries, including both traditional managed care plans (such as those offered by HMOs that had been offered under section 1876 of the Act), and new options that were not previously authorized. Four types of M+C plans were authorized under the new Part C, as follows:

- M+C coordinated care plans, including HMOs (with or without point-of-service options (POS)), provider sponsored organizations (PSOs), and PPOs.
- M+C MSA plans (combinations of a high deductible M+C health insurance plan and a contribution to an M+C MSA).
- M+C private fee-for-service (PFFS) plans.
- M+C religious and fraternal benefit (RFBs)plans.

The BBA changed the payment methodology to Medicare health plans and initially afforded beneficiaries more choice of plans nationally. However, payment rates grew modestly in relation to the costs health plans incurred, resulting in fewer health plans participating in the M+C program, decreased choice of plans available to beneficiaries, and fewer extra benefits available to enrollees. Although there were large payment increases in rural areas as a result of the BBA provisions, access to Medicare coordinated care plans declined significantly in rural areas after 1997.

To implement these changes, we published an interim final rule in the **Federal Register** on June 26, 1998 (63 FR 34968); a final rule on February 17, 1999 (64 FR 7968); and a final rule with comment on June 29, 2000 (65 FR 40170).

2. Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. 106–113 (BBRA) amended the M+C provisions of the BBA. Many of these amendments were reflected in the June 29, 2000 final rule with comment period. In addition, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106–554 (BIPA), enacted December 21, 2000, further amended the M+C provisions of the BBA and BBRA. A final rule containing BIPA provisions was published in the **Federal Register** on March 22, 2002 (67 FR 13278), as well as on August 22, 2003 (68 FR 50855).

These laws enacted subsequent to the BBA made incremental changes to M+C payments and provided financial incentives to plans to participate in the M+C program. While these efforts helped stabilize the M+C program, they did not generally improve plan participation in the M+C program nor did they increase overall beneficiary enrollment or access to plans in rural areas.

3. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)

The specific sections of Part C of the Social Security Act that were impacted by the MMA are as follows:

Section 1851—Eligibility, election and enrollment.

Section 1852—Benefits and beneficiary protections.

Section 1853—Payments to MA organizations.

Section 1854—Premiums.

Section 1855—Organizational and financial requirements for MA organizations.

Section 1856—Establishment of standards.

Section 1857—Application procedures and contracts with MA organizations.

Section 1858—Special rules for MA regional plans [added by the MMA].

Section 1859—Definitions; Miscellaneous provisions.

This final rule addresses the new MA provisions in Title II of MMA. The requirement in 1858(a)(2)(D) of the Act to conduct a market survey and analysis before establishing MA regions took place concurrent with the publication of the MA proposed rules. The announcement of the establishment of the MA and Prescription Drug Plan (PDP) regions occurred on December 6, 2004. The regions may be found at *http://cms.hhs.gov/medicarereform/mmaregions*.

Provisions of the MMA addressed in this final rule outside of Title II of the MMA include Section 722—Medicare Advantage Quality Improvement Program, of Title VII. Quality improvement provisions in this final rule may be found under Subpart D—Quality Assurance.

C. Codification of Regulations

The final provisions set forth here are codified in 42 CFR Part 422, The Medicare Advantage Program.

The regulations for managed care organizations (MCOs) that contract with CMS under cost contracts will continue to be located in 42 CFR part 417, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans.

D. Organizational Overview of Part 422

The MMA amended the existing provisions of the Medicare statute found in Part C of Title XVIII, sections 1851 through 1859 of the Act, and added a new section 1858 to the Act. This final rule covers a wide range of topics included in the existing part 422, including eligibility and enrollment, benefits and beneficiary protections, payment, contracting requirements, and grievances and appeals. We have generally retained the organization of the sections from part 422, except for reordering subparts F and G to place the bidding and payment provisions in sequential order.

Where the MMA did not amend existing statute, this final rule does not set forth unchanged regulations text from the previous part 422. Thus, this final rule contains only the necessary revisions to existing part 422. In some subparts of part 422, the only changes are in nomenclature, that is, the replacement of M+C references with MA references. The regulations in that subpart H are not set forth in this final rule. The subparts with substantive changes are as follows:

Subpart A—General provisions, establishment of the Medicare Advantage Program, definitions, types of MA plans, and cost-sharing in enrollment-related costs (user fees).

Subpart B—Requirements concerning beneficiary eligibility, election, and enrollment and disenrollment procedures.

Subpart C—Requirements concerning benefits, access to services, coverage determinations, and application of special benefit rules to PPOs and regional plans.

Subpart D—Quality improvement program, chronic care improvement program requirements, and quality improvement projects.

Subpart E—Relationships with providers.

Subpart F—Submission of bids, premiums, and related information and plan approval.

Subpart G—Payments for MA organizations.

Subpart I—Organization compliance with State law and preemption by Federal law.

Subpart J—Special rules for MA regional plans, including the establishment of MA regions, stabilization fund, and risk sharing.

Subpart K—Application and contract requirements for MA organizations.

Subpart L—Effect of change of ownership or leasing of facilities during term of contract.

Subpart M—Beneficiary grievances, organization determinations, and appeals.

Subpart N—Medicare contract determinations and appeals.

Subpart O—Intermediate sanctions. Each of these subparts is discussed below in section II of this preamble.

II. Analysis of and Responses to Public Comments

A. Overview

1. Comments on the August 3, 2004 Proposed Rule

We received 186 items of correspondence containing more than a thousand specific comments on the August 3, 2004 proposed rule. Commenters included MCOs and other industry representatives, representatives of physicians and other health care professionals, beneficiary advocacy groups, representatives of hospital and other providers, insurance companies, employers, States, accrediting and peer review organizations, members of the Congress, Indian Health Service (HIS), Indian Health Service, Tribal and Urban Health Programs (I/T/U), American Indians and Alaska Natives (AI/AN), and others. Consistent with the scope of the August 3, 2004 proposed rule, most of the comments addressed multiple issues, often in great detail. We received many comments expressing concerns unrelated to the proposed rule. Some commenters expressed concerns about Medicare unrelated to the MA program, while others addressed concerns about health care and health insurance coverage unrelated to Medicare. Because of the volume of comments we received in response to the August 3, 2004 proposed rule we will be unable to address comments and concerns that are unrelated to the proposed rule. Listed below are the six areas of the proposed regulation that generated the most concern:

- Bidding and Payment.
- Access issues, including network adequacy and access providers, including rural providers.
- Specialized Medicare Advantage Plans.
- Establishment of MA Regions.
- Eligibility and enrollment issues, including disenrollment for failure to pay cost sharing and lock in.

In addition, we received many comments on the proposed rule relating to Part 417 for Health Maintenance Organizations; Competitive Medical Plans, and Health Care Prepayment Plans that contract with CMS under cost contracts. A discussion of those comments may be found separately at that Part.

2. Organization of the Final Rule

In this final rule, we address all comments received on the proposed rule. We are addressing issues according to the numerical order of the relative regulation sections.

B. General Comments

1. Administrative Procedure Act (APA) Issues

We received several comments on various aspects of the rulemaking process, as discussed below:

Comment: One commenter suggested that we waive the APA provision that requires at least 30 days notice prior to a final regulation becoming effective in order to allow applicants applying to become specialized MA plans for special needs individuals, or ''SNPs,'' to have the new requirements apply as soon as possible. The commenter made this recommendation in the event that this final regulation was not issued prior to the MMA statutory deadline for issuing a final regulation for SNPs that was 1 year following the date of enactment, or December 8, 2004.

Response: The first two categories of special needs individuals, institutionalized persons and dual eligibles, were specified in the statute, and we have already begun working with plans wishing to become specialized MA plans for these categories of special needs individuals. We discuss in subpart A below our approach to allowing for the additional category of special needs individuals—those with severe or disabling chronic conditions. This final rule will take effect March 22, 2005, *except where otherwise noted*. We do not believe it is necessary to waive the 30-day notice period because it likely will take longer than the 30-day period for a plan's application and approval process to occur. However, we intend to work with applicants who wish to offer specialized MA plans to ensure that the approval process is as efficient and timely as possible.

Comment: We received a number of comments on the timing of the regulation and the short timeframe between issuance of the final regulation and preparation of applications and bids early in 2005 for contract year 2006. One commenter stated that the time required to re-contract with its commercial provider networks to ensure that the PPO contracts contain the Medicare required language and rate structure that are reflective of CMS reimbursements, is substantial. The commenter indicated that it needed more time to build the system infrastructure to support a new systems platform than would be required for commercial enrollees. The commenters suggested that plans may have to limit the number of regions in which they participate because of the short timeframes between issuance of the regulation and the application filing deadline.

Response: We agree that working within the statutory constraints of the MMA, including the relatively short period of about 13 months between enactment of the legislation and issuance of final regulations, there is little time between issuance of the regulation and the preparation of applications and bids in 2005 for contract year 2006. With respect to the short time frame in applications and submission of bids, please refer to the comments and responses related to bidding at § 422.254 and § 422.502 related to application requirements. Our goal beginning on the date of enactment of the MMA was to issue final regulations as soon as possible so that prospective MA plans would have the necessary information to be able to make business decisions before bids are due mid 2005.

Comment: Several commenters recommended that CMS issue a final rule with comment period prior to implementation of the final rules. The commenters expressed concern that certain aspects of the proposed rule that would impact rural providers have not been specified in sufficient detail. One commenter recommended that CMS conduct a second notice of proposed rulemaking incorporating changes from the first round of comments and allowing for public comment on the additional details that are currently under development, or issue the regulations on an interim basis with a second comment period on the additional, important details that are currently under development or that reflect decisions made following this round of comments.

Response: Under the APA, we are required to provide the public with the opportunity to review and comment upon proposed regulations. We have done this through the publication of the August 3, 2004 proposed rule and its corresponding comment period. We believe that allowing for a second round of comments or publishing interim regulations would make it difficult for MA organizations wishing to offer MA plans in 2006 to prepare to meet the new requirements imposed by the MMA and implemented by this final rule.

2. Other General Comments

Comment: A number of commenters stated that the final regulation must

address the unique state of AI/AN people and the Indian health program. In particular, these comments raise concerns about the implications of the proposed rules on the Indian health care delivery system. For example, there is concern that the proposed rules will jeopardize significant revenues the Indian health system now collects from Medicaid for ''dual eligibles,'' that is, those individuals who are eligible for both Medicare and Medicaid. They ask for substantial modifications to the proposed rules to enable voluntary enrollment by AI/AN populations in MA plans. Some of the suggested modifications include: (1) encouraging MA enrollment by AI/AN by removing financial barriers, such as waiving AI/AN cost sharing for all plans; (2) ensuring that I/T/U Health Programs are held harmless financially, and are fully reimbursed for covered services provided to AI/AN who enroll in a MA plan.

Response: We appreciate the numerous comments that provided information on unique health needs for the AI/AN populations. As noted elsewhere, we are implementing the MMA statute through this rulemaking. We do not have the flexibility to include language that would carve out a subset of Medicare beneficiaries, such as AI/AN populations, if it is not provided for in statutory language. Specific comments raised by the AI/AN and I/T/U organizations will be addressed in the respective subparts under which the comments were submitted. In general, however, we believe that the newly created regional plans will create new choices for the AI/AN populations, and that access to MA plans will be improved. Similarly, because MA regional plans must reimburse for all covered benefits in and out of network, IHS facilities may receive reimbursement for out of network care provided to a regional MA plan AI/AN beneficiary by that MA regional plan. Under provisions designed to protect the Medicare program from fraud and abuse, a broad waiver of beneficiary cost sharing of the type the commenter requests would not be permitted. However, we make no statement regarding the applicability of existing statutory and regulatory provisions that may allow for the waiver of cost sharing in certain cases.

Comment: One commenter recommended that CMS develop and conduct educational and informational activities on the differences in the various MA options, particularly in areas where there are choices of original Medicare, managed care plans, PPOs, MSAs and PPFs plans. The commenter believes that there is a potential for confusion and error for beneficiaries with so many choices.

Response: We agree that strong outreach to beneficiaries about their new choices of MA plans, as well as the drug benefit, is critical to the success of these new programs. We will be devoting more resources to providing new information and education on the new plan choices and drug benefit.

Comment: We received a number of general comments on specialized MA plans for special needs individuals, sometimes referred to as ''SNPs'' or ''special needs plans''. Comments relating to definitions of SNPs may be found in subpart A and comments on enrollment may be found in subpart B below. Among the general comments was a suggestion to disseminate a set of guiding principles for SNPs and further refine them as experience increases. We also received a comment that network adequacy for SNPs should be evaluated to ensure timely, accessible, and appropriate care and that all necessary specialists are represented. Further, it was suggested that the provider network should be broad enough to ensure that vulnerable populations served have timely access to all necessary specialists required to address special needs.

Additionally, several commenters stated that CMS should incorporate into regulation the authority to waive or modify MA requirements that conflict with the intent of the SNP provision. Finally, some commenters requested that CMS provide guidance with regard to the States' role in developing and approving SNPs for dual eligibles. It was recommended that CMS give states maximum flexibility in using waiver authority to integrate Medicare and Medicaid benefits for dual eligibles under SNP programs. A commenter suggested that CMS consult with State Medicaid agencies where Home and Community-based waivers are operating before allowing these populations to be enrolled in SNPs because this could add to the cost and complexity of providing services.

Response: We provided Interim Guidance for SNPs in the 2005 Call Letter in June 2004 and will provide additional operational guidance for SNPs after publication of the final rule. Interim guidance may be obtained at *www.cms.hhs.gov/healthplans/specialneedsplans/qaspecneeds06-23.pdf*. Consistent with current policy for network adequacy for MA plans as found at § 422.112, we will require that MA organizations submit information about their provider network and will review this information as part of the application and approval process to ensure that timely, accessible, and appropriate care is provided. We will be particularly interested in the availability of care designed to address the needs of the enrolled special needs population. While the MMA allows SNPs to limit enrollment to a defined population, as described in § 422.52, the law does not provide for waiver of other MA requirements for SNPs. We encourage States and MA plans to work cooperatively in developing programs to serve dual eligibles and will help to coordinate these efforts where appropriate. We believe that SNPs can be appropriate for care and services to those in the community and lead to the coordination of the complex services they need.

Finally, we note that program oversight is an essential government function that is an integral component of implementing the MA program. Throughout this rulemaking, we refer to government activity necessary to implement this section, which includes program oversight authority.

III. Provisions of the Proposed Rule, Analysis of and Responses to Comments on the Proposed Rule, and Final Decisions

Part 417—Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans

Subpart J–Qualifying Conditions for Medicare Contracts Extension of Reasonable Cost Contracts (§ 417.402)

Authority for cost HMOs/CMPs (cost plans) was due to expire on December 31, 2004. Section 234 of the MMA provides an initial extension of cost plans through December 31, 2007. It also provides for a continued extension of cost plans beyond December 31, 2007, under specific conditions.

Effective for contract years beginning on or after January 1, 2008, cost plans may be extended where there are fewer than two coordinated care plan-model MA plans of the same type available to Medicare beneficiaries in the same service area. Both of the ''competing'' MA plans of the same type must meet minimum enrollment requirements for the entire previous year in order to trigger mandatory cost plan non-renewal or service area reduction. We interpreted the statute to require cost plan service area reduction where there are two or more MA plans of the same type meeting minimum enrollment requirements competing for Medicare members in a portion of the cost plan's service area. We asked for comment on our interpretation in the proposed rule related to mandatory service area reductions, saying that an alternative

reading of section 234 of the MMA might permit renewal of a cost plan in all parts of its service area until there was competition from two (or more) MA coordinated care plans throughout the cost plan's service area. After reviewing comments and responding (below), we are adopting the proposed policy as final.

At § 417.402, we proposed to permit existing cost plans to expand their service areas through September 1, 2006. Thereafter, service area expansion applications by cost HMOs/CMPs will be initially evaluated and accepted only when there are not two or more MA plans of the same type meeting minimum enrollment requirements in the area in which the cost plan proposes to expand. After reviewing comments and responding (below), we are adopting the proposed policy as final.

We received the following comments on the proposed provisions for subpart J of part 417 and have provided our responses:

Comment: Many commenters supported the non-renewal of cost HMOs/CMPs as proposed in the proposed rule. These commenters made reference to the statutory and Conference Committee Report language that indicated the Congressional intent that cost plans are to be required to operate under the same provisions as other private plans to the extent other private plans are willing to enter the cost plan's service area. Many other commenters objected to the partial non-renewal proposal made in the proposed rule. Many stated that competition from MA coordinated care plans was more likely in urban areas, where most cost plan enrollment is concentrated. These commenters stated that even where there is no MA coordinated care plan competition in rural areas, the viability of a cost plan without an urban ''core'' would likely be threatened. To the extent CMS non-renewed cost plans in urban areas, the financial viability of the organization offering the cost plan would be undermined in rural areas as well because of the loss of economies of scale. Such a result would be contrary, these commenters said, to an underlying concept of the MMA, which is to increase choices for Medicare beneficiaries in rural areas. Finally, many of these commenters stated that continuity of care would be needlessly lost for members in urban areas enrolled in cost plans that were partly non-renewed, because the members would be forced to change Medicare plans and providers.

Response: We generally support the notion of continuity of care. However, we believe that when competing MA coordinated care plans are available in an area that will be non-renewed for a cost plan, non-renewed cost members are able to continue to receive services from current providers through either enrollment in one of the competing MA coordinated care plans or by returning to FFS Medicare. We recognize that when a cost plan is non-renewed in an urban area with MA coordinated care plan competition, the financial viability of the cost plan in rural areas without MA coordinated care plan competition may be undermined. However, we believe that allowing a cost plan to continue to compete for members in areas of MA competition would unfairly undermine the financial viability of the competing MA coordinated care plans. Therefore, we have not modified our regulation. We believe that this interpretation is consistent with the statutory intent that cost plans will not be permitted to compete for new members under different provisions from those applicable to other private plans that have entered the cost plan's service area.

Comment: Some commenters stated that the proposed regulation text at § 417.402(c)(1) and (2) did not specify what kind of ''year'' was meant—calendar year, 12 month period, or something else. All of these commenters also recommended that CMS specify in regulation text that the ''year'' referred to is a calendar year.

Response: We agree with this comment and have modified the regulation text to specify that the ''year'' in question is a calendar year. This is consistent with the statute, in that MA and cost plan offerings are for calendar years. To the extent that competition has been present for the entire previous calendar year, it should mean the calendar year immediately prior to the year in which the cost plan will be required to non-renew in a portion of its service area or have its contract non-renewed.

Comment: Many commenters recommended that CMS distinguish between the meaning of ''plan'' within the section 1876 cost program and the meaning of ''plan'' within the MA program. Under the section 1876 cost program, each CMS-contracting HMO/CMP is allowed to offer a single Medicare cost ''plan''—see section 1876(c)(2)(A)(I) of the Act. On the other hand, under the MA program, each CMS-contracting MA organization is permitted to offer many MA ''plans''—see § 422.4(b).

Response: We disagree with the commenters. Section 234 of the MMA expressly provides that a cost contract may not be extended or renewed for a service area if such service area during the previous year was within the service area of two or more coordinated care plans of the same type (that is, regional or local) that meet the relevant enrollment requirements. Because a single MA organization may offer two different MA coordinated care plans within a cost plan's service area, a single MA organization can trigger the non-renewal of the cost contract, if the other requirements of Section 1876(h)(5)(C)(ii) of the Act are met.

Comment: Several commenters submitted comments stating that specialized MA plans for special needs individuals (special needs plans or SNPs) (defined at § 422.2) should not count in the MA coordinated care plan competition tests in § 417.402(c)(1) through (3), because they are not available to the general public and therefore not a true test of the availability of MA coordinated care plans in the service area of a cost plan.

Response: We agree with the commenter that the Congress intended to permit cost plans to remain in place in an area until the enrollees in that cost plan have at least two local or two regional MA plan options to choose from in the area. Because in many cases cost enrollees would not be eligible to enroll in a SNP, we do not believe that the existence of a SNP in a service area should automatically count as an option available in that service area. We note that the statute refers to a cost plan's service area being within the ''service area'' of two local or regional MA plans. The MA regulations at § 422.2 define a plan's service area as an area within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Although a SNP's service area is open to all individuals in the service area who are in the special needs category served by the plan, it may not be open generally to MA-eligible individuals (for example, if it is a SNP that exclusively, rather than disproportionately, enrolls special needs individuals). For this reason, we believe that a cost plan may not be ''within the service area'' of a SNP, as this term is used in the competition test, in some cases. We will therefore apply the competition test on a case-by-case basis with respect to SNPs. If the SNP is an option available to the cost plan's enrollees, and the SNP meets the requirements of section 1876(h)(5)(C)(ii) of the Act and § 417.402(c), it will be taken into account in determining whether the cost plan may be renewed. Similar considerations apply to MA plans that exclusively enroll employer/labor group members under authority provided in section 1857(i) of the Act

and § 422.106(c) and (d). To the extent the employer/labor group MA plan is available to the cost plan's enrollees, and the MA plan meets the requirements of section 1876(h)(C)(ii) of the Act and § 417.402(c), it will be taken into account in determining whether the cost plan may be renewed. Thus, we will also apply the competition test on a case-by-case basis with respect to employer/labor group MA plans.

Comment: One commenter suggested that implicit in the ''competition'' tests was the fact that the MA coordinated care plans that caused the non-renewal in a portion of the service area, or that caused the non-renewal of the cost plan in its entire service area, would be available in the coming year. The commenter was concerned that CMS might enforce this section of the cost regulations, even if one of the MA plans used in establishing the ''competition'' threshold were non-renewing or withdrawing from the service area in the year in which enforcement would occur.

Response: Because such a result would be contrary to statutory intent, CMS will not proceed with enforcement when fewer than two MA coordinated care plans will be offered to Medicare beneficiaries in the affected area at the time of enforcement.

Comment: One commenter asked CMS to state its clear intent in regulatory text that we will allow cost plans to expand service areas after September 1, 2006.

Response: As we said in the preamble of the proposed rule and repeated in this preamble: ''We will permit existing cost plans to expand their service areas through September 1, 2006. Thereafter, service area expansion applications by cost HMOs/CMPs will be initially evaluated and accepted only when there are not two or more MA plans of the same type meeting minimum enrollment requirements in the area in which the cost plan proposes to expand.'' We specifically included the first sentence in regulation text at § 417.402(b). However, service area expansions are not guaranteed after that date. Please note that the regulation text at § 417.402(b) specifically authorizing service area expansions through September 1, 2006, does not preclude them thereafter. Additionally, the new language replaces identical language in this section of the regulation (and which language first appeared in section 634 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)) which provided service area expansion authority for cost plans through September 1, 2003. The commenter should note that we have previously interpreted the language in BIPA and in our regulations to be permissive in this area, rather than proscriptive. We will continue to apply it permissively in this area to the extent that the conditions for non-renewal under Section 1876(h)(5)(C) and § 417.402(c) are not present.

Subpart Q—Beneficiary Appeals

Changes to subpart Q are addressed in the preamble discussion for subpart M, which deals with appeals policy for MA plans, cost plans and HCPPs.

A. Subpart A—General Provisions (§ 422.1)

1. Conforming Changes

Subpart A of the August 3, 2004 proposed rule set forth several general and conforming changes dictated by MMA. Below is a summary of the provisions in subpart A. (For a broader discussion of the provisions, please refer to our proposed rule.) The provisions are as follows:

- Section § 422.1 lists the statutory authority that is implemented in part 422. In § 422.1, we have added the new section 1858 of the Act that pertains to ''Special rule for MA Regional Plans.''
- We removed provisions relating to application requirements and evaluation and determination procedures in § 422.6 and § 422.8 and added them to § 422.501 and § 422.502 of subpart K, so that all application and contracting information is in one place.
- We redesignated and amended § 422.10 as § 422.6 and amended newly redesignated § 422.6. Section 422.6 (formerly § 422.10) described the user fees associated with the Medicare Beneficiary Education and Information Campaign, required under section 1857(e)(2) of the Act.

2. Definitions (§ 422.2)

The majority of the proposed changes in subpart A concerned new, revised, and obsolete definitions for the new MA Program in § 422.2. The MMA required several new and broad definitions; ''MA regional plans,'' ''specialized MA plans,'' ''ACR,'' ''Additional benefits,'' ''Adjusted community rate,'' and ''M+C'' obsolete after 2006.

In proposed § 422.2, we also revised several existing definitions to make them consistent with the MMA statute. For example, Mandatory supplemental benefits are redefined to incorporate language reflecting that these benefits may be paid for through premiums and cost sharing or through the application of a rebate, or both. Therefore, mandatory supplemental benefits are defined as health care services not covered by Medicare that an MA enrollee must purchase as part of an MA plan. Benefits may include reductions in cost sharing for benefits under the original Medicare FFS program, and are paid for in the form of premiums and cost sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

However, optional supplemental benefits retained the same definition as under the M+C program as health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost-sharing. (Throughout the regulation, the phrase ''supplemental benefits'' refers to both mandatory and optional supplemental benefits.) The terms ''mandatory supplemental'' and ''optional supplemental'' are used when referring specifically to one of the types of supplemental benefits.

We removed ''additional benefits'' from the definition of ''basic benefits'' because MA plans will no longer offer additional benefits. In addition, we replaced the word ''ACR'' process with the words ''annual bidding'' process in the definition of ''benefits'' to reflect the new bidding process for submission and approval of benefits. Finally, we revised the definition of ''service area'' to incorporate the concept of the new MA regional plan's service area that consists of an entire region.

Under section 1851(a)(2)(A) of the Act, two new types of coordinated care plans were established; MA Regional plans, which are regional PPO plans, and specialized MA plans for special needs individuals, or SNPs. We defined an ''MA local area'' as a county or other area specified by us because it is important to distinguish an MA local area from an MA region. We defined an ''MA regional plan'' because it is a new type of coordinated care plan choice for beneficiaries. While PPOs first became a choice for beneficiaries under the BBA, they operated as ''local'' plans on a county (including multi-county) or partial county basis. The MA regional plan functions like a local PPO but must serve an entire region.

A regional MA plan's service area is one or more entire MA regions; thus, we defined an ''MA regional plan'' as a private health plan that operates as a PPO, but serves an entire CMS-designated region. Local PPOs that may offer MA plans under the MA program, the regional PPOs must have a network of contracting providers that have agreed to a specific reimbursement for covered benefits that are offered by the MA regional plan, and must also provide for reimbursement for all

covered benefits regardless of whether the covered benefits are provided through the network providers or outside of the network.

We defined an ''MA local plan'' as one that is not an MA regional plan. Also defined under part 422 are the ''Prescription Drug Sponsor,'' ''PDP,'' and a ''MA Prescription Drug (MA-PD) plan.'' A sponsor must be a private entity that meets our requirements and standards. PDP sponsors may offer multiple plans throughout the country or in a region, but sponsors must submit an individual bid for each plan.

An MA-PD plan is an MA plan that also provides qualified prescription drug coverage as found in Part D of the Act. An organization offering a coordinated care MA plan must have an MA-PD plan in each of the service areas in which it operates, as required under section 1860D 21(a)(1) and (2) of Part D of the Act.

In section 1859(b)(6)(A) of the Act, specialized MA plans for special needs individuals or SNPs are defined to be MA plans that exclusively serve special needs individuals defined in section 1859(b)(6)(B) of the Act. The establishment of specialized MA plans allows MA plans to exclusively enroll special needs individuals in MA plans that have targeted clinical programs for these individuals.

Section 1859(b)(6)(B) of the Act identifies three types of special needs individual as: (1) institutionalized individuals; (2) individuals entitled to medical assistance under a State plan under Title XIX; and (3) other individuals with severe or disabling chronic conditions as the Secretary determines would benefit from enrollment in a SNP plan.

Comment: One commenter supported a broad definition that tracks section 1859(b)(6) of the Act in order to provide CMS with the flexibility needed to approve a wide range of proposals to meet the unique needs of special populations and expand their choices.

Response: We agree with the commenter. We are providing general guidelines in our regulations in order to maintain the flexibility to approve a wide range of proposals, while also protecting the interests of special needs beneficiaries.

The Secretary may also designate an MA plan as a specialized MA plan for special needs individuals, ''SNP,'' if the plan ''disproportionately'' serves special needs individuals.

Comment: Several commenters responded to the question in the proposed rule as to whether CMS should allow specialized MA plans that disproportionately enroll special needs individuals, or ''disproportionate percentage'' plans and how they should be defined. Most commenters supported including ''disproportionate percentage'' plans in the definition of SNPs. One of the reasons given was to allow married beneficiaries, or children of special needs individuals, to enroll in the same plan as the spouse or parent, even if only one individual meets the definition of a special needs individual.

Many commenters suggested that CMS not establish detailed criteria to define disproportionate percentage, particularly at the outset. It was felt that enrollment thresholds might act as a barrier to plan participation and limit choices available to Medicare beneficiaries. Some commenters suggested that CMS identify ''exclusive'' and ''disproportionate'' plans at the time of each application. Some commenters recommended that the criteria be national, not regional or local.

Several commenters agreed that the criteria should be quantitative, for example, an MA plan risk score in the upper quintile of all MA plans, or a frailty score in the upper quintile of all MA plans as measured by Activities of Daily Living (ADL) scores on the Health Outcomes Survey (HOS).

Some commenters recommended that a ''disproportionate percentage'' SNP enroll fifty (50) percent or more special needs individuals. Another commenter suggested that SNPs remain exclusive, but if plans were able to enroll those without special needs, at least eighty-five (85) percent of the plan's enrollees should be individuals with special needs. Another commenter stated that requiring an upper limit of more than seventy-five (75) percent of special needs individuals would be problematic. One commenter believes that ''redesignated'' SNPs, that is, regular MA plans that become SNPs, be allowed to continue enrolling non-special needs individuals as long as overall enrollment contains a higher proportion of special needs individuals than exist in the plan's service area. One commenter suggested that—(1) an annual certification and compliance process; (2) that new plans have a 3-year startup period to attain the threshold, and (3) that CMS annually publish risk score distributions. Another commenter recommended that non-exclusive plans be defined as having a higher than average enrollment of one or more of the special needs individuals groups as estimated for MA plans and/or the FFS population.

Response: We agree that a special needs individual's family members may want to join the same plan. We acknowledge that MA plans do not have to be exclusive to provide quality specialized programs for special needs individuals. We received a wide range of recommendations for defining a ''disproportionate percentage'' SNP. We acknowledge that there are numerous ways to define and identify disproportionate percentage SNPs and agree with those commenters who felt the parameters should not be overly restrictive, particularly at the outset. SNPs are a new type of coordinated care plan and we believe that plans and CMS might not anticipate all factors that should be considered in determining an acceptable percentage. We also want to encourage plans to develop programs to more effectively care for special needs individuals. In order to ensure flexibility, and take into consideration the experience gained by plans and CMS as SNPs mature, we will define a ''disproportionate percentage'' SNP as one that enrolls a greater proportion of the target group (dually eligible, institutionalized, or those with a specified chronic illness or disability) of special needs individuals than occur nationally in the Medicare population based on data acceptable to CMS. We will provide further guidance as to what data sources may be used to determine a national percentage for a special needs group being targeted by the disproportionate percentage plan. Under our authority as provided in section 231(d) of the MMA, we are revising the definition of specialized MA plan to include ''disproportionate percentage'' plans.

Comment: Several comments were received regarding how CMS should identify those with severe or disabling chronic conditions that would make them eligible for enrollment in a SNP. Several commenters suggested using broad flexibility, reflecting the language in section 1858(b)(6) of the Act. Other commenters recommended that SNPs should serve as laboratories for developing population-based management protocols, not single-disease State management protocols for diagnoses that could be well-served by a standard MA plan. Another commenter recommended limiting enrollment to those with late-stage chronic conditions, those with co-morbidities, adult disabled, and frail elderly. Some commenters suggested basing the definition on conditions for which alternate care delivery models, such as disease management and evidence-based medicine, exist, and also take into consideration conditions that are expensive and prevalent for

there to be savings and risk-management potential.

Commenters also recommended that conditions should be those associated with recognized quality measures, so that CMS may carefully monitor specialized MA plans. None of the commenters objected to including those individuals who are not institutionalized but require an equivalent level of care. ESRD, diabetes, congestive heart failure, Alzheimer's and other dementias along with one or more other serious conditions, HIV/AIDs, and frail elderly and adult disabled with multiple chronic conditions requiring complex medical management were among the specific conditions suggested for specialized MA plans.

Another commenter suggested that on an interim basis CMS restrict the definition to those who are nursing home certifiable, as defined by each State; ESRD patients; and those diagnosed with AIDs, and, in the meantime, collect ADL data through the Health Outcomes Survey (HOS) and use this measure in conjunction with Activities of Daily Living (ADL) measures to identify high-risk groups. Other commenters suggested additional detailed formulas for identifying groups eligible for specialized MA plans.

Response: Because this is a new ''untested'' type of MA plan, we are not setting forth in regulation a detailed definition of severe and disabling chronic condition that might limit plan flexibility. We will review and evaluate proposals for specialized MA plans that serve severe or disabling chronic disease categories, including HIV/AIDs, on a case-by-case basis. Among the criteria to be considered will be the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against ''sicker'' members of the target population.

Other Comments on § 422.2

We requested comments on § 422.2 on the development of an HIV/AIDS special needs plan that would address the special health needs, including prescription drugs, of the Medicare-eligible population living with HIV/AIDS.

We received several comments supportive of the development of an HIV/AIDS special needs plan. Therefore, we will consider this type of plan application to become a special needs plan for Medicare-eligible individuals living with HIV/AIDs.

For purposes of specialized MA plans, we proposed to define ''institutionalized'' in the proposed rule as residing in a long-term care facility for more than 90 days as determined by the presence of a 90-day assessment in the Minimum Data Set (MDS).

Comment: Several commenters suggested that the 90-day residence requirement (as determined by a 90-day assessment in the minimum data set) be modified. One commenter suggested determining institutional status based on the discharge potential at admission. Another commenter suggested changing the requirement to 30 days. One commenter did not object to 90 days, but recommended changing the language to allow CMS to approve exceptions in case the institution failed to perform the assessment. In addition, one commenter suggested that ''institutionalized'' also include those residing in Intermediate Care Facilities for the Mentally Retarded (ICF/MR). Several commenters recommended that those living in the community while requiring an institutional level of care be considered institutionalized.

Response: In response to comments, we are clarifying and broadening the definition of institutionalized for purposes of defining a special needs individual to take into consideration those with chronic mental conditions and other chronic conditions. For purposes of defining a special needs individual, ''institutionalized'' means residing in or expected to reside in a long-term care facility which is a skilled nursing facility (SNF) as defined in section 1819(a) of the Act; a nursing facility (NF) as defined in section 1919(a) of the Act; a SNF/NF; an intermediate care facility for the mentally retarded (ICF/MR) as defined in section 1905(d) of the Act; or an inpatient psychiatric facility as defined in section 1861(f) of the Act for 90 days or longer.

A SNP may enroll special needs individuals prior to a 90-day stay based on an assessment of the potential for a stay of that length as long as the assessment is of a type approved by CMS.. For example, a SNP for individuals with serious mental conditions may show us that the State requires a plan of care or similar assessment prepared by a health professional upon admission. We recognize that this definition is not the same as the definition of ''institutionalized individual'' in 42 CFR § 423.772. That provision is an income and resource-based definition for the purpose of determining Part D premiums and cost-sharing subsidies for low-income individuals. The term ''institutionalized'' as used for purposes of defining a special needs individual under this Part is for the purpose of identifying a vulnerable population that might benefit from enrollment into a SNP. We also wish to clarify that our definition of institutionalized for purposes of defining a special *needs individual does not relate to the MA payment methodology*.

For purposes of SNPs, we may also consider as institutionalized those individuals living in the community but requiring a level-of-care equivalent to that of those individuals in the aforementioned long term care facilities. We believe that 90 days is the most appropriate and accurate timeframe for determining long-term residence in an institution. We base this on information we collected showing that, once a beneficiary is institutionalized for 90 or more days, it is less likely that that individual will return to a community setting. However, SNPs may enroll institutionalized beneficiaries based on a CMS-approved assessment (as described in further operational guidance following publication of this rule) showing the beneficiary is expected to reside in the institution for 90 days or more. Given the latitude provided under the disproportionate percentage criteria, we do not think that the 90-day definition for institutionalized will adversely affect specialized MA plans' ability to enroll eligible beneficiaries.

Comment: Several commenters supported the proposed approach to require all specialized MA plans to provide Part D coverage.

Response: We agree with the commenters, especially in light of the fact that special needs individuals in particular need access to prescription drugs to manage and control their severe or disabling chronic conditions. Therefore, we are including the Part D coverage requirement for all specialized MA plans at § 422.2 in the definition of a specialized MA Plan.

Comment: One commenter recommended that CMS change the definition of PDP as it is incorrect and not consistent with the Medicare Prescription Drug Benefit Program proposed rule.

Response: We agree with the recommended change to the definitions of PDP and PDP sponsor found at § 422.2. To avoid any confusion, we are revising the definitions in Title II to cross-reference the definitions of PDP and PDP sponsor found in part 423, the Medicare Prescription Drug Benefit.

Comment: Several commenters recommended that CMS make a revision to the basic benefits definition found at § 422.2 to add ''including covered services received through an IHS

program.'' Other commenters recommended that CMS add to the special needs individual definition ''AI/IN are exempt from mandatory enrollment in Title XIX plans but would qualify for optional enrollment in an AI/AN specialized need plan.''

Response: We do not believe there is a statutory basis in the MMA to include non-covered Medicare services received through an IHS program in the definition of basic benefits. We also do not believe it is necessary to include a specific reference to Medicare covered services provided through an IHS program in the definition of basic benefits. If a service is a covered service, it is already included in the definition. Therefore, we are not making the requested change. Similarly, the MMA does not authorize us to revise the definition of special needs individual as suggested. The statute defines special needs individuals who are defined as those who are Medicaid, institutionalized or those with severe or disabling chronic conditions. Clearly, AI/AN individuals who fit any of those definitions could choose to enroll in a specialized MA plan if one were offered in their area. The suggested change to the definition of special needs individuals to add optional enrollment in an AI/AN specialized MA plan suggests that some AI/AN organizations may be interested in offering a specialized MA plan. Under the statute, a specialized MA plan must be open to all eligible Medicare beneficiaries who are within the class of special needs individuals the plan serves. We see no statutory basis for allowing a plan to limit enrollment only to AI/AN Medicare beneficiaries. Conceptually, supplemental benefits could be offered in the specialized MA plan to assist chronically ill enrollees to prevent or treat illnesses that affect AI/AN populations and others enrolled in the plan. As described at § 422.501, a prospective SNP would need to submit an application to CMS detailing its plan for treating those with severe or disabling chronic conditions. Finally, we would note that we are not adding language exempting AI/AN from mandatory enrollment in Title XIX plans as it is not within the scope of this rulemaking. We note however, that under sections 1115 and 1915(b) of the Act, mandatory enrollment under Medicaid for such populations is permitted.

Comment: Several commenters suggested that CMS add a new definition to § 422.2 to afford specialized MA plans the status of regional MA plans for most purposes (including special rules and incentives applicable to regional MA plans), without having to cover multiple States. The commenters suggested that plans may be reluctant to take on multiple State regions with enrollment limited to Medicaid eligibles in the region.

Response: As described in section 1858(a)(1) of the Act and as reflected in § 422.455(a), a MA plan must cover an entire region, including offering enrollment to all eligible Medicare beneficiaries within that region whether the region is a single State or multiple State area. Therefore, a special needs plan may receive the stabilization fund payments and other incentives for its participation as a regional plan only if the plan would comply with all requirements in section 1858 of the Act applicable to Regional MA plans. This means, that it would have to be open to enrollment for every member of the special needs category in the entire region in question, meet access standards for the individuals in all areas of the region, market to all areas of the region, and offer uniform benefits and cost-sharing in all areas of the region.

Comment: A commenter recommended that CMS revise the definition of service area as found in § 422.2. The commenter indicated that as proposed, the language of § 422.2 appears to have established a lower standard for approval of regional PPO service areas. The commenter recommended that CMS separately define service area requirements for HMOs and PPOs and that the requirements for approval of a PPO apply to both local and regional PPO plans alike.

The commenter also recommended that CMS consider the more flexible design of a PPO and in turn allow for more flexibility with respect to service area approval. The commenter understands that local PPOs are not required to cover an entire region, but also indicated that it is difficult even in small States to meet the availability and accessibility requirements by the time the service area application is due.

Response: We appreciated the comment to clarify this definition as we found it had been improperly numbered and created some confusion. Therefore, we have renumbered the sub-definitions and included language that makes clear that we may consider whether the contracting provider network meets the access and availability standards set forth in § 422.112, for all MA coordinated care plans and network MA MSA plans. We also have made technical corrections because the distinction between non-network and network MSA plans is no longer applicable, as discussed in further detail below. We believe this change will further reduce confusion.

3. Types of MA Plans (§ 422.4)

The MA program is intended to provide beneficiaries access to a wider array of private health plan choices than under the M+C program and to increase the number of areas in which private health care options are available to Medicare beneficiaries. Entities can contract with us to provide five general categories or types of plans: (1) local MA coordinated care plans; (2) MA MSA plans; (3) MA PFFS plans; (4) regional PPO coordinated care plans; and (5) specialized MA coordinated care plans.

In the August 3, 2004 proposed rule, we proposed to clarify that the PPO definition that was in existence before (defined by the BBRA) was solely for purposes of the application of the more limited quality assurance requirements. For PPO-type plans that are offered by MA organizations that are licensed or organized under State law as HMOs, the quality assurance requirements that apply to all other coordinated care plans in section 1852(e) of the Act also apply to those PPO-type plans.

Effective January 1, 2006, MA organizations that offer MA local plans that are PPOs will need to provide only for the collection, analysis, and reporting of data that permit the measurement of health outcomes and other indices of quality insofar as services are furnished by providers that have contracted with the MA organization under those PPO plans. However, a local PPO offered by an MA organization that is licensed or organized under State law as an HMO will be required to meet the normal data collection, analysis, and reporting requirements. We proposed to modify the definition of PPOs in § 422.4 to account for this more limited interpretation of State licensure requirements and modified headings in § 422.152(b) and (e).

Under section 233 of the MMA, MA organizations are authorized to offer MSA plans as a permanent option. MMA also eliminated the limits imposed on MSA plans by the BBA, including a time limit on enrollment and a limit on the number of beneficiaries who could enroll in the plans, and exempted MSA plans from certain quality assurance requirements that the BBA applied to ''network'' MSA plans.

To conform with MMA's changes to MSAs, we proposed to delete the descriptions of the M+C network MSA plan and M+C non-network MSA plan as different types of plans at

§ 422.4(a)(2)(ii), since the distinction between network and non-network MSAs for the purpose of quality assurance requirements was no longer applicable. As noted above, we are making similar changes to the definition of service area at § 422.2.

We are making a technical correction to the final MA regulation. Our current regulations at § 422.2 read ''Religious and Fraternal Benefit (RFB) Society.'' We are amending the definition of ''Religious and Fraternal Benefit (RFB) Society'' by removing the words ''Religious and fraternal'' and adding the words ''Religious fraternal'' in their place. We are making this change to the definition as it is potentially confusing and is not consistent with the statutory definition of ''Religious Fraternal Benefit Society'' at section 1859(e)(3) of the Social Security Act. We are also making a technical change to § 422.4(a) to clarify that RFB Society plans may be any type of MA plan, and are not restricted to being a type of coordinated care plan only, as implied by the inclusion of ''RFBs'' exclusively in § 422.4(a)(1)(iii). Thus, we are removing the reference to RFBs from that section. We also are deleting the word ''network'' from the parenthetical at the end of § 422.4(a)(1)(iii) because the distinction between network and non-network MSAs no longer applies.

Comment: Many commenters suggested that CMS more clearly coordinate between the Medicare Prescription Drug Benefit Rule at part 423 and the MA Program Rule at part 422.

Response: In response to this comment, we are making several changes to clarify the interaction between Part C and Part D. Specifically, we are clarifying the language at § 422.4 on types of MA plans and Part D prescription drug coverage. We are adding a new paragraph (c), Rule for MA Plans' Part D Coverage. This paragraph clarifies the requirements for MA coordinated care plans, MA MSAs, and MA PFFS plans by stating that a coordinated care plan must offer qualified Part D coverage meeting the requirements in § 423.104 in that plan or in another MA plan in that area. We also added language that MSAs cannot offer drug coverage, other than that required under Parts A and B of Title XVIII of the Act. Finally, we added language that MA organizations offering PFFS plans can choose to offer qualified Part D coverage meeting the requirement in § 423.104 in that plan.

Comment: One commenter recommended that CMS clarify the language at § 422.4(a)(1)(v). The commenter wants to ensure that an organization that wants to apply as a local HMO, but does not have an HMO license in its State, but is otherwise licensed as a risk-bearing entity in its State, will not be considered a PPO and thus subject to the 2-year moratorium on local PPOs as found at section 221(a)(2) of the MMA and proposed at § 422.451.

Response: We do not believe that a clarification of § 422.4(a)(1)(v) is required as § 422.400 already provides that an MA organization must be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more MA plans. Therefore, an organization that wishes to apply as a local MA plan HMO and has a State-risk bearing license would be considered an HMO and not be considered as a local MA plan PPO nor subject to the PPO moratorium described at § 422.451. However, a plan would have to market itself as an HMO or an HMO with a POS option. A plan could not market itself as a PPO because of the potential for confusion.

Comment: Several commenters recommended that CMS include new language in the final regulation that ensures that the type of denial of covered services as described in the Government Accountability Office (GAO) report entitled ''Medicare Demonstration PPOs: Financial and Other Advantages for Plans, Few Advantages for Beneficiaries (GAO–04–960)'' never happens again. One commenter, also referring to the GAO report, expressed concern that the Agency is not effectively enforcing current law, based on the recent GAO findings.

Response: In response to the GAO evaluation, we agreed to implement the GAO recommendation for us to instruct Medicare PPO Demonstration plan participants to remove impermissible restrictions on an enrollee's access to providers for all covered plan benefits. We are committed to assuring that local and regional PPOs provide reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers as found in § 422.4(a)(1)(v).

Comment: Several commenters recommended that CMS require non-contracted providers to accept Medicare fees as payment in full with no balance billing to the beneficiary. The commenters believe that this approach will protect beneficiaries from excessive payment liability for out of network services.

Response: As discussed in further detail in subpart C of the preamble to this final rule, there are several existing limitations on balance billing that apply to protect Medicare beneficiaries regardless of whether they are enrolled in an MA plan. Further, under existing rules, beneficiaries may not be held liable for more than the amount of out-of-network cost sharing for the service specified in the plan. For these reasons, we do not believe the changes requested by the commenter are necessary.

Comment: Several commenters supported the amendment found in the proposed rule that clarifies that a plan licensed as an HMO may still become a PPO under its HMO license as long as the State allows the HMO to offer a PPO under its HMO license. However, the commenters suggested that CMS revise § 422.4(a)(1)(v) in the following two ways: (1) clarify that PPOs may establish before authorization requirements for services obtained out-of-network that would allow for a review based on medical appropriateness; and (2) modify the provision to indicate that PPOs are not obligated to make available out of network certain types of programs, like health and wellness programs, for which no non-network counterpart is available.

The commenters also recommended that CMS clarify that only original Medicare benefits must be covered both in and out of network and that covered benefits that are not part of original Medicare need not be covered out of network. The commenters opposed CMS' requirement that for 2005, PPO plans must offer all benefits both in and out of network. The commenters stated that many plans in the private sector and in the FEHB program limit out-of-network coverage for some services. The commenters believe that requiring coverage of all non-original Medicare benefits in and out of network implies that there is a standard allowance or price reference upon which to base payments for these services. The commenters also suggest that there are no balance billing protections for the beneficiary who seeks care out of network. The commenter expressed similar concerns around the Medicare drug benefit and the lack of specificity regarding coverage of non-original Medicare benefits. The commenter also believe that covering certain benefits out of network (for example, disease management, 24-hour advice nurse lines, and wellness programs) will pose a significant challenge.

Response: To respond to the first recommended change to § 422.4(a)(1)(v)requesting that MA plans be allowed to impose pre-authorization

requirements on out-of-network care by PPOs, section 1852(e)(3)(A)(iv)(II) of the Act states that a PPO plan must provide for reimbursement for all covered benefits, regardless of whether the benefits are provided within the plan's network of providers. Similarly, section 1859(b)(4)(B) of the Act, which defines MA regional PPOs, includes the same requirement to provide for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers. These provisions indicate the Congress's clear intent to ensure that PPOs provide coverage for all plan-covered benefits both in and out of network. Further, although other coordinated care plans may include mechanisms to control utilization, such as referrals from gatekeepers for an enrollee to receive services within the plan, the definition of PPO contained in sections 1852(e)(3)(A)(iv) and 1859(b)(4)(b) of the Act indicates that local and regional PPOs may not use similar mechanisms, such as pre-authorization, to restrict enrollee access to out-of-network services. However, there are several ways PPOs can appropriately seek to promote the use of in-network services. For example, PPOs may encourage beneficiaries to notify them before seeking care out of network, so that care is coordinated in and out of network. PPO plans may offer incentives to beneficiaries to provide notice of their intent to seek out-of-network services by discounting out-of-network cost sharing when beneficiaries provide notice before receiving services. Further, MA organizations are required to have procedures for making determinations of whether an enrollee is entitled to receive a health service and the amount that the enrollee will be required to pay for the service. Thus, a PPO plan enrollee and provider may seek an advance determination of coverage before receiving the service, and we encourage PPO enrollees to avail themselves of this option.

On the commenters' request to clarify in § 422.4(a)(1)(v) that only original Medicare benefits must be covered in and out of network, we believe that the clear language in the statute at section 1859(b)(4)(B) of the Act relating to regional MA plans and section 1852(e)(3)(A)(iv)(II) of the Act relating to local PPOs, does not permit us to limit the requirement that PPOs provide for reimbursement for all plan-covered benefits both in and out of network. Therefore, we are not modifying the definition of PPOs at § 422.4(a)(1)(v). However, to respond to some of the concerns raised in the comment, we again note that plans can reduce the regular cost sharing for out-of-network benefits for beneficiaries who voluntarily seek pre-authorization for those benefits. As described by another response to comment above, we disagree with the commenter that there are no balance billing protections for beneficiaries. There are limitations on balance billing to protect beneficiaries regardless of whether they are involved in an MA plan or not. Finally, on the issue of benefits, such as nurse advice lines, which plans believe should not be made available out of network, we believe that as a practical matter, most of these types of benefits will be unattainable out of network because they are designed to be provided exclusively to plan members. Additional discussion of these types of out-of-network benefits can be found in the subpart C preamble.

Comment: Comments were received on § 422.4(a)(1)(v). Several commenters suggested that CMS address perceived inconsistencies in licensing requirements for PPOs as compared to HMOs by confirming the scope of State licensure requirements that apply to entities offering MA PPO plans, as State licensing laws may restrict an HMO's ability to offer a PPO plan.

Response: We do not believe there are inconsistencies. All MA plans must be licensed by the State as a risk-bearing entity. State law controls whether the MA organization is licensed or authorized to offer the type of MA plan it proposes to offer. As we explained in the preamble discussion in subpart A of the proposed rule, the fact that MA organizations offering local PPOs that are (or are not) licensed as HMOs is pertinent to the MA program solely for purposes of the application of quality improvement standards in section 1852(e) of the Act, and has no specific bearing on whether an MA organization has State authority under applicable State law to offer an HMO or PPO under the MA program. Whether an MA organization (licensed either as an HMO or otherwise) can offer a specific type of MA plan continues to rest upon whether the organization has State licensure or authority to offer such a type of MA plan.

Comment: One commenter requested that CMS consider enabling the PFFS model as an option under the regional preferred provider organization structure. The PFFS model in the MA program enables broader geographic coverage without the specific provider contracting requirements. This option could expand participation in the regional program by enhancing participation and access in rural areas without specific provider contracting access requirements as is currently available under the existing MA PFFS plans.

Response: Since a PFFS plan is not defined as a type of coordinated care plan under section 1851(a)(2)(A)(i) of the Act, it would not be possible to allow an MA organization to offer a PFFS plan as an MA regional plan. Additionally, MA PFFS plans are defined at section 1859(b)(2) of the Act, while MA regional plans are defined at section 1859(b)(4) of the Act. The definitions are mutually exclusive.

Comment: A few commenters asked whether SNPs could be any type of coordinated care plan.

Response: We believe that section 1851(a)(2)(A)(ii) of the Act clearly states that SNPs can be any type of coordinated care plan.

4. Expansion of the Beneficiary Education and Information Campaign ''User Fees'' (§ 422.6, formerly § 422.10)

The last section of subpart A contained regulations implementing the user fees provided for in section 1857(e)(2) of the Act. MMA expanded the user fee to include PDP sponsors as well as MA plans as contributors. The expansion of the user fee recognizes the increased Medicare beneficiary education activities that we would require around the new prescription drug benefit.

As before, the user fee would pay for the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1–800 telephone line, community based outreach to support SHIPs, and other enrollment and information activities required under section 1851 of the Act and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103–66).

As indicated in the proposed rule and in this final rule (§ 422.6), in fiscal year 2006 and thereafter, the MMA authorizes up to $200,000,000, reduced by the fees collected from MA organizations and PDP sponsors in that fiscal year. (The total amount is not indexed in any way.) In each year, the total amount of collected user fees may not exceed the estimated costs in the fiscal year for carrying out the enrollment and dissemination of information activities in the MA and Part D prescription drug programs or the applicable portions of $200,000,000, whichever is less.

These user fee provisions establish the applicable aggregate contribution portions for MA organizations and PDP

sponsors. The applicable portion of the user fee for MA organizations will be based on the total proportion of expenditures for Medicare Part C as well as for payments under Part D that are made to MA organizations as a percent of Title XVIII expenditures. The PDP sponsor's applicable portion is the estimate of the total proportion of expenditures under Title XVIII that are attributable to expenditures made to PDP sponsors for prescription drugs under Part D. The fees charged to individual MA plans and PDP sponsors would continue to be determined by CMS. These fees are calculated by a percent of plan's revenue to avoid over-burdening smaller plans.

Comment: One commenter supported CMS' efforts to increase user fees to support beneficiary education. The commenter recommended that CMS collect the entire amount authorized under the statute and work with the Congress to either index it or otherwise lift the cap if needed to adequately inform beneficiaries about the new complexities with private plans.

Response: The changes the commenter requested are beyond the scope of this rulemaking. We do not intend for the user fee to be exclusively for education on MA plans. We anticipate that the user fee will also be used on the new Part D drug benefit, which we believe will consume a large portion of the user fees, due to the newness of the benefit.

Comment: Two commenters believe that there is insufficient funding of the SHIP program and recommended that CMS use a portion of the MA and PDP user fees to support SHIPs.

Response: Early in the implementation of the M+C program, SHIPs received some funding from the user fee. However, for the last several years, SHIP funding has been a specific line item appropriation by the Congress. We have some discretion regarding how the user fees are spent in terms of beneficiary education, so it is possible for SHIPs to get some of their funding from the user fee. However, decisions on how to spend user fees are internal management decisions relating to resource allocation, and therefore will not be included in this regulation.

Comment: One commenter recommended that beneficiary educational materials be shared with Congressional committees of jurisdiction prior to releasing them.

Response: The timelines for providing education materials are limited. Although we do not intend to seek Congressional authorization before the release of the education materials, the materials will comply with the provisions of the statute and regulations, and we will make every effort to ensure that they are useful to beneficiaries in making their choices. CMS' Office of Legislation works closely with the Congressional offices to ensure that they are aware of and have open access to copies of various educational materials either before or in the same timeframe as their constituents to help with education and outreach activities.

Comment: One commenter expressed concern that the funds used to educate beneficiaries may be more focused on explaining the array of choices and not focused enough on encouraging beneficiaries to actually make a choice. The commenter encouraged CMS to work directly with experienced plans to conduct information campaigns that result in significant Part D uptake rates for PDPs and MA-PDs. The commenter was concerned that beneficiaries may be confused by the changes beginning in 2006.

Response: We appreciate the commenter's suggestion for us to work with experienced plans to conduct information campaigns that could expand enrollment in MA-PDs and PDPs beginning in 2006 (especially in light of the new options that will be available at that time). We expect to engage a strong network of experienced plans, providers, and other stakeholders and partners to provide input and feedback on beneficiary education plans and to provide specific suggestions on ways to communicate the changes that will occur in the MA program in 2006.

Comment: One commenter believes that CMS will require the resources, both financial and human, to help beneficiaries make choices about benefit and plan options that appropriately reflect their needs and preferences. The commenter recommended that CMS bolster programs such as one-on-one counseling, which beneficiaries prefer, and to design beneficiary materials in formats that make information easy to interpret and understand. The commenter also recommended that CMS create information resources, such as the 1–800 number, but also help beneficiaries understand the information that is being presented.

Response: We agree that we will have to continue to educate beneficiaries on MA program changes in a way that helps the beneficiary to understand the program and understand what type of Medicare plan would best suit his or her individual health and financial needs. We routinely test education and outreach products with beneficiaries during development to ensure that they are broadly accessible and understandable to the appropriate target audiences.

Comment: A commenter indicated that there are high costs to I/T/U for MMA implementation costs related to outreach, education and enrollment of an AI/AN individual. The commenter encouraged CMS to acknowledge the need for funding that is specifically directed to local I/T/U to support these activities where the work is done and where bearing the costs is the most difficult. The commenter believes that unlike other Medicare populations, AI/AN beneficiaries are unlikely to enroll in MA plans without specific information from their I/T/U.

Response: We agree that education and outreach efforts should be tailored to the needs of specific populations interested in enrolling in MA plans, to the greatest extent possible. We will continue our collaboration with the IHS and other partners to identify the most effective ways to reach beneficiaries in the AI/AN population.

Subpart B—Eligibility, Election and Enrollment

We proposed generally to retain the same eligibility, election and enrollment rules that currently apply to the Medicare Advantage program. We received numerous comments on this subpart in response to the August 2004 proposed rule. These comments and our responses are presented below.

1. Eligibility to Elect an MA Plan (§ 422.50)

In this section, we specified the following:

- Reference to an ''MA plan'' includes both MA local and MA regional plans, unless specifically noted otherwise in the text.
- We reserve the authority to allow additional optional mechanisms for elections (for example, website enrollment) to provide a more efficient and simplified election process for beneficiaries and partner organizations.

Comment: Several commenters supported the proposal to retain the authority to allow additional optional MA election mechanisms, stating that this change will promote the development of more efficient and simplified processes for beneficiaries. One commenter requested clarification that any such alternate election mechanism would be optional for individual MA organizations to use. Another commenter supported the change, but stated that CMS should not mandate that MA organizations accept electronic elections.

Response: The revision made to this section is intended only to permit us to

approve alternate optional election mechanisms (in addition to paper election forms) in the future. We anticipate that such mechanisms will be available at the option of each MA organization. Furthermore, we believe it is important to clarify that, as other election mechanisms are approved and implemented, we do not intend to permit MA organizations to require beneficiaries to use any such election mechanism. We will require all MA organizations to establish a minimum standard process, which, at this time, will be a paper process, and will be made available to prospective enrollees and plan members in conjunction with any optional election mechanism. In the future, as technology evolves, another process may be a more appropriate minimum standard. To ensure that these points are clear, we are amending § 422.50(a)(5) to provide that beneficiaries may make elections by completing an enrollment form or by completing another CMS-approved election mechanism offered by the MA organization.

Comment: One commenter requested that CMS clarify the use of alternate election mechanisms with respect to employer or union group MA plans.

Response: Section 422.50 applies equally to all beneficiaries making MA elections and therefore applies to those individuals making an election to or from an MA plan sponsored by an employer or union as well. Current processes already established in our manual guidance for MA plans offered by employer or union groups are not changed by this revision.

Subpart B—Eligibility, Election and Enrollment

2. Eligibility to Elect a Special Needs MA Plan (§ 422.52)

Section 231 of the MMA authorized the creation of a new type of MA coordinated care plan, called a ''Specialized MA Plan for Special Needs Individuals.'' These plans will be referred to throughout as SNPs.

We believe the new requirements regarding SNPs are primarily intended to encourage more choices for certain populations by allowing organizations that specialize in the treatment of beneficiaries with particular needs to have MA contracts. These organizations could provide and coordinate services for these individuals and would be permitted to limit plan enrollment to such individuals, or to a certain proportion of such individuals. This provision could encourage organizations to develop new products in the marketplace by giving them the opportunity to develop expertise in efficiently serving special needs populations. Our overall policy goal will be to allow MA organizations as much flexibility as possible (within defined parameters), while maintaining beneficiary protections.

SNPs may restrict enrollment solely to those who are entitled to Medicaid (dually eligible), institutionalized individuals who meet the definition in § 422.2, and/or beneficiaries who have a severe or disabling condition, as defined by the Secretary in regulations. Section 231 of the MMA also gives the Secretary the authority by regulation to designate certain MA plans as SNPs if they ''disproportionately serve(s) special needs individuals.'' Special needs individuals are defined in § 422.2.

In the proposed rule, we asked for comment as to whether SNPs should be allowed to exclusively enroll certain subgroups of those categories of special needs individuals described in § 422.52(b)(1) and § 422.52(b)(2) (dual eligible or institutionalized beneficiaries) and, if so, what categories would be appropriate.

The MMA gave us the authority to waive section 1851(a)(3)(B) of the Act, which precludes beneficiaries with ESRD from enrolling in MA plans. In the proposed rule, we solicited comments as to whether we should waive this section of the Act and whether beneficiaries with ESRD should be considered to meet the requirement for special needs status.

We also have the authority to apply to SNPs a provision under section 1894(c)(4) of the Act that applies to enrollees in the Program of All-Inclusive Care for the Elderly (PACE). This section provides for deemed continued eligibility in certain situations. Specifically, it allows an beneficiary enrolled in a PACE plan who no longer meets the eligibility criteria, but who can reasonably be expected to, in the absence of continued coverage under the PACE plan, meet the criteria of the plan within a period of time not to exceed 6 months. In the proposed rule, we proposed applying this provision to individuals enrolled in SNPs who longer meet a plan's unique eligibility criteria, who can reasonably expected to meet the plans criteria within a period of time not to exceed 6 months.

In the proposed rule, we provided in § 422.52(e) that individuals who are enrolled in MA plans that are subsequently designated as SNPs would be ''grandfathered,'' that is, allowed to continue to be enrolled or choose to elect another MA plan during appropriate election periods provided to all MA eligible individuals. We proposed this based on the belief that the Congress did not intend for individuals already enrolled in an MA plan to be involuntarily disenrolled. However, we also invited comment on an alternative approach wherein any non-special needs individuals in an MA plan that is subsequently designated as an SNP would have to be involuntarily disenrolled. In this situation, we proposed to establish, through further operational guidance, an SEP for these individuals. Statutory language also provided that a newly designated MA plan may restrict future enrollment of individuals to those specialized individuals it intends to serve.

We also indicated in the proposed rule that, if we did allow ''grandfathered'' members to remain in the SNP, we would distinguish them from those individuals who join a new SNP and then lose their special needs status on other than a temporary basis. Those special needs individuals would be involuntarily disenrolled after losing their special needs status (and after any period of deemed continued eligibility, if appropriate) and receiving proper notice. SNPs that exclusively enroll special needs individuals would be required to inform individuals before their initial enrollment that they could only remain enrolled in the plan for as long as they were considered special needs individuals as defined by CMS.

Comment: One commenter felt that CMS should not allow SNPs to exclusively enroll certain subgroups of dual eligible or institutionalized beneficiaries. The commenter's rationale was that requiring MA organizations to accept all dual eligibles into its specialized MA plan would maintain the integrity of the dual-eligible risk pool and prevent the offering of an SNP plan to those who are the least poor (and presumably, most healthy) segment of duals. On the other hand, several commenters suggested that CMS allow SNPs that would enroll subgroups of dual eligibles if supported by a State Medicaid agency. The vast majority of commenters supported allowing SNPs to serve subsets of both the dual eligible and institutionalized populations.

The most prevalent rationale for allowing subsets of dual eligibles was to allow States to develop specialized Medicaid programs to compliment Medicare coverage by SNPs. Most commenters described the difficulties and complexities of serving all dual eligibles as impediments and disincentives to developing a program to coordinate Medicaid managed care programs with Medicare. If required to serve all dual eligible beneficiaries, MA organizations would have to offer

Medicaid-covered benefits, such as long-term care, to individuals who are not eligible for full Medicaid benefits. One commenter stated that allowing subsets of dual eligibles would also facilitate transitioning full dual eligibles from Medicaid prescription coverage to Medicare Part D coverage in 2006. Another commenter suggested that CMS clarify that plans must uniformly offer the same set of benefits to all classes of dual eligibles as provided under the State's Medicaid program. Several commenters recommended that CMS let the MA organization propose eligibility criteria and then evaluate its plan, delivery systems, and related programs, possibly modifying them as part of the review and approval process. Some commenters noted the significant investment of time and resources required to develop targeted clinical programs for different subgroups with different, complex conditions.

Commenters also suggested allowing specific subsets, including full benefit dual eligibles, the frail elderly, those who are nursing home certifiable, children or adults with physical disabilities, developmental disabilities or mental impairments, and community-based or institutional individuals.

Two commenters recommended that CMS not include subsets of duals in the third category of specialized MA plan eligibles, those with severe or disabling conditions. The rationale given was that the identifying characteristics of subsets of duals are not appropriately described within the third category and these individuals should remain in the second category.

Once commenter recommended allowing organizations to serve other subgroups of Medicaid eligible and institutionalized if there is a pervasive justification based on common characteristics of the subgroup, that is, institutionalized beneficiaries in a specified network of nursing homes.

Several commenters stated that adverse selection would be mitigated by phase-in of risk adjustment because payment would take into consideration the individual's disease category.

Response: Consistent with the majority of these comments, we do not intend to adopt a regulation that would preclude MA organizations from offering SNPs to appropriate subsets of the population in a plan service area, including subsets within the SNP populations identified in the statute. Thus, in the interest of facilitating the coordinated delivery of Medicare and Medicaid services, we will consider requests for SNPs that serve certain subsets of dual eligibles and institutionalized individuals on a case-by-case basis. Subsets of those two categories will be included in category one and category two respectively, rather than in the third category of special needs individuals, those with chronic or disabling conditions. In addition, because of the unique nature of some plans serving the institutionalized and dual eligibles, we will also consider subsets based on common characteristics, such as a specific network of facilities and Medicaid eligibility. We will provide further operational guidance following publication of this rule.

Comment: The MMA allows for the enrollment of ESRD beneficiaries in SNPs designed for this population. One commenter said that CMS should delay enrollment of ESRD beneficiaries in MA plans until results of CMS' capitated ESRD Disease Management demonstration are available. The commenter also objected to allowing ESRD patients to enroll in managed care because, in the commenter's view, managed care plans disrupt existing relationships between patients and health care providers. The commenter expressed concerns that an ESRD patient who drops or declines Medigap insurance to join a managed care plan would permanently be locked into the managed care plan and could not switch to Original Medicare, since ESRD would make him/her ineligible for Medigap coverage. The remainder of those commenting on permitting ESRD SNPs supported the proposal.

Response: Individuals with ESRD may choose to receive care under an MA plan for a variety of reasons, including coordination of care and lower out-of-pocket costs. Anecdotal experience with the MA program has shown that MA enrollees with ESRD generally remain enrolled in their plan, or join another existing plan if the one in which they are enrolled terminates. We believe that these beneficiaries should have the option of enrolling in an MA plan, if they so desire. Therefore, we will amend § 422.50(a)(2) by adding language to allow SNPs to serve ESRD individuals.

In order to mitigate the commenter's concerns, we would require that, prior to enrollment in an MA SNP, the organization notify potential enrollees that enrollment is fully optional and of the potential impact that their enrollment could have on their Medigap rights. In addition, MA Organizations will be required to provide clear and accurate provider information for potential enrollees so they may determine whether their current providers are part of the specialized MA plan's network.

Comment: Many commenters supported the proposed approach at § 422.52(e) to allow individuals already enrolled in an MA plan that we subsequently designate as an SNP to remain enrolled or be allowed to elect another other MA plan. Most of these commenters also recommended that CMS allow for a Special Election Period (SEP) to facilitate selecting a new MA plan or Original Medicare. Several commenters remarked on the need to maintain adequate enrollment levels once an SNP gains a new designation. None of the commenters supported the alternative proposal under which non-special needs individuals would have to be involuntarily disenrolled if their MA plan became an SNP.

Response: We will allow members of MA plans that are subsequently ''redesignated'' as SNPs to be ''grandfathered,'' that is, remain enrolled in that plan indefinitely. These individuals may not be involuntarily disenrolled on the basis of not meeting the definition of special needs individual. However, once a grandfathered individual voluntarily disenrolls from the SNP, he or she would not be eligible to reenroll in that SNP unless he or she meets the definition of special need individual. We will establish an SEP for these individuals for exceptional circumstances in further operational guidance. An SNP that chooses to exclusively enroll special needs individuals will not be considered a ''disproportionate share'' SNP, as defined in § 422.2, on the basis of serving ''grandfathered'' members.

Comment: Many commenters supported not requiring plans to involuntarily disenroll beneficiaries who lose their special needs plan eligibility if it is reasonable to assume that they would again meet the special needs eligibility criteria within a certain period as determined by CMS. Some commenters stated that it is not uncommon for beneficiaries to have temporary lapses in eligibility, particularly in situations where a dual eligible loses Medicaid eligibility due to a temporary change in financial circumstances or failure to provide information for recertification. The commenters generally believed that continued eligibility leads to continuity of care and improved clinical outcomes. Two commenters requested an additional 6-month ''grace period'' (commenter's terminology) for individuals who lose their eligibility as well as retroactive payments for their care in the event that eligibility is established retroactively.

One commenter recommended that CMS continue funding Part D and other benefits for the entire ''30-day notice period'' (commenter's terminology) regardless of an individual's eligibility to enroll in a SNP.

One commenter requested continued eligibility for ''exclusive'' as well as ''non-exclusive'' plans (commenter's terminology), including MA plans that may temporarily fall below the required threshold for the special needs designation.

Response: We believe that the Congress' goal was to encourage continuity of care for these at-risk individuals and that a period of deemed continued eligibility for a minimum of 30 days but no longer than 6 months is reasonable for beneficiaries who are likely to regain eligibility. The 6-month period is consistent with the PACE language at § 460.160, which provides that a participant may be deemed to continue to be eligible if, in the absence of continued coverage, the participant reasonably would be expected to meet the requirement within the next 6 months. However, we will not include ''in the absence of continued coverage'' in § 422.52(d).

Our rationale is that this appears to reference ineligibility due to a health condition that could deteriorate without plan membership. In the case of an SNP for dual eligibles, a lapse in SNP eligibility could be due to a lapse of Medicaid eligibility, and such eligibility may be based on the beneficiary's financial circumstances, not his or her health condition.

The MA organization may choose any length of time from 30 days through 6 months for deemed continued eligibility as long as it applies this period consistently among all members in its plan and fully informs its members of this time period. Further guidance on applying deemed eligibility will be provided in operational instructions following publication of this regulation.

We believe that the ''30-day notice period'' referred to by one commenter is from our interim guidance for SNPs, issued as part of its 2005 Call Letter. This guidance established a 30-day minimum timeframe for continued eligibility for an SNP enrollee who loses his or her special needs status. This individual is a member during the period of deemed continued eligibility and until his or her disenrollment becomes effective. Payments will continue on the enrollee's behalf until the period of deemed continued eligibility ends and the enrollee is involuntarily disenrolled. Retroactive payment will not be necessary in these instances.

All SNPs, including ''disproportionate percentage'' SNPs, as defined in § 422.2, may apply the deemed eligibility provision. Deemed eligibles would be counted toward the number of special needs individuals enrolled in the SNP rather than toward the number of non-special needs individuals.

Comment: Several commenters supported allowing SNPs to disenroll enrollees who no longer meet the special needs eligibility criteria. Two commenters wanted SNPs to have the choice of whether to continue to provide Medicare services to individuals who lose special needs status. Another commenter supported involuntary disenrollment for exclusive MA SNPs only, stating that this requirement would hinder disproportionate SNPs' ability to maintain enrollment at or above the regulatory threshold.

Response: In our interim guidance and our proposed rule, we interpreted the statutory phrase ''exclusively serves special needs individuals'' to mean that the plan is exclusively marketed to special needs individuals and exclusively enrolls special needs individuals. This interpretation allowed us to permit existing non-special needs enrollees to remain enrolled in an MA plan that changed its status to an SNP.

Thus, under this definition, existing enrollees who did not enroll when the plan was an SNP would not be affected by the plan definition, and we do not believe they should be disenrolled. Moreover, the existence of such enrollees does not preclude the plan from remaining a plan that ''exclusively serves≥(that is, markets to and enrolls) special needs individuals. As noted above, however, an individual who enrolls in an SNP as a special needs enrollee is different, since he or she would have no expectation of being enrolled in that plan if he or she were not in the special needs category. The case of an SNP that has never had non-SNP enrollees is also different, as any enrollee that it markets to or enrolls would have to be a special needs enrollee, if it is an ''exclusive'' plan.

In order to address these latter situations, we will add a new part (iv) to § 422.74(b)(2) to show that in these cases loss of special needs status (and of deemed continued eligibility, if applicable) is a basis for required disenrollment from an SNP that enrolls only special needs individuals.

We have the authority to waive minimum enrollment requirements as necessary. Therefore, we do not envision the minimum enrollment requirements adversely affecting disproportionate share SNPs.

Comment: One commenter recommended that CMS allow MA SNPs to charge an enrollee for benefits no longer covered by the State or Federal cost-sharing arrangements and to terminate coverage for nonpayment of premiums or cost sharing.

Response: An SNP is the same as any other MA plan with respect to rules governing the charges that may be imposed on enrollees. Enrollees may be charged for benefits that would not otherwise be covered by Medicare. Under § 422.74(d)(1), coverage may be terminated for a failure to pay premiums. As discussed below in connection with disenrollment for disruptive behavior, a failure to pay cost sharing is not in itself a basis for disenrollment.

Comment: Two commenters asked for clarification of whether the regulation refers to Special Needs Health Plans or the Special Needs Health Options.

Response: The regulation refers to a ''Specialized MA plan for special needs individuals'' (SNPs), as created by Section 231 of the MMA.

3. Continuation of Enrollment for MA Local Plans (§ 422.54)

The MMA limits the offering of MA plan continuation areas to MA local plans only and we made this conforming change at § 422.54. We received no comments on this section and adopted the conforming changes as proposed.

4. Enrollment in an MA MSA Plan (§ 422.56)

Section 233 amended the Act to eliminate the cap on the number of individuals that may enroll in MA MSA plans removed the existing deadline for enrolling in such a plan. Because this deadline had already passed without anyone enrolling in an MSA plan, the original MSA plan provisions had become a nullity. The effect of section 233 was to make the authority to offer MSA plans permanent and unlimited. This change is reflected at § 422.56, along with new language allowing the Secretary to permit enrollment in MSAs by enrollees of other Federal. We included this language to reflect the fact that, under the statute, such enrollment could be authorized contingent on the adoption of new policies by the OPM.

Comment: Two commenters suggested deleting the language authorizing the Secretary to permit enrollment in MSAs by enrollees of the Federal programs specified. Both commenters contended that it was unlikely that OPM would ever be able to certify that MSA enrollment would not raise costs in the FEHB, Veterans' Administration, or

TRICARE programs and that, accordingly, the inclusion of this language is unnecessary.

Response: The statute at section 1851(b)(2) provides for the potential for such individuals to become eligible to enroll in an MSA plan. Therefore, our clarification of § 422.56(b) supporting this provision is appropriate.

5. Election Process (§ 422.60)

In proposed § 422.60, we set forth changes that would allow other election and notice mechanisms other than paper forms or written documents. We also clarified that MA organizations may submit requests to restrict enrollment for capacity reasons to CMS at any time during the year.

Comment: Two commenters supported the conforming revisions to § 422.60 permitting us to approve alternate election mechanisms, as discussed in the comments on proposed § 422.50(a)(5). The commenters also approved of the clarification to § 422.60(b) regarding requests for enrollment limits due to capacity reasons.

Response: We adopt these revisions as proposed.

Comment: One commenter suggested that CMS make further amendments to the regulatory text to ensure that the current options we have established for individuals to elect MA plans sponsored by employer or union groups are retained, including the policy that documentation may be retained by an employer or union group rather than the MA plan.

Response: As discussed above, we are confident that the proposed revisions provide us with sufficient flexibility to foster innovative election processes that use modern technology for all individuals, not just employer or union groups. Therefore, it is not necessary to reiterate that these alternative enrollment mechanisms are also available to employers or union groups. We will continue to retain current policy for employer or union group elections in our operational guidance and as an option for MA organizations.

Comment: One commenter suggested that CMS require MA and MA-PD plans to accept AI/AN enrollees even if a plan has received CMS approval to close enrollment for capacity reasons.

Response: The ability to request a capacity limit is an important element of the MA program that helps ensure that plan enrollees will have sufficient access to needed providers and services. CMS' approval of a capacity limit request indicates that we agree with the requesting MA organization that its defined network of providers is sufficient to deliver health care only to a limited number of plan members. Thus, we do not permit the MA organization to enroll any individual beyond the capacity limit of a given plan, and we do not believe it would be appropriate to undermine this protection by waiving capacity limits for the AI/AN population or any other group.

Comment: Two commenters requested that CMS modify the regulations to more clearly allow for what the commenter referred to as ''passive elections.''

Response: The elections to which the commenters are referring are those in which an individual is informed that the process for making an election of a particular plan is taking no action, while other options are exercised by declaring an affirmative intent to elect that option. CMS have limited such a process to situations when it can be reasonably concluded that an individual will clearly want to enroll in the MA plan offered by the same organization.

We do not believe that a regulatory change is needed to continue to allow such elections. The revisions made to § 422.50(a)(5) and the conforming revisions to § 422.60 provide us with appropriate flexibility to define and approve MA election mechanisms, including allowing such ''passive elections'' as described above in specific limited circumstances.

6. Election of Coverage Under an MA Plan (§ 422.62)

Similar to the election periods in place in past years, the MA *Annual Coordinated Election Period* will run from November 15 through December 31 of each year. For 2006, the annual coordinated election period is extended through May 15, 2006.

Based on our interpretation of the MMA, we proposed revising § 422.62 to ensure that an individual who is newly eligible for MA has the full opportunity to elect an MA plan as part of their *Initial Coverage Election Period*. In developing the proposed rule, we determined that the intent of the Congress was to provide for an initial coverage election period for MA that ends on the later of the day it would end under pre-MMA rules or the last day of the Medicare Part B initial enrollment period. This approach extends an individual's MA initial election period in some instances, and never reduces or eliminates it.

Through 2005, the *Open Enrollment Period* extends throughout the year, providing unlimited opportunities for MA eligible beneficiaries to enroll in, disenroll from, and or change enrollment in an MA plan. This change was reflected in § 422.62(a)(3) of our proposed regulations.

Section 1851(e)(2)(B)(1) of the Act was revised to establish that the open enrollment period in 2006 will be the first 6 months of the year. In addition, individuals who are newly eligible for MA in 2006 are provided an open enrollment period that consists of the first 6 months the individual is MA eligible, but cannot extend past December 31, 2006.

Under revised section 1851(e)(2)(C)(i) of the Act, the open enrollment period for 2007 and subsequent years will be the first 3 months of each year. In addition, individuals who first become MA eligible during 2007 and subsequent years will be provided an open enrollment period that consists of the first 3 months the individual is MA eligible, not to extend past December 31, 2006. Although this specific period does not extend past December 31, 2006, it is important to remember that all individuals will be provided a 3-month open enrollment period from January through March 2007, as discussed in this section.

Section 1851(e)(2)(C) of the Act limits a change of election made during an open enrollment period in 2006 and later years to the same type of plan in which the individual making the election is already enrolled. Specifically, an individual in an MA plan that does not provide drug coverage may change only to another similar MA plan, or to original Medicare, but may not enroll in an MA plan that provides Part D coverage, or enroll in a Part D plan. Similarly, an individual enrolled in an MA plan that includes Part D coverage may enroll only in another MA plan with Part D coverage, or change to original Medicare coverage with an election of a Part D plan. As noted in the proposed rule, we clarified a conflict between clause I and II of section 1851(e)(2)(C)(iii) of the Act. Clause (I) of section 1851(e)(2)(C)(iii) states that an individual who is ''enrolled in an MA plan that does provide qualified prescription drug coverage,'' may only elect a plan that does not provide that coverage. A literal reading of this language would be in direct conflict with clause (II) of that same section, which says that an individual who is enrolled in an MA plan that provides qualified prescription drug coverage may not enroll in an MA plan that provides no Part D coverage.

This contradiction, plus (1) the fact that section 1851(e)(2)(C)(iii)(I) of the Act refers to a ''another'' MA plan that ''does not'' provide Part D coverage, (2) the fact that clause (I) is contrasted with

clause (II) with the word ''or'', and (3) committee report language, make it clear that the word ''not'' was inadvertently omitted from the first clause of section 1851(e)(2)(C)(iii) of the Act.

Comment: Numerous commenters opposed the ''lock-in'', that is, the statutory provisions that limit beneficiaries from choosing a different type of coverage to certain times of the year. Several commenters stated that these provisions severely limit the choice of beneficiaries. Others commented that implementing lock-in under the MA program at the initiation of the new Part D program would be confusing to beneficiaries. Commenters also noted that such a provision would have a negative impact on the MA organizations, by making it difficult to maintain a dedicated sales staff and increasing the administrative costs and burden of educating beneficiaries about both Part D and MA changes.

Response: The provisions that limit the times in which an individual may change his or her election were originally created by the BBA, and were to become effective during 2002. However, because of subsequent statutory changes, these provisions have never taken full effect (except for a temporary period during 2002). These provisions were modified by the MMA to incorporate the Part D prescription drug benefit and the statute is clear on their applicability. Thus, we have no authority to modify these requirements.

Comment: One commenter suggested that CMS develop appropriate procedures to administer these election restrictions and inform organizations as to what type of plan an individual is eligible to elect (for example, an MA only or an MA-PD plan). Another commenter recommended that the organization have access to information about whether an individual is eligible to elect a certain plan, both in advance of an enrollment application and upon receipt of an enrollment application.

Response: We understand that we will need to maintain data history of the number of times an individual has made an election during a specific election period, as well as the type of plan an individual is eligible to elect. Such information will be necessary in order to determine whether an individual is eligible to elect an MA plan at a given time. We will work with plans to establish a reliable process to determine the eligibility of an individual based on these requirements.

Comment: Several commenters responded to the request for comments on the provision that an enrollee may only change to the same type of plan (either with drug coverage or without) during the open enrollment period. Some commenters opposed the interpretation that restricts a beneficiary from switching plans, even when life circumstances had changed. Others supported the interpretation and indicated that such a provision reinforced the overall integrity of the program. Others believe that we need to maintain flexibility with employer-sponsored plans.

Response: After review of the statutory provisions and the comments, we believe that the Congress clearly intended that a beneficiary may obtain or discontinue Part D coverage *ONLY* during the annual coordinated election period that begins in November each year. Notwithstanding SEPs established by the statute and in our regulations and subsequent guidance, it is only during the Annual Coordinated Election Period that all Medicare beneficiaries are free to elect among all available options, whether original Medicare, MA plans, MA-PD plans or PDPs. The statutory provisions governing Part D in 1860D–1 do not provide for an open enrollment period that would allow beneficiaries to elect the prescription drug benefit outside of the AEP. Permitting beneficiaries to discontinue Part D coverage at any time during the year, without a corresponding election period to enroll in such coverage, could result in a gap in coverage that may result in a late enrollment penalty. Therefore, we believe that it is appropriate to interpret the statute to require that individuals may not make an election that would result in adding or dropping prescription drug coverage except during the annual election period.

Comment: One commenter recommended that CMS clarify how the annual coordinated election period and the open enrollment period will be administered in 2006, since these periods overlap from January 2006 through May 15, 2006.

Response: In 2006, we envision that the annual coordinated election period will provide each individual with the ability to choose either an MA plan or original Medicare, with or without drug coverage. The open enrollment period will provide individuals the opportunity to change their election from the MA program to original Medicare (or vice versa), but not to obtain or discontinue drug coverage. We will provide information about these election periods in beneficiary materials, such as the Medicare & You Handbook.

Comment: A few commenters submitted comments regarding the special election periods (SEPs), as described at § 422.62(b). One commenter asked if CMS expected to apply the SEPs established under the M+C program to the MA program. Another commenter requested confirmation that the current SEP for PACE enrollees (described in manual guidance) would be applied to the MA program. One commenter suggested that CMS consider an exception to the Open Enrollment Period for SNPs and for individuals eligible for both Medicare and Medicaid.

In addition, a commenter asked CMS to consider the creation of an SEP for beneficiaries in markets with MA market penetration rates below 20 percent; such an SEP would allow time for educating beneficiaries on MA plans and how they operate. Many commenters submitted comments on establishing SEPs for special needs plans. The commenters generally approved of a permissive special election period policy to allow special needs individuals to change plans at any time. Others believe that the enrollment periods established in § 422.62 do not provide sufficient opportunity for beneficiaries to enroll in a special needs plan.

Response: We have historically included in our regulations those SEPs that have been specifically named in the statute, and established SEPs for exceptional circumstances in our operational guidance. We will review the SEPs in current MA guidance and consider their applicability for the MA program in 2006, as well as consider new SEPs that may be necessary to coordinate the new Part D program. We appreciate the suggestions provided by the commenters and will consider these in developing guidance following publication of the rule.

Comment: Several commenters addressed the AI/AN population and the need to modify the regulations to allow AI/AN individuals to switch between MA or MA-PD at various times rather than be limited to changing only at certain times during the year.

Response: We recognize the need to coordinate between the IHS, Tribe, or Tribal organization, or Urban Indian (I/T/U) programs. We have the authority to recognize certain circumstances as exceptional and provide special election periods. Providing such exceptions, however, would not always benefit an individual, as we discussed in our response to a previous comment under § 422.50 regarding capacity limits. Such limits are necessary to ensure that health plans have the appropriate number of providers and are able to provide access to all beneficiaries enrolled in their plan. As discussed in the previous comment regarding

establishment of SEPs in operational guidance, we are not establishing any non-statutory SEPs in the regulation, but retain the authority to establish an SEP in the future under exceptional conditions. This same policy applies to the AI/AN population.

7. Coordination of Enrollment and Disenrollment through MA Organizations (§ 422.66)

In keeping with our proposed clarification at § 422.50(a)(5) regarding election mechanisms other than, and in addition to, paper forms, we proposed conforming changes at § 422.66. We also proposed similar changes in § 422.66(b) to provide for a more efficient notice process, including eliminating the requirement for MA plans to send a copy of the individual's disenrollment request back to the individual.

Section 1860D–21(b) provides the Secretary with the authority to implement default enrollment rules at 1851(c)(3)(A)(ii) for the MA-PD program, which begins in 2006. This provision permits the establishment of procedures whereby an individual currently enrolled in a health plan offered by an MA organization at the time of his or her Initial Coverage Election Period is deemed to have elected an MA-PD plan offered by the organization if he or she does not elect to receive coverage other than through that organization. In our proposed rule, we discussed the requirement for individuals to make affirmative elections upon becoming entitled to Medicare as provided under § 422.66. Affirmative elections may ensure that individuals have the ability to remain with the organization that offers their health plan and protects beneficiary choice by requiring an individual to make an affirmative election. However, based upon comments received, we will revise the regulatory language to retain the ability to allow for default enrollment, as discussed in our responses below.

At § 422.66(e) we also proposed to add language that implemented new rules for continuing MA coverage for individuals enrolled in MA plans as of December 31, 2005. Under section 1860D–21(b)(2), individuals enrolled in an MA plan that, as of December 31, 2005, provides any prescription drug coverage would be deemed to be enrolled in an MA-PD plan offered by that same organization as of January 1, 2006. If an individual is enrolled with an MA organization that offers more than one MA plan that includes drug coverage, and is enrolled in one of those plans as of December 31, 2005, the individual would be deemed to have elected to remain enrolled in that plan on January 1, 2006 if it becomes an MA-PD plan on that date. An individual enrolled in an MA-PD plan on December 31 of a year would be deemed to elect to remain enrolled in that plan on January 1 of the following year (that is, the next day).

Comment: Several comments were received regarding the revisions to the disenrollment process described above. Several commenters supported the change in language allowing optional mechanisms for disenrollment elections. Several commenters also supported the elimination of the requirement that organizations return a copy of the disenrollment request to the individual.

Response: We received no opposing comments to these provisions and adopt these provisions as proposed.

Comment: One commenter recommended that CMS clarify that MA plan members who have selected prescription drug coverage as an optional supplemental benefit, and are receiving such benefits as of December 31, 2005, will be deemed to have enrolled in an MA-PD plan.

Response: Individuals who are enrolled in an MA that offers any prescription drug coverage, including coverage offered as an optional supplemental benefit, as of December 31, 2005, will be deemed to have enrolled into an MA-PD plan offered by that organization.

Comment: Several commenters stated that additional information is needed to implement the deemed enrollment provision for MA enrollees who do not make an affirmative election into an MA-PD plan. If the MA organization offers more than one MA-PD plan, it is unclear into which plan the individual will be deemed enrolled.

Response: We will provide further guidance to MA organizations on this issue, as we do at the end of each contract year through our plan ''cross-walk'' guidance. Under this guidance, the existing policy, under which the MA organization may designate the plan that is ''continuing'' into the next year, would apply to this situation.

Comment: Several commenters supported and opposed the implementation of default enrollment rules as discussed at section 1851(c)(3)(A)(ii) of the Act for the MA-PD program.

Several commenters support implementing the default enrollment provision and believe that it would simplify the enrollment process for beneficiaries. They believe that such a process could be coupled with advanced notice that would also give the member the opportunity to ''opt-out'' of the ''default'' enrollment. Other commenters stated that the MA organization should have the option of applying ''default'' enrollment in certain situations, for example, with its employer group members. Commenters stated that if the MA organization chose to implement the option, each beneficiary would also be provided the option to decline prior to enrollment.

Several commenters opposed default enrollment and supported requiring an affirmative election by the beneficiary. These commenters believe that a default enrollment process would be difficult and confusing for beneficiaries. They do not believe that beneficiaries should be ''defaulted'' into the same health plan that provided pre-Medicare coverage. Many commenters recommended that MA plans obtain accurate information from prospective enrollees through the affirmative election process, and, without such a process, MA plans may not have up-to-date information about the beneficiary. Finally, there are those who neither support nor oppose the default enrollment process, but instead suggest that we modify the regulatory language to allow us to implement such a provision in the future.

Response: The commenters raise several good points regarding the implications of default enrollment. The intent of default enrollment is not to reduce beneficiary choice, but rather to ensure continuity of care. At this time, we will retain the flexibility to implement this provision through future instructions and guidance to MA organizations. We do not envision mandating that organizations use default procedures, but instead would give organizations the option of implementing such a process for its enrollees. Any such process would require that advance notice be provided to an individual, and that affected individuals have the ability to ''opt out'' of such an enrollment. We believe that we can achieve the same flexibility provided with respect to default enrollment that exists at § 422.60(b)(3)(c), which allows for elections using alternative mechanisms. Thus, we have revised proposed § 422.66(d)(5) to allow us to offer default enrollment as an option in the future, in a form and manner specified by CMS.

Comment: One commenter suggested that, rather than prohibit default enrollment, CMS should develop a method to allow enrollees in an MA plan with or without prescription drug coverage, who do not make an election by December 31, 2005 to remain with their current MA organization in an MA-PD plan. Another commenter assumed that CMS intends that

individuals enrolled in an MA plan without drugs who do not make a plan election into an MA-PD plan for January 1, 2006 will be defaulted into original Medicare.

Response: The statute provides for an individual in an MA plan with drug coverage on December 31, 2005, to be deemed enrolled in an MA-PD plan as of January 1, 2006. However, the statute does not allow an individual who is in an MA-only plan that continues in January 2006 to be deemed to make an MA-PD election. The statute is clear that those individuals will remain in an MA-only plan unless those individuals take an action to elect an MA-PD plan. Pursuant to section 1861(b)(3) of the Act, individuals may be deemed to have elected Original Medicare only if the MA-only plan in which they are enrolled is terminated. Thus, in general, we would not be defaulting MA plan members into original Medicare.

Comment: Several commenters recommended that CMS coordinate the enrollment of full benefit dual eligible individuals. A few commenters suggested that CMS apply the default enrollment provisions for dual eligible individuals who have not otherwise elected an MA-PD or PDP into an MA-PD that is administered by an MA organization that operates the Medicaid managed care organization in which the individual is enrolled. Another commenter supports the inclusion of sufficient flexibility in our regulations to enable us to develop solutions that best meet the needs of beneficiaries and are coordinated with the MA organizations.

Response: As discussed above, we will consider requests to adopt such default enrollment processes only with respect to a newly-Medicare eligible individual who is enrolled with an organization as a Medicaid enrollee at the time he or she becomes eligible for Medicare. In such a case, the individual could be considered by default to have elected that organization for purposes of Medicare benefits upon the individual's becoming eligible for Medicare. The default authority in 1851(c)(3)(A)(ii) of the Act would not, however, permit an individual to be considered by default to have elected an MA-PD plan if he or she was already a Medicare beneficiary and had elected not to receive Medicare benefits through an MA organization. Therefore, we decline to enroll by default existing full-benefit dual eligible individuals into an MA-PD if they are currently in Original Medicare and only receive Medicaid benefits through that organization. We will continue to evaluate alternatives to facilitate enrollment in Part D for this population.

Comment: Several commenters suggest that each MA plan that becomes an MA-PD plan send a notice to their enrollees that the enrollees will be automatically enrolled in the MA-PD plan unless they choose to change plans. Further, it is suggested that CMS create a model letter for this purpose.

Response: MA plans are required to send out notices in October of every year to their members, also known as the annual notice of change (ANOC). We will revise the language in the ANOC for MA plans to provide to members in October 2005 in order to reflect this policy.

Comment: Several commenters recommend that CMS establish a default enrollment process for AI/AN if a certain plan meets AI/AN needs.

Response: CMS recognizes the need to coordinate between the I/T/U programs. Given the new regulatory language at § 422.66(d)(5), which allows us to offer default enrollment as an option to MA organizations, we could consider requests by MA organizations to offer default enrollment to the AI/AN population in the case of newly-Medicare eligible individuals who are enrolled in a non-Medicare product of an MA organization at the time they become Medicare eligible.

8. Effective Dates of Coverage and Change of Coverage (§ 422.68)

To coordinate the effective date of elections with the 2006 special annual coordinated election period (to be held November 15, 2005 through May 15, 2006), section 1851(f)(3) of the Act was amended by the MMA to provide that the effective date of elections for the annual coordinated election period does not apply during the 2006 special annual election period, when enrollment will be effective on the first day of the month following the month in which an election is made. We proposed to revise § 422.68(b) to provide for this coordination and to make the effective date of elections in the annual coordinated election period for 2006 that are made in 2006 (that is, from January 1 through May 15, 2006) the first day of the calendar month following the month in which the election is made. We received no comments on this section and adopted the proposed language as final.

9. Disenrollment by the MA Organization (§ 422.74)

Under the current regulations at § 422.74(d)(1), MA plans are required to provide, at a minimum, a 90-day grace period before disenrolling individuals for failure to pay plan premiums. Thus, MA plans must maintain enrollment for individuals who do not pay their premiums for more than 90 days.

We proposed to provide greater flexibility to MA organizations by replacing the 90-day grace period in § 422.74(d)(1) with the long-standing approach under § 417.460(c)(1), which governs disenrollment from HMOs with cost contracts under section 1876. Under this proposal, we would instead specify that a disenrollment could be effectuated no sooner than 1 month from the date the premium was due.

We have also proposed revisions to the regulations at § 422.74(d)(2) regarding disenrollment of an individual for disruptive behavior. Our goal was to create a more objective definition that is based upon an individual's behavior, rather than upon the application of such subjective terms as ''unruly,'' ''abusive,'' and ''uncooperative.'' We also recognized that, in revising this definition, we needed to strike a balance that would ensure all individuals are afforded protection from unwarranted disenrollment actions while protecting the health and safety of all those concerned including the individual. The best solution is to create a definition of disruptive behavior based on objective criteria, ensure that MA organizations make serious efforts to resolve problems with beneficiaries who are disruptive, and to require MA organizations to make ''reasonable accommodations'' for vulnerable beneficiaries, including those with serious mental illness. Furthermore, we will ensure that CMS staff with appropriate clinical or medical expertise will be involved in the review of the MA organization's request before we make a final decision. We will work with organizations that ask to disenroll these individuals on a case-by-case basis to ensure that they are not left without Part D coverage. We will also remove the provision for an expedited disenrollment we had proposed and ensure that MA organizations provide due process before disenrolling an individual.

Comment: Several commenters supported the proposed revisions to § 422.74(d)(1) regarding procedures for involuntary disenrollment for failure to pay plan premiums. Other commenters opposed these revisions as ''overly broad'' and felt the lack of a specific time frame could be a disadvantage for plan enrollees.

Response: Our proposed changes to this section were intended to provide flexibility for MA organizations in addressing the issue of plan members who fail to pay required plan premiums. Under the existing rule, MA organizations were obligated to provide

all plan benefits to an individual who has failed to pay required plan premiums for a full 90-day period. This period often exceeded 90 days because the notice requirements we imposed fell after the end of the 90-day period, but must still be met by the organization before the individual could be disenrolled. Our experience and feedback from MA organizations indicated that these requirements, while intended to protect beneficiaries enrolled in MA plans, may instead artificially inflate plan premiums because MA organizations are required to continue to provide services to these beneficiaries for up to 4 months, even though they have not paid the required plan premiums.

After reviewing the comments and feedback we received on the proposed rule, we determined that it would be prudent to include a minimum grace period in the revisions we are making to address this issue. Therefore, we have revised this section to include a 1-month grace period during which an enrollee who has failed to pay required premiums must be notified of the impending disenrollment action and afforded the opportunity to pay past due premiums in full or under payment terms agreed upon by the beneficiary and the MA organization, as the organization allows. This period will begin on the first day of the month for which the premium was unpaid. For example, the grace period for a March premium will begin March 1st and, if the organization does not receive payment by March 31st, the individual will be disenrolled effective April 1st. We will provide specific time frames for required notices in additional guidance to ensure beneficiaries have adequate time to respond before disenrollment takes effect. Since we are establishing this 1-month grace period as a minimum requirement, MA organizations still have the option of lengthening this period.

Comment: Three commenters suggested that CMS allow MA organizations to ''move'' or ''default'' plan members who have failed to pay premiums in one MA plan to another MA plan in the same organization that is offered at a lower or no premium, so that beneficiaries do not suffer an interruption in MA benefits.

Response: This suggestion is inconsistent with the statute. Section 1851(g)(3)(C)(i) of the Act clearly provides that individuals who are disenrolled from an MA plan for failing to pay premiums are deemed to have elected original Medicare.

Comment: Several commenters submitted comments on the proposed revisions to § 422.74(d)(2) concerning the disenrollment of individuals who exhibit disruptive behavior. Some commenters supported the proposed approach, noting that the inability to effectuate such disenrollment has been an ongoing issue for MA plans. Other commenters recommended that CMS further clarify the meaning of the term ''decision-making capacity,'' and one commenter in particular suggested that CMS adopt a definition based on legal conservatorship.

Several commenters, on the other hand, expressed concern that the expanded definition of disruptive behavior does not adequately protect individuals whose behavior is induced by a mental illness, a medical condition, or certain prescribed drugs. These commenters were concerned about the loss of protection for individuals with diminished mental capacity. Several commenters expressed concern that the definition of disruptive behavior was overly subjective, particularly the use of terms such as ''unruly'', ''abusive'' and ''uncooperative.''

Response: In the final rule, we aim to strike a balance between allowing MA organizations to disenroll individuals who exhibit disruptive behavior and creating adequate protections for individuals who face involuntary disenrollment from a plan. Since the statute (at section 1851(g)(3)(B)(ii) of the Act) permits an MA organization to disenroll an individual who engages in disruptive behavior, we must establish a process for allowing these types of disenrollments. At the same time, we recognize that such a process must include adequate safeguards for individuals whose disruptive behavior is due to mental illness or a medical condition, especially in light of the crucial importance of prescription drug therapy for these individuals. It is also important to recognize that some prescription drug therapies may well induce such behavior.

Therefore, we are revising our proposed definition of disruptive behavior in § 422.74(d)(2)(i) of the final rule to focus on the behavior that substantially impairs the plan's ability to arrange or provide care for the individual or other plan members. We recognized that terms such as ''unruly'', ''abusive'', ''uncooperative'', as well as an assessment of the enrollee's ''decision-making capacity'' are subjective terms that make reviewing and approving such requests difficult.

In addition, we agree with commenters that arranging or providing care for individuals with mental illness, cognitive impairments such as Alzheimer's disease or other dementias, and medical conditions and treatments that may cause disruptive behavior warrants special consideration. Therefore, we are revising § 422.74(d)(2)(v) to also require MA organizations to provide a ''reasonable accommodation'' to individuals in such exceptional circumstances that we deem necessary. Such accommodations could include providing the individual with a SEP to choose another plan, or requiring the plan to maintain the individual's enrollment until the end of the year, when the individual could choose another plan. We will determine the type of accommodation necessary after a case-by-case review of the needs of all parties involved. This review will be conducted as part of CMS' existing review and approval process required under § 422.74(d)(2)(v). The regulations (at § 422.74(d)(2)(iii)), will continue to require that that before an organization can request to disenroll a member for disruptive behavior, it first must make a serious effort to resolve the problems presented by the individual's behavior, including the use of the organization's grievance procedures. The MA organization must then document the individual's behavior, its own efforts to resolve the problem, and the use or attempted use of its internal grievance procedures.

We believe that these policies will achieve the twin goals of permitting involuntary disenrollment when appropriate due to an individual's disruptive behavior, while also establishing necessary protections for beneficiaries in certain circumstances.

Comment: One commenter stated that the proposed rule denies protection to individuals who comply with medical advice by trying an on-formulary drug instead of the drug originally prescribed or by seeing their primary care physician rather than a specialist and subsequently experience an adverse reaction that triggered the disruptive behavior. Another commenter believed that, in cases where an individual is unstable, disruptive behavior could be related to unsuccessful attempts to find the proper medication or due to a plan's step therapy requirement.

Response: We agree with the commenter, and clarify in the final rule at § 422.74(d)(2)(i) that an individual's behavior cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or non-compliance) with medical advice or treatment. For example, an individual who chooses to disregard medical advice, such as not heeding the advice to stop using tobacco products, is not exhibiting disruptive behavior.

Comment: Several commenters supported the flexibility afforded by allowing MA organizations to limit re-enrollment for individuals who are disenrolled for disruptive behavior. One commenter however, opposed the provision on the grounds that prohibiting an individual from re-enrolling in a plan for a specified period could cause undue harm.

Response: In the proposed rule, we specified that, under § 422.74(d)(2)(vi), an MA organization had the option to decline future enrollment by an individual who had been disenrolled for disruptive behavior. Although a prohibition on re-enrollment would still be possible under this final rule, we are not leaving this matter to the discretion of the MA organization. Instead, we are providing that an organization must request any future conditions on re-enrollment with their disenrollment request. We will then review each request on a case-by-case basis, consistent with § 422.75(d)(2)(v).

Comment: Several commenters submitted mix comments on the proposed expedited disenrollment process. Some commenters felt that the expedited process undermines the standards and requirements that are in place to protect beneficiaries, while other commenters supported the greater flexibility in cases where such behavior poses an immediate threat of health or safety to others.

Response: We believe that all individuals facing involuntary disenrollment for disruptive behavior must have sufficient opportunity, as provided by the notice requirements, to change their behavior and/or grieve the MA organization's decision to request involuntary disenrollment from CMS. Although we recognize that threatening behavior is a real, if rare, problem, we do not believe that expedited disenrollment is the appropriate remedy. Rather, we would recommend either a medical approach or, if warranted, a law enforcement solution for truly threatening situations. Therefore we are removing this provision from the final regulation.

Comment: One commenter recommended that the process for disenrolling AI/AN from MA organizations that contract with the HIs, an Indian Tribe or Tribal organization, or an I/T/U include direct communication with the I/T/U entity with adequate documentation of and steps taken to resolve the problem as well as adequate timelines.

Response: MA organizations have the statutory authority at Section 1851(g)(3)(B)(ii) of the Act to disenroll an individual from a plan if the individual has engaged in disruptive behavior and are required to provide sufficient notice to the individual in accordance with the timeframes specified in manual instructions. Because an individual is an enrollee of MA plan, the individual's relationship with the plan is primary. The MA organization, not the health care provider, is obligated to communicate with the individual or the individual's authorized representative as defined under State law. We believe that a provision requiring consultation with I/T/U entities would not be within the scope of the authority in section 1851(g)(3)(B)(ii) of the Act.

Comment: Several commenters submitted comments on whether nonpayment of cost-sharing should constitute disruptive behavior. Many commenters supported this interpretation, noting the negative impact that non-payment of cost sharing has on an MA organization's ability to provide or arrange for services for the individual. These commenters generally recommended that CMS establish a clear and uniform process for plans to follow. Another commenter suggested that such disenrollments be permitted only for certain types of services that represent significant portions of a member's overall cost-sharing responsibility. One commenter suggested that CMS establish a threshold of $2,000 of outstanding cost sharing, including two or more failures to pay cost sharing.

Other commenters, however, opposed including nonpayment of cost sharing as a basis for disenrollment. Some commenters stated that this policy would be discriminatory, placing very ill patients with high medical costs at a severe disadvantage and leading plans to cherry pick healthier patients. Another commented that CMS needed to take into account an individual who experiences a change in circumstances that may affect his or her ability to pay cost sharing.

Several commenters raised questions about how CMS would treat low-income individuals. Some commenters were supportive of a low-income exception for such disenrollments, while other commenters noted the administrative difficulty in applying the exception, since plans do not have mechanisms in place to determine beneficiary income levels or intervene on behalf on the enrollee with the provider.

Response: We appreciate the feedback provided on whether the nonpayment of cost-sharing should constitute disruptive behavior. We continue to believe that disenrollment for failure to pay cost-sharing may be disruptive under certain circumstances. At the same time, we believe that all the protections, such as notice requirements and case-by-case CMS review, should apply in these situations. Thus, we are not ruling out such disenrollment in certain cases, and we will consider these comments in developing guidance for the disruptive behavior provisions.

Comment: Other commenters recommended that CMS institute specific protections for individuals facing involuntary disenrollment, including an appeals process.

Response: Although we agree with the commenter that CMS should establish a procedure for beneficiaries to dispute enrollment denials, we do not believe that a formal appeals process is necessary. Instead, we intend to address beneficiary complaints regarding enrollment in a similar manner as we have done under the MA program. Under the MA program, individuals are advised through their notice of denial of enrollment that if they disagree with the decision, they may contact the MA organization. We provide assistance to MA organizations to handle beneficiary inquiries and complaints regarding enrollment through staff assigned to each MA organization. We envision a similar process being established under the PDP program.

10. Approval of Marketing Materials and Election Forms (§ 422.80)

We proposed to codify at § 422.80(a)(3) the ''file-and- use'' program already in place. This provision recognizes an MA organization's consistent compliance with marketing guidelines by providing for streamlined approval of marketing materials submitted by that organization. Organizations that have demonstrated to us that they continually meet a specified standard of performance are allowed to have certain types of marketing materials deemed to be approved by us if they are not disapproved within 5 days of submission to us for prior approval. In addition, the time frames under § 422.80(e)(5) were made consistent with those provided under § 422.80(a)(1). Lastly, we proposed clarifying changes to the discussion of prohibited marketing activities for MA plans.

Comment: Several commenters submitted comments regarding the ''file-and-use'' provisions. Many commenters supported incorporating this provision into the regulation and suggested that CMS consider even further flexibility as plans transition to the new Part D benefit in 2006. One commenter in support of the provision did note,

however, that small plans are more affected by the process since these plans submit fewer materials and a smaller number of errors impact their ability to participate. This commenter recommended that CMS consider this issue with regard to smaller organizations.

Many commenters opposed this provision and believe that the provision weakens the marketing rules and that MA organizations have not demonstrated that they deserve such a process. Given the new upcoming options and diversity of plan benefits, many believe stronger marketing requirements are needed. They were concerned that this process would perpetuate the perceived inconsistency in the marketing material approval process within CMS. Others were concerned that the short timeframe for CMS to review and approve would result in essentially CMS ''rubber stamping'' materials. One commenter suggested that plans present all marketing materials at least 30 days before proposed distribution.

Response: The ''file-and-use'' program streamlines the marketing review process while assuring that beneficiaries marketing materials are of a high quality and clarity. While we understand the concerns raised by smaller organizations, this program was developed to be available to those MA organizations that demonstrate they can consistently achieve a high level of performance with respect to producing accurate and clear marketing materials over a sustained period of time, regardless of the size of the organization.

It is also important to note that there are marketing materials that are not ''eligible'' to be considered under this program. Any marketing materials that describe benefits, cost sharing or plan rules are not eligible for the file-and-use status.

We retain the right to rescind file-and-use status from an MA organization if the organization fails to meet the rigid standards of compliance laid out in the file-and-use guidelines. We do not believe that the beneficiary is at greater risk as a result of the file-and-use program, but may actually benefit from being able to receive certain educational and outreach materials in a timely manner.

In response to the commenters seeking greater marketing flexibility, we also are providing in § 422.80(a)(2) of this final rule for organizations that are not currently eligible for the file-and-use method to use this method with respect to materials that pose the lowest risk of confusing or misleading beneficiaries. With respect to these materials, any MA organization may follow the file-and-use procedures if it certifies that it followed all applicable marketing guidelines, or that it used, without modification, model language specified by CMS.

Comment: One commenter expressed disappointment that CMS retained the prohibition on door-to-door solicitation. The commenter did not believe that retaining this ban was justified and the ban is outdated, since it was added 20 years ago when this activity was more difficult to monitor.

Response: We understand the need by MA plans to have additional flexibility in developing their marketing strategies. The purpose of this prohibition was to provide beneficiaries with appropriate beneficiary protections. Some individuals may not welcome unsolicited visits or may not be prepared to discuss their options, yet may feel pressured to do so. Given the complexity of the new programs and the upcoming limitations when individuals are able to make choices in their coverage, as well as increased competition, we believe that prohibition of door-to-door solicitation remains to be in the best interest of the beneficiary.

Comment: One commenter did not believe the regulatory language addressed the CMS timeline for review when materials are submitted after CMS' initial 45-day review period. Current guidance allows for an additional 45-day review period for CMS to review a document after it has been resubmitted. The commenter recommends instituting a 10-day review period for resubmitted materials.

Response: We appreciates this feedback and will take this under further consideration.

Comment: One commenter supported the extension of file and use to SNPs.

Response: Since SNPs are MA plans, all MA rules will apply to SNPs unless otherwise provided by us. Therefore, SNPs will qualify to participate in the file-and-use program provided the necessary requirements are met.

Comment: Several comments requested clarification from CMS that outreach workers employed by tribal and IHS facilities will continue to be encouraged to provide information about Medicare alternatives to the AI/AN elderly and this outreach would not fall under the prohibition against door-to-door marketing.

Response: We appreciate these concerns and will work with Tribal and IHS organizations to find solutions that both meet the needs of the AI/AN population and satisfy the requirements of the MA program.

Subpart C—Benefits and Beneficiary Protections

In the areas of benefits and beneficiary protections, we proposed regulatory reforms based on our program experience, as well as provisions implementing new requirements in the MMA. We tried to integrate new requirements in the MMA with existing regulations, while at the same time removing impediments in the existing rules that have tended to stifle innovation by M+C organizations. We believe our proposals addressed the paramount task of ensuring that beneficiaries continue to be fully informed and protected in their receipt of essential health care services under the Medicare program.

The regulatory reforms we proposed included: (1) New beneficiary protections related to receipt of covered health care services from contracted providers; (2) revisions to the rules limiting beneficiary cost sharing related to emergency episodes; (3) new rules affording additional protections to MA regional plans enrollees; (4) incentives for MA organizations to offer MA regional plans that would serve all beneficiaries in all areas; (5) the elimination of administratively burdensome requirements on MA organizations that are duplicative of other activities already conducted by us; and (6) the elimination of a number of unnecessary, duplicative, or overly burdensome access to care provisions.

We received hundreds of comments on subpart C from approximately 150 commenters in response to our August 3, 2004 proposed rule. Below we provide a brief summary of the proposed provisions and respond to public comments. (For a broader discussion of the proposed provisions, please refer to our proposed rule.)

1. General Requirements (§ 422.100)

MA MSAs are ''high deductible'' MA plans and are defined at section 1859(b)(3) of the Act. Until the deductible is met, the MA MSA enrollee is generally responsible for payment for all covered services. Once the MA MSA deductible is met, the MA organization offering the MSA plan is responsible for payment of 100 percent of the expenses related to covered services. In both cases, whether it is the enrollee or the MA organization offering the MSA that assumes responsibility for payment, providers and other entities are required to accept the amount that FFS would have paid (including permitted beneficiary cost sharing) as payment in full.

Section 233(c) of the MMA amended the Act to include enrollees in MSA plans offered by an MA organization with MA coordinated care plans as having protection from balance billing by noncontracting providers. In our proposed rule, we stated that for covered services provided to an MA MSA plan enrollee, a physician or other entity that does not have a contract with an MA MSA plan must now accept as payment in full the amount they could have collected had the individual not been enrolled in the MA MSA plan.

In the proposed rule, we specified that:

- The proposed provision applied to physicians and other entities. (Note that ''providers of services,'' as defined in section 1861(u) of the Act, are similarly restricted from balance billing MA MSA enrollees under section 1866(a)(1)(O) of the Act.)
- In cases in which Medicare participating physicians do not have an agreement with an MA organization in place governing the amount of payment, they must accept the amount they would have received under FFS Medicare as payment in full (including permitted beneficiary cost sharing).
- In cases in which Medicare non-participating physicians do not have an agreement with an MA organization in place governing the amount of payment, they also must accept the amount they would have received under FFS Medicare as payment in full (including permitted beneficiary cost sharing). (Medicare non-participating physicians are permitted to accept assignment on a case by case basis. For non-assigned claims, Medicare non-participating physicians are subject to the ''limiting charge.'')

These FFS charge limits have always applied to the charges that providers and other entities could impose when providing covered services to enrollees in MA coordinated care plans and private FFS plans, when there is no agreement with an MA organization in place governing the payment amount. The MMA added the same protections for MA MSA plan enrollees and we proposed conforming changes in subpart C and at § 422.214.

In addition to the new MA MSA ''charge'' protections, we proposed amending § 422.100 to provide for other changes for purposes of administrative simplification and clarification:

- We deleted the parenthetical ''(other than an M+C MSA plan)'' from the first sentence of § 422.100(b)(2) and replaced it with ''(and an MA MSA plan, after the annual deductible in § 422.103(d) has been met).''
- We modified the reference to ''additional benefits'' in § 422.100(c), as those benefits are no longer applicable to MA plans offered on or after January 1, 2006.
- We removed § 422.100(e) because it was duplicative, and we made the necessary redesignation changes.
- We removed the reference to operational policy letters in § 422.100(f).
- We added ''or encourage disenrollment'' to § 422.100(f)(2), after ''discourage enrollment,'' as one of the prohibitions on the design of benefit packages.

Comment: One commenter recommended that CMS clarify whether the proposed provider rules will now require providers accepting Medicare assignment to limit their charges to 100 percent of Medicare allowable costs for members of an MA MSA plan.

Response: The protections from physician balance billing that are described in section 1848(g) of the Act apply to all Medicare beneficiaries, including those enrolled in any type of MA plan. This includes enrollees of MA MSA plans. This means that for a Medicare participating physician, for instance, the billed charges cannot exceed the Medicare participating fee schedule amount for a Medicare-covered service. For Medicare non-participating physicians that do not accept Medicare assignment in a specific case, the charges cannot exceed 115 percent of the Medicare non-participating fee schedule amount for a Medicare-covered service.

Similarly, for providers of services, as defined at section 1861(u) of the Act, the participation agreement with Medicare requires the provider to accept the FFS payment amount as payment in full for services provided to Medicare beneficiaries, including those enrolled in any type of MA plan (see section 1866(a)(1)(O) of the Act).

Comment: A few commenters stated that CMS should clarify regulatory language to require MA plans to include statutory add-on payments under FFS Medicare to the noncontracting provider payments they are required to make under § 422.100(b)(2). Some commenters specifically mentioned such add-on payments (for example, DSH, outliers, GME, and IME payments) as part of the total payment amount that the provider would have received under original Medicare, and also including the balance billing permitted under Part A and Part B. Some commenters specifically mentioned the ''special'' hospital category payments for sole community hospitals, Medicare dependent hospitals, and critical access hospitals. Another commenter recommended that CMS clarify this ''new'' provision and asked why CMS made a distinction between providers of services, physicians, and other entities.

Response: This section of the regulation has been in place since the original M+C interim final regulation was published on June 26, 1998. In our August3, 2004 proposed rule, we simply added the billing protections for MA MSAs based on the amendment to section 1852(k)(1) of the Act provided in section 233(c) of the MMA. Otherwise, the distinction between providers of services, physicians, and other entities is statutory and based on the fact that noncontracting providers of services are required to accept Medicare payment rates from MA organizations based on section 1866(a)(1)(O) of the Act, while noncontracting physicians and other entities are required to accept Medicare payment rates from MA organizations based on section 1852(k) of the Act.

Additionally, we believe our regulation already requires FFS ''add-on'' payments (including those to both providers of services, physicians, and other entities), because they are generally considered part of the FFS payment that an MA organization must make to noncontracting providers, physicians, and other entities for covered services. However, an MA organization is not required to include IME and GME payments to noncontracting hospital providers to the extent the hospital providers receive IME and GME payments for MA plan enrollees directly from the fiscal intermediary (see § 422.214(b)). The fiscal intermediary's direct payments to hospitals of IME and GME amounts for MA enrollees are based on sections 1886(d)(11) and 1886(h)(3)(D) of the Act, respectively. Finally, § 422.100(b)(2) references the balance billing permitted under Part A and Part B of Medicare, which represents the maximum required payment due from the MA organization, less applicable MA enrollee cost sharing.

Comment: Several commenters recommended that CMS adopt blanket policies that would require MA and MA-PD plans to pay I/T/U facilities that serve AI/AN in a special manner. Among other proposals, these commenters suggested that CMS require MA organizations to waive cost sharing for AI/AN and that CMS require MA organizations to pay the ''full IHS Medicaid'' rate to I/T/U facilities, or that we establish other special payment methodologies related to MA reimbursement to I/T/U facilities.

Response: We are implementing the MMA statute through this rulemaking. The MMA did not provide for special

treatment under the MA program for AI/AN beneficiaries. For this reason, we do not see a statutory basis to apply different rules to a subset of Medicare beneficiaries, such as AI/AN populations. In general, however, we believe that MA regional plans will create new choices for beneficiaries, including AI/AN populations, and that access to MA plans will be improved. Similarly, because MA regional plans must reimburse for all covered benefits in and out of network, IHS facilities may receive reimbursement for out-of-network care provided to an MA regional plan AI/AN enrollee that they may otherwise not have been entitled to under the M+C program. However, the rate of reimbursement actually paid to an I/T/U facility for an AI/AN enrollee will vary based on the type of plan, type of service, and the plan-required level of enrollee cost sharing. For instance, for emergency department services, an MA plan enrollee's cost sharing would be limited to $50 and the MA organization (regardless of plan type) would be responsible for payment of the rest of the billed amount, up to the full Medicare rate. Similarly, an I/T/U, for an AI/AN MA PPO enrollee, could expect MA organization reimbursement for routine covered services provided to such an enrollee, although the amount of reimbursement directly provided by the MA organization would be limited to the full Medicare rate, less applicable enrollee cost sharing.

Finally, a broad waiver of beneficiary cost sharing of the type the commenters requested would not be permitted under provisions designed to protect the Medicare program from fraud and abuse. However, existing statutory and regulatory provisions may allow for the waiver of cost sharing in certain cases.

Comment: One commenter suggested that CMS require pre-approval before permitting an MA organization to adopt a local coverage determination for an MA regional plan under § 422.101(b)(4). This commenter also suggested that CMS require public comment on the choice of local coverage determination by an MA organization for either a local MA plan under § 422.101(b)(3) or an MA regional plan under § 422.101(b)(4).

Response: We do not interpret the statute at section 1858(g) to require CMS pre-approval of the local coverage determination an MA organization sponsoring an MA regional plan selects to apply to all enrollees of the MA regional plan. The statutory provision also does not include a requirement for public notice, but rather allows the MA organization to elect to have a local coverage determination apply to all enrollees of the MA regional plan. The MA organization must comply with applicable statutory and regulatory requirements in making such election, including the requirement, discussed below, that all local coverage determinations of the contractor selected by the MA organization be applied to the MA regional plan's enrollees.

Comment: One commenter recommended that CMS clarify whether or not MA organizations are required to provide all Medicare covered benefits in the MA plans they offer to Medicare beneficiaries. This commenter had specific concerns related to outpatient occupational therapy and whether a home visit by an occupational therapist to evaluate for safety and function post stroke, for instance, is a Medicare benefit that MA organizations have to offer enrollees of MA plans.

Response: Occupational therapy is a Medicare-covered outpatient benefit under section 1861(s)(2)(D) of the Act. Under section 1852(a) of the Act, an MA organization must provide all benefits under the original Medicare FFS program option. Therefore, MA plans must cover all services covered under Medicare Parts A and B.

Comment: One commenter stated that CMS is directed to ''replace'' Medicare carriers and fiscal intermediaries with Medicare Administrative Contractors (MACs) by section 911 of the MMA. The commenter asked what impact such a ''replacement'' would have on MA plans, which will likely cover larger areas than current FFS contractors.

Response: Transition from Medicare carrier and fiscal intermediary contractors to MACs is to occur between 2005 and 2011. We have modified the regulatory language in § 422.101(b)(3) to account for the transition to MACs by removing specific reference to Medicare carriers and fiscal intermediaries. We expect the impact this ''replacement'' will have on MA plans related to this section of the regulation will be insignificant. To the extent MACs will cover larger geographic areas than current FFS contractors, and to the extent MACs will apply local coverage determinations across those larger geographic areas, the opportunity for MA organizations to elect to apply uniform coverage rules in § 422.101(b)(3) or (b)(4) will also be likely to decline.

2. Requirements Relating to Basic Benefits (§ 422.101)

Section 221 of the MMA added a new section 1858(g) to the Act that provided for a special rule related to the way local coverage determinations (for example, ''local medical review policies,'' or ''LMRPs'') will be applied by MA regional plans. MA regional plans are permitted to elect any one of the local coverage determinations that applies to original Medicare FFS beneficiaries in any part of an MA region to apply to its enrollees in all parts of the MA region. Based on our interpretation of the statute, we proposed at § 422.101(b)(4) that an MA regional plan, if it chooses this option, must elect a single FFS contractor's local coverage determination that it will apply to all members of an MA regional plan. The MA organization would not be permitted to select local coverage policies from more than one FFS contractor that it would apply to all members of an MA regional plan.

Comment: A number of commenters recommended that CMS clarify the proposed language in § 422.101(b)(4). Some commenters recommended that CMS ensure that the understanding comported with ''the common understanding'' that regional plans can select coverage determinations issued by different intermediaries and carriers within the region. Some commenters also suggested that CMS extend the same flexibility to local MA plans. Others suggested that CMS allow MA organizations that sponsored multiple local MA plans to apply one FFS contractor's coverage determinations to its entire MA population.

Response: We disagree with the commenters who have requested the ability to select coverage determinations of multiple intermediaries or carriers within a region. As we stated in the proposed rule, our interpretation of section 1858(g) of the Act is that an MA regional plan exercising this option must elect a single FFS contractor group of local coverage determinations or policies that it will apply to all members of an MA regional plan and that an MA regional plan may not select local coverage policies from more than one FFS contractor. We are adopting this interpretation in the final rule.

The reason for this interpretation is two-fold. First, to the extent that local carrier and intermediary medical directors apply uniform experience to a broad range of coverage policies, it would be inappropriate to allow selection of a specific coverage policy from one carrier medical director and a different coverage policy on a different medical item or service from another carrier medical director. Second, to the extent that local carrier and intermediary coverage policies are generally statements of non-coverage, restricted coverage, or conditions for receipt of a specific health care item or service, it would be inappropriate to

allow an MA regional plan to adopt coverage policies issued by more than one carrier or intermediary. This interpretation would permit MA regional plans to deny coverage for what would otherwise be Medicare-covered services at a frequency and under conditions that no individual FFS beneficiary would ever face. For example, carrier ''X'' might have decided that Medicare coverage was not available for ''A'' in a local coverage area. Carrier ''Y'' might have decided that Medicare coverage was not available for ''B'' in a local area. In such a situation, were we to permit an MA regional plan to adopt the coverage policies of both carrier X and carrier Y, an MA plan enrollee of that regional plan would not have coverage for either A or B, while original FFS enrollees residing in carrier X's service area would have coverage for B, and those residing in carrier Y's service area would have coverage for A. Therefore, to emphasize these points and to correct the apparently common misunderstanding mentioned in the comment, we are modifying the language in § 422.101(b)(4). Further, the statutory language will not permit an extension to local MA plans of the requirement we are codifying in regulation at § 422.101(b)(4). Local MA plans whose service areas encompass more than one local coverage policy area will continue to be required to follow rules previously established for them in § 422.101(b)(3) based on statutory authority at section 1852(a)(2)(C) of the Act.

Finally, we respond to the commenters that asked whether an MA organization could apply a single FFS contractor's coverage determinations to its entire MA population and across local MA plans. Such a policy would not be in accord with the statute, which is specific as to both local and MA regional plans. The selection of a uniform coverage determination policy for both MA local and regional plans is available only at the plan level.

Comment: A commenter recommended that CMS revise the regulation at § 422.101(b)(4) in order to permit MA organizations that offer MA regional plans in more than one MA region to apply local coverage policies across regional boundaries.

Response: We are interpreting section 1858(g) of the Act as generally preventing such an interpretation or revision to the regulation. The statute specifically allows MA regional plans to apply coverage policies only from 'any part of such region.'' It would only be where one FFS contractor had a uniform coverage policy that straddled two regions, and where an MA organization offered MA regional plans in both of those regions, that such a result would be possible.

Comment: A commenter recommended that CMS allow an MA organization offering multiple local MA plans to apply the rule in § 422.101(b)(3) across MA local plans, or if local MA plans could adopt the new rule in § 422.101(b)(4) related to MA regional plans.

Response: The specific language at section 1851(a)(2)(C) of the Act is clear in not permitting such an interpretation or revision to the regulation. The statute specifically allows an MA organization sponsoring a local MA plan to apply the coverage determination most beneficial to enrollees from the service area of that local MA plan to all enrollees of that local MA plan, and subjects that to pre-CMS review before implementation.

Comment: A number of commenters pointed out the difficulty noncontracting providers will have ascertaining the local coverage policy that will apply to a specific MA regional plan enrollee. Some commenters suggested that CMS require MA regional plans to notify both enrollees and potential noncontracting providers of the LMRP that will apply to specific MA regional plan enrollees. Others stated that providers are most familiar with LMRPs that apply in the area in which they primarily practice medicine or provide services and that it will be difficult, if not impossible, to know whether a specific service will be covered for a specific MA regional plan enrollee when LMRPs are applied from different, and possibly remote, geographic areas. Some commenters pointed out the potential impact this would have on MA regional plan enrollees who could incur financial liability for services that are otherwise Medicare-covered in the geographic location in which they are provided. Many commenters stated that the problems related to knowing what LMRP applies to a specific MA regional plan enrollee are compounded by the fact that MA regional plan enrollees, as MA PPO enrollees, have the right to access all covered benefits (albeit at potentially higher cost sharing) from out-of-network providers.

Response: We have added a new paragraph to the regulation at § 422.101(b)(5) that will require MA organizations that elect to apply local coverage policies uniformly across a local MA plan's service area, or across an MA regional plan's service area, to inform enrollees and potential providers, including through the Internet, of the applicable local coverage policy that applies to the MA plan enrollees. This means that MA organizations choosing to avail themselves of the option of applying uniform LMRPs to a local or regional MA plan must create a web site upon which to post links to or copies of the applicable LMRPs. We believe that this requirement will not create a significant burden on MA organizations and will provide convenient access for both providers and enrollees to such information. We are also making a conforming change to § 422.111(f)(11) that requires MA organizations to notify providers through the Internet that such an election has occurred and what local coverage policy will apply to MA plan members.

We proposed to add a new § 422.101(d) to provide for new cost-sharing requirements mandated by MMA related to MA regional plans. There were three specific requirements:

1. MA regional plans, to the extent they apply deductibles, are required to have only a single deductible related to combined Medicare Part A and Part B services. Applicability of the single deductible may be differential for specific in-network services and may also be waived for preventative services or other items and services.

2. MA regional plans are required to have a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the original Medicare FFS program.

3. MA regional plans are required to have a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the original Medicare FFS program. (This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under original Medicare, could be higher than the in-network catastrophic limit, but may not increase the limit applicable to in network services.)

MA regional plans would be responsible for tracking these beneficiary out-of-pocket limits and for notifying members when they have been met. We also proposed to require MA regional plans to track and limit incurred rather than paid out-of-pocket expenses.

Comment: Many commenters recommended that CMS explain the significance of requiring MA regional plans to track ''incurred'' rather than paid expenses related to the deductible and caps on beneficiary cost sharing.

Response: There are two reasons for requiring MA regional plans to track incurred rather than paid beneficiary cost-sharing expenses. The first is that

we foresee a potential for disputes arising between providers and MA organizations related to the ''full'' reimbursement the MA organization will owe, once a cap had been met. If ''full'' reimbursement were not required until cost sharing had been paid (rather than incurred), then disputes might arise over what amount a beneficiary had actually paid in cost sharing, and when. Administratively, it is more feasible and less burdensome for plans to track incurred cost-sharing amounts than amounts actually paid, if for no other reason than the latter would require a feedback mechanism to the MA organization whenever an enrollee makes a payment of cost sharing. Second, it is possible that in many instances a beneficiary will be unable to pay full cost sharing for a service at the time of service. Many MA organizations, for instance, require inpatient hospital copays of more than $100 per day, even when in-network hospitals are used. Beneficiaries might need to pay cost sharing to providers over a period of time. Such delays in the actual payment of cost sharing should not affect the MA organization's responsibility for timely payment of claims.

Comment: A number of commenters recommended that CMS require MA organizations to make deductible and out-of-pocket information readily available to providers to facilitate billing at the time of service. Some commenters suggested requiring MA organizations to send notices of additional financial liability to enrollees on a monthly basis. Others suggested requiring that a standardized notice be used to ensure consistent reporting across all plans. Commenters also suggested requiring MA organizations to post enrollee deductible and catastrophic cap information on the Internet, so providers could easily and quickly determine enrollee liability at the time of service.

In addition, commenters suggested that CMS require MA organizations offering MA regional plans to provide information on deductible and out-of-pocket limits related to specific MA regional plan enrollees to hospitals, similar to the method by which hospitals are notified of Medicare beneficiary eligibility and Part A deductible status under the original FFS system. Others suggested that we require MA organizations offering MA regional plans to supply deductible and catastrophic cap information when health care providers and/or hospitals notify the MA organization that an MA plan member has presented for services.

Response: In response to these comments, we have modified § 422.101(d)(4) to indicate that notification to providers of enrollee status related to a deductible (if any) and catastrophic caps is also required. To the extent an MA regional plan enrollee is not aware of his or her deductible and/or cap status, the enrollee or a provider should have reasonable access to such information at the time of service.

Comment: A number of commenters recommended that CMS add a special provision for AI/AN to § 422.101(d) that would have the affect of requiring all MA regional plans to provide ''full reimbursement'' to all I/T/U facilities that treated enrollees of that MA regional plan.

Response: The MMA did not provide for special treatment under the MA program for AI/AN beneficiaries. For this reason, we do not see a statutory basis to apply different rules to a subset of Medicare beneficiaries, such as AI/AN populations.

Comment: A commenter generally supported the requirement at § 422.101(d)(4) that MA regional plans will be responsible for tracking the incurred beneficiary cost sharing related to the deductible and the catastrophic caps on beneficiary out-of-pocket expenses. The commenter expressed disappointment that a specific dollar amount or limit had not been set related to the caps on out-of-pocket expenses in § 422.101(d)(2) and (d)(3). The commenter also asked that we provide a definition of ''incurred'' costs that ensures that all cost sharing, whether paid by the beneficiary, or on his or her behalf, is counted and tracked.

Response: We did not establish maximum deductible or cap-levels in regulation, since the statute does not set such limits. We interpret the statute to allow for flexibility in plan design, within the constraints of statutory language, to promote competition. However, under our authority at section 1852(b) of the Act to disallow the offering of an MA plan where we determine that the plan design or its benefits are likely to substantially discourage enrollment by certain MA eligible individuals, we will review deductible and cap-levels to ensure that they do not substantially discourage enrollment. Additionally, as required by section 1854(e)(4) of the Act, beginning in 2006 (and for all MA plans other than MSA plans), the actuarial value of the deductible, coinsurance, and copayments applicable on average to individuals enrolled in an MA plan related to benefits under the original Medicare program may not exceed the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to FFS Medicare enrollees related to benefits under the original Medicare program. As provided for in statute at section 1852(a)(1)(B)(ii) and in our regulation at § 422.101(e)(2), while the catastrophic limit on in-network receipt of benefits under the original Medicare program applies to the overall cost-sharing limit that an MA regional plan can impose per § 422.256(b)(3), the out-of-network catastrophic limit is not likewise constrained.

Finally and related to the tracking of incurred costs, we will require MA regional plans to track incurred as opposed to paid enrollee cost sharing. We will require MA regional plans to provide reimbursement to providers for covered services once the deductible or caps have been incurred regardless of who has actually paid the cost sharing, or for that matter, regardless of whether the deductible or other cost sharing has been paid at all. An MA organization with financial liability to reimburse a provider for covered services may not delay reimbursement until an enrollee first pays deductible or cost-sharing amounts.

The MMA also added a new section 1859(b)(4) to the Act requiring MA regional plans to provide reimbursement for all covered benefits, regardless of whether the benefits are provided within or outside of the network of contracted providers. As PPOs, MA regional plans are permitted to impose differential cost sharing related to non-emergency services received from non-network providers. To the extent differential cost sharing is part of the benefit package, the MA regional plan will generally be responsible for its portion of payment to a non-network provider, and the enrollee will be responsible for the remainder, up to the limits discussed above. We accommodated these requirements in the proposed rule at § 422.101(e).

MA PPO Benefits

We received many comments on § 422.101(d) and (e) related to the benefits and cost-sharing protections enrollees in MA regional plans can expect to receive. We also received comments specifically related to the definition of MA PPOs provided at § 422.4(a)(1)(v), which we responded to in the subpart A preamble above. Because of the interaction of the statutory and regulatory definitions of PPO (for both local MA plans and MA regional plans, which are offered as PPOs), and the benefits they must provide, we address a number of comments related to MA PPO benefits

in this section of the preamble that have a close bearing on the definition of MA PPOs.

As we stated in the subpart A preamble of the August 3, 2004 proposed rule: ''Section 520(a)(3) of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) added section 1852(e)(2)(D) of the Act and defined PPO plans under the MA program for purposes of quality assurance requirements. As we discussed in the preamble to the final rule with comment period titled, ''Medicare Program; Medicare+Choice,'' published on June 29, 2000 (65 FR 41070), the definition of PPOs at section 1852(e)(2)(D) of the Act was explicitly for purposes of applying quality assurance requirements in 1852(e)(2)(B) of the Act and was limited in its applicability to paragraph (2) of section 1852(e) of the Act. Before the enactment of the BBRA, PPOs had been treated under the M+C statute and regulations in the same manner as all other M+C coordinated care plans for purposes of applying quality assurance requirements. In the June 29, 2000 final rule with comment period, we incorporated this new definition into the M+C regulations at § 422.4 and by revising § 422.152.

The PPO plan definition added by section 520 of the BBRA included three elements, they were as follows: (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; (2) provides for reimbursement for all covered benefits regardless of whether those benefits are provided within the network of providers; and (3) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

Because the definition of PPO plan in section 1852(e)(2)(D) of the Act only applies for the limited purpose of eligibility for PPO quality improvement requirements, we do not believe that the limitations in this definition should have been set forth in a generally applicable definition of PPO plan in § 422.4, as is currently the case. We propose to clarify in regulation that it is solely for purposes of the application of the more limited quality assurance requirements in section 1852(e)(2)(B) of the Act that PPOs must be offered by MA organizations that are not licensed or organized under State law as a HMO. For PPO-type plans that are offered by MA organizations that are licensed or organized under State law as HMOs, the quality assurance requirements that apply to all other coordinated care plans in section 1852(e) of the Act also apply to those PPO type plans.''

Based on this better interpretation of section 520(a)(3) of the BBRA, we proposed to modify the third element (related to State licensure) of the definition of MA PPO plan at § 422.4 to read as follows: ''A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and, only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed under State law as an HMO.''

We also proposed to define MA regional plan at § 422.2 based on the definition in section 1859(b)(4) of the Act, which was added by section 221(b) of the MMA. The first and second elements of the definition of MA regional plan at section 1859(b)(4)(A) and (B) of the Act are identical to the first two elements of the definition of MA PPO plan at sections 1852(e)(3)(A)(iv)(I) and (II) of the Act , which was added by section 722(a) of the MMA. Note that the definition of MA PPO plan in section 1852(e)(3)(A)(iv)(I) of the Act is identical the definition of MA PPO plan that had appeared at section 1852(e)(2)(D) of the Act, as added by section 520(a)(3) of the BBRA. Therefore, the statute requires that both local MA PPOs and MA regional plans (which are offered as PPOs) must provide reimbursement for all covered benefits regardless of whether such benefits are provided within the network of providers.

Comment: Although some commenters supported, as a beneficiary protection, the fact that MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within or outside the network of contracted providers. Many commenters suggested that statutory language requiring PPOs to provide reimbursement for all covered benefits should simply mean that PPOs need to provide out-of-network coverage for Medicare Part A and Part B services. The commenters also stated that they believe the statute never intended out-of-network coverage to apply to supplemental benefits, which are not part of the original Medicare benefit package.

Response: We disagree. The placement of the definition and other requirements related to MA regional plans in the MMA is instructive in this regard. As we noted earlier, section 221(b) of the MMA added the definition of MA regional plan, which includes the second element of the definition, ''that provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers,'' at section 1859(b)(4)(B) of the Act. Section 221(c) of the MMA establishes ''Rules for MA Regional Plans'' by inserting a new section 1858 into the Act. In both, section 1858(b)(1) of the Act related to the single deductible that MA regional plans are permitted to apply, and section 1858(b)(2) of the Act related to the catastrophic limits that MA regional plans must apply, the statute is clear in stating that only ''benefits under the original Medicare FFS program'' are included. Where the intent is to limit application of MA plan requirements to only benefits under the original Medicare program (Parts A and B), the statute states such a limitation. Because no such limitation appears in either section 1852(e)(3)(A)(iv) of the Act, related to all PPOs, nor in section 1859(b)(4) of the Act, related to MA regional plans, we cannot apply such a limitation in the regulations.

Comment: Several commenters stated that benefits such as gym, eyewear, dental discounts, discounts on hearing aids, massage, acupuncture, weight control programs, or health-related magazines are unavailable out-of-network because as a practical matter, such benefits and discounts are negotiated and offered to MA organizations primarily in consideration of the guaranteed volume the exclusive service provider believes it will receive. Many commenters stated that, to the extent such discounted benefits are available from out-of-network service providers, the basis for the negotiated discount (guaranteed volume) becomes null and void.

One commenter stated that discount arrangements such as these, which secure a larger volume of business for the entity providing the discount, provide financial profits and are a common business model not limited to the world of health insurance. The commenter also stated that in these arrangements, there is typically no payment by the plan, and no cost sharing by the enrollee.

Response: Although we fully support discounts and volume purchasing where appropriate, it is important to note that discounts are not benefits under the MA program unless they meet the definition of ''benefits'' contained in the regulations. The definition of MA benefits is found at § 422.2 and reads as

follows: ''Benefits are health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.'' Note that unless an MA organization actually pays for a health care item or service, the item or service is not a ''benefit'' of the MA plan. Therefore, negotiated discounts for services for which the plan incurs no cost or liability are not MA benefits, and are not subject to the requirement that PPOs provide reimbursement for all benefits, whether or not they are provided within the network of providers. That said, it is important to note that we have termed these types of negotiated discounts ''value added items and services,'' which are discussed in Chapter 3 (Marketing) of the CMS Medicare Managed Care Manual.

Comment: Some commenters stated that MA organizations frequently subcapitate ancillary provider networks (such as dental providers) and that such subcapitated arrangements make it difficult for the MA organization to provide reimbursement for all benefits, in- and out-of-network.

Response: The statute is clear that all MA organizations offering PPOs (local and regional) must provide reimbursement for all plan benefits in- and out-of-network. A number of MA organizations subcapitate Independent Practice Associations (IPAs), Physician-Hospital Organizations (PHOs), and similar subnetworks of providers, for most (or all) original Medicare Part B and/or Part A services. Such subcapitation arrangements are permitted within the MA program, subject to § 422.208 (the physician incentive plan requirements and limitations) and other statutory and regulatory provisions. However, to the extent an MA organization wants to offer a PPO (either local or regional), it will also need to make arrangements for providing reimbursement for all out-of-network benefits in such a subcapitated environment, or it will need to make arrangements with its subcapitated contractors for providing reimbursement for out-of-network benefits directly. Two points need to be made. First, the cost sharing that an enrollee will be required to pay when obtaining covered benefits out-of-network can be higher than the cost sharing that applies when services are obtained in-network. Second, to the extent that subcapitated arrangements make the provision of reimbursement for all benefits out-of-network impractical, an MA organization might consider offering an HMOPOS product, where out-of-network coverage and reimbursement can be limited in a number of ways.

Comment: Commenters stated that it would be impossible for plans to provide reimbursement for out-of-network receipt of benefits such as 24-hour nurse hotline services or disease management services.

Response: These services are not likely to be available from out-of-network providers because of the unique nature of the services and the integration between the plan and the service provider necessary for the delivery of such services. To illustrate, a provider of in-network disease management services to a plan's enrollees is likely to need access to plan and patient information in order to provide services to enrollees. An out-of-network disease management services provider would not have such access, and so would be unlikely to be able to provide the service out-of-network. Finally, to the extent that such services are available without cost sharing from in-network providers, the imposition of cost sharing of any amount for their receipt out-of-network should deter virtually all enrollees from seeking them out-of-network.

Comment: Some commenters pointed out the difficulty inherent in requiring MA-PDs that are offered as PPOs to provide reimbursement for mail-order drugs or Part D (prescription drug) benefits received by enrollees from out-of-network providers.

Response: As a practical matter, an MA PPO plan that offers Part D coverage as an MA-PD will need to provide out-of-network coverage of Part D drugs consistent with the requirements of the Part D program and the regulations at part 423.

Comment: A commenter stated that further complications might arise were CMS to interpret ancillary services (for example, dental and eyewear) as being services subject to the catastrophic limit on out-of-pocket expenses. The concern was that once an enrollee has met the out-of-network cap, cost sharing would no longer act as a deterrent to the unrestricted and ''free'' access by PPO enrollees to these benefits from out-of-network providers.

Response: The statute and our implementing regulations at § 422.101(d)(2) and (d)(3) are clear in limiting application of the catastrophic caps to Part A and Part B benefits. To the extent dental or eyewear benefits of an MA PPO plan are not also original Medicare benefits, cost sharing can continue to apply, even after the out-of-network additional catastrophic limit in § 422.101(d)(3) has been met.

Comment: A number of commenters recommended that we revise the proposed rule to clarify that MA regional plans may establish prior authorization requirements for services obtained out-of-network and that both MA regional plans and local PPOs should be permitted to offer certain services only through network providers, where, for instance, the services have unique characteristics. The commenters stated that private sector PPO benefits are commonly offered in this manner. Therefore, the commenters believe that by providing this flexibility, CMS would allow the offering of MA PPO plans and benefits in a comparable manner to those generally available to consumers, and that this will make it possible for them to continue to offer certain services that add value for beneficiaries.

Response: Although we support the offering of added value to beneficiaries where possible, as we have previously discussed, there is a clear statutory requirement that all covered benefits of an MA PPO plan (regional or local) must be available out-of-network. The statute provides a definition of PPO that may not, in all respects, conform with business models that might be present (or even prevalent) in the commercial sector. Unlike plans serving commercial populations, the Medicare program is primarily intended to serve aged and vulnerable beneficiary populations. Therefore, the dynamics of the MA program may not match those in the commercial market. Also, for all MA plans they offer, MA organizations are required to follow FFS coverage rules related to items and services covered under FFS Medicare. Although MA organizations are permitted to adopt a single local coverage policy that will apply to all enrollees in an MA plan, in accordance with § 422.101(b), MA organizations are not permitted to impose a more stringent test related to medical necessity determinations for Medicare-covered services than the one that applies under the FFS program.

For items and services not covered by Medicare that the MA organization provides under section 1852(a)(3) of the Act, similar considerations apply. In other words, to the extent and under the conditions that a non-Medicare supplemental benefit would be available to a plan enrollee within the network of providers, such a service would also need to be available to an MA PPO enrollee out-of-network. That is not to say that differential cost sharing cannot be applied to out-of-network receipt of covered services, nor does it mean that

out-of-network cost sharing cannot be differentially applied to specific services or types of services. We believe that MA organizations offering MA PPOs (both local and regional) can accomplish their business strategies while still working within the statute.

For instance, an MA PPO can warn enrollees that to the extent that an item or service is not a covered benefit of the plan, the enrollee would be required to pay the full cost of the service. This warning might have the desired effect of encouraging the enrollee to call the MA plan before seeking care out-of-network, as a means of ensuring that a specific item or service is actually a covered benefit of the plan. Similarly, for specific services for which the plan has established substantial out-of-network cost sharing, the enrollee can be encouraged to contact the plan for pre-authorization that would reduce cost sharing. For instance, for out-of-network receipt of a specific inpatient hospital service the normal cost sharing might be 40 percent of charges. To the extent an enrollee or provider calls and receives plan pre-authorization for a specific out-of-network hospitalization of this type, the MA plan might reduce enrollee liability to 20 percent (or less) of charges. MA PPOs must be able to provide coverage and medical necessity determinations to enrollees (and providers) before the enrollee receives out-of-network services. This will act as a beneficiary protection.

A prudent enrollee will have reason to ensure that such services are medically necessary and covered by the plan before self-referring to out-of-network providers. Similarly, a prudent provider will have a means of ensuring that plan coverage will be provided. However, the idea that a gatekeeper must provide a referral or that an MA plan must pre-authorize a service before it will be covered at all, or that such a referral or plan pre-authorization is a necessary condition for receipt of any medically necessary out-of-network plan covered service is not in accord with the statutory language pertaining to MA PPOs.

Our belief is that the statute precludes requiring a medical necessity determination, a plan pre-certification or pre-authorization, or a coverage decision before receiving a covered service out-of-network. As long as an MA PPO enrollee is willing to pay the higher cost sharing associated with out-of-network care, there can be no additional barrier to receipt of plan covered benefits. If an MA organization offering an MA PPO is particularly concerned with over-utilization or inappropriate utilization of services (or of a particular service) out-of-network, the organization has the authority to impose relatively high out-of-network cost sharing overall, or related to a specific service. Also note that to the extent a referral or plan pre-authorization has been provided for in-network care, the enrollee has the right to use the referral or plan pre-authorization for receipt of the same care out-of-network (with applicable out-of-network cost sharing).

Comment: A commenter recommended that CMS offer alternative regional PPO product designs, which the commenter called ''Performance Risk PPOs.'' The commenter included a proposal that would, offer plan incentives for higher quality, better customer service and benefits, improved outcomes and program savings, and penalize plans that do not perform well on these measures. The commenter explained that such a model would offer a range of out-of-network benefits, but not all Medicare-covered services would be available out-of-network. In addition, the commenter stated that although referrals would not be required for accessing out-of-network care, pre-certification might be required.

Response: Under the definitions of regional PPO contained in the MMA, the MA regional plan must provide for reimbursement for all covered benefits, regardless of whether such benefits are provided within the plan's network of providers. Therefore, a plan of the type that the commenter proposes would not meet the statutory definition of MA regional plan. Further, as we have stated above, plan pre-certification or pre-authorization may not be a necessary condition for receipt of out-of-network covered services.

3. Supplemental Benefits (§ 422.102)

In the August 3, 2004 proposed rule, we stated that an MA plan could reduce cost sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act as a mandatory supplemental benefit. Beginning in 2006, an MA plan can reduce the cost sharing that applies to plan members below the actuarial value of the cost sharing that would apply to those members if they were enrolled in the original Medicare program. This amount is not just the limit on the amount of cost sharing that an enrollee can be charged in the plan's bid for Medicare Part A and Part B services (and for which and when such plan cost sharing exceeds FFS cost sharing, a supplemental premium is necessary), but it also expresses the value of the bid-based cost sharing when the bid is below the benchmark. When we reference section 1854(e)(2)(B) of the Act in § 422.102(a)(4), we are referring to the latter value, not the former. This reduction in cost sharing can be included as a mandatory supplemental benefit and was proposed at § 422.102(a)(4).

We also proposed the following conforming changes to § 422.102:

- We removed the reference to ''additional benefits,'' as those benefits are no longer applicable to MA plans offered on or after January 1, 2006.
- We removed the reference to operational policy letters (OPLs) in § 422.102(a)(3), as guidelines related to benefits that had been contained in OPLs have been incorporated into regulation, into the Medicare Managed Care Manual, or into other instructions.

We received no comments on this section, so we finalize it as proposed.

4. Benefits Under an MA MSA Plan (§ 422.103)

For clarification purposes, we proposed to remove the extraneous word ''under'' from paragraph (a) of § 422.103.

We received no comments on this section, so we finalize it as proposed.

5. Special Rules for Self-Referral and Point of Service Option (§ 422.105)

''Point of Service'' (POS) is an option in some plans that allows enrollees to obtain non-network services, with the plan providing some limited level of reimbursement for such services. To clarify an issue that has created confusion for both beneficiaries and MA organizations, we proposed to clarify at § 422.105 that if an MA organization does not offer a POS benefit to members of a plan (or if it offers a POS benefit as an optional supplemental benefit and the member has not selected that benefit), the member cannot be financially liable for more than the normal in-plan cost sharing for covered items or services from contracted providers.

We stated that we believed that indemnifying the Medicare member in such a situation conforms with normal industry practice and also clarified our long-standing policy that members cannot be held financially liable when contracting providers fail to follow or adhere to plan referral or pre-authorization policies before providing covered services. If a plan member insisted on receiving what would otherwise be covered services from a contracted provider (but for the lack of a referral or plan pre-authorization), then the contracted provider would be required to inform the member that those services would not be covered under the plan. We proposed to require

the provider to document the medical record as to why the services are medically necessary but not available through the plan.

In addition, an MA regional plan might choose to provide for a POS-LIKE benefit where beneficiary cost sharing would be less than it would otherwise be for non-network provider services, but where it still might be greater than it would be for in-network provider services, if an enrollee follows pre-authorization, pre-certification, or pre-notification rules before receiving out-of-network services. Note that such pre-authorization, pre-certification, or pre-notification cannot be a necessary condition for receipt of, or required MA plan reimbursement for, out-of-network covered services by a PPO enrollee; however, it can act as a financial incentive (by lowering the normal out-of-network cost sharing that would otherwise apply) to an enrollee to voluntarily participate.

In this final rule, the title of this section is being changed to emphasize the fact that it contains not only rules related to POS options or benefits, but that it also contains a rule related to enrollee self-referral to plan contracted providers in all MA plans.

Comment: Many commenters recommended that we clarify the meaning of the introductory statement proposed to § 422.105(a). Other commenters suggested that the statement was misplaced, because the proposed regulation would apply to plans with and without POS offerings. Others commenters stated that in plans in which a POS option was provided as a mandatory supplemental benefit, the introductory statement we proposed to add would have no effect and would therefore be confusing.

Response: We agree with the comments regarding potential confusion and have renamed the title of this section of the regulation and reorganized it to indicate that it covers not only POS offerings, but that it also applies to all situations in which an MA plan member self-refers to a plan-contracting provider, whether or not a POS benefit is involved.

Comment: One commenter stated that while some types of services may not be covered under any circumstances, other services might not be covered by an MA plan because they are not medically necessary or appropriate for the enrollee. The commenter suggested that CMS clarify the applicability of the introductory statement to circumstances in which a service does not meet coverage criteria based on medical necessity.

Response: Many commenters responded to our request for comment in the subpart M preamble of the August 3, 2004 proposed rule related to whether or not we should permit or require (and under what circumstances) advance beneficiary notices (ABNs) to be issued by network or non-network providers to MA plan enrollees. Many of the commenters opposed such a requirement as being overly intrusive on the patient and doctor relationship and other commenters supported it as being a valid and necessary beneficiary protection. We address the specific comments related to ABNs in the subpart M preamble of this rule.

Although we decided not to incorporate an ABN requirement into the MA program at this time, we believe that there is an important beneficiary protection at stake, especially in light of the projected growth in MA PPO enrollment due to the advent of the MA regional plan program. MA organizations have a responsibility to ensure that contracting physicians and providers know whether specific items and services are covered in the MA plan in which their patients are enrolled. If a network physician provides a service or directs an MA beneficiary to another provider to receive a plan covered service without following the plan's internal procedures (such as obtaining the appropriate plan pre-authorization), then the beneficiary should not be penalized to the extent the physician did not follow plan rules. MA plan enrollees cannot be held to a higher standard than plan contracting providers. To the extent a contracting provider performs a service or refers a patient for health care services that an enrollee reasonably believes would be covered services of the plan, then an MA plan enrollee cannot be liable for more than applicable plan cost sharing for those services. To the extent an MA organization does not properly inform contracted providers, or to the extent an MA contracted provider does not properly enforce referral procedures, then to that same extent, an MA plan enrollee cannot be held financially liable for the organization's or provider's failure. Under its contract with the MA organization, a provider is contractually bound to look solely to the MA organization for reimbursement for covered services (see § 422.502(g)(1) and § 422.502(i)(3)). Similarly, MA organizations are required to communicate clear and consistent coverage guidelines and medical management procedures to contracting physicians (see § 422.202(b)).

Comment: Some commenters recommended that CMS be more flexible and not require the network contracted physician or provider to document the medical record as to why the items or services were medically necessary but not available through the plan. These commenters suggested that it was inflexible to require that such documentation appear only in the medical record.

Response: We agree with this comment that it was overly proscriptive to require that such documentation could only appear in the medical record and will permit flexibility regarding where such information is documented. We have added language at the end of § 422.105(a) that does not specify where such documentation must reside.

Comment: A few commenters asked us to clarify the issue of the provider's ability to bill the beneficiary, if all actions specified in § 422.105(a) have taken place. Commenters stated that the clarification should specify the conditions under which they are permitted to bill a beneficiary. One commenter asked whether the rules established in this section of the regulation also apply to hospitals and other types of contracted providers.

Response: The intent of our revision to § 422.105 is to clarify a beneficiary protection and not necessarily to clarify under what conditions an MA-contracting provider may or may not bill an MA plan enrollee. As mentioned above, all contracting providers are bound to look solely to the MA organization for reimbursement for services covered under the MA plan in which a Medicare beneficiary is enrolled. To the extent an MA-contracting provider provides a non-covered service to an MA enrollee, then payment for such a service is not generally within the regulatory purview of the MA program.

However, where the enrollee is notified in advance by the contracted provider that a service will not be covered unless the beneficiary receives a referral or takes some other action, and that notification is documented, and the beneficiary receives the service without obtaining the referral or taking the necessary action, then the enrollee can be billed and may be held financially liable for the service. Additionally, even if a beneficiary is informed (either verbally or in writing) that a specific service will not be covered by the MA plan in which the beneficiary is enrolled, that beneficiary is entitled to appeal such a determination, whether or not the service is actually provided after such notification. Finally, § 422.105(a) applies to all contracted providers, including physicians, hospitals, and other provider types.

Comment: One commenter suggested that CMS was proposing an odd and fundamentally misguided rule governing members of MA plans who self-refer. Another commenter stated that the requirement was unnecessary, inflexible, and burdensome for contracted providers. The first commenter stated that the proposed rule contradicted fundamental managed care principles and that the proposed rule would shift payment responsibility from the self-referring member to the contracted provider and/or the MA organization.

The first commenter asserted that enrollees who self-refer should be required to pay the entire cost of the service and should not be rewarded by having to pay only the normal, in-network cost sharing. The second commenter stated that both contracting providers and MA plan enrollees are well aware when there is a requirement to secure a referral from a PCP before receipt of specialty care. Finally, both commenters stated that the proposed rule was flawed by not contemplating, or providing exceptions for, situations in which the service is not covered by the MA plan in which the individual is enrolled, or situations in which the service is not medically necessary.

Response: We do not agree. The language in § 422.105 states that only covered items and services are subject to the regulatory provision. Covered plan services do not include services that are inappropriate or not medically necessary for a specific individual in a specific situation. The intent of the regulatory provision is to limit patient liability in situations where a contracted provider provides a covered service, but for which certain technical, non-medical conditions of coverage have not been met.

Although we agree that the enrollee should not be ''rewarded'' for failing to follow proper plan pre-authorization or referral procedures, we also believe that the contracted provider and the MA organization also should not be ''rewarded'' by shifting financial responsibility to the enrollee for covered services that are actually the financial responsibility of the MA organization. The contracting provider is, or should be, aware of the MA plan's technical requirements for referral and/or plan pre-authorization related to covered services. If the contracted provider believes the covered service is medically necessary, then the contracted provider needs to explain the plan referral/pre-authorization process and should consider assisting the enrollee in obtaining necessary plan pre-service documentation. Finally, the contracted provider needs to inform the enrollee in instances when a service will not be covered unless the enrollee obtains a referral or plan pre-authorization and in which that enrollee will have full financial liability absent such referral or pre-authorization.

6. Coordination of Benefits With Employer Group Health Plans and Medicaid (§ 422.106)

Section 222(j) of the MMA revised section 1857(i) of the Act in order to facilitate employer sponsorship of MA plans. The MMA allowed us to waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered directly by an employer, a labor organization, or the trustees of a fund established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of labor organizations. Section 222(j) of the MMA further stated that such an employer-labor organization sponsored MA plan may restrict enrollment to individuals who are beneficiaries and participants in such a plan. We proposed a new § 422.106(d) to account for this new statutory authority. (The August 3, 2004 proposed rule also contained a number of clarifying, conforming, and editorial changes to this section.)

Comment: One commenter recommended that CMS use the authority provided in section 1857(i)(2) of the Act to waive requirements related to MA regional plans. The commenter wanted to know if CMS would permit employer/labor sponsored MA plans that have been created for the sole enrollment of the sponsors' own employees, retirees, or members to participate in the MA regional plan stabilization fund or in risk-sharing through risk corridors, both described in regulation at § 422.458. The commenter was concerned that these special ''incentive'' payments for organizations sponsoring MA regional plans were primarily intended to foster the growth of MA regional plans for the enrollment of all eligible Medicare beneficiaries, and that it would be inappropriate to make such special payments to organizations offering plans that are only available for enrollment to employer/labor group members.

Response: We agree and have exercised this discretion under section 1857(i) of the Act to waive program requirements that facilitate employer/labor group enrollment. For instance, we have waived the requirement that MA organizations offer MA plans for enrollment to all Medicare Part A and Part B enrollees, and have allowed MA organizations to create plans that exclusively enroll employer/labor group members. We will continue to do so. However, we will not waive the ''general'' enrollment requirement that MA plans enroll all MA eligible individuals (see section 1851(a)(1)(A) of the Act) for either MA organizations or for employer/labor MA plan sponsors, if these entities seek to offer an MA regional plan solely to employer/labor group members.

Comment: The same commenter asked whether specialized MA plans for special needs individuals could be offered as MA regional plans.

Response: The statute is clear in saying that specialized MA plans for special needs individuals can be offered as any type of MA coordinated care plan (see section 1851(a)(2)(A)(ii) of the Act). MA regional plans are a type of MA coordinated care plan (see section 1851(a)(2)(A)(i) of the Act).

Comment: One commenter asked whether CMS would exercise the waiver authority under section 1857(i) of the Act in order to allow MA organizations to offer non-actuarially equivalent prescription drug coverage to MA plan enrollees who do not purchase Part D.

Response: We will not. Section 1860D–21(a)(1)(B)(ii) of the Act states that MA organizations may not offer prescription drug coverage (other than that required under Parts A and B of Medicare) to an MA plan enrollee unless it is qualified Part D prescription drug coverage.

Comment: One commenter asked if CMS would use the waiver authority to provide for special enrollment or conversion of enrollment rules for Medicaid beneficiaries enrolled in special needs plans, similar to what CMS have provided for employer/labor group members.

Response: As previously stated, we have waived the requirement that MA organizations offer MA plans for enrollment to all Medicare Part A and Part B enrollees, and have allowed MA organizations to create plans that exclusively enroll employer/labor group members. The authority for such waivers is contained in section 1857(i) of the Act and does not apply to individuals entitled to Medicaid. Note that section 1857(i) of the Act waiver authority is exclusive in its application to employees or former employees of an employer, or members or former members of a union, or a combination thereof. Waivers for individuals entitled to Medicaid are not provided for under the waiver authority in section 1857(i) of the Act. SNPs for Medicaid eligibles are authorized in section 231 of the

MMA. Finally, note that § 422.106(a) and (b) do not discuss employer/labor groups in the context of section 1857(i) waiver authority. Regulations related to employer/labor group waiver authority are exclusively discussed in § 422.106(c) and (d).

Comment: A number of commenters asked whether CMS would apply the new waiver authority in section 222(j)(2) of the MMA to AI/AN beneficiaries. The commenters stated that such a waiver might permit I/T/Us to sponsor MA plans exclusively designed for AI/AN beneficiaries.

Response: Section 222(j)(2) of the MMA added a new paragraph to the Act at section 1857(i)(2). This new provision created the opportunity for directly-sponsored employer/labor group MA plans. Section 1857(i) of the Act waiver authority is exclusive in its application to employees or former employees of an employer, or members or former members of a union, or a combination thereof. Waivers for AI/AN beneficiaries are not provided for under the waiver authority provided in section 1857(i) of the Act.

Comment: One commenter, in relation to a comment on § 422422.560 through § 422.626 (subpart M), recommended that CMS include benefits that are separately negotiated between the MA organization and an employer/labor group in the benefits governed by the MA regulations and therefore subject to the MA appeals and grievance processes.

Response: This comment has been addressed at greater length in the subpart M preamble. However, it is important to note that for purposes of subpart C, separately negotiated benefits between MA organizations and employer groups, labor organizations, and Medicaid (and as discussed in § 422.106(a)(a) and (b)) are not part of any MA plan. Such employer/labor/Medicaid benefits are discussed only in terms of the fact that they complement the benefits of an MA plan.

Comment: A commenter requested CMS to clarify that employer groups or labor organizations that become MA organizations may retain the services of entities to assist in the development and operation of the employer-sponsored MA plan. The commenter asked CMS to implement the waiver authority under Section 1857(i)(2) of the Act in a way that does not inadvertently hinder the efficient operation of support services for employer groups and labor organizations.

Response: We agree with the commenter that our waiver authority under 1857(i)(2) of the Act should be applied to allow employers and labor organizations to offer MA plans through arrangements with entities (such as existing MA organizations) that will facilitate the offering and efficient operation of such MA plans. We have revised § 422.106(d) to clarify this point and to clarify that, as provided in section 1857(i)(2) of the Act, we may exercise this authority on our own initiative as well as upon written request from an applicant. In each case, as specified in § 422.106(d)(3), our waivers and modifications will apply to all similarly situated MA plans.

Comment: A few commenters asked for specific waivers. Some commenters recommended waivers already provided, such as a waiver that would allow MA organizations to create separate MA plans solely for employer/labor group members.

Response: As we have done in the past, we will continue to provide specifics on approved waivers in guidance and in direct communication with waiver recipients, rather than in formal rulemaking.

7. Medicare Secondary Payer (MSP) Procedures (§ 422.108)

Section 232 of MMA amended section 1856(b)(3) of the Act to remove all ambiguity related to State authority over the MA program. The Congressional intent is now unambiguous in prohibiting States from exercising authority over MA plans in any area other than State licensing laws and State laws relating to plan solvency. We proposed to amend § 422.108(f) to remove language that suggests States can limit the amount an MA organization can recover from liable third parties under Medicare secondary payer procedures.

We received no comments on this section, so we finalize it as proposed.

8. Effect of National Coverage Determinations (NCDs) (§ 422.109)

Section 1853(c)(7) of the Act requires us to ''adjust'' MA payments when a national coverage determination (NCD) or legislative change in benefits will result in a significant increase in costs to MA organizations sponsoring MA plans. We historically interpreted what constituted ''significant'' costs in regulation at § 422.109, where the costs of a coverage change are considered ''significant'' if either the average cost of providing the service exceeds a specified threshold, or the total cost for providing the service exceeds an aggregate cost threshold.

In a final rule published in the **Federal Register** on August 22, 2003 (68 FR 50839), we amended § 422.109 to refine the definition of ''significant'' cost to include a new test. By adding a new paragraph at the end of § 422.109(a)(2), we provided that, for purposes of determining whether to make an additional payment adjustment under § 422.256, the tests for reaching the ''significant'' cost threshold were to include the aggregate costs of all NCDs and legislative changes in benefits made in the prior calendar year.

Under that new test, the ''average cost'' of every NCD and legislative change in benefits for the contract year would have been added together. If the sum of these average amounts exceeded the threshold under § 422.109(a)(l), then an adjustment to payment would have been made in the following contract year under § 422.256 to reflect this ''significant'' cost. Alternatively, if the costs of the NCDs and legislative changes in benefits, in the aggregate, exceeded the level set forth in § 422.109(a)(2), an adjustment to payment would also have been made under § 422.256 on that basis.

Among the reasons for the above change was that even when the ''significant'' cost threshold had been met under the existing definition, the methodology then employed for making a payment adjustment under section 1853(c)(7) of the Act did not result in an adjustment in the capitation rate in those counties with the ''minimum'' update rate (the ''2 percent minimum update'' counties paid under section 1853(c)(l)(C) of the Act.) In accordance with section 1853(c) of the Act, the CMS Office of the Actuary (OACT) used the annual growth rate to update only the floor and blended rates, so the ''minimum'' 2 percent update rate, which was 102 percent of the prior year's rate, did not reflect the costs of new benefits effective in the middle of the previous payment year. Therefore, we decided that payments in counties in which payment was based on the ''minimum'' 2 percent update rate were not appropriately adjusted to reflect new coverage costs as required by section 1853(c)(7) of the Act.

The MMA changed the ''minimum'' percentage payment prong of the former M+C payment methodology by adding a new basis for a minimum update. The ''minimum'' percentage increase rate is changed, effective January 2004, as follows: Instead of being set at 102 percent of the prior year's rate, the minimum increase rate will now be the greater of 102 percent of the prior year's rate, or the annual MA growth percentage. This means that under the MMA payment methodology, the minimum percentage increase will now reflect the cost of mid-year NCDs and legislative changes in benefits. These

costs are now automatically built into the annual MA growth percentage and will no longer require an additional adjustment under § 422.256.

As a result of these MMA changes to the MA payment methodology we proposed in the August 3, 2004 proposed rule to remove the portion of § 422.109(a)(2) after § 422.254(f).

We also proposed clarifying language in § 422.254(f) and § 422.109(c)(3).

We received no comments on this section, so we finalize it as proposed.

9. Discrimination Against Beneficiaries Prohibited (§ 422.110)

We proposed to correct § 422.110(b) to bring it into conformance with § 422.50(a)(3)(ii). Specifically, we proposed to modify the language of § 422.110(b) to state that if an MA organization chose to apply the rule in § 422.50(a)(3)(ii), and allowed individuals who are enrolled in a health plan at the time of first entitlement to Medicare, but residing outside the MA plan's service area to remain enrolled, the MA plan must also allow this for individuals with ESRD.

We also proposed to remove § 422.110(c), since it is duplicative of a requirement now appearing in § 422.502(h).

We received no comments on this section, so we finalize it as proposed.

10. Disclosure Requirements (§ 422.111)

Section 1851(d)(2)(A) of the Act and § 422.111(d)(2) establish disclosure requirements. MA plans must provide notice to plan members of impending changes to plan benefits, premiums, and copays in the coming year so that plan members will be in the best position to make an informed choice on continued enrollment in or disenrollment from that plan. We proposed to amend this section to reflect that notice must be provided at least 2 weeks before the Annual Coordinated Election Period commences, instead of listing a specific date in order to provide flexibility in the event that the beginning date of the Annual Coordinated Election Period changes in the future.

We also proposed to remove § 422.111(f)(4), as the requirement to provide information on Medigap and Medicare Select plans is a Secretarial responsibility under section 1851(d)(2)(A)(i) and (d)(3)(D) of the Act and is to occur as part of the ''open season notification'' required by section 1851(d)(2)(A) of the Act.

In addition to an ''open season'' notification, information on Medigap and Medicare Select is available year-round from the Federally funded SHIP and the 1–800 MEDICARE telephone number. Both the local SHIP and the 1–800 MEDICARE telephone numbers are prominently displayed in MA plan literature. In addition, we stated that we would continue to require MA plans to publicize the availability of information on Medigap, Medicare Select, and other MA plans through appropriate CMS information channels (for example, *www.Medicare.gov*, 1–800–MEDICARE). This not only would remove an unnecessary administrative burden, but also would ensure that reliable, accurate, and complete information is made available to those seeking it.

To accomplish the above proposed changes, we proposed conforming organizational changes to § 422.111. We also proposed the following disclosure requirement changes:

- We removed the requirement that MAs and MSAs provide comparative information related to other MA plans.
- To prevent what might otherwise be the unreasonable result that MA regional or national plans would be required to provide comprehensive lists of contracting providers to all enrollees, we modified paragraph (b)(3). (We specifically proposed to require MA organizations, however, to provide information on contracted providers in other parts of the plan's service area upon request in § 422.111(f)(10). Note that we changed the specific wording of this paragraph to more plainly express our intent and in response to comments, as described in further detail below.)
- We modified paragraph (b)(3) to read: ''The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services;≥
- We added a new paragraph (f)(10), which reads: ''The names, addresses, and phone numbers of contracted providers from whom the enrollee may obtain in-network coverage in other parts of the service area.''
- At § 422.111(b)(11), we proposed to require MA regional plans to provide members an annual description (at the time of enrollment and annually thereafter) of the catastrophic stop-loss coverage and single deductible (if any) applicable under the plan.
- We changed the existing paragraph (f)(11) (the new paragraph (f)(9)) related to supplemental benefits.
- We also said that we were considering a requirement that all MA organizations sponsoring MA plans would be required to maintain plan-specific information on Internet web sites. We discuss this in more detail below.

In § 422.112(a)(1)(ii), we provide an ''exception'' to the requirement in § 422.112(a)(1) related to contracted provider networks in MA regional plans. We received a number of comments on this ''exception'' and address them later in this section of the preamble. We also explain later in this preamble why we are establishing a new beneficiary notification requirement related to enrollees of MA regional plans in § 422.111(b)(3)(ii). This new MA regional plan notification requirement is intended to parallel a similar OPM requirement imposed on the FEHB Blue Cross and Blue Shield Basic Option plan, which addresses similar circumstances and situations encountered by Federal employees and annuitants when seeking health care.

We have added a new paragraph to the regulation at § 422.101(b)(5) that will require MA organizations that elect to apply local coverage policies uniformly across a local MA plan's service area, or across an MA regional plan's service area, to inform enrollees and potential providers of the applicable local coverage policy that applies to the MA plan enrollees. We make conforming changes to § 422.111.

Comment: A commenter recommended that CMS explicitly state in the disclosure requirements related to MA plans that there were additional disclosure requirements under Part D with which MA-PD plans would also need to comply.

Response: We accept this comment. Although such a requirement is implicit in § 422.111(a)(2), where we require MA plans to disclose the ''benefits offered under the plan,'' we will explicitly state the requirement at § 422.111(a)(2). To the extent an MA plan offers Part D to its MA enrollees as an MA-PD plan, it will also be required to follow the disclosure requirements in § 423.128 related to the disclosure of its Part D offering.

Comment: A commenter recommended that CMS more directly address the ''free access'' MA enrollees have to Medicare hospice services and the fact that MA enrollees have the right to continue to receive non-hospice services, unrelated to the terminal illness, from the MA plan. The commenter wanted to ensure that MA enrollees knew that they could continue to receive from the MA plan non-hospice services unrelated to the terminal illness, as long as enrollees remain members of the plan.

Response: We do not believe a specific disclosure requirement of the type the commenter requests is necessary because our existing regulations already require disclosure of Medicare hospice availability, rules related to receipt of care, and financial responsibility, in § 422.111(b)(2)(iii) and

§ 422.320(a) (formerly codified at § 422.266(a)). Otherwise, because non-hospice benefits of an MA plan continue to be available after hospice election and while an individual remains enrolled in an MA plan, such availability must be disclosed under § 422.111(b)(2).

Comment: Several commenters recommended that CMS require MA organizations to inform beneficiaries about their benefits or restrictions on those benefits. For example, one commenter suggested providing information on the average number and type of home health visits per episode that were covered by an MA plan during the prior year and beneficiaries' average cost sharing; the names of home health providers in the plan's network and the number of years the provider has operated as a Medicare home health agency.

Response: We agree that disclosure of MA plan benefits continues to be an important feature that permits beneficiaries to make informed decisions on enrollment. As previously stated, MA plans are obligated to disclose information on benefits, including applicable conditions and limitations on their receipt, the plan premiums, and the cost sharing related to specific benefits when obtained both in- and out-of-network. We also require MA organizations to disclose information on the number, mix, and distribution (including addresses) of providers from whom enrollees may obtain services. These disclosure requirements are described in regulation at § 422.111 and have not materially changed. Although MA plans are not required to specify the average number of visits or types of visits per episode from the prior year, as the comment suggests, the plans are required to provide all covered home health services, which include, at a minimum, the Medicare FFS level of benefits. We will not require MA plans to specify the number of years a home health agency has operated, nor the other specifics that the comment suggests because this would impose an additional burden upon plans that we think in unnecessary in light of the existing ways in which beneficiaries can obtain such information.

The requirement that a plan disclose the name(s) and address(es) of the contracting home health agency or agencies is already set forth in our regulations at § 422.111(b)(3), redesignated as subparagraph (i). The additional information about which the commenter suggests requiring disclosure may be available, upon request, from either the MA plan or through a direct request to the contracting home health agency or agencies.

Comment: Several commenters noted the deletion of the word ''written'' from the first sentence of § 422.111(e). One commenter stated that removing the word might allow an MA organization to meet this disclosure requirement by simply posting information on its web site.

Response: The deletion of the word ''written'' was unintentional. We have reinserted it in the regulations text at § 422.111(e). We will continue to require MA organizations to make a good faith effort to notify members in writing of changes in provider networks.

Comment: A commenter recommended that we convey the language in § 422.111(f)(10). The commenter asked if the intent of paragraph (f)(10) was to complement the requirement in § 422.111(b)(3)(i) that routine disclosure of contracting providers was limited to those from whom an enrollee would ''reasonably be expected to obtain services.'' The commenter suggested that the language in paragraph (f)(10) was imprecise, if that was our intent, since it required disclosure, upon request, of other providers ''in other areas,'' although we may have actually meant to convey the disclosure, upon request, of contracted providers ''in other parts of the service area.''

Response: We agree with this comment and have corrected the language in § 422.111(f)(10). Our intent was to make information on the availability of other contracted providers in other parts of the service area of the MA plan available to plan enrollees upon request, to the extent such information was not provided at the time of enrollment, because of the large geographic area encompassed within the service area of the MA plan.

Comment: Some commenters opposed the deletion of § 422.111(f)(7)(i) through (iv) that eliminates the requirement that MA PFFS and MSAs plans provide comparative information related to other MA plans that are available in the geographic area in which the PFFS and MSAs plans are offered. These commenters stated that potential MA enrollees should be able to easily see how these plans compare to other MA plans and original FFS Medicare.

Response: We agree that individuals considering enrollment in an MA MSA or PFFS plan should have comparative information regarding their choices for receiving Medicare coverage. All MA plans, including MA MSA and PFFS plans, must continue providing comparative information on FFS Medicare through pre-enrollment materials including the Summary of Benefits. The Summary of Benefits contains a matrix that provides a comprehensive comparison of the benefits of an MA plan with the benefits of original FFS Medicare. As we discussed in the August 3, 2004 proposed rule, we believe that the *Medicare and You Handbook* in conjunction with other CMS information channels (such as the 1–800 MEDICARE call center and direct beneficiary counseling provided through federal SHIP grants to the states) provides the best opportunity for Medicare beneficiaries considering MA plan enrollment to receive clear, impartial, and complete information on the choices available to them. Therefore, we will delete these requirements, as they represent an unnecessary administrative burden on MA MSA and PFFS plans.

Comment: Some commenters suggested including a provision in § 422.111(e) that would allow AI/AN to switch to another MA plan whenever there is a change to the provider network of the MA plan in which the AI/AN is enrolled.

Response: We cannot accommodate this request because there is no statutory basis for differentiating between AI/AN and non-AI/AN beneficiaries. However, to the extent that conditions in § 422.62(b), where special election periods are discussed, are present for *any* MA plan enrollee, the opportunity to switch plans or to return to original FFS Medicare is available.

Comment: One commenter recommended that CMS remove the annual requirement for distribution of network provider directories. The commenter stated that for a vast majority of enrollees, the provider directory is not referenced and the information could more reasonably be made available on an ''as requested'' basis after initial provision upon enrollment.

Response: Under section 1852(c)(1)(C) of the Act, MA organizations are required to provide annually, in clear, accurate and standardized form, detailed information about the number, mix and distribution of plan providers. We have interpreted this requirement in regulations to include annual disclosure of plan providers' addresses.

Comment: Most commenters supported the new language in § 422.111(b)(3)(i). A few commenters recommended that CMS define or explain the statement, ''MA organizations would be responsible for providing the number, mix and addresses ''of providers from whom

enrollees may reasonably be expected to obtain services.'' One commenter suggested that the language was unclear, subject to broad interpretation and would result in confusion and an inconsistent application by MA organizations.

Response: We believe that the standard of ''reasonable'' disclosure of network providers is both appropriate and sufficiently clear within our current regulatory standards. We believe that MA organizations are in the best position to determine what would be ''reasonable'' in this context, based on service usage and community patterns of care. In order to preserve flexibility for MA organizations to provide information appropriate to the needs of their enrollees, we do not intend to change the proposed language in § 422.111.

Comment: A number of commenters recommended that CMS apply special disclosure requirements to AI/AN beneficiaries, stating that such special disclosure requirements should include a right by AI/AN beneficiaries to select another MA plan at any time without penalty.

Response: We cannot accommodate this request because there is no statutory basis for differentiating between AI/AN and non-AI/AN beneficiaries.

Internet

In the August 3, 2004 proposed rule, we asked for comments on whether or not we should require all MA organizations for all MA plans they offer to set up an Internet web site that would make basic MA plan information and materials available to interested Medicare beneficiaries and other parties. The basic information and materials could include the Evidence of Coverage, the Summary of Benefits, and information (names, addresses, phone numbers, specialty) on the network of contracted providers. Those Internet materials and information would duplicate materials already produced in print format and made available by MA organizations relative to the MA plans they offer.

Comment: Many commenters stated that it would be difficult for providers to know whether an MA organization had chosen to adopt one of the uniform coverage policies in § 422.101(b)(3), related to local MA plans, or § 422.101(b)(4)—related to MA regional plans.

Response: As we discuss at more length earlier in this preamble related to § 422.101(b)(3) and (b)(4), we agree with this comment and therefore have added a requirement at § 422.111(f)(11) that MA organizations must make uniform coverage policies related to an MA plan readily available to members and providers, including through the Internet.

Comment: Many commenters were supportive of the proposed requirement that all MA organizations provide basic materials, such as the Evidence of Coverage, Summary of Benefits, and information (names, addresses, phone numbers, specialty) on the network of contracted providers. Some commenters suggested that CMS not be overly prescriptive in the requirements for what MA organizations post to a web site. Some suggested that the provision of information over the Internet should relieve MA organizations of their responsibility to provide identical information to enrollees in hard-copy format. One commenter suggested that CMS make plan enrollees ''opt-in,'' if they want plan information sent to their homes.

Other commenters stated that most Medicare beneficiaries do not have access to the Internet, and that regardless of whether an MA organization provides plan information electronically, we should continue to require MA organizations to send enrollees required information through the mail. One commenter stated that it did not want its member handbook or Evidence of Coverage to appear on the Internet. The commenter stated that it would prefer to have the documents available only to members. Other commenters stated that requiring an MA organization to duplicate materials such as the Evidence of Coverage or the Summary of Benefits on the Internet would be administratively redundant, costly, and burdensome to maintain. One commenter suggested leaving the decision on an Internet web site to the discretion of the MA organization. This commenter stated that although it supports use of the Internet, MA organizations should not be required to post specific documents to the Internet, since they are already provided to enrollees in hard copy.

Response: Based on these comments, we will be as flexible as possible, while still ensuring that beneficiaries receive the information necessary to make informed choices. We will require MA organizations exercising options under § 422.101(b)(3) or (b)(4) to communicate, via the Internet and through other means, the fact that a specific local coverage determination is in effect for its plan members. We have placed this requirement at § 422.111(f)(11). Use of the Internet in this way will ensure that potential providers have access to plan coverage information to the extent that it differs from the Medicare coverage policy in the geographic area in which the provider is actually treating an MA plan enrollee. Similarly, we will require MA organizations that have Internet web sites to post the Evidence of Coverage, the Summary of Benefits, and information on the network of contracted providers at § 422.111(f)(12). Because we apply this requirement only to organizations that otherwise maintain Internet web sites, we do not believe that such a requirement is overly burdensome or that it will entail a significant administrative effort. In addition, because the Evidence of Coverage and the Summary of Benefits do not change during the course of a calendar year, maintaining or updating the information in them will be a once-a-year activity, which will coincide with the update of the hard copy version of these documents. Updating of the provider directory might entail additional administrative effort; however, to the extent that MA organizations are already required to update provider information in written materials, we do not believe that extending this requirement to an electronic version of the same document would entail a great deal of additional administrative effort.

In response to the commenters that asked if the use of Internet versions of required documents would eliminate (or mitigate) the requirement for hard copy documents, we have added a final sentence to § 422.111(f)(12) that states that we will maintain our current requirement that MA organizations provide to enrollees written, hard copy materials providing information at the time of enrollment and annually thereafter as required by § 422.112(a) and (b). Most Medicare beneficiaries do not routinely use the Internet. To the extent they do and do not wish to receive hard copy plan materials, they can and will indicate such a preference. In response to commenters who did not believe it appropriate to post plan materials to the Internet, we respond that we believe it is an important feature of beneficiary choice to be fully informed regarding the benefits and features of an MA plan *before* enrollment. Plan materials, including the Evidence of Coverage, the Summary of Benefits, and a list of contracting providers are essential pre-enrollment materials that allow Medicare beneficiaries an opportunity to compare MA plans and to make an informed decision on enrollment.

11. Access to Services (§ 422.112)

There are no new access standards for MA regional plans, and existing MA standards will generally apply. We

reviewed our existing regulatory requirements related to network adequacy and proposed to remove some that are either duplicative or, in our view, overly onerous. We stated we expected competition to be the best method for ensuring network adequacy, as enrollees will favor and enroll in plans with more extensive networks and tend to avoid those without. Furthermore, Medicare beneficiaries can always choose to remain enrolled in the original Medicare FFS program.

We proposed to remove or modify some the requirements from § 422.112 of the regulation, none of which were required by statute, and some of which became unnecessary as they were replaced or superseded by requirements in the MMA:

- We proposed to delete § 422.112(a)(4), because we believed it would be redundant to suggest a specific approach to quality improvement activities in the context of, and as a means of ensuring, enrollee access to care. After reviewing and responding to comments (below), we will implement as proposed and delete § 422.112(a)(4).
- We proposed to remove the written standards requirements in § 422.112(a)(7) since they were duplicative of other provisions in the regulation. Based on a comment we received, we will not delete the requirement.

In the final rule we make editorial corrections to § 422.112(a) heading and introductory text to remove reference to ''network M+C MSA plans'' and ''additional'' services, neither of which terms have relevance in the MA program.

Comment: We received a few comments related to our proposal to remove requirements in § 422.112(a)(7). One commenter asked us to articulate what tools, other than written standards, an MA plan should use to ensure adequate access to medically necessary health care items and services. Other commenters objected to removal of written standards.

Response: Written standards are simply one aspect of an MA coordinated care plan's guarantee of access to care. Such written standards do not, in and of themselves, constitute a sufficient guarantee of access to care. To the extent that written standards are not enforced, they guarantee little. However, we agree with the commenters and believe that the requirement for written standards will, at the very least, prompt plans to affirmatively address and memorialize how they intend to provide access to care. In light of the comments we received and upon further consideration, we will retain the requirement for written access standards in § 422.112(a)(7).

Comment: One commenter recommended that CMS modify the rules to create waivers that would allow ESRD patients to be referred to nephrologists, dialysis centers, or vascular surgeons who are out-of-network if the patient prefers another physician or center, or if the referring nephrologist believes that the vascular access outcomes would be better with the out-of-network surgeon. The commenter also suggested allowing self-referrals to specialists, such as allowing ESRD patients to self-refer to nephrologists, dialysis centers, or vascular surgeons who were out-of-network. Another commenter suggested including certain benefits in the MA benefit package, such as medical nutrition therapy (MNT) benefits for diabetes and renal diseases.

Response: To respond to the first comment on the provision of benefits to ESRD beneficiaries out-of-network, PPOs are a type of coordinated care plan, as described in § 422.4(a)(1)(iii), that are required to provide reimbursement for all covered benefits regardless of whether they are provided in- or out-of-network. Therefore, a beneficiary with ESRD who is enrolled in an MA PPO plan may go out-of-network for all covered services, albeit with a potentially higher cost-sharing liability. Coordinated care plans are permitted to use mechanisms to control utilization, such as requiring referrals from a ''gatekeeper'' PCP, before an enrollee can receive in-network specialty services at in-network cost sharing levels, as codified in regulations at § 422.4(a)(1)(ii)and § 422.112(a)(2). Therefore, access to a specialist at in-network cost-sharing levels can generally be limited to contracted providers in coordinated care plans. When an individual beneficiary chooses a coordinated care plan, information is available about the availability of providers, including specialists, and under what conditions they are available in-network. Information on the routine availability of out-of-network care (either because the plan is an HMOPOS or a PPO, for instance) is also provided at the time of enrollment and annually thereafter. On the second point related to requiring MNT benefits for diabetes and renal diseases in MA plans, we remind the commenter that all MA plans are required to include all Medicare FFS benefits in their MA plan benefit packages.

Comment: One commenter recommended that CMS require all MA plans to include podiatric physicians in their networks to ensure that the necessary and vital services provided by these physicians continue to be available to patients. The commenter stated that § 422.205(a) prohibits MA organizations from discriminating against providers on the basis of license or certification.

Response: We do not see a basis for requiring MA organizations to contract with a specific provider type. As the commenter stated, our existing regulations prohibit discrimination on the basis of license or certification. Further, our existing regulations, as amended in this final rule, require MA organizations to ensure that covered services are available and accessible within an MA plan's network consistent with applicable access standards. However, § 422.205(b), which is not being amended in this rule, allows MA organizations to refuse to grant participation to health care professionals in excess of the number necessary to meet the needs of an MA plan's enrollees (with the exception of PFFS plans).

Comment: One commenter agreed that the requirements in § 422.112(a)(4) are duplicative of the proposed chronic care improvement requirements in § 422.152(c), and therefore generally agreed that it should be deleted. However, the commenter also stated that deletion of requirements at § 422.112(a)(4) should be made contingent on our addition of a requirement in § 422.152(c) that chronic care improvement programs be based on objective and evidence-based criteria, such as clinical practice guidelines.

Response: We address comments related to § 422.152(c) in the subpart D section of the preamble (below). Because chronic care improvement programs will be regulated under the provisions in subpart D of the 42 CFR part 422, we believe it remains appropriate to delete regulatory requirements concerning complex or serious medical conditions from § 422.112(a)(4).

Comment: One commenter asked whether access to covered MA plan services can be denied, if the MA plan enrollee does not pay plan required cost sharing at the time of service.

Response: The MA organization's responsibility for provision of plan covered services supersedes the member's responsibility for payment of cost sharing at the time of service. Therefore, the MA organization cannot deny provision of a medically necessary covered service for want of the payment of applicable cost sharing at the time of service.

Comment: One commenter stated that CMS should add a provision in the regulation that would apply section 1861(s)(2)(H) of the Act to MA plans offered by MA organizations.

Response: We do not agree. Both section 1861(s)(2)(H)(i) and (ii) of the Act are specific in their applicability to contracts under section 1876 of the Act. Contracts with MA organizations for MA plans are under section 1857 of the Act.

Continuity of Care

Section 422.112(b) requires all MA organizations for all MA plans they offer to ensure continuity of care through integration of health care services. Additional requirements in § 422.112(b)(1) through (b)(6) require specific methods by which MA organizations are to ensure an effective continuity and integration of health care services. Although all of the enumerated services and processes are clearly desirable, it is not as clear that the responsibility for them is appropriately or reasonably placed on organizations whose business is primarily insurance coverage. Although it may be reasonable to expect coordinated care plans to undertake these coordination, continuity, and integration requirements, it is less clear that MA PFFS plans, MSAs, and (to a lesser extent) local PPO plans and MA regional plans (which will be offered as PPOs) should also be expected to. One might argue that continuity of care rules cannot apply in the same manner to MA plans in which the enrollee is free to choose his or her own providers without restraint, such as MSAs and PFFS plans. We stated that we were considering eliminating most of the requirements in § 422.112(b) for MSAs and PFFS plans. We also stated that we were considering eliminating or modifying many of the requirements in § 422.112(b) for local PPOs and regional MA plans. Finally, we stated that we were considering the continued appropriateness of these continuity of care standards for all other coordinated care plans. We specifically welcomed input on the extent to which requirements similar to those in § 422.112(b)(1) through (b)(6) are established for commercial health insurers offering HMOs, PPOs or indemnity plans.

Based on comments we received, we will continue to apply existing continuity of care requirements in § 422.112(b)(1) through (b)(6), but we will limit their scope of applicability to coordinated care plans and then only to the services provided and coordinated by contracted, network providers.

Comment: Many commenters provided input on this issue. A large number of commenters stated that continuity of care and integration of services is a key aspect of managed care. To the extent the original FFS Medicare program has been perceived to be deficient in this aspect of health care delivery, many commenters believe that CMS should ensure that a similar ''failure'' in managed care is not allowed. A number of commenters supported the removal of continuity of care requirements related to MA MSA and PFFS plans in recognition of the fact that these types of MA plans are primarily in the business of paying claims and not in the business of coordinating health care through contracted networks of health care providers. Other commenters stated that it was especially for MA plans that did not have contracted provider networks, such as PFFS plans or MSA plans, that continuity of care requirements were most needed.

Some commenters agreed with CMS proposal to eliminate and/or reduce continuity of care requirements for open network MA plans, such as PFFS plans and PPO plans. Other commenters suggested removing all continuity of care requirements for all MA plans, saying that such requirements were duplicative of QI program activities required under section 1852(e) of the Act.

Response: Based on the comments, and because PPOs operate as both coordinated care plans and ''open network'' plans at the same time, we will modify this portion of the regulation. We will specify in § 422.112(b) that the enumerated coordination of care requirements in § 422.112(b)(1) through (6) are applicable only to coordinated care plans. We will also limit applicability of coordination of care requirements to only contracting, in-network providers, thus limiting applicability for MA PPOs to only those services provided by contracted providers. We believe such an approach strikes the appropriate balance between the need for coordination and continuity of care and the burden associated with seeking to undertake such activities in the absence of contractual relationships with providers.

Finally, we do not agree that continuity of care requirements are duplicative of QI program activities required under section 1852(e) of the Act. QI activities will generally and primarily be focused on individuals with multiple or severe chronic conditions. Access to an initial health assessment, on the other hand, as provided in § 422.112(b)(4)(i), should include all enrollees of an MA coordinated care plan, and not only those with multiple or severe chronic conditions.

Comment: A few commenters stated that CMS appeared to be deleting a paragraph (i) from paragraph (b)(4) in the regulations text at § 422.112, but had no corresponding discussion in the preamble of the proposed rule.

Response: We thank the commenters for identifying this oversight and have corrected the regulations text related to § 422.112(b)(4) to show that none of the subparagraphs is to be deleted and that renumbering is unnecessary.

Access ''Exception'' for MA Regional Plans

The MMA created a special access rule for MA regional plans in the form of an ''essential hospital'' payment. Section 1858(h) of the Act and implementing regulations related to ''essential hospitals'' are discussed in greater detail later in this section of the preamble.

We noted that in attempting to create region-wide networks, MA regional plans will be forced to bargain with hospitals that may be the only hospital (or the only hospital with a particular service or services) in a broad area. We believed that such a hospital would have a ''monopoly power'' in negotiating with plans that are, in effect, forced to contract with it in order to secure an adequate network of contracted providers with which to serve anticipated Medicare enrollees. The MMA attempted to partly address this situation through a provision that would make limited funds available to supplement payments to such ''essential hospitals.'' We proposed an additional special access requirement that also would only apply to MA regional plans at § 422.112(a)(1)(ii).

In § 422.112(a)(1)(ii), we proposed an ''exception'' to the normal access requirements that would otherwise apply to MA regional plans by adding language that provided for a relaxation of comprehensive network adequacy requirements, but only to the extent that beneficiaries were not put ''at risk'' for high cost sharing related to services received from non network providers. We believed that flexibility did not need to apply on a plan-wide basis, but rather could be applied in a county or a portion of a region where, for example, the MA regional plan was unable to secure contracts with an adequate number of a specific type of provider or providers to satisfy our comprehensive network adequacy requirements that

would otherwise apply to coordinated care plan models.

We considered two forms of beneficiary cost sharing. One was the cost sharing related to a specific item or service—for instance, a hospital coinsurance charge. Another was the ''catastrophic limits'' that MA regional plans must apply to original Medicare FFS benefits. MA regional plans are required to provide reimbursement for all covered benefits regardless of whether those benefits are received from network providers (see section 1859(b)(4)(B) of the Act and the new § 422.101(e)(1)). MA regional plans are also required to apply a catastrophic out-of-pocket limit on beneficiary cost sharing for covered in-network services and another on all covered services (in and out-of-network). See section 1858(b)(2)(B) of the Act and the new § 422.101(d)(2) and (d)(3).

We proposed to permit MA regional plans with lower out-of-network cost sharing to have less robust networks of contracted providers and to permit MA regional plans with more robust networks of contracted providers to impose higher cost sharing charges for out-of-network services. This was because to the extent the plans' networks were robust, we would not expect beneficiary access to be unduly limited by higher cost-sharing requirements when care was sought from non-network providers. However, for plans with less robust networks, we proposed to limit the plans' ability to impose higher cost-sharing requirements for out-of-network care. We believed that higher cost-sharing requirements imposed by plans with limited provider networks could unduly limit access and that more equitable cost-sharing requirements would serve as a safety valve to ensure that beneficiary access is not compromised. We discussed various methods for testing the robustness of MA regional plan provider networks. Along similar lines, we would require MA regional plans with a less robust network of contracted providers to have ''catastrophic limits'' on out-of-pocket expenditures for in-network and for all services that are closer in value. For plans with more robust contracted networks, we would allow the in-network and total ''catastrophic limits'' to differ to a greater degree.

Based on the comments we received and which we respond to (below), we will not be prescribing specific levels of cost sharing based on robustness of contracted provider networks. Rather, we will require MA organizations sponsoring MA regional plans to ensure enrollees have access to in-network levels of cost sharing for covered services. We will require MA organizations sponsoring MA regional plans to reduce cost sharing to in-network levels for the receipt of out-of-network services in cases in which covered services cannot be readily obtained from contracted, network providers.

In this part of the preamble of the proposed rule we also discussed the OPM requirement imposed on the FEHB Blue Cross and Blue Shield Basic Option plan, which addresses similar circumstances and situations encountered by Federal employees and annuitants when seeking health care. We stated that the ''exception'' process related to access to care requirements for MA regional plans might require the MA regional plan enrollee to contact the sponsoring MA organization when seeking a specific service that is not otherwise available from a contracted provider. We are adopting that proposal. We will require MA organizations sponsoring MA regional plans to designate a non-contracted provider from whom (or from which) the enrollee can obtain covered services at network cost-sharing levels, to the extent that such services are not available and accessible from a contracted, network provider. Alternatively, the MA organization can allow the enrollee to seek the service from any qualified provider and guarantee that in-network cost sharing limits will apply. We have established a new beneficiary notification requirement related to enrollees of MA regional plans in § 422.111(b)(3)(ii). We add this requirement to ensure that the access ''exception'' in § 422.112(a)(1)(ii) does not disadvantage beneficiaries seeking in-network care.

Comment: Several commenters were received on this proposed provision. Many of the commenters suggested that the ''exception'' should also apply to all local MA coordinated care plans, or even all local MA plans, while others suggested limiting it to local and MA regional PPOs.

Response: Local MA plans of all types have discretion to limit their service areas based on their network of contracted providers. Unlike local MA plans, MA regional plans are required, as a condition of offering an MA regional plan, to include the entire geographic area of an MA region in the service area of the plan. In some ways, the ''exception'' we provide at § 422.112(a)(1)(ii) for MA regional plans is comparable to the ''partial county'' provision provided for local MA plans in the service area definition at § 422.2. Under § 422.2, we permit an MA organization to contract with CMS for a local MA plan where the organization has a contracted network in only a portion of a county and when such a ''partial county'' is necessary, nondiscriminatory, in the best interests of the beneficiaries and where other conditions are met. We will also permit MA organizations to contract with CMS for an MA regional plan where beneficiaries are not put ''at risk'' even though the MA organization does not have contracts with robust networks of providers throughout the MA region. For these reasons, it is both inappropriate and unnecessary to provide such an ''exception'' for local MA plans.

Comment: Other commenters were opposed to allowing an ''exception'' to the normal access to care requirements to any MA coordinated care plan, including MA regional plans. One commenter suggested limiting the ''exception'' to only an initial start-up period, the first contract year, for instance even for MA regional plans.

Response: As noted above, we believe the ''exception'' we proposed for MA regional plan access to care requirements is essential to foster the growth of the MA regional plan program, a goal consistent with the Congressional intent in creating the program. We are concerned that in the absence of this ''exception,'' the provisions we discuss below related to beneficiary access to ''essential hospitals'' would not be sufficient to allow MA regional plans to meet access to care requirements for coordinated care plans.

The ''exception'' we provide at § 422.112(a)(1)(ii) is necessary because ''essential hospitals'' will not be contracting with MA organizations for MA regional plan members, but will be a necessary part of the MA regional plan's network in order for the MA regional plan to meet the applicable provider access requirements under section 1852 of the Act. Section 422.112(a)(1)(ii) acknowledges that some providers, such as ''essential hospitals,'' will not have a contract, but will be considered part of the network because they will be providers at which beneficiaries can seek care at in-network cost sharing levels. We do not believe it is appropriate to limit the ''exception'' to an initial start-up period, particularly because the ''essential hospital'' provision is not so limited. On the other hand, we agree that it would be appropriate to annually evaluate the ''subsection d'' hospitals that have been designated as ''essential hospitals'' by MA regional plans to ensure that the

conditions that permitted such designation continue to exist.

Therefore, we have added a requirement at § 422.112(c)(7) under which we will evaluate the continued applicability of ''essential hospital'' status on an annual basis at the time of annual contract renewal. Please see below for a more extensive discussion of ''essential hospitals.''

Comment: A few commenters suggested that CMS subject MA organizations offering MA regional plans to review by external entities and the general public to ensure that MA regional plans meet community access standards.

Response: We do not believe a mandatory external review of network adequacy is appropriate because the delay and burden associated with such a process could negate the competitive and market forces that the Congress intended should apply in the regional MA program. Ultimately, such a result could have the very effect the commenters are seeking to avoid, an adverse impact on beneficiary access. Section 1852(e)(4) of the Act provides for a private accreditation organization's external review of MA organizations in specific areas, including access to services. Nothing in section 1852(e)(4) can be construed as imposing mandatory external review on an MA organization of the type the commenters propose. Otherwise, the time frame between an organization's submission of an application for an MA contract year and CMS' approval or denial of that application would be too short to permit sufficient time for a formal, public comment period.

Comment: Many commenters expressed concern that CMS seemed to be relaxing the community access standards with the ''exception'' process we provided for MA regional plans in § 422.112(a)(1)(ii). Some commenters stated that to the extent CMS will pay MA regional plans more through various mechanisms, such as the ''stabilization'' fund, risk corridors in 2006 and 2007, and the new MA payment formula, therefore CMS also has reason to hold them to the same access standards to which CMS holds local MA plans. Other commenters supported the ''exception'' process and suggested that it be extended to local MA PPOs.

Response: As we have previously said, we will not permit local MA coordinated care plans to take advantage of the ''exception'' process in § 422.112(a)(1)(ii). The exception process is necessary precisely because we will require MA regional plans to meet community access standards. We explained in the proposed rule that to the extent an MA regional plan is unable to secure contracts with specific providers in specific areas of an MA region, beneficiaries would nonetheless be protected from excessive out-of-network cost sharing. In other words, it is exactly because we will continue to enforce community access standards that we will require MA regional plans to reduce cost sharing to in-network levels where covered services cannot be readily obtained from contracted, network providers. We establish a new beneficiary notification requirement related to enrollees of MA regional plans in § 422.111(b)(3)(ii) to reinforce this concept.

Comment: Some commenters stated that CMS should require hospitals to treat MA regional plan enrollees when they are offered the Medicare FFS payment rate that is payable under section 1886 of the Act by an MA regional plan, as long as in-network cost sharing levels are applied to enrollees that seek care at such non-contracting hospitals. One commenter stated that sole community hospitals, or hospitals serving medically underserved areas or non-urban areas should be required to treat MA regional plan enrollees if they refused to contract for FFS rates. One commenter recommended that CMS reevaluate the non-discrimination obligation of hospitals under the Medicare program and suggested that CMS establish a policy that would promote access to services at hospitals participating in the Medicare program on the same basis for all Medicare beneficiaries, regardless of whether they are MA enrollees or receiving coverage under the Medicare FFS program. One commenter recommended that CMS develop further regulations that would require providers to treat MA patients in all cases, even for elective services.

Response: We do not necessarily agree that we should establish a policy that would require Medicare participating hospitals to treat MA enrollees or to contract with MA organizations under specific terms or conditions. Were we to establish a specific price relative to FFS inpatient hospital payment rates as a baseline that would compel a hospital to treat MA plan enrollees, for instance, we would also be administering inpatient hospital pricing. We do not believe that a requirement to treat for an administered price is consistent with the overall intent of the MMA to increase plan choices for Medicare beneficiaries through competitive market forces. However, we acknowledge that MA provider contracting, especially in areas where there are few available providers, is a concern. We will continue to evaluate our current authorities outside of the MMA as a means of ensuring reasonable access at reasonable prices to medical services for all Medicare enrollees, including those electing to receive their coverage through an MA plan.

Comment: Some commenters stated that the ''exception'' CMS proposed in § 422.112(a)(1)(ii) would tend to put providers at a disadvantage vis-à-vis MA regional plans. The commenters stated that MA regional plans would offer reimbursement rates below FFS rates and as such, unilaterally dictate the terms of the contract. The commenters stated that this would be unfair to physicians and other providers. The commenters also stated that this would create an unfair playing field, especially because MA regional plan enrollees in such an area would then be required to go out-of-network at higher cost sharing levels, to receive covered medically necessary care.

Response: We disagree. MA regional plans will be required to make all covered services available at in-network cost sharing levels, even if an MA regional plan fails to reach mutually agreeable contracting terms with a specific provider or group of providers. In other words, MA regional plan enrollees will have access to medically necessary covered health services at in-network cost sharing levels. The MA regional plan must meet the access requirements either through contracted providers or through the ''exception'' process discussed above. Because section 1852(a)(2) of the Act requires MA organizations that use a contracted network to pay non-contracting providers at the Medicare FFS rate, once the MA regional plan enrollee pays in-network cost sharing, the MA organization will be financially responsible for the rest.

Comment: One commenter stated that CMS should adopt URAC, NCQA or JACHO standards related to MA PPO network adequacy requirements and privacy of beneficiary information requirements. The commenter stated that for network adequacy requirements and privacy requirements, as for all other federal regulatory requirements, to the extent that any accreditation standard of any of the three accrediting bodies applies to the same activity, compliance should be deemed for the PPO to be in compliance with the federal requirement.

Response: We do not necessarily agree. Under section 1852(e)(4) of the Act, when a private accrediting organization applies and enforces certain enumerated requirements that meet or exceed CMS standards, CMS can deem that an MA plan has met such

requirements. These enumerated requirements include access requirements under section 1852(d) of the Act and confidentiality requirements under section 1852(h) of the Act. To the extent the one of the three named parties has applied to CMS and been approved in accordance with statutory and regulatory requirements to be a private accrediting organization for external review of PPO access and/or confidentiality requirements, then deeming would be permissible. Note, however, that this deeming mechanism applies only for the purposes of CMS' enforcement of this regulation and neither CMS' enforcement of the regulation nor accreditation by an accrediting body supersedes the jurisdiction of the HHS Office for Civil Rights to enforce the HIPAA privacy rule.

Comment: One commenter asked whether the access ''exception'' in § 422.112(a)(1)(ii) for MA regional plans would preempt State licensing laws related to HMO access requirements.

Response: MA regional plans are offered as PPOs and not HMOs. We responded to a similar inquiry in the June 2000 M+C final rule with comment (65 FR 40257). An entity does not have to have a commercial license of the same type of MA plan it seeks to offer under the MA program. Rather, the entity must demonstrate that it is authorized by the State to assume the risk involved in offering the type of plan it wishes to offer. Thus, an entity that is licensed by the State to assume risk commercially as an HMO would need to demonstrate that it is authorized by the State to offer a PPO product. The access standards that would apply to such an MA product would be the MA PPO access standards.

Comment: Two commenters stated that CMS should rely on MA regional plans to demonstrate access to covered services throughout their service areas at in-network cost sharing amounts and that should CMS continue to review cost sharing levels to ensure that they are not discriminatory.

Response: We agree with this comment and will continue to review cost sharing levels as a means of ensuring beneficiary access to care and that cost sharing is not discriminatory. When we evaluate access to care for an MA regional plan that relies, in part, on the ''exception'' in § 422.112(a)(1)(ii), we will evaluate the means by which the MA regional plan proposes to ensure that access requirements are met. Such means might include the designation of ''essential hospitals'' in accordance with § 422.112(c), the designation of other noncontracting providers from which an MA plan enrollee can obtain covered plan services at in-network cost sharing levels (including the catastrophic limit described in § 422.101(d)(2)) in a timely manner, and the manner in which MA regional plan enrollees will be notified as to how they can secure in-network cost sharing when covered services are not readily available from contracted providers, in accordance with § 422.111(b)(3)(ii).

Unlike local coordinated care plans, such as MA local HMOs and MA local PPOs, where we have historically required comprehensive contracted networks of providers as a condition for meeting our access requirements, we will allow MA regional plans to contract with CMS with less robust networks of contracted providers. As long as an entity proposing to offer an MA regional plan pays noncontracted providers at the Medicare FFS rate, and as long as they can guarantee access through such payment to non-contracting providers, and as long as they limit enrollee cost sharing liability to in-network levels, then we will contract with such an entity for an MA regional plan as long as other non-access requirements are met.

Comment: One commenter stated that the ''exception'' at § 422.112(a)(1)(ii) is not in the best interest of beneficiaries and that neither the preamble nor the regulation text in the proposed rule said how promptly an MA regional plan would be required to respond to a request for access to non-network sources of care, or the basis upon which such a request could be denied, or the penalty to the MA regional plan for not acting in a timely manner on such a request, or finally, what recourse the member would have if a denial or non-response from the MA regional plan occurred.

Response: An MA regional plan would be required to provide assurances of reasonable response times, if it proposed to use the ''exception'' in § 422.112(a)(1)(ii) in such a manner. Reasonable response times proposed by the MA regional plan would need to be consistent with community patterns of care. Where a routine or follow-up specialist visit might ordinarily be available within 30 days, an MA regional plan would be expected to respond in such a manner that the MA regional plan enrollee could secure covered specialist services within a similar time frame. Similarly, as part of the MA plan's disclosure to both CMS and an MA regional plan enrollee, we would require a full explanation of the denial process (where services are readily available from contracting providers, for instance) and the appeal process the enrollee should follow in cases of disagreement. The potential penalty to the MA regional plan for not acting in a timely manner on such a request is explained in our current regulation at § 422.750 and § 422.758 for a violation of § 422.752(a)(1) and § 422.510(a)(10), respectively.

Essential Hospitals

We proposed at § 422.112(c) that if an MA organization certifies that it was unable to reach an agreement with an ''essential hospital,'' under specific circumstances we are authorized to pay additional amounts to that hospital from the Federal Hospital Insurance Trust Fund. This additional payment to the ''essential hospital'' is in addition to and does not affect the normal monthly MA payment that we would make to the MA organization. The MA organization must provide assurances that it will make payment to the hospital for inpatient hospital services in an amount not less than the amount that would be payable under section 1886 of the Act and the ''essential hospital'' must demonstrate to our satisfaction that the amounts normally payable under section 1886 of the Act are less than the hospital's costs for providing services to MA regional plan enrollees.

Comment: A number of general comments were received on potential contracting difficulties between rural providers and health plans. On the one hand, several commenters were concerned that MA organizations offering MA regional plans would not make a ''good faith'' effort to contract with hospitals, especially hospitals located in rural areas. On the other hand, several commenters suggested that MA organizations offering MA regional plans in areas with limited competition could be ''held up'' for non-competitive or predatory payment rates as a condition of securing a contract with a specific provider. The commenters on both sides recommended various solutions, such as mandating the method by which MA organizations offering MA regional plans could show they have made a ''good faith'' effort to contract with providers.

Response: In response to comments that an MA regional plan should be required to show that it made a ''good faith'' effort to contract with an ''essential hospital,'' we added a requirement at § 422.112(c)(3) that the MA regional plan will need to establish its ''good faith'' effort by showing that the designated hospital refused to contract after it was offered a payment rate no less than the amount the

hospital would receive under section 1886(d) of the Act.

We agree that in certain rural areas, difficulties may arise in obtaining contracts that will satisfy the providers or the health plans, or both. However, we do not have the statutory authority to mandate contracts between MA plans or providers, or to intervene in contract negotiations. Section 1854(a)(6)(B)(iii) of the Act prohibits us from intruding in the contractual relationships between MA organizations and health care providers. This prohibition is intended to ensure that free market conditions continue to promote competition and efficiency in the MA program. We believe that it is clear that the Congress provided incentives for MA regional plans in the form of additional payments through the stabilization fund and risk sharing in 2006 and 2007, neither of which is provided for local MA plans.

Additionally, the Congress also provided for payments for noncontracting acute care hospitals that provide inpatient hospital services to MA regional plan enrollees through the ''essential hospitals'' authority. As stated previously, we believe competition will be the best method of ensuring network adequacy because enrollees will favor and enroll in plans with more extensive networks and tend to avoid those without. Competition will also allow the more efficient health care providers to offer discounted rates to MA organizations, which will, in turn be able to pass these savings on to enrollees in the form of additional health care items and services or reduced premiums.

Finally, we believe enrollees will be attracted to MA organizations that contract with efficient providers, because costs will be lower. Clearly, the competitive forces are more complex than we can address in this forum. We have been careful not to disturb the new competitive balance created by the MMA related to MA regional plans.

Our access standards are found at § 422.112, § 422.114, and in other sections of subpart C of the MA regulation. These standards must be met before an MA organization will be allowed to offer an MA plan in an area. Continuing compliance with these requirements is an essential condition of maintaining an MA contract. For instance, CMS has the authority, provided at § 422.502(a)(3)(ii) and § 422.512(a), to deny an application or to terminate a contract if an MA organization fails to establish or maintain adequate access to care for Medicare beneficiaries. In order to meet access standards, MA organizations offering coordinated care plans will generally need to secure contracts that they have negotiated with health care providers. This will require an effort by both parties to ensure a choice of health plans with strong provider networks that will be available to all beneficiaries, including those residing in rural areas.

Comment: One commenter stated that in the State in which it operates, the contracts it has with hospitals for all lines of business (Medicare, Medicaid, and commercial) cause it to pay more on the Medicare side, that cost-shifting occurs from its Medicare line of business to its commercial line of business. The commenter expressed concern that to the extent the ''essential hospital'' provision permits an MA regional plan to ''deem'' a hospital into the MA regional plan's network, that it provides an unfair competitive advantage to MA regional plans. The commenter also suggested permitting hospitals to select a single Medicare contractor (section 1876 cost, MA local or regional plan) with which to contract, and through such a contract ''immunize'' itself from all other MA regional plans' attempts to designate it as an ''essential hospital.''

Response: We do not believe it would be appropriate or reasonable to so allow a hospital to ''immunize'' itself from designation as an ''essential hospital'' by any MA regional plan. To the extent we accepted or adopted such an interpretation, we would also be nullifying the very intent of the ''essential hospital'' statutory provision. The intent of this provision is, simply put, to ensure access to hospital care for regional MA plan enrollees. The opening clause of section 1858(h)(1) of the Act is instructive in this regard: ''For purposes of enabling MA organizations that offer MA regional plans to meet applicable provider access requirements under section 1852 with respect to such plans.'' Additionally, as we provide for in regulation at § 422.112(c), before a hospital can be designated as an ''essential hospital'' by an MA regional plan, there must be a showing by convincing evidence that such a hospital is uniquely able satisfy the access requirements for the MA regional plan. If we were to limit designation of a specific hospital as an ''essential hospital'' to the first PPO in an MA region, we would also likely limit MA regional plan competition in all MA regions with rural areas to a single MA regional plan per region. Such a result clearly was not the intent of the statute.

In addition, the ''essential hospital'' provision partly addresses hospital financing issues, to the extent that we will pay additional costs to ''essential hospitals,'' up to the amount provided in statute at section 1858(h)(3) of the Act. Thus, the MA organization would not bear these additional costs for MA regional plan enrollees.

Comment: One commenter asked for clarification on how payment will work under the ''essential hospital'' provision. While the statute is clear, the commenter stated, that the additional payment is limited to inpatient services, it is unclear to the commenter whether add-ons such as medical education or disproportionate share payments will also be made to ''essential hospitals.'' The commenter recommended that CMS encourage or even require plans to provide additional reimbursement to include these amounts, which are available under inpatient PPS, to qualifying hospitals because they would be available if the beneficiary were enrolled in FFS Medicare.

Response: IME and GME payments will continue to be made by the Medicare fiscal intermediaries (FIs) to all appropriate hospitals for all Medicare beneficiaries (including MA plan enrollees). Disproportionate Share Hospital (DSH) payments are part of the normal FFS reimbursement amount and will be the responsibility of the MA regional plan, to the extent it is making a payment under § 422.100(d)(2), because, by definition, ''essential hospitals'' are defined as noncontracting hospitals per section 1858(h)(1) of the Act. In our regulation at § 422.112(c), we clarify that ''essential hospitals'' are always noncontracting with the specific MA regional plan involved.

Comment: Some commenters suggested that to the extent an MA regional plan offers to pay a hospital no less than the amount that would be payable to the hospital under section 1886 of the Act, that CMS consider this to be evidence that the MA regional plan has made a ''good faith'' effort to contract with the hospital.

Response: We agree with the commenters and have established the FFS payment level as the baseline for MA regional MA plans in establishing that they have made a ''good faith'' effort to contract with an ''essential hospital'' at § 422.112(c)(3).

Comment: Many commenters recommended that CMS specify in regulation exactly how the ''essential hospital'' provision will work and whether or not (and how) it would apply to critical access hospitals (CAHs). Other commenters cautioned CMS not to disrupt the competitive balance between MA organizations and hospitals related to MA plan contracting. Many commenters also recommended that CMS clearly explain

that CAHs are not ''essential hospitals'' as defined in the MMA. Other commenters stated that CAHs are indeed essential providers and have been designated as such under the FFS Medicare program. Some commenters suggested requiring MA regional plans to pay CAHs the ''interim'' Medicare rate in effect at the time the service was furnished.

In addition, one commenter stated that such an ''interim'' payment rate would put parties at risk that such a payment would be more (or less) than actual costs. The commenter also suggested that CMS devise a means of ensuring that MA regional plans are properly advised on the ''interim'' payment rate, should CMS accept the commenter's proposal. Still other commenters stated that CMS should not permit MA organizations to bargain in ''bad faith'' with hospitals. However, other commenters stated that CMS should not permit hospitals to bargain in ''bad faith'' with MA organizations. In general, all expressed concern and cautioned CMS not to upset the delicate balance of competition and pointed to the scarce resources and fragile financial condition of health care delivery in rural areas.

Generally, CMS was asked not to undermine the already precarious condition of rural providers, including rural health clinics, CAHs and others, while at the same time we were encouraged to increase the availability of MA plans in rural areas. One commenter recommended that CMS put in a ''hold harmless'' or ''cost-reimbursement'' requirement for insurers that contract with critical access hospitals. The commenter was concerned that as more Medicare beneficiaries opt for participation in private insurance plans, unless CAHs receive adequate funding for the services they provide, their continued existence (and consequently continued access to medical care for the beneficiaries they serve) will be greatly jeopardized. Another commenter suggested that CMS require MA plans to provide reimbursement to CAHs using a cost-based methodology similar to that required under FFS Medicare.

Another commenter stated that as more Medicare beneficiaries enroll in MA plans that do not contract with CAHs, the marginal costs (per Medicare beneficiary) at CAHs will rise and so, consequently, will Medicare payments per FFS beneficiary to CAHs. A few commenters suggested extending the ''essential hospital'' payment to local MA plans. Other commenters called on CMS to require MA plans to pay claims from noncontracting providers in a ''timely'' manner and under the same rules that apply to original FFS claims processors, the Medicare carriers and intermediaries.

In addition, several commenters expressed confusion with the following sentence from the subpart C preamble to the August 3, 2004 proposed rule: ''In a specific case, the actual payment to an 'essential hospital' from the Federal Hospital Insurance Trust Fund would be the sum of the difference between the amount that would have been paid to the hospital under section 1886 of the Act and the amount of payment that would'' have been paid for those services had the ''essential hospital'' been a critical access hospital.''

Response: We will address the last comment first. We need to clarify that the quoted sentence from the subpart C preamble of the August 3, 2004 proposed rule simply echoes the statutory language at section 1858(h)(2)(A) of the Act. The intent of the statutory ''essential hospital'' provision and the implementing regulation at § 422.112(c) is to provide an additional payment to the ''essential hospital'' of up to 101 percent of its actual costs for providing inpatient services to a specific MA regional plan enrollee. In other words, there was never an intent to designate or allow a CAH to become an ''essential hospital'' for purposes of the MA regional plan program. The definition of ''essential hospital'' in the statute prevents such an outcome. Section 1858(h)(4) of the Act is clear in defining an ''essential hospital'' as a ''subsection (d) hospital,'' as that term is defined at section 1886(d)(1)(B) of the Act. CAHs are not included in this definition and therefore can never be ''essential hospitals'' for purposes of an MA regional plan offered by an MA organization.

In § 422.112(c)(1), we are clear in limiting the applicability of the ''essential hospital'' provision in a similar manner to only hospitals defined in section 1886(d) of the Act, and thus excluding CAHs. We have addressed concerns related to maintaining a ''competitive balance'' previously in our responses in this section of the preamble. We cannot intrude in the contracting relationships between MA organizations and providers because the statute prohibits us from doing so at section 1854(a)(6)(B)(iii) of the Act. Additionally, to the extent the statute provides the additional ''essential hospital'' payment only for inpatient hospital services provided by 1886(d) hospitals to MA regional plan enrollees, we cannot extend its applicability to local MA plans of any type.

Comment: One commenter suggested that CMS maintain a comprehensive and accessible database of Medicare FFS reimbursement rates for all providers and allow MA plans access to the database so they would be better equipped to make the correct and full payment to out-of-network providers. The commenter also stated that there should be penalties or sanctions for plans that habitually under-pay out-of-network noncontracting providers. The commenter also suggested that CMS require MA organizations to follow FFS timely payment rules, including accrual of interest when claims are not paid in a timely manner. Some commenters stated that the additional difficulties inherent in paying CAHs timely and correctly, explaining that CAHs are paid on a ''cost plus'' basis.

Response: We provide public access to the FFS fee schedules and reimbursement rates. We also assists MA organizations in pricing claims for out-of-network providers by making ''Grouper/Pricer'' software and other Medicare claims'' pricing tools available to them. However, with payment rates and computations varying by provider type, locality, provider ID, and service, and with the potential that an MA plan enrollee might access covered emergency services in any part of the United States, the task of correctly applying fee schedules that are generally updated on a quarterly basis can be daunting. When one considers the low volume of such claims that an MA organization would expect to receive and the administrative effort involved in correctly pricing them, one begins to understand that simply making such data and systems available to MA organizations does not ensure that correct payment calculations will always occur. We already have the authority to apply penalties and sanctions to MA plans that habitually fail to pay out-of-network noncontracting providers in a timely manner (see, for instance, § 422.520). MA organizations are required to follow the same timely payment requirements related to con-contracting provider claims, including interest penalties, that apply to FFS carriers and intermediaries.

Although MA organizations are required to pay noncontracting providers the amount that would otherwise be payable under original Medicare (§ 422.100(b)(2), and although Medicare providers are required to accept from noncontracting MA organizations the amount original Medicare would have made (§ 422.214), the amount original Medicare pays to CAHs is paid on a periodic interim

basis, is cost-based, and is subject to cost settlement. Additionally, section 405(c) of the MMA provides for development of alternative timing methods for the periodic interim payments already made to CAHs for inpatient services. This provision will further complicate the computation of amounts due CAHs under Medicare and will represent an additional administrative burden on MA organizations offering MA regional plans that will need to pay noncontracting CAHs based on a number of unique and changing factors. Similarly, to the extent CAHs are located in areas served by MA regional plans, they would potentially suffer a disruption in the normal cash-flow provided for them through periodic interim payments in the Act, even were MA regional plans able to provide correct reimbursement amounts in a timely manner. Although timely reimbursement for claims received from noncontracting providers by MA organizations is already required (see § 422.520(a), the timely claims-payment standard (claims must be paid within 30 or 60 days, depending on whether they are clean claims), is not a substitute for the guaranteed cash-flow related to periodic interim payments made by the Medicare FFS intermediary to CAHs.

Additionally, to the extent CAHs settle costs with CMS related to services they provide to Medicare beneficiaries, MA organization computation of payments due CAHs is further complicated, because of the potential difference between the Medicare interim payment and the final settlement.

In light of the special status provided to CAHs in section 1820 of the Act and implementing regulations, and in recognition of the unique status of CAHs related to access to care for FFS beneficiaries, we also note a special concern for them related to the MA program and specifically to MA regional plans. While we are constrained by the non-interference clause in section 1854(a)(6)(B)(iii) of the Act from requiring MA organizations to contract with CAHs, or from requiring contracts voluntarily entered into with CAHs to specify the level or manner of reimbursement, we will increase our level of monitoring of CAHs. For instance, we might review MA regional plan payment to non-contracting CAHs during our routine biennial monitoring visits. We will use our authority in section 1857(f)(2) of the Act when needed to ensure MA organization compliance with existing non-contractor timely payment requirements. We do not interpret the statute to permit CMS enforcement of contracts voluntarily entered in to by MA organizations and health care providers. Although our regulations require that all MA organization contracts with providers and suppliers contain a prompt payment provision (see § 422.520(b)), details of such prompt payment provisions and enforcement thereof would be as specified in the contract.

Comment: One commenter requested clarification regarding the ''essential hospital'' payment from the HI Trust Fund. The ''essential hospital'' must demonstrate that the amount of the MA plan payment is less than the cost of providing services to MA regional plan enrollees. The commenter asked whether this additional payment is equivalent to the full PPS rate, or to cost (which may be greater than the PPS rate), or cost plus one percent (because of the reference to CAHs at section 1858(h)(2)(A)) of the Act. The commenter also recommended that CMS provide guidance on how the hospital will demonstrate it is eligible for an ''essential hospital'' payment. The commenter is concerned that the procedures that we establish not be too cumbersome so that the additional reimbursement is not sufficient to compensate for the reporting effort.

Response: The ''essential hospital'' will need to establish that its actual costs for providing inpatient care to a specific MA regional plan enrollee actually exceeded the amount that is normally paid under FFS Medicare. The amount normally paid under FFS Medicare is the PPS payment normally made to the ''subsection d'' hospital under Part A of the Act for similar inpatient hospital services provided to an original FFS Medicare beneficiary. As we have already discussed in this part of the preamble related to § 422.100, the normal PPS payment (less the amounts paid by the fiscal intermediary under sections 1886(d)(11) and 1886(h)(3)(D) of the Act) will be the responsibility of the MA organization sponsoring the MA regional plan in which the beneficiary is enrolled. Thus, after the normal FFS amount has been paid to the ''essential hospital,'' the ''essential hospital'' can seek additional funding from CMS for up to 101 percent of the inpatient costs it actually incurred in treating a specific MA regional plan enrollee. The availability of funds to make such an additional payment to ''essential hospitals'' is limited by section 1858(h)(3) of the Act. We have clarified in the regulatory text in § 422.112(c)(6) that we will pay from funds appropriated in section 1858(h)(3) of the Act until such funds are exhausted. In other words, we will pay based on the order in which claims from ''essential hospitals'' are received. Finally, we have prescribed in regulation the method through which an ''essential hospital'' will establish that its costs for treating a specific MA regional plan enrollee exceeded the normal PPS payment amount. We will use the principles of reasonable cost reimbursement in part 412 of this chapter to determine whether costs in a specific case exceed the normal PPS payment amount in an individual case. To the extent an ''essential hospital'' can show, using methods of reasonable cost reimbursement, that the amount it reasonably expended in its treatment of an MA regional plan enrollee exceeded the normal PPS reimbursement amount for inpatient services, then CMS will make an additional payment to the ''essential hospital,'' limited by the statutorily appropriated amount in section 1858(h)(3). The statute initially authorizes $25,000,000 in 2006 and increases the annual amount available for ''essential hospital'' payments in subsequent years by the market basket percentage increase as defined in section 1886(b)(3)(B)(iii) of the Act.

Comment: One commenter recommended that CMS eliminate ambiguity and to clearly define which types of hospitals are eligible for ''essential hospital'' designation.

Response: Our regulation indicates that any ''subsection (d)'' hospital can qualify as an ''essential hospital.'' The regulation mirrors the statute in this respect. Note that ''subsection (d)'' hospitals are defined in statute at section 1886(d)(1)(B) of the Act and refer to hospitals paid under a ''prospective'' (PPS) method. We have added language to § 422.112(c)(1) to clarify this issue. Also note that we have further defined ''essential hospital'' in regulation text at § 422.112(a)(4) as one where there is no competing Medicare participating hospital in the area to which MA regional plan enrollees could reasonably be referred for inpatient hospital care. We believe MA organizations are in the best position to determine what is ''reasonable'' in this context, based on service usage and community patterns of care. However, we will evaluate such claims based on standards that will include: an evaluation of the ownership and control of other hospitals in the area; the normal patterns of community access; the physical proximity of other inpatient facilities; the referral patterns to inpatient facilities in the area; and other factors pertinent to the analysis.

Comment: A number of commenters recommended that CMS apply special rules to I/T/U hospitals so that all hospitals operated by I/T/U or the

Indian Health Service would be considered ''essential hospitals.''

Response: We cannot accommodate this request because there is no statutory basis for including all hospitals operated by Tribes or the Indian Health Service as ''essential hospitals.'' Section 1858(h) of the Act is explicit in defining ''essential hospitals'' as subsection (d) hospitals as defined in section 1886(d) of the Act. To the extent a Tribal or IHS hospital is designated by an MA regional plan under section 1858(h)(1) of the Act and to the extent all other conditions in section 1858(h) of the Act are present, then such a hospital can be an ''essential hospital.''

Comment: Some commenters recommended that CMS establish rules for ''essential hospitals'' that would require them to participate in the utilization management, discharge planning or quality improvement programs of the MA plans of the enrollees they treat.

Response: We will not separately establish such requirements related to ''essential hospitals.'' As ''subsection d'' hospitals, ''essential hospitals'' are already required to meet quality assurance, discharge planning and utilization management standards applicable to Medicare participating hospitals.

Comment: One commenter asked who would be responsible for the ''essential hospital'' payment, once the annual allocation specified in section 1858(h)(3) of the Act has been exhausted.

Response: In response to this comment, we have clarified this section of the regulation to say that once ''essential hospital'' payments exceed the limit prescribed in statute in a calendar year, no additional ''essential hospital'' payment will be due from any party. The statute is clear in allocating up to $25,000,000 for calendar year 2006 and a similar amount, adjusted for inflation, in subsequent years. We will make appropriate payments from the Part A Trust Fund on a ''first come-first served'' basis. We have specified these requirements in regulation at § 422.112(c)(6). Once the amount authorized in statute has been exhausted in a calendar year, no additional ''essential hospital'' payment is due nor can one be made by us for inpatient hospital services received by an MA regional plan enrollee in that calendar year.

Comment: One commenter asked if the in-network cost sharing requirement would still apply to services received in an ''essential hospital,'' even after the ''essential hospital'' allocation has been exhausted.

Response: To the extent an ''essential hospital'' is needed to meet the access requirements in § 422.112, we have added a requirement at § 422.112(c)(7) that in-network cost sharing applies to covered inpatient services received by an MA regional plan enrollee in an ''essential hospital.'' This is consistent with the ''exception'' in § 422.112(a)(1)(ii) and the beneficiary notification requirement in § 422.111(b)(3)(ii). The requirement for an MA regional plan to provide, or reimburse for, medically necessary inpatient hospital care (and to limit member liability to in-network cost sharing levels when reimbursing an ''essential hospital'') is independent of the ''essential hospital'' payment provision. Section 422.112(c)(7), where cost sharing is limited to in-network amounts for covered inpatient care reimbursed to an ''essential hospital'' by an MA organization for an MA regional plan member, applies even when § 422.112(c)(6) does not. Even if no ''essential hospital'' payment is due per § 422.112(c)(6) because conditions in § 422.112(c)(5) are not met (rather than due to exhaustion of the ''essential hospital'' annual allocation), in-network cost sharing for covered inpatient services at an ''essential hospital'' is still required. In other words, once a hospital is designated as an ''essential hospital'' by the plan, in-network cost sharing applies regardless of whether an ''essential hospital'' payment is due or paid.

Comment: One commenter said that to the extent the ''exception'' in 422.112(a)(1)(ii) is used, that not only normal per service in-network cost sharing should apply to services so obtained, but also that the in-network catastrophic limit on Medicare A/B services in § 422.101(d)(2) should also apply.

Response: We agree and reference the in-network catastrophic cost sharing limit in § 422.101(d)(2) as an additional limit on MA regional plan enrollee cost sharing liability in § 422.112(c)(7) when covered inpatient care is received at an ''essential hospital.''

Comment: One commenter asked whether we would permit or require MA regional plans to list ''essential hospitals'' in their provider directories. The commenter said that allowing an MA regional plan to so list ''essential hospitals'' would be inappropriate because such marketing would provide the hospitals with an advantage that should only accrue to contracting providers. We received a number of comments from other parties that objected to the listing of ''essential hospitals'' in MA regional plan provider directories on the basis that such a listing would provide the MA regional plan with an advantage that should only accrue to MA regional plans that actually have the ''essential hospital'' under contract.

Response: While we generally concur with both commenters that neither party is entitled to an undue advantage, MA regional plans are required to provide enrolled members a provider directory on an annual basis in accordance with § 422.111(a)(3). Note that as part of that requirement a description of any out-of-network coverage is also required. So, while it would not be permitted to list ''essential hospitals'' in an MA regional plan's provider directory as if they were contracting providers, it is also true that a description of their status as ''essential hospitals'' would be required.

12. Special Rules For Ambulance Services, Emergency Services, and Urgently Needed Services, and Maintenance and Post-Stabilization Care Services (§ 422.113)

We proposed to modify § 422.113(b)(2)(v) to clarify that the $50 limit for ''emergency services'' applies only to the emergency department, and that while the limit on cost-sharing for ''post-stabilization'' care at § 422.113(c)(2)(iv) continues to apply, its application would always begin upon inpatient admission. Thus, emergency cost-sharing limits would shift from being tied to the type of service (emergency services) to being tied to the site of service (emergency department). We believe that making this clarification retained cost-sharing limits for both emergency services and post-stabilization care, while eliminating the unanticipated complexities and administrative burden previously associated with this section of the regulation.

Comment: A number of comments supported the clarification that the $50 limit on cost sharing for emergency services applied only to emergency department services. Commenters supported the notion that once an MA enrollee is admitted to a hospital, normal hospital cost-sharing levels apply, even if the inpatient admission originates from the emergency department. On the other hand, many commenters recommended that CMS reexamine the $50 limit itself. Some commenters recommended that CMS set the limit higher (at $75, $100 or higher) and other commenters recommended that CMS index the emergency department cost-sharing limit for inflation.

Response: We believe that the $50 limit on cost sharing for emergency

department services continues to provide the appropriate financial disincentive to MA plan enrollees not to frivolously use emergency rooms in non-emergency situations. For instance, there is no MA plan currently imposing cost sharing for in-network physician office visits that approach $50. Similarly, MA organizations are permitted to deny emergency department services as medically unnecessary, to the extent that the member can be shown to have acted in ''bad faith'' or not as a ''prudent layperson'' in presenting at an emergency room for non-emergency services.

Finally, we do not set forth in regulation the maximum amount an MA organization can impose in cost sharing for receipt of urgently needed services. Because we have restricted the applicability of the $50 limit on enrollee cost sharing to emergency department services, we believe we have appropriately balanced the financial interests of MA organizations and MA plan enrollees requiring emergency services.

13. Access to Services Under an MA Private Fee-For-Service Plan (§ 422.114)

Section 211(j) of the MMA allows MA PFFS plans to charge higher co-pays to members who receive services outside of a PFFS plan's contracted network. This provision does not apply to PFFS plans that meet access requirements solely through ''deemed'' networks as defined in § 422.114(a)(2)(i). We proposed to add a new paragraph (c) to account for section 211(j) of the MMA.

We received no comments on this section, so we finalize as proposed.

14. Return to Home Skilled Nursing Facility (§ 422.133)

We proposed to extend the provisions in § 422.133 (Return to home skilled nursing facility) to SNF services provided in cases in which an MA organization elects, as permitted under § 422.101(c), to provide Medicare covered SNF care in the absence of a prior qualifying hospital stay. In such an instance, we proposed to require that an individual who would be eligible under section 1852(l) of the Act for admission to a ''home SNF'' upon discharge from a hospital stay, would nonetheless retain his or her right to receive ''home SNF'' benefits in the absence of such a hospital stay.

We proposed to deem that a hospital discharge has always occurred before an admission for SNF services, and therefore provide all MA enrollees full rights to the ''home SNF'' benefit.

We received no comments on this section, so we finalize as proposed.

Subpart D—Quality Improvement Program

1. Overview

The MMA amended section 1852(e) of the Act in a number of significant ways that will affect how MA organizations pursue their quality improvement activities. Below we summarize the proposed provisions and respond to the public comments. (For a more in-depth discussion of the provisions, please refer to the preamble to the proposed rule.)

Quality Improvement Program (§ 422.152)

To reflect the Congressional intent to refocus the section on quality improvement, rather than quality assurance, we changed the heading of § 422.152 to ''Quality improvement program.'' Proposed § 422.152 specified that each plan (except MA PFFS and MSA plans) offered by an MA organization must have an ongoing quality improvement program and that a chronic care program must be a part of this program.

We believe that the broad requirements in proposed § 422.152(d) for QI projects did not present an undue burden for MA organizations, as these organizations have significant experience in carrying out such projects under the current § 422.152(d) requirements that we believe are more prescriptive than those we proposed in the August 2004 proposed rule.

Our previous quality improvement requirements for M+C coordinated care plans focused on attaining improvement in specific clinical topics and included specific performance measures for improvement. As a result of the MMA amendments, we proposed that MA organizations have the flexibility to shape their QI efforts to the needs of their enrolled population. In addition, we continue, based on our interpretation of section 1852(e)(3)(B)(i) of the Act, to require MA coordinated care plans to collect, analyze, and report their performance using measurements outlined by us or to participate in surveys administered by us (for example, HEDIS, HOS, and/or CAHPS).

Proposed § 422.152(b)(4) would require MA local PPO plans that are offered by an organization that is licensed or organized under State law as a HMO, to follow the same quality improvement requirements as other MA coordinated care plans.

A. General Comments

Comment: A number of commenters made a variety of general comments about the proposed rule. These comments include: (1) require that plans disseminate educational materials to beneficiaries; (2) require that all plans review all problems that come to their attention; (3) CMS should recommend that plans seek Quality Improvement Organization (QIO) technical assistance; (4) require plans to have physician advisory committees, and that these committees advise CMS on performance measures; and (5) CMS should begin to provide information on MA quality starting in 2006.

Response: MA plans are responsible for ensuring that beneficiaries are fully informed of the benefits covered under the contract as part of its marketing material, evidence of coverage, and summary of benefits. We do not have any requirements that plans conduct educational programs. While the dissemination of educational materials may be worthwhile in improving health outcomes, we do not believe it should be mandatory. Most plans already provide QI, for example, in marketing materials. Furthermore, we post HEDIS and CAHPS data on the *www.Medicare.gov* web site. To the extent an MA plan decides to furnish educational materials to its enrollees, the plan is responsible for the type of information it wishes to furnish, and it is in the best position to determine which information is most appropriate for the enrolled population.

We agree with the commenter that plans should review all problems that are brought to their attention. Depending on the nature, extent, and substance of the problems, an MA plan may implement immediate corrective action, or may need to implement more systemic changes to address the identified problem.

We agree with the commenters and encourage plans to seek technical assistance from QIOs. Plans should review the current scope of work to determine the areas for which the QIOs can provide assistance; a draft outline of the 8th scope of work is available on our web site. Plans that seek QIO assistance will receive it on both Part C and Part D services.

We disagree with the commenters that propose that we require physician advisory committees. We do not believe this is necessary because most plans already have Medical Director committees that advise plans on QI measures. Moreover, at the national level, we have a physician advisory

committee. These bodies should ensure an appropriate level of physician input.

We agree with the commenters with respect to our providing information on quality measures. HEDIS and CAHPS data are already on our website (*www.Medicare.gov*), and the data has been available for several years

Comment: Several commenters stated that CMS should include PFFS and MSAs in all of the QI requirements. However, there were also commenters that supported the exclusion of these plans.

Response: Because section 722(a) of the MMA specifically exempts these types of plans from the majority of QI requirements, we have excluded them from the same requirements in the regulations. These plans, however, must meet the following requirements: maintain health information systems; ensure information from providers is reliable and complete; make all collected information available to us' conduct quality reviews; and take corrective action for all problems that come to their attention.

Comment: Several commenters have recommended that we provide payment incentives to MA plans for providing better quality care, also known as pay for performance (P4P).

Response: We agree with the commenters concerning the merits of P4P. We are very interested in this approach and believe that we should pay not just for providing a service but for results. P4P should stimulate care that is efficient and effective for every patient while eliminating waste. We are currently working on four P4P demonstration projects. These are as follows:

The Premier Hospital Quality Incentive Demonstration

The Premier Hospital Quality Incentive Demonstration is a 3-year project that will recognize and provide financial rewards to hospitals that demonstrate high quality performance in a number of areas of acute care. The demonstration involves a CMS partnership with Premier Inc., a nationwide organization of not-for-profit hospitals, and will reward participating top performing hospitals by increasing their payment for Medicare patients. Through the Premier Hospital Quality Incentive Demonstration, we aim to see a significant improvement in the quality of inpatient care by awarding bonus payments to hospitals for high quality in several clinical areas, and by reporting extensive quality data on our web site. Participation in the demonstration is voluntary and open to hospitals in the Premier Perspective system as of March 31, 2003.

Section 646—Medicare Health Care Quality Demonstration Program.

The MMA mandates a 5-year demonstration program to examine factors that encourage the delivery of improved patient care quality, including financial incentives, appropriate use of best practice guidelines, examination of service variation and outcomes measurement, shared decision making between providers and patients, appropriate use of culturally and ethnically sensitive care, and related financial effects associated with these factors. In the demonstration, Medicare may provide benefits not otherwise covered, but may not deny services that are otherwise covered against the wishes of beneficiaries. The demonstration is required to be budget neutral.

Section 649—Medicare Care Management Performance Demonstration.

The MMA mandates a 3-year demonstration program where physicians will be paid to adopt and use health information technology and evidence-based outcome measures to promote continuity of care, stabilize medical conditions, prevent or minimize acute exacerbations of chronic conditions, and reduce adverse health outcomes. The statute limits the program to four sites meeting eligibility criteria. Payment can vary based on performance; however total payments must be budget neutral. QIOs could help enroll physicians, evaluate their performance, and provide technical assistance.

The Physician Group Practice (PGP) Demonstration.

The PGP Demonstration rewards physicians for improving the quality and efficiency of health care services delivered to Medicare FFS beneficiaries. Mandated by Section 412 of the Benefits Improvement and Protection Act of 2000, the PGP Demonstration seeks to encourage coordination of Part A and Part B services, reward physicians for improving health outcomes, and promote efficiency through investment in administrative structure and process. Under the 3-year demonstration, physician groups will be paid on a FFS basis and may earn a bonus from savings derived from improvements in patient management. Annual performance targets will be established for each participating physician group equal to the average Part A and Part B expenditures of beneficiaries assigned to the group during a base period, adjusted for health status and expenditure growth.

We are also paying close attention to P4P for managed care plans. We are aware that MEDPAC has developed proposals along these lines in its June 2004 report. Furthermore, many private sector organizations are sponsoring such projects. See, for example, a compendium developed by The Leapfrog Group (*www.leapfroggroup.org*). In addition, the Agency for Healthcare Research and Quality (AHRQ) has sponsored an evidence based report entitled ''Strategies to Support Quality-based Purchasing: A Review of the Evidence,'' published in fall 2004, which includes managed care plans. Finally, we have a contract with the Institute of Medicine to study P4P, which will also address managed care.

B. Measures

This portion of the discussion addresses measures for all MA plans. A specific discussion of measures for PPOs appears below.

Comment: Several commenters stated that CMS should include measure reporting requirements in regulations.

Response: Based on past experience, we disagree with the commenters recommending that we include specific measure reporting systems in the regulation. We believe it is a better approach to provide specific guidance through the Medicare managed care manual rather than including specific requirements in the regulation. In this way, we have the flexibility to implement appropriate changes in the measure systems and individual measures in a more timely manner. The industry and accreditation organizations, are constantly making changes to these reporting systems. Thus, having more flexibility to change measures as well as add and delete measurements systems allows us to be more responsive to the state of the art as to measurement systems.

Comment: A commenter stated that performance assessment data is outdated and that CMS should not use HOS to rank plans because there is no benchmark.

Response: We disagree with the commenter. HEDIS, CAHPS, and HOS are updated on a regular basis. We recognize that there are no benchmarks currently available and therefore use relative ranking in the performance assessment data system. Benchmarks also refer to standards or minimum performance levels.

Comment: A commenter stated that CMS should use a standardized core set

of performance measures, clinical and non-clinical that are applied to all MA plans. The commenter suggested that CMS not require MA plans to demonstrate that QI program size and scope are proportionate to plan size.

Response: In general, we agree with the commenter that a standardized set of measures should be used across all plan types because it allows the greatest comparison among plans. The one exception as discussed later, is that we have decided to allow some variation in the early stages of the PPO program as compared to the HMO program. As also noted, MMA specifies a different set of requirements for PFFS plans and MSAs.

Comment: One commenter stated that CMS should compare quality measures of MA plans to those for the FFS Medicare program.

Response: On the *www.Medicare.gov* website, we provide consumer assessment data from CAHPS on FFS Medicare and the MA plans, as well as a comparison of an Original Medicare rate (on State and national levels) compared to the MA health plan rates on the HEDIS measure—Access to Ambulatory Health Services.

Comment: A commenter suggested that CMS reduce the burden on plans by reducing the number of measures or by conducting HEDIS by telephone.

Response: We agree that it is important to minimize the MA plans' reporting burden and do so by using data submission tools, systems, and processes that are consistent with HEDIS reporting for the plan's commercial lines of business.

We believe that it is not appropriate, however, to collect HEDIS measures by phone because information collected by phone is less reliable.

C. Special Needs Plans (SNPs)

Comment: Many commenters suggested that CMS develop special measures for specialized MA plans for SNPs. Several commenters suggested that CMS use the ACOVE measures developed by Rand. They further suggested that quality oversight should take into account the populations being served by the SNP. In addition, they suggested that CMS should ensure that SNPs have comprehensive and coordinated care.

Response: We agree with the commenters and have already indicated to several demonstration plans that have institutionalized populations and are converting to SNPs that HEDIS and HOS will not be required. Instead we will work with them to identify measures that are similar to the national nursing home quality measures reported on the Nursing Home Compare website at *www.medicare.gov* and the CHSRA quality indicators, both of which are derived from the Minimum Data Set (MDS). SNPs for dual eligibles will be required to meet the requirements of other MA plans. We are also willing to explore special measures with other types of SNPs.

We are certainly open to considering the ACOVE measures and will explore their feasibility. As to other aspects of quality oversight, we will apply the same basic types of quality requirements for all MA plans but take into account beneficiary needs for SNPs. As to comprehensive and coordinated care, SNPs will need to meet chronic care improvement program (CCIP) requirements.

Comment: A commenter recommended that SNPs should not serve dialysis patients. The commenter stated that CMS cannot monitor the quality of care provided to dialysis patients in managed care plans because dialysis providers do not bill Medicare for services to MA beneficiaries, thus, the ESRD Clinical Performance Measures data, which are extracted from billing information, are not available.

Response: We appreciate the concerns expressed by the commenter and will definitely take them into consideration. We anticipate that will be able to collect the data. However, at this time, we have not determined with certainty that we can and share the commenter's concern that we not approve the plans unless we can collect the data. In Subpart A of this preamble, we indicate that we are not setting forth a detailed definition of severe and disabling chronic condition for purposes of the definition of special needs individuals, and we will review and evaluate SNP proposals on a case-by-case basis. This evaluation will take into consideration whether we can collect sufficient quality of care monitoring data.

D. Report to the Congress

Comment: Some commenters expressed concern that CMS could not add measures without issuing a Report to the Congress as required under Section 1852(e)(3)(A). They suggested that because of several of the unique populations that might be served in SNPs, that CMS extend the Report to the Congress, and that CMS form an expert panel, enhance clinical knowledge on high risk populations, disseminate best practices, enhance coordination care, and refine payment to support outcomes.

Response: As indicated in the proposed rule, we interpret that this requirement does not prevent us from making changes within each of the existing measurement systems, such as HEDIS. Further, although we need to submit a Report to the Congress to add new systems, we do not interpret this to mean that we need the Congressional approval before we proceed to implement new systems.

E. Types of performance measures

Comment: A commenter suggested that CMS develop clearly defined, nationally recognized quality measures based on objective criteria for all facets of the Medicare program to truly achieve the MMA's goal of offering Medicare beneficiaries a meaningful choice. It is feasible that the measures be based on pharmaceutical information, medical claims, and other routine administrative information already easily accessible across the Medicare program.

Response: We will be pursuing the development of the measures and will take into consideration the commenter's suggestion.

2. Chronic Care Improvement Program Requirements (§ 422.152(c))

At proposed § 422.152(c), we would require that MA plans develop criteria for a chronic care improvement program. The criteria must–

- Include methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions who would benefit from participating in a chronic care improvement program; and
- Provide mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program.

Comment: A commenter recommended that CMS use the standard definition of disease management adopted by the Disease Management Association of America (DMAA) for the CCIP. The commenter also recommended that the CCIP be population based and that CMS focus on congestive heart failure (CHF), diabetes, and chronic obstructive pulmonary disease (COPD). They further suggested that CCIPs be accredited, and be evaluated on clinical quality, beneficiary and provider satisfaction, and impact on cost. Other commenters recommended that CMS provide maximum flexibility for plans as to these requirements. A commenter suggested that plans can identify patients from claims, self-reports, by providers, socio-economic data primarily using existing measures, for example, HEDIS to monitor plus other evidence-based measures. A commenter also suggested plans should use clinical variables, for example, weight, use of ACE inhibitors, health and functional status, emergency room and hospital

use, satisfaction, total costs, as measures for CCIP.

Response: We certainly encourage plans to consider the definition provided by Disease Management Association of America (DMAA), as well as the other aspects of the programs developed by DMAA. However, we believe it is premature to provide more prescriptive requirements. We will look for information on the CCIP pilot under section 721 of the MMA as well as the early stages of the MA plans' implementation of this section 722 CCIP to shape guidance for this component of the program.

3. QI Projects (§ 422.152(d))

While we proposed to delete many of the prescriptive requirements for QI projects that appeared in § 422.152(d), we still retained the basic requirements of the projects including the collection, analysis, and reporting of data. We believed, though, that MA plans should have the ability to select topic areas and proposed deleting the requirements of including the entire relevant population and having to do both national and statewide projects.

In proposed § 422.152(d)(1), we would require that QI projects be initiatives that include the entire organization and focus on clinical and non clinical areas. The projects would need to follow the current quality improvement process. We retained the provisions that QI projects must measure performance, and the interventions must be system-wide and include the establishment or alteration of practice guidelines. In addition, we propose to require that the projects focus on improving performance for the Medicare population and involve systemic and periodic follow-up on the effect of the interventions. To ensure that the measures (or quality indicators) used in QI projects are reliable and relevant for improving the health care and services furnished to MA enrollees, we proposed in § 422.152(d)(2) to require that the quality indicators be objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research. The measures must also be capable of measuring outcomes, such as changes in health status, functional status, and enrollee satisfaction, or valid proxies of those outcomes. Likewise, we proposed in § 422.152(d)(3)to require that the data used in an MA plan's QI projects be valid and reliable and based on systemic ongoing collection and analysis of information. We also proposed in § 422.152(d)(4) that the interventions achieve demonstrable improvement.

Finally, in § 422.152(d)(5), we proposed to retain the requirement that MA plans report the status and results of their projects when requested by us. We believe that this reporting and review burden would be much smaller than the process used in the M+C program. We intend to provide further guidance on the reporting requirements later.

Comment: A commenter stated that QI should involve more than measure, intervene, and remeasure. The commenter also stated that it should set performance expectations, collect and analyze data, identify undesirable events, develop interventions, collect data to monitor improvement, and require that all plans meet the same QI requirements.

Response: We agree that all HMOS and PPOs should have to meet the same basic requirements as to QI projects, and the regulation requires this. However, although we will encourage plans to adopt the commenter's other recommended steps, we do not believe that it is necessary to build them into mandatory requirements. The requirements that we have already specified should be sufficient, and to add additional requirements will create unnecessary burden.

A. National projects

Comment: A commenter requested that CMS provide guidance to plans on the meaning of 'encouraging' physicians to participate in quality improvement initiatives. The commenter also proposed that CMS provide plans with the flexibility to design and conduct QI projects based on topics relevant to the plan's population. However, the commenter stated that CMS should continue to provide suggestions and examples of topics for QI projects that are relevant to the Medicare population. The commenter also suggested that CMS should provide guidance regarding meaning of ''sustained improvement,'' and consider evaluating clinical and non-clinical performance improvement using HEDIS and CAHPS 3.0H results.

Response: As to encouraging physicians to participate in QI projects, we recommend plans to coordinate their efforts with their providers. Some possible options are that the plans will send letters to their providers encouraging participation or pay them a bonus. This will be up to the plans. As indicated, we will provide suggestions as to topics for plan consideration and guidance on these topics. We will give further consideration to the suggestion of using HEDIS and CAHPS for evaluating QI projects.

Comment: Some commenters recommended that CMS require plans to participate in national projects.

Response: The MMA specifically deleted the requirement for national projects. We interpret the Congress's deletion of this requirement as an indication of its intent that participation in national projects not be required. Therefore, we are not requiring the projects, and we believe the best alternative is to encourage plans to participate voluntarily in our proposed national projects.

B. Racial-ethnic QI projects

Comment: Some commenters opposed elimination of the racial-ethnic QI projects, while one commenter supported its removal.

Response: The MMA specifically eliminated this requirement. Again, we interpret the Congress's deletion of this requirement as indicating its intent that plans not be required to pursue these types of projects. However, we encourage plans to consider pursuing such projects voluntarily. We have a current racial-ethnic national project that started in 2003 and will not be completed until 2005. We will share results of this project when it is completed. Lovelace Clinic Foundation was selected by us to develop two cultural competency guides through an AHRQ Integrated Delivery System Network Funding task order. The first manual, ''Providing Oral Linguistic Services: A Guide for Managed Care Plans,'' provides a practical step-by-step process for the improvement of oral language services to patients with limited English proficiency (LEP). The second manual, ''Planning Culturally and Linguistically Appropriate Services: A Guide for Managed Care Plans,'' assists health plans in assessing the ethnically diverse populations they may serve, and assessing the cultural competency of the managed care plan. Lovelace recently completed a report ''Evaluation of Usefulness of CLAS Guides to M+CO Plans'' which is available from AHRQ.

C. Performance levels

Comment: A commenter suggested that CMS set guidelines on the minimum percent of enrollees that are identified and managed. Others opposed the removal of requirements as to minimum performance levels, sustained improvement, and clinical-nonclinical requirements and external review.

Response: We retain our view from the proposed rule that plans should select topics areas that best meet their needs rather than being required to select both clinical and nonclinical

topics. We do not believe that it is appropriate for us to specify minimum percent identified and minimum performance level. In the preamble discussion to § 422.152(d), we proposed not to define demonstrable improvement, but indicated that we would look for some movement in the quality indicator in an upward or downward direction as appropriate.

MMA eliminated the requirement that MA organizations contract with QIOs (external review organizations) to review appeals. However, QIOs are still involved in all appeals that they currently conduct such as hospital and nursing home discharges. Elimination of this requirement just means that the MA plans do not need to contract with the QIOs or other external review organizations.

D. Project selection

Comment: A commenter suggested that CMS require all plans to participate in QI projects, as long as the projects are based on data to which the plan has reasonable access. When developing QI and data collection requirements, the commenter suggested consideration of the plan's experience in conducting the activities. Further, the commenter recommended using a standardized core set of performance measures, clinical and non-clinical that are applied to all Medicare Advantage plans. Commenters also stated that CMS should not require MA plans to demonstrate that QI program size and scope are proportionate to plan size.

Response: We believe that plans should take these suggestions into consideration, but we are not requiring them. We agree that we should not require MA plans to demonstrate that QI program size and scope are proportionate to plan size. To do so will place unnecessary restrictions on plans and would be inconsistent with what we understand to be the Congressional intent to allow for more flexibility in this area.

4. Requirements for MA Regional Plans and MA Local Plans

Section 1852(e)(3)(A)(ii) of the Act provided for us to establish separate regulatory requirements for MA regional plans relating to the collection, analysis, and reporting of data that permit the measurement of health outcomes and other indices of quality. Section 1852(e)(3)(A)(ii) of the Act further provided that these requirements for MA regional plans could not exceed the requirements established for MA local plans that are PPO plans.

In § 422.152(e)(1), we proposed a definition for the term ''local PPO plan'' as used in this section. The other requirements in this paragraph were the requirements that apply to PPOs under current regulations.

In § 422.152(f), we retained the provisions that address health information systems, QI program review, and remedial action. MA organizations will be required, for all the MA plans they offer, to maintain a health information system that collects, analyzes, and integrates the data necessary to implement their QI program. The organization will also be required to ensure that the information it receives from providers of services is reliable and complete. In addition, for each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

Finally, for each plan it offers, we proposed that an MA organization will be required to correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms. As noted above, as a result of MMA we also made conforming changes to remove the provision that each MA organization's quality assurance program include a separate focus on racial and ethnic minorities and the requirement that for each plan it operated the MA organization would have an agreement with an external quality review and improvement organization.

The MMA provided that all the part D (Voluntary Prescription Drug Benefit) requirements are to be included as among those that could be deemed to be met through accreditation, and we accordingly proposed to add this provision to the list of deemable requirements in § 422.156(b).

Comment: Many commenters recommended that CMS use the same metrics across plan types. Others commenters recommended that CMS develop future plans to make PPOs comparable to HMOs. They suggested that CMS convene key stakeholders to develop measures. They further suggested that CMS set goals and timetables for implementing the same measures across plan types.

Response: For the most part, we will have uniform reporting requirements for HMOs and PPOs. For instance, we will require both types of plans to submit HEDIS and HOS data. Further, we will administer the CAHPS survey to both types of plans. The HEDIS measures will differ between the two plan types, as PPOs will not be required to submit HEDIS measures that require medical record review, because they have difficulty obtaining medical records from out-of-network providers. However, for PPOs, many of the HEDIS measures are available from administrative records. We are working with NCQA and other experts, MA organizations and other stakeholders to identify which HEDIS measures are most appropriate for quality performance measurement in PPO plans.

We held an open door forum on December 10, 2004, to receive input from the public on the HEDIS measures for PPOs. We expect to publish a final set of measures for field testing in January 2005. Materials from the open door forum can be found at *http://www.cms.hhs.gov/healthplans/performance/*. We expect to field test these measures in the Spring 2005, and we expect to finalize them in Fall 2005. In addition, we expect to disseminate the final list of measures for reporting, with detailed instructions, in the MA Manual in Fall 2005. In the near future, we expect that additional HEDIS measures that require PPOs to capture and submit data from medical records will also be required for reporting. We desire to measure performance and compare plans on as many dimensions of care as possible, so we plan to move progressively toward having all relevant HEDIS measures reported while allowing PPOs the opportunity to develop the capacity to collect information that requires medical record review.

After we implement NCQA's recommendations on HEDIS measures for PPOs, we will make an assessment of the possibility of making HEDIS reporting even more comparable between HMOs and PPOs

5. Deeming § 422.154

We did not have a discussion on deeming in the preamble nor proposed changes to the regulation text. Nevertheless, we did receive comments on this section and are responding to those comments.

Comment: Commenters suggested that CMS allow the American Association of PPOs (AAPPO) to be an Accreditation Organization (AO)and that CMS allow disease management associations to be AOs.

Response: Any organization that wants approval as an AO for PPOs must meet our AO requirements for PPOs.

Subpart E—Relationships with Providers (§ 422.210)

The MMA made very limited changes to existing MA program requirements concerning MA organization relationships with providers. Since these aspects of the program have

worked well, we generally proposed to keep the existing provisions of subpart E as they were. The only exceptions, are modifications to the physician incentive plan requirements to reflect changes made by MMA to section 1852(j)(4) of the Act.

Below is a summary of the proposed provisions in this subpart that were proposed in the August 3, 2004 proposed rule:

• We proposed to remove § 422.208(h) that required that, where a physician incentive plan places physicians at substantial financial risk, M+C organizations conduct ''periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.''

• We proposed to revise § 422.210 to eliminate the requirement that information on physician incentive plans be disclosed to CMS.

Comment: A commenter supported the changes made to the reporting requirements in the August 22, 2003 final rule (68 FR 50855). Other commenters requested that CMS require plans to submit assurances that they are in compliance with the requirements.

Response: The MMA specifically requires that MA plans provide assurances to us that they are in compliance with the physician incentive plan requirements. We specified this requirement in the regulation text of the proposed rule at § 422.210 and have retained it in this final rule. Further details on the assurances will be provided in subsequent guidance. As noted in the preamble of the proposed rule, the reporting requirement had already been eliminated in a final rule published on August 22, 2003 (68 FR 50855). The assurances required by MMA are a new requirement that helps to ensure that plans are meeting the various regulatory requirements of the physician incentive plan section. Plans must provide information on their physician incentive plans when requested by us.

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

Under the current MA regulations, subpart F addresses payments to MA organizations, and subpart G discusses beneficiary premiums and cost sharing. Given the substantial revisions that the MMA makes to pricing and payment rules for MA organizations, we proposed to generally replace these subparts in their entirety. Subpart F will cover provisions addressing bid submissions and our review of bids and subpart G will describe the methodology and process for CMS' payment to MA organizations.

This subpart addresses provisions related not only to submission, review, and approval of bids, but also ''bid-to-benchmark'' comparisons, including how local and regional benchmark amounts are determined and how beneficiary premiums and savings are calculated; how beneficiary savings are used for beneficiary rebates and Government savings; the various premium payment options available to beneficiaries; and the options for distributing the beneficiary portion of the rebate.

We received 60 comments on subpart F in response to the August 2004 proposed rule. Below we provide a summary of the provisions of this subpart and respond to comments. (For a broader discussion of the provisions, please refer to the proposed rule.)

1. Basis and scope (§ 422.250)

Proposed § 422.250 set forth the basis and scope of the revised subpart F, noting that it was based largely on section 1854 of the Act, but included provisions from sections 1853 and 1858 of the Act. Section 422.250 indicated that subpart F addressed the bidding methodology upon which MA payments will be based beginning in 2006 and provisions for CMS' negotiation and approval of organizations' bids.

2. Terminology (§ 422.252)

The proposed definitions throughout both subparts F and G were intended to reflect the statutory definitions they implement in a simplified manner. The following terms were defined in proposed § 422.252:

• The ''annual MA capitation rate'' is the county rate. As set forth at section 1853(c)(1) of the Act, capitation rates are called ''MA local area'' rates, and references throughout the MMA to capitation rates are to county rates (or in the case of end-stage renal disease (ESRD) enrollees, to State rates).

• ''MA-PD plan,'' means an MA local or regional plan that offers prescription drug coverage under Part D of Title XVIII of the Act.

• ''Unadjusted MA statutory non-drug monthly bid amount'' is defined as the plan's estimate of its monthly required revenue to provide coverage of original Medicare Part A and Part B benefits.

• ''Monthly aggregate bid amount'' is defined as the total monthly plan bid for coverage of an MA eligible beneficiary with a nationally average risk profile. This bid is composed of: the unadjusted MA statutory non-drug monthly bid amount (also called the ''basic A/B bid''); an amount for coverage of basic prescription drug benefits under Part D (if applicable), and an amount for provision of supplemental benefits, if any.

• ''Plan basic cost sharing'' means cost sharing that would be charged by a plan for benefits under the original Medicare FFS program option before any reductions resulting from mandatory supplemental benefits.

• ''Unadjusted MA area-specific non-drug monthly benchmark amount'' is defined, for local MA plans serving one county, as the county capitation rate. For local MA plans serving multiple counties, it is the weighted average of county rates in a plan's service area, where the weights are the plan's projected enrollment per county.

• ''Unadjusted MA region-specific non-drug monthly benchmark amount'' is the sum of two components: the statutory component and the plan bid component.

• ''MA monthly basic beneficiary premium'' is the amount that an MA plan (other than an MSA plan) charges an enrollee for original Medicare benefits if its basic A/B bid is above the benchmark.

• ''MA monthly prescription drug beneficiary premium'' is the base beneficiary premium, adjusted to reflect differences between the plan bid and the national average bid, less the amount of rebate the MA-PD plan elects to apply toward a reduction of the base beneficiary premium, as described in proposed § 422.266(b).

• ''MA monthly supplemental beneficiary premium'' is the portion of the plan bid attributable to mandatory and/or optional supplemental health care benefits described in § 422.102, less any rebate applied to a mandatory supplemental benefit under § 422.266(b)(2).

• ''MA monthly MSA premium'' is the amount of the plan premium for coverage of benefits under the original Medicare program through an MSA plan, as described in proposed § 422.254(e).

As a result of our policy decision on the geographic ISAR adjustment, presented in the G preamble discussion of § 422.308(d), we are making a clarifying change to the definition of MA local area at § 422.252.

3. Submission of Bids (§ 422.254)

General rule. The MMA amended section 1854 of the Act to replace the adjusted community rate (ACR) proposal system currently in effect under the MA program with a bid

submission process. Proposed § 422.254(a) implemented section 1854(a)(1)(A) by requiring that no later than the first Monday in June, MA organizations must submit bids for each MA plan that they intend to offer in the following year (other than MSA plans, which have separate requirements), beginning for contract year 2006. Plan bids would be required to meet the requirements specified at proposed § 422.254(b), and bid submissions would be required to include the information listed in proposed § 422.254(c).

Under the previous M+C program, we permitted M+C organizations to offer new plans mid-year and to offer mid-year benefit enhancements to existing benefit packages. However, in order to maintain the integrity of the annual bidding process mandated in statute, we proposed that it is no longer appropriate to allow MA organizations to enter the program with a new plan mid-year (including service area expansions) or to offer mid-year enhancements to an existing plan (which essentially represents a redefinition of revenue needs, that is, a new bid).

Program of All Inclusive-Care for the Elderly (*PACE*) *organizations and the MMA bidding methodology*. We proposed to exempt PACE organizations from the Title II bidding process, so payments for PACE plans would be based on MA capitation rates. However, this exemption does not apply to Part D drug coverage for PACE enrollees. PACE plans will be required to submit bids for providing Part D drug benefits (although PACE bids will not be included in the national average monthly bid amount), as indicated in § 423.279(a).

ESRD enrollees. Section 1853(a)(1)(H) of the Act gives us the authority to determine if ESRD MA enrollees should be included in the MMA bidding process. We proposed at § 422.254(a)(2) that ESRD enrollees be fully incorporated into the plan's aggregate bid for contract year 2007 and succeeding years. For 2006, we proposed three options for pricing Part C benefits for ESRD beneficiaries: exclude ESRD costs from the basic A/B bid and the supplemental bid pertaining to Parts A and B benefits; exclude ESRD costs from the basic A/B bid but include them in the supplemental bid for A/B benefits; and fully include End Stage Renal Disease (ESRD) costs in the plan bid. We invited comments on specific proposed approaches. (We noted that ESRD costs must be included in the Part D bid at the outset, including the Part D supplemental bid amount.)

We noted that regardless of whether or not ESRD enrollee costs are included in the plan bid, ESRD enrollees would be subject to the same premium and cost sharing as other plan enrollees under the uniformity of premiums provision in § 422.262(c). That is, if ESRD enrollees were excluded from the plan bid, the rebate (or basic beneficiary premium, for a plan with the bid above the benchmark) would be determined based on costs for non-ESRD enrollees. ESRD enrollees would be subject to cost sharing and premium amounts based on estimated non-ESRD enrollee costs. Finally, we stated in the proposed rule that if the policy chosen were to exclude ESRD enrollees from the 2006 bids, for any plan offering a Part B premium reduction to MA plan enrollees, the amount of this reduction also would be subtracted from the payment for each ESRD enrollee.

Comment: Two commenters disagreed with any limitation on mid-year plan entry (including service area expansions) and mid-year benefit enhancement (MYBEs). One of these commenters asked if CMS' proposal were implementing statute. Another commenter stated that new mid-year plans should be allowed in a market if no other competitors existed in the market. One commenter acknowledged that an issue may exist with offering Part D benefits in any mid-year plan due to the formula used to calculate beneficiary premiums, but recommended that plans that do not offer Part D benefits should be allowed to enter at any time. This commenter added that nothing in the legislative history of the MMA supports CMS' position to limit mid-year plan entry and enhancements.

Several commenters did not state an objection to the restriction on new mid-year plan entry, but believed service area expansions (SAEs) should be allowed, to expand the availability of MA plans to Medicare beneficiaries. Finally, a number of commenters expressed concern that any restriction on offering mid-year plans, including SAEs, would undermine the ability of MA organizations to negotiate with employers or unions.

Response: We believe that the MMA both supports and requires the annual contracting methodology and the elimination of new mid-year plans, mid-year service area expansions and mid-year benefit enhancements (with exceptions that are listed below). We will require that organizations make their MA bid submissions once a year in June. We are retaining in regulation the language from the current MA regulations at § 422.306(a)(2), which states that if the submission is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

We are doing as much as possible to support a competitive bidding process by removing uncertainty that would lead to inefficient bids, through mechanisms such as the design of the Intra-Service Area Rate (ISAR) adjustment, our models for risk adjustment of payments, and our policy on what plan expenditures we will include in risk sharing with regional plans, which by law must serve all of an MA region. (See the discussion on rebatable integrated benefits in subpart J.)

We do not believe that we should reduce the kind of ''uncertainty'' that comes from not knowing what products competitors will offer. This type of uncertainty should be a feature of a competitive bidding system. An annual plan bidding and entry process supports competitive bidding by ensuring an equal playing-field for all organizations. For example, MA organizations should not be able to design new plan benefit packages open to all beneficiaries in new service areas with post hoc knowledge of the regional MA benchmarks and national average drug bid.

However, after consideration of the public comments, we have identified certain exceptions to the end of flow contracting under the bidding methodology. (Mid-year plan entry is discussed in this comment, and MYBEs are discussed in the following comment.)

Mid-year plan entry. In general, we will not allow mid-year entry of new MA organizations, and new contracts with MA organizations for MA plans will be effective only on January 1 of each year beginning on January 1, 2006. In general, current MA organizations may not offer new plans mid-year, either in a current or new service area. We will still allow for applications to be submitted throughout the year, and we will make an eligibility determination in time for the next required bid submittal date.

However, we do not wish to discourage new plan offerings in areas where there are no MA options for beneficiaries. We also wish to support a competitive bidding process, as explained above. Therefore we will allow certain exceptions to the policy prohibiting new mid-year plans.

MA plans. The Part D bid is based on a national average of plan bids for the year, and the regional plan A/B benchmark is partly based on the average of regional plan bids for the region for the year. Accordingly, to

ensure an equal playing-field for all organizations and maintain the integrity of the Part D and MA regional benchmarks, we cannot approve mid-year regional MA plans because the regional benchmarks are established during bid review. We can only make the following exceptions for local plans. We may approve a local mid-year MA plan whose Part D bid is not included in the national average bid (that is, PFFS and cost plans offering Part D benefits, and special needs plans), if the plan will be offered in counties where there are no other PDPs (except fallback plans) or MA-PD plans. We could also approve a local mid-year MA plan that does not offer Part D benefits, if the plan is offered in an area with no other MA competitors. We believe that allowing mid-year plans could reduce the incentive to bid competitively, so we will carefully review applications.

PACE plans. New PACE organizations will be allowed to offer a PACE plan mid-year. As noted elsewhere in this preamble, PACE plans are governed by section 1894 of the Act. Under section 1894 of the Act, PACE plans must serve individuals who are ''nursing home certifiable,'' that is, require the level of care required under the State Medicaid plan for coverage of nursing facility services, and PACE plans have coverage requirements that differ from the coverage requirements for MA and MA-PD plans. Given the statutory requirements for defining the PACE-eligible individual, the PACE review and approval process is an extended process that requires intensive coordination with States and CMS. For this reason, new PACE plans will be exempt from the restriction on new-mid year plans, in order to promote coordination of Part C and Part D benefits with the benefits PACE plans are required to offer under section 1894 of the Act.

Employer/union group health plans. EGHPs not open to general enrollment will be allowed to offer new mid-year plans. Group health plans not open to general enrollment include both the ''800–series'' employer-only plan and group plans where we directly contract with the employer/union offering an MA product. However, an MA plan that enrolls both individual beneficiaries and employer/union members (in other words, a plan open to general enrollment) will be subject to the rule not allowing new mid-year plans (except under limited circumstances). As we have done in the past, we will publish separate guidance on employer/union group health plans.

Comment: Several commenters recommended that allowing mid-year benefit enhancements (MYBEs) would not affect the integrity of the bidding process, at least for original Medicare benefits. One commenter stated that plans sometimes find during the year that their benefit designs contain a problematic component, and seek to make mid-year changes. For example, an organization could discover that a plan co-payment for a preventive service was the source of widespread enrollee dissatisfaction that the plan would like to address, or the organization could learn mid-year that the cost assumptions for a particular benefit may have been higher than actual costs proved to be, and the plan would like to enrich the benefits to account for the lower costs. The commenters believe that retaining the flexibility to make mid-year changes to adjust for the circumstances could be quite beneficial to enrollees and could be done in a way to protect the integrity of the bidding process. This commenter recommended that we not allow MYBEs during the first quarter of the calendar year to remove the incentive to manipulate the process by bidding in June with the intention of making later mid-year enhancements to improve the package. Finally, several commenters requested that MYBEs be allowed for employer group plans, because MA organizations need the flexibility to enter into contracts with employer groups at any time during the year because employer groups may have plan years that differ from Medicare's calendar year cycle.

Response: We believe that in order to maintain the integrity of the bidding process, it is no longer appropriate to allow MA organizations to offer MYBEs at any time during the contract year, as they would be a de facto adjustment to the benefit packages for which bids were submitted earlier in the year. However, in response to public comments, we have designed an MYBE policy that we believe allows beneficiaries to receive the advantage of mid-year enhancements of non-drug benefits while protecting the integrity of the bidding process by reducing the incentive to overbid in June. The general rule is that we will allow MYBEs to non-drug benefits only under the following circumstances: (1) An MYBE can be effective no earlier than July 1 of the contract year, and no later than September 1 of the contract year; (2) MA organizations cannot submit MYBE applications later than July 31 of the contract year; and (3) 25 percent of the value of the MYBE will be retained by the government. The MA organization would submit, for each plan or segment, a revised bid and any supporting documentation related to the enhancement, including information on where the revenue requirements were overstated in the annual June bid submission. We will consider whether there is a current year MYBE request when analyzing a plan's bid for the following year. Continuing current practice, we will release guidance on the revised MYBE bid submission, including what types of non-drug MYBEs will be allowed and what documentation is required, in the annual Call Letter.

We consider this an interim policy for the initial years of the competitive bidding system (when drug benefit and regional plan pricing will be new terrain). We will review whether there is a continuing need for this policy.

We will allow the following exceptions to this policy of restricted MYBEs:

PACE plans will be allowed to offer MYBEs to non-drug benefits on a flow basis (unrestricted MYBEs), given the special nature of these plans and for the reasons specified above with respect to the ability of these plans to contract on a flow basis. (Under sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, PACE plans are required to offer enrollees a package of benefits tailored to individual needs, as determined by the PACE interdisciplinary team. Because PACE enrollees may receive additional services at any point in the contract year, we note that an enrollee's access to additional benefits mid-year is in compliance with existing PACE statutory requirements and therefore in a technical sense is not the same as a mid-year expansion of benefits for MA plans.)

Employer and union group health plans. We recognize that employers and unions offering group health plans through an MA organization may operate on different bidding and negotiation timelines. Employer and union group health plans not open to general enrollment will be allowed to offer MYBEs on a flow basis. This includes both the ''800–series'' employer-only plan and the new type of employer and union plan, where we directly contract with the employer and union offering an MA product. As noted above, consistent with past practice, we will publish separate guidance on employer/union group health plans.

However, an MA plan will be subject to the restricted MYBE rule if it is a plan that enrolls both individuals and employer and union members, that is, a plan open to general enrollment. (''Plan'' in this context refers to the benefit offering of an MA organization

under an MA contract. MA organizations may offer multiple ''plans'' in a service area under one MA contract, including a mix of plans open to any Medicare beneficiary and plans open only to Medicare beneficiaries covered under an employer/union retiree plan.). Employers would still be free to enhance benefits mid-year for the part of the package that is a ''wrap-around'' to the MA plan and that is only available to employer and union members. However, it should be noted that ''wrap-around'' benefits are not technically part of the MA plan.

Comment: Several commenters were concerned that the MA bidding process is inappropriate for Special Needs Plans (SNPs), given the unique elements involved in managing the care of high risk and high cost beneficiaries. They compared SNPs to PACE organizations, which we are excluding from the Part A and B bidding process. They also indicated that the MMA explicitly excludes SNPs from the calculation of the Part D national average premium, and stated that this exclusion should be extended to bidding for Part A and B benefits. These commenters are concerned that including SNPs in the bidding process could affect participation rates by plans, thereby limiting access for beneficiaries to these types of plans. A few commenters also suggested that we could use a separate Part A and B benchmark for SNPs in recognition of the expanded benefits offered the enrollees in SNPs.

Response: First, the comparison of PACE plans to SNPs is not accurate from a statutory perspective, because PACE plans are governed by section 1894 of the Act, which is separate from the statute governing the MA program. The fact that PACE plans are governed by a separate statutory authority gives us the discretion to exempt PACE plans from the MA bidding process. However, SNPs are created under the MA statute, at section 1859(a)(6) of the Act. SNPs are coordinated care plans, per section 1851(a)(2)(A)(ii) of the Act. SNPs are governed by the payment provisions that apply to all coordinated care plans in the MA program. Section 1854(a)(6) of the Act requires all MA plans (other than MSA plans) to submit aggregate bids: a basic A/B bid, a prescription drug bid if applicable, and a supplemental bid, if any. Therefore, SNPs cannot be excluded from the bidding process. Moreover, SNP are paid under section 1853 of the Act, the same provision as other MA plans.

If the commenter is referring to Medicaid benefits when referring to the expanded benefits offered by SNP plans, we would like to emphasize that the basic A/B bid is only for coverage of original Medicare benefits.

Comment: Several commenters stated that the actuarially equivalent cost-sharing requirement will cause difficulty for SNPs serving dual eligibles because the cost-sharing payments made by State Medicaid agencies on behalf of dual eligibles are not required to equal the full Medicare cost-sharing amount.

Response: SNPs serving dual eligibles must show in their bids a level of cost sharing that is actuarially equivalent to the level of cost sharing charged to these beneficiaries under the original Medicare program option.

Comment: Several commenters asked whether and how the MA bidding methodology would apply to demonstration plans, including but not limited to those serving dual eligibles.

Response: The application of MA bidding rules to demonstration plans depends on the specific demonstration authority. Decisions about which demonstrations will be expected to submit bids will be announced in the Advance Notice of Methodological Changes for 2006 MA Payment Rates, which we expect to publish February 18, 2005 on our website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*.

Comment: Many commenters recommended that we exclude the costs for MA enrollees with ESRD from the bidding methodology for 2006, both for the Part A and B bids and the supplemental bids. Commenters stated that MA organizations would have inadequate experience with the new ESRD payment methodology to submit sound bids in June 2005. A delay in including these services in the bid is also desirable to these commenters because it removes an added degree of complexity from the bidding process at a time when MA organizations are initially becoming familiar with the new and otherwise complicated requirements. One commenter also stated that ESRD enrollee costs should be omitted from both the basic A/B bid and supplemental benefits bid because payment for ESRD MA enrollees is based on a different risk adjustment methodology such that the meaning of ''1.0'' is different for ESRD than non-ESRD enrollees. The commenter added that MA plans are paid for ESRD enrollees in accord with a different ''rate book'' that is based upon state rates rather than county rates.

Response: The MMA amended section 1853(a)(1)(H) of the Act to state that we ''may apply'' the competitive bidding methodology to MA enrollees with ESRD, with appropriate adjustments made through application of the ESRD risk adjustment methodology. Since publication of the proposed rule, we have modeled bidding and payments under the new system, and have developed a way to apply the bidding method to ESRD enrollees. This ''merged bid'' method addresses commenters' concern that the ''1.0'' national average beneficiary does not mean the same under the non-ESRD and ESRD risk adjustment models. Our method involves converting non-ESRD and ESRD beneficiary risk scores (which are based on different risk adjustment models) into a common metric so that all costs for projected enrollees can be combined into a weighted average per capita benchmark and a weighted average basic A/B bid.

Therefore, beginning contract year 2007, we will require that MA organizations include costs for ESRD enrollees in their plan bids. As discussed above, ESRD enrollees must be subject to the same premium and cost sharing as other plan enrollees under the uniformity of premiums provision in § 422.262(c), for both original Medicare benefits and supplemental benefits. For this reason, we believe that the estimated costs for all enrollees should be included in plan bids. We will explain the ''merged bid'' method in the 2006 Call Letter for 2007 contracts and in the 2006 Instructions for Completing the 2007 MA Plan Bid Form.

However, we have concluded that we will not implement the merged bid method for incorporating ESRD beneficiary costs into plan bids for the 2006 contract year, because of the transition blend requirement for payments to aged and disabled MA enrollees. While 25 percent of aged/disabled MA payments must be based on the demographic model and 75 percent of payments on the risk adjustment model, 100 percent of ESRD payments must be based on the risk adjustment model. Under the bidding methodology, the transition payment blend must be reflected in the bid, since plans are paid either their bid (plus rebate) or part of their bid (benchmark, with the remainder of the bid coming from beneficiary basic premiums). We concluded, therefore, that exclusion of ESRD costs from plan bids for 2006 would reduce complexity in what will be an unfamiliar bidding process. Guidance on excluding ESRD costs from the 2006 bid will be provided in the 2005 Instructions for Completing the 2006 MA Plan Bid Form. See the subpart G preamble for information on payments for ESRD enrollees.

Comment: Several commenters recommended that we consider further delaying inclusion of costs for ESRD

enrollees in the basic A/B bid and supplemental bids in years beyond 2006.

Response: We believe that, beginning in contract year 2007, it will be feasible to implement a merged bid methodology for MA plans where non-ESRD and ESRD costs are appropriately weighted together into a single bid because 100 percent of MA bids and payments can be based on the CMS-HCC risk adjustment models. Moreover, the uniformity requirement means that it is to the MA organization's advantage to include ESRD enrollees in its bid. ESRD enrollees would be subject to the cost-sharing rules and premium amounts based on the plan's estimated non-ESRD enrollee costs. For example, if plan bids are calculated based only on lower-cost non-ESRD enrollees, MA organizations would have their supplemental premium under-funded because ESRD beneficiaries are likely to use more of certain supplemental benefits such as cost-sharing reductions and drug coverage. A significant financial impact may result from plan pricing based only on unit costs for services and expected utilization for the plan's non-ESRD enrollees.

Bid requirements

Proposed § 422.254(a) and (b) implement sections 1854(a)(1)(A) and 1854(a)(6)(A) of the Act, which set forth requirements for plan bids. MA organizations must submit an aggregate monthly bid amount for each MA plan the organization intends to offer. We proposed that each bid submission for an MA plan represents the MA organization's estimate of its average monthly estimated required revenue to provide coverage in the service area of the plan for an MA eligible beneficiary with a nationally average risk profile; that is, the aggregate bid is a standardized bid. This aggregate bid is the sum of several amounts the plan estimates are its revenue requirements: (1) the ''unadjusted MA statutory non-drug monthly bid,'' to provide original Medicare benefits (which we also call the ''basic A/B bid''); (2) the amount to provide basic prescription drug coverage; and/or (3) the amount to provide supplemental coverage, if any.

We proposed at § 422.254(b)(2) that each bid would be for a uniform benefit package for the service area (or service area segment, if applicable, for local plans). Plan premiums and all applicable cost sharing would also be uniform.

We stated in proposed § 422.254(b)(3) that the bid submission contain all estimated required revenue, including administrative costs and return on investment (profit or retained earnings). We stated that a determination that supplemental benefits are appropriately priced is essential for the integrity of the bidding process. A plan could overstate its revenue needs for covered services with the intention of maximizing those payments while under-pricing supplemental benefits to make the offering attractive to enrollees. To prevent this kind of strategy, we indicated that the accurate pricing of Part A, Part B, and Part D benefits and supplemental benefits will have equal importance in the bid review process. We will verify the reasonableness of these projections as part of the bid review process (in the same way that we will verify the reasonableness of plans' projections of enrollment numbers and enrollment mix for an optional supplemental product).

Supplemental benefits

We proposed at § 422.254(b)(3) that when estimating required revenue, a plan will include adjustments for the effect that providing any non-Medicare benefit has on utilization. We proposed that this requirement would apply to both mandatory and optional supplemental benefits. In both the Title I and Title II proposed rules, we took the position that the basic portion of the bid should represent basic benefits only; it should not reflect the utilization impact on basic benefits induced by the presence in the benefit package of supplemental or enhanced benefits. We proposed that this utilization impact should be included in the pricing of supplemental benefits (Title II) or the enhanced portion of the bid (Title I). We took this position to ensure the integrity of the bid. In other words, when a plan offers a benefit package that includes reductions in cost sharing, the pricing of such a mandatory supplemental benefit would include not only the cost of ''buying down'' the cost sharing (that is, the estimated revenue needed to cover the amounts enrollees would have otherwise paid as cost sharing), but also the cost of financing the expenditures associated with the additional utilization resulting from offering the cost-sharing benefits.

We also proposed to exercise our authority under section 1856(b) of the Act to establish a rule prohibiting MA organizations from offering, as optional supplemental benefits, reductions in Part A, Part B, and Part D cost sharing, or enhancements to Medicare Parts A and B benefits. Under the rule, MA organizations will still be permitted to offer non-Medicare benefits, for example, dental and optical services as optional supplemental benefits.

We stated in proposed § 422.254(b)(4) that the bid amount is for plan payments only but must be based on plan assumptions about the amount of estimated revenue required from enrollee cost sharing. The estimate of plan basic cost-sharing for plan basic benefits must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare program option.

Comment: A number of commenters disagreed with CMS' proposal that MA organizations develop a supplemental bid reflecting the effects on utilization of Part A and B services of providing non-Medicare covered benefits. First, most commenters stated that the benchmark, which is the maximum amount we will pay for coverage of Part A and B benefits, reflects Medicare FFS costs. Medicare carriers and intermediaries make payments for Medicare Part A and B services based on fee schedules without regard to whether the beneficiaries have supplemental coverage. According to the commenters, because most Medicare beneficiaries have some form of private or governmental supplemental coverage that has an impact on these costs, the MA benchmark also reflects this impact. The commenters believe that because ''induced demand'' is already accounted for in the benchmark, requiring plans to shift these costs to the supplemental benefit package would result in a misalignment of the relationship between the basic A/B bid and the benchmark.

Second, several commenters recommended that allocation of costs to the supplemental bid may have a tangible effect on the MA organization and on beneficiaries. To the extent that the MA plan's Part A and B bid is below the benchmark, moving these costs from the basic A/B bid to the supplemental bid increases the amount of savings, and increases the supplemental premium by the same amount. However, because we retain 25 percent of the savings, the rebate dollars will not fund 100 percent of the increase in the supplemental premium attributable to these costs. Thus, the proposed policy is likely to produce an increase in the aggregate beneficiary premium. In contrast, if utilization is included in the basic portion of the bid, basic bids will be higher and bid and premiums for supplemental benefits will be lower.

Third, commenters also were concerned that there are no existing standards to evaluate the effect that

providing non-Medicare benefits has on utilization and therefore on premiums and competition. For example, one commenter noted that frequently there are multiple impacts from a single benefit change. For example, lower primary care physician (PCP) copays may drive higher utilization among primary care physicians; however, it may also help result in lower specialist, hospital and prescription drug utilization. Several commenters concluded that it would be impossible to apply this requirement uniformly and therefore equitably.

One commenter noted another barrier to uniform application of this requirement: a large portion of an MA plan's enrollment will have supplemental coverage through a source other than the MA organization (for example, Medicaid, other government programs, employee benefit plans, Medigap plans), and these incremental, additional costs will necessarily be reflected in the level of the basic A/B bid. Therefore, this requirement would result in an uneven playing field among competitors. Finally, another commenter asked where plans will obtain data to make these adjustments and whether additional adjustments would be needed for potential adverse selection.

Response: We believe that the pricing of the supplemental benefit is critical to the integrity of the bidding process. For this reason, we proposed that when a plan offers a benefit package that includes reductions in A/B cost sharing, the price of the supplemental benefit would include not only the cost of ''buying down'' the cost sharing (that is, the estimated revenue needed to cover the amounts enrollees would have otherwise paid as cost sharing), but also the cost of financing the expenditures associated with the additional utilization resulting from offering the cost sharing benefits. We believe it was important to align pricing policies for medical benefits (in the MA rule) and drug benefits (in the Part D rule).

We recognize, however, that it can be very difficult to disentangle the effects of induced utilization from the effect of plan management of utilization of medical benefits. For Parts A and B benefits, the effect of induced demand may be insignificant. For example, it is reasonable to recommend that there is no induced demand for hospital services or skilled nursing facility (SNF) (additional hospital admissions) because of plan utilization management of those services. Thus, it is unlikely that a change in cost sharing (up or down) would create or reduce utilization of hospital or SNF services. On the Part B side, induced demand here may also be quite limited due to plan utilization management. In contrast to Part A and B benefits, there is likely to be induced demand for Part D benefits, especially for those individuals who will be receiving new coverage. Also, there is likely to be some induced demand if supplemental benefit options are provided that reduce the initial deductible or fill in part of the what is lacking in the standard Part D package. We further recognize that there are no universal actuarial standards for separating these effects. Therefore, after discussion of the public comments and further analysis, at this time we will not require that the non-drug portion of the supplemental bid be adjusted to include expenditures associated with induced demand for Medicare-covered benefits resulting from offering cost sharing reductions.

Therefore, in this final rule, we are deleting the sentence at proposed § 422.254(b)(3) that plan assumptions about revenue requirements must include adjustments for the utilization effects of non-drug cost sharing reductions. As we indicate in responses to comments below, we will not implement this aspect of estimating revenue requirements for the Part A and B benefits through rule making. However, we have the authority to refine guidance in the future on how MA organizations should estimate their revenue requirements under § 422.254(b). For the Part D benefit, the bid amount must reflect an adjustment for the effect that providing alternative prescription drug coverage (rather than defined standard drug coverage) has on drug utilization. Costs associated with any increased utilization must be included in the price of the drug portion of the supplemental bid for MA-PD plans. (See proposed § 423.265(d)(2) and the discussion in the F preamble of August 3, 2004 proposed rule for the Medicare prescription drug benefit.

As discussed below, we intend to analyze the effects of induced demand in the near future and will review this policy.

Comment: One commenter suggested that we delay implementation of this requirement concerning pricing induced demand in the supplemental package for a period of 2 years (until 2008) for both regional PPO and local plans. Another commenter was concerned about the short timeframe for a 2006 implementation of this proposal and made the following suggestions for implementation: (1) we develop a standard data set or set of utilization assumptions and distributions with which to quantify the utilization impact; and (2) plans should have the option of using those assumptions in their bid or plan-specific assumptions that are actuarially justified.

Response: As indicated above, we are withdrawing our proposal. However, we believe that improvements can be made in the accuracy of pricing supplemental benefits. We intend to conduct analysis in the near future using accumulated bidding and payment data, because we believe that over time it is possible to develop factors for the MA program that could be applied to estimate the cost of induced demand.

Comment: Some commenters stated that this requirement, coupled with the actuarially equivalent cost sharing requirement at section 1852(a)(1)(A), would cause particular difficulty for Special Needs plans (SNPs). Attribution of ''induced demand'' costs to the A/B benefit package would increase the cost of the bid and reduce potential savings, and shifting these costs to the supplemental benefit package would result in increased premium costs for SNP beneficiaries, because SNP cost structures may limit opportunities for rebates. Limited rebates also could result in cost shifting to plans or, in the case of duals, to States that cover cost-sharing amounts.

Response: As noted above, we are withdrawing this proposal. This withdrawal applies to all MA plans, including SNPs.

Comment: Two commenters disagreed with our proposed rule prohibiting MA organizations from offering, as optional supplemental benefits, reductions in Part A, Part B, and Part D cost sharing, or enhancements to Medicare Parts A and B benefits. One commenter requested that we continue to permit the flexibility of offering reductions of Parts A, B, and D cost sharing as optional supplemental benefits, because offering separate plans requires separate bids, system enhancement, and modification of enrollment and eligibility procedures. The other commenter requested that we make an exception to this rule for employer group plans.

Response: First, under Part D, optional supplemental benefits do not exist. Under § 423.265(c), we are requiring that enhanced alternative coverage be a uniform package for all enrollees. Second, in terms of Part A and Part B benefits, we would exclude from this requirement employer and union group health plans that are not open to general enrollment, which includes both the ''800–series'' employer-only plan and the new type of employer and union plan, where we directly contract with the employer and/or union offering an MA product.

However, an MA plan that enrolls both individuals and employer and union group health plan members (in other words, a plan open to general enrollment) would be subject to the restricted optional supplemental policy. Employers would still be free to fund ''wrap-around'' optional supplemental benefits that would be only available to employer/union members. The ''wrap-around'' benefits are not technically part of the MA plan.

MA organizations would still be able to provide choice by offering multiple plans within the same service area that have different mandatory supplemental benefits. Many MA organizations take this route today.

Comment: Several commenters support the proposed policy that MA bidders submit a single bid amount in 2006 based on the blending of the demographic and risk adjustment payments as required under § 422.308(c)(2)(ii)(B). The reasons cited are the administrative and analytic complexity of developing two bids to be compared against two different benchmarks.

Response: We will provide instructions for determining a blended bid, in the Instructions for Completing the MA Plan Bid Form. Information regarding payments based on blended bids will be provided in the Advance Notice of Methodological Changes for MA Payment Rates.

Actuarial equivalence

In the August 2004 proposed rule, we discussed at length how to implement the requirement at § 422.254(b)(4) to determine an actuarially equivalent amount of cost sharing. MA plans must provide Medicare-covered benefits to enrollees. The MMA amended section 1852(a)(1)(B) of the Act to include the term ''benefits under the original Medicare FFS program option,'' which are defined as those items and services (other than hospice care) for which benefits are available under Parts A and B to individuals entitled to benefits under Part A and enrolled under Part B, with cost-sharing for those services as required under Parts A and B or an actuarially equivalent level of cost-sharing as determined in this part.'' (Cost sharing refers to service-specific cost sharing for Part A and Part B benefits; it does not include a beneficiary premium.)

First, we discussed the current approach, the national uniform dollar amount. The MMA provision on determining whether a rebate is applicable is similar to a provision that continues to apply to MA plans through 2005, dealing with the determination of ''excess amounts'' used to fund extra benefits. Before 2006, when Medicare payments (based on administratively-set amounts) exceed the revenue a plan needs for providing the Medicare benefit, the plan must ''return'' the excess amount to enrollees in the form of extra benefits (or cost sharing reductions). An excess amount exists if CMS' average capitation payment for the plan exceeds the adjusted community rate, taking into account cost sharing for Medicare services that is the responsibility of the enrollees. Through 2005, all plans are required to use a uniform national figure that we provide as the amount to be subtracted from their computed revenue needs for the Medicare benefit package to determine the excess amount. The uniform national dollar amount represents our projection of the monthly actuarial value of Medicare coinsurance and deductibles (that is, the amount, on average, of cost-sharing expenses beneficiaries incur in receiving Medicare services across the nation).

We recognized that this approach does not adequately recognize geographic variations in cost sharing, cost differences among private health plans, and utilization and price differences between private plans and FFS Medicare. It distorts the statement of revenue needs of a plan. If a plan operates in a high-cost area, the national actuarial value of cost sharing may understate cost sharing in the area, while in low cost areas, cost sharing is overstated.

We proposed several alternative approaches to defining an actuarially equivalent amount of cost sharing for the basic A/B bid amount: (1) localized uniform dollar amount; (2) plan-specific approach; and (3) proportional approach. In this final rule, we also make a clarifying change to § 422.254(c)(5) to reflect the statutory requirement.

Localized uniform dollar amount

We would publish localized (for example, county-level or MSA-level) cost-sharing values, and an MA organizations would determine its basic A/B bid for a plan by subtracting the appropriate geographically weighted average of these cost sharing values for the plan's service area from the plan's stated revenue needs. The local cost sharing values would be based on actual per-beneficiary FFS cost sharing, projected to the contract year and standardized to a 1.0 risk score.

Plan-specific approach

The MA organization would use its own pricing and utilization assumptions to determine a basic A/B bid for its plan, as if the plan were offering Medicare-only benefits under Medicare cost sharing rules or an actuarially equivalent structure. A cost-sharing structure would be actuarially equivalent if the projected average cost sharing as percent of the sum of average cost sharing and projected average plan payout equals the percentage using Medicare's cost-sharing rules, based on the projected experience of the same group and using the same pricing assumptions. The average amount of cost sharing and the average plan revenue requirements for the assumed basic A/B package would then be adjusted to reflect cost-sharing and plan requirements based on an enrollee with a national average risk profile. The adjusted plan revenue requirements would serve as the organization's basic A/B bid.

Proportional approach (including national, regional, or local proportions)

Actuarial equivalence under this approach would be met if the ratio of a plan's cost sharing amount for the basic A/B bid to the total cost of plan benefits equals this proportion under original Medicare. For example, if the national average actuarial value of cost sharing under original Medicare in a year were 16.8 percent of the total (value of cost sharing plus value of benefits, using the actual 1999 figure for Medicare), then an MA plan would have to offer a basic A/B bid based upon a plan basic cost-sharing amount that is 16.8 percent of total costs. We would announce the projected percentage of total expenditures that represent cost sharing in the same way that we currently announce the national average actuarial value of Medicare cost sharing as part of the rate announcement for private health plans. To address the issue of geographic variation in cost sharing, we proposed regional or local proportions over national proportions. While a fixed national proportion recognizes variation in expenditures at the health plan level, even within FFS Medicare there is significant variation by area in the cost-sharing proportion, for example, for Part A ranging from 13 to 20 percent in 1999 (compared to the national average of 16.8 percent).

We further proposed breaking regional or local proportions into service-specific proportions of cost sharing applied to the different categories of expenditures health plans would have (for example, Part A versus Part B, or further disaggregated into inpatient, SNF, home health, physician, and/or outpatient).

We received a number of comments on the issue of actuarial equivalence, revealing a range of opinion. A few commenters recommended the local uniform dollar amount method, several recommended the plan-specific method, and some preferred the proportional method. Some commenters did not specify a choice but recognized the importance of accounting for regional variation in costs, with some expressing concern about the plan-specific method.

Comment: One commenter stated that CMS should retain the current uniform absolute dollar method. However, the commenter believes that CMS should adjust from national to local dollar amounts. The commenter believes that this aspect of the program, which is familiar to the industry, should remain constant given substantial changes to plan reimbursement under the MA program and the introduction of competitive bidding. The commenter also recommended that the plan-specific approach creates the possibility that the projections will be inaccurate and result in unfair cost-sharing burdens on members and hospitals. Thus, the proportional method may suffer from the same flaw, as it also relies on plan pricing assumptions.

The plan-specific method drew the most commentary from those in favor of and those opposed to this approach. Several commenters felt the plan-specific method would be the most precise because it was based on each plan's own utilization and pricing estimates, reflects the different mix of services in managed care versus FFS Medicare, and would be most administratively efficient since it is based on data readily available.

Several commenters objected to the plan-specific method. One commenter felt this approach would allow MA organizations to use unreasonable assumptions, and another commenter objected because it would disadvantage organizations that tightly manage care and/or have more efficient provider networks. Commenters objecting to the plan-specific approach supported beneficiary cost-sharing rules that require the same dollar amount of cost sharing across all affected plans in a local geographic area rather than any method that would allow variation by plan.

Response: There are two basic principles behind Section 1852(a)(1)(B) of the Act. First, the MA program must reflect a feature of the Medicare program, that a certain share of the cost of covered care is to be borne by beneficiaries (or third parties paying on behalf of beneficiaries), and not the government. Therefore the MA enrollee's share of costs will not be financed by government funds in the bidding system, unless rebate dollars are available. Second, for competitive bidding, the determination of whether a rebate (bid below benchmark) or a premium (bid above benchmark) is applicable to a plan must be based on an ''apples-to-apples'' comparison of the same set of benefits (Part A and Part B benefits) reflecting a specific cost-sharing structure.

Section 1852(a)(1)(B) of the Act affects how MA organizations develop their basic A/B bids. It does not determine what a plan's actual cost-sharing structure will be, because a plan can have an actuarial value of cost sharing that is less than that under original Medicare.

However, actual average per-member-per-month (PMPM) cost sharing under any plan offered by an organization cannot exceed the actuarial value of the FFS average. (This limit on actual in-plan cost sharing is a continuation of the pre-existing M+C provision except that, unlike the earlier M+C provision, the limit on the cost sharing does not include the premium.) Also excluded from this limit, and excluded from the Part A and Part B cost-sharing computation in the bid, is any cost sharing for Part A and Part B benefits that enrollees of MA regional plans obtain from non-network providers (because section 1852(a)(1)(B)(ii) of the Act specifically excludes out-of-network cost sharing (section 1858(b)(2)) from the determination of the ''actuarially equivalent level of cost-sharing with respect to benefits under the original Medicare fee-for-service program option''). We have made a change to § 422.254(b)(4) to conform the regulation to the statutory provision.

After further analysis, we do not support the use of localized dollar amounts. This approach shares a key problem with the national uniform dollar amount. An average absolute dollar amount would be too small for some plans in a local area or region (leading to shortfalls in rebates that could otherwise be used to fund supplemental benefits), yet too large for other plans (leading to bids lower than a plan's estimated revenue requirements). In either case, the distortion we are seeking to minimize would remain.

We believe the proportional approach is the best approach, based on local proportions that are service-specific. This approach supports the MMA goal of making ''apples to apples'' comparisons among basic A/B bids, which creates a level playing field because all MA organizations in a market area must apply the same standards.

This approach has the advantage over the local uniform dollar amount because plan pricing assumptions are built into the total value of the benefit package. Also, plans that efficiently manage care would be disadvantaged by local uniform dollar amounts because these amounts would overstate cost-sharing revenue, thus lowering the plan bid and resulting in larger rebates than the plan could actually ''afford.''

We believe the proportional approach is more straightforward to understand and implement than the plan-specific approach, which is crucial in the context of a bidding methodology that must build in several complex adjustments (for example, the geographic ISAR adjustment). The plan specific method is more precise (in that it reflects not only plan pricing but also plan utilization assumptions) but it is the most complicated method because it requires organizations to figure out the utilization effects of a cost-sharing structure they likely will not use in order to determine how plan payout and member cost sharing would change if the package were based on original Medicare cost sharing.

Comment: Several commenters requested that we consider using, for each local area or region, proportions by service category. The commenters believe that this refinement would yield proportions more closely reflecting the cost sharing associated with the mix of services used in these areas and could, therefore, result in a more accurate projection of the actuarially equivalent costs sharing in each geographic area.

Response: We agree with the commenters and intend to incorporate service-specific categories in the bid pricing tool. We are considering the following approach. Each year the Office of Actuary (OACT) would publish five proportions for each county representing average FFS cost-sharing: Part A inpatient hospitalization; Part A SNF; Parts A & B home health; Part B outpatient facility; Part B, all other. We will provide guidance on the proportional method and details on the service proportions in the Instructions for Completing the MA Plan Bid Form.

Comment: Two commenters also suggested that we allow MA organizations to choose whether to use the plan-specific or proportional method.

Response: We do not support the idea of allowing MA organizations to choose which method to use when estimating their MA bids. This would create further complexity in a complex bidding process. For example, it could create

confusion in bidding because each method could interact differently with the other rate and payment adjustments required under the MMA. It also would make it difficult for us to apply consistent standards in our bid review process. We want to set a single standard that applies to all MA organizations because we believe that is the intent of the statute and it ensures everyone is subject to the same rules.

Comment: Several commenters recommended that if we select the proportional method, the proportions should be established for each local area or region and also disaggregated by service category (for example, inpatient hospital cost sharing versus physician cost sharing). This refinement would yield proportions that will more closely reflect the cost sharing associated with the mix of services used in these areas and could, therefore, result in a more accurate projection of the actuarially equivalent costs sharing in each geographic area. If we select the proportional method, one commenter stated opposition to the development of proportions based on assumptions of how health plan enrollees generally use services, because it would be difficult for us to develop a distribution of services that would be consistent with the experience and practices of individual plans.

Response: We agree that further disaggregation of local or regional proportions by service category would result in proportions that are more accurate. See the discussion above for our proposed approach. Details on the method and the proportions for 2006 will be published in the Advance Notice of Methodological Changes for MA Payment Rates, which we expect to be released on February 18, 2005 on the CMS website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*

Information required

Proposed § § 422.254(c) and (d) would implement section 1854(a)(6)(A) of the Act by setting out the information MA organizations must submit for coordinated care plans and PFFS plans. Proposed § 422.254(e) specified information that must be submitted for MSA plans.

Proposed § 422.254(c) established that, in addition to submitting an aggregate bid amount, MA organizations must submit the proportions of the aggregate bid attributable to coverage of Part A and Part B benefits, Part D basic benefits, and supplemental coverage. They must also identify the plan type, projected enrollment, any capacity limits, the actuarial bases for determining the bid amounts and proportions, information on the plan's cost sharing, including the actuarial value of deductibles, coinsurance, and co-payments, and information required to calculate risk corridors for regional plans for 2006 and 2007. Additional information required on drug coverage was proposed at § 423.265, which implements section 1860D–11(b) of the Act.

In the final rule, we added § 422.254(c)(9) to address information requirements for the geographic Intra-Service Area Rate (ISAR) adjustment. See the G preamble discussion of § 422.308(d) regarding our policy decision on the geographic ISAR adjustment.

Under proposed § 422.254(d), for MA organizations required to provide a monthly rebate because the plan bid is less than the plan benchmark, the organization must submit information to us about how this rebate would be allocated across the statutorily mandated options specified at § 422.266(b). All rebate dollars must be applied to a mandatory supplemental benefit.

Since MA regional plans may serve multiple regions, and each region is a separate service area, section 1854(a)(1)(C) of the Act requires us to encourage the offering of regional plans by developing procedures to allow MA organizations to file consolidated information for multi-region MA plans (including national plans). We believe our new bid pricing tool will capture MA pricing information in an efficient manner and reduce filing burden for all MA organizations, including those offering national plans. Much of the supporting documentation required for the Adjusted Community Rate Proposal (ACRP) will no longer be required. Specifically, we will no longer collect commercial pricing and corporate financial data, and the number of cost-sharing categories has been reduced. In addition, the electronic bid form includes data elements that were filed paper format for the ACRP process, for example, actuarial utilization and cost data, trends in medical expenses, and non-medical expense projections. We are committed to working with organizations to reduce duplicative information in the application, bidding, and contracting process. For example, we would expect that a single legal organization offering an MA regional plan in more than one region would submit much the same legal and organizational information for all regions, with the main differences being the provider networks. We expect the application process to be an area where paperwork burden can be reduced. Ideas for consolidating regional filings that are under development include a master contract, a single actuarial certification covering multiple bids, and consolidated supporting exhibits across regional bids where there are common elements (for example, the development of manual rates). We will continue to identify ways to consolidated filing as the program develops.

In addition, we will apply the projected revenue and medical expense values (including administrative expenses) captured by the MA bid pricing tool to calculate the risk corridor amounts used to determine risk-sharing payment adjustments for regional MA plans for contract years 2006 and 2007. See the subpart J preamble for the discussion of risk sharing on costs of providing original Medicare benefits and rebatable integrated benefits. See the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates for guidance on information to submit for determination of risk sharing payments.

Finally, section 1854(a)(6)(A)(iii) of the Act gives us the authority to require information in addition to that listed above to allow us to verify the actuarial bases for plan bids. We expect to use the authority given us under this provision in two ways. First, our review of an organization's bid submissions may identify problems that would trigger our request for additional, more detailed information (for example, data the MA organization used on average utilization and pricing to model the expected distribution of costs in the plan bid). We would not want to require such detail for every plan bid in the initial submission, and we are confident that forthcoming bid submission guidance (in the annual Instructions for Completing the MA Plan Bid Form) will limit the occurrences of our requests for additional data. Second, as we did with the ACRP tool for the M+C program, we expect to make annual updates to the bid pricing tool. The updates may or may not involve changes to the information required to verify actuarial bases of the bid. We will announce the updates in the annual Call Letter.

Special rules for MSA plans

Proposed § 422.254(e)(2) would implement sections 1854(a)(3) and 1854(b)(2)(D) of the Act by indicating that bids are not required for MA MSA plans. That is, MA organizations will not complete the bid pricing tool developed for non-MSA plans. However, for MSA plans MA organizations must file a bid submission with information on coverage, the

enrollment capacity, the monthly MSA premium amount, which is the amount of revenue the plan requires to offer original Medicare benefits (analogous to the basic A/B bid for other MA plans). MA organizations must also submit the amount of the MSA deductible, and the beneficiary supplemental premium, if any. MSA plans are prohibited from offering Part D coverage (although MSA enrollees may choose to enroll in a prescription drug plan).

Comment: One commenter recommended that we consider allowing MA organizations to subsidize the Part D premium for dual eligible beneficiaries with revenue from the medical benefits part of the MA-PD plan.

Response: We believe the commenter's phrase ''the medical benefits part'' is referring to Part A and B benefits. MA organizations offering the Part D benefit may fund a reduction in the Part D premium with rebate dollars, pursuant to section 1854(b)(1)(C)(ii)(II) of the Act, and as proposed at § 422.266(b)(2). However, the resulting premium amount must be uniform for all members of the plan, in accordance with section 1854(c) of the Act. A plan may not offer an additional premium reduction only to a subset of members (for example, dual eligible beneficiaries).

Comment: One commenter asked that we clarify the ''enrollment assumptions data requirement,'' that is, how these assumptions will be used in computations and how errors in them will be corrected over time. The commenter believes that our assumption about a plan's enrollment mix will be a critical competitive factor in determining how rebate dollars are used to buy mandatory supplemental benefits and/or how beneficiary premiums for mandatory supplemental benefits are set. Our oversight on this issue will be vital to ensure a level playing field.

Response: See the discussion in the subpart G preamble on the geographic Intra-Service Area Rate (ISAR) adjustment, which takes into account the difference between the distribution of enrollment across counties in the plan's service area assumed in the plan's bid and the actual geographic mix of enrollment at the time payment is made. Also, we will release detailed guidance on the bidding methodology in the Instructions for Completing the MA Plan Bid Form and the Call Letter. Information on the payment methodology, including the ISAR adjustment, will be provided in the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates, published annually on our website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*.

Comment: Several commenters supported development of procedures for MA organizations to file consolidated bid information for multi-regional plans, including national plans, and believe that this will facilitate the offering of regional plans.

Response: In light of the statutory mandate to allow consolidated bids for multi-regional plans, we are committed to allowing bid consolidation where appropriate. However, in order to maintain the integrity of the bid submission and review process, section 1854(a)(1)(A) of the Act requires MA organizations to submit a bid for each MA region. However, we believe our new bid pricing tool will capture MA pricing information in an efficient manner and reduce filing burden for all MA organizations, including those offering national plans. See the discussion above for examples of burden reduction in the new bid pricing tool.

Comment: A few commenters recommended that we establish streamlined documentation requirements for MA organizations to follow in supporting the actuarial basis of their bids. The commenter requested that these requirements strike a balance between providing us with sufficient information to review the bid and ensuring that MA organizations are not burdened with onerous requirements.

Response: We support the commenters' position that the requirements built into the new bid pricing tool and supporting documentation should be thorough enough to allow a fair and accurate review of bids but should avoid undue burden. See the discussion above regarding the new bid pricing tool MA organizations will use for bid submission. Most of the supporting documentation required for the ACRP will no longer be required. For example, we will no longer collect commercial pricing and corporate financial data, and the number of cost-sharing categories has been reduced.

Comment: Several commenters are interested in having bid formats, documentation requirements for submission and criteria for actuarial substantiation as early as possible to assist in the bid preparation and to minimize the uncertainty in dealing with employer retiree groups and other contractors, including providers. One commenter stated that our negotiation and approval process will be completed later than most plans' rate quotes to employer retiree groups for the following contract year. To the extent that MA organizations must negotiate changes to retiree premiums, benefit packages and our payments after these organizations have provided rate quotes to employer groups, this destabilizes the MA organization's relationship with, and reduces its appeal to, employer groups. The commenter indicated that early and clear expectations of plans' documentation requirements for submission would help to minimize this.

Response: We have been working hard to develop all aspects of the new bidding methodology to ease the transition for all parties. In December 2004, we released for public comment drafts of the drug and non-drug bid pricing tools that will, with the plan benefit package, constitute the annual June bid submission, with the intention of developing the new program. We do recognize the special circumstances surrounding the offering of employer and union group health plans (EGHPs), and as noted above, we will release separate guidance regarding EGHPs.

Comment: One commenter strongly objected to the proposed regulatory requirement that MA organizations that have Part B-only enrollees submit a separate bid for these enrollees. Some MA organizations have only a handful of these members and the cost of preparing a separate bid is very substantial. The commenter recommended that we identify a means for bidding organizations to submit their Part B-only enrollee bid in conjunction with another bid. The commenter recommended this approach so that MA organizations are relieved of the administrative burdens of submitting two bids for their enrollee population while the underlying objectives of the bid process are still accomplished.

Response: The requirement at § 422.254(f) is substantially the same language as the previous § 422.310(a)(3) for the M+C program. Preparation of a separate adjusted community rate (ACR) for Part B-only enrollees is a long-standing policy, and we do not see a basis for changing the existing policy. We have made editorial changes to the text at § 422.254(f) to conform it to the previous § 422.310(a)(3).

There are two types of Part B-only enrollees: current members of employer or union group health plans and Part B-only enrollees ''grandfathered'' from pre–1999 risk contracts. Since 1998, only those beneficiaries who are members of employer or union groups have been allowed to elect a Part B-only plan. However, section 1876(k)(2) of the Act created ''grandfathered'' Part B-only enrollees by permitting a Part B-only beneficiary enrolled with an

organization under a section 1876 risk contract on December 31, 1998 to continue enrollment with that organization if that organization had entered into an M+C contract effective January 1, 1999.

Our operational policy has recognized that the number of ''grandfathered'' beneficiaries has been decreasing over time, and in the past we have provided guidance on grandfathered enrollees in the annual Call Letter, including an option to simplify rate filing. Call Letters from prior years with guidance on grandfathered Part B-only enrollees can be found on our website at *http://www.cms.hhs.gov/healthplans/acr/*. We will continue to provide guidance regarding this policy in the Call Letter.

Comment: A number of commenters asked questions about the procedures for bidding. For example, a few commenters asked how we will define administrative expenses in the bid pricing tool, and whether the definitions will be the same for Part C and Part D. Other examples are whether we would allow rounding of premiums after adjustments to the allocation of rebate dollars, and how MSA plans could provide risk adjustment data for payment.

Response: As in the past, we will address questions on the procedural details of bidding in the Instructions for Completing the MA Plan Bid Form and the Call Letter.

4. Negotiation and Approval of Bids (§ 422.256)

Authority to review and negotiate bids

The provisions in proposed § 422.256 would implement section 1854(a)(6)(B) of the Act, which provided us with the authority to negotiate the monthly aggregate bid amount and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits. The MMA grants us the authority to negotiate bids that is ''similar to'' the statutory authority given the Office of Personnel Management (OPM) to negotiate with respect to health benefits plans under the FEHBP program.

Chapter 89 of Title 5 gives OPM broad discretion to negotiate prices and levels of benefits. We believe that the Congress used ''similar to'' in the statute to recognize the differences between the FEHBP and the MA program. For example, the OPM authority applies to negotiating the level of plan benefits, while MA plans must offer, at a minimum, benefits covered under the original Medicare program, which are defined in law. Also, the authority to negotiate payment rates would seem to be limited for the MA program by other provisions of the MMA (for example, statutory formulas for determining benchmarks, premium and rebate amounts, and payments to plans.)

However, MA plans are able to modify the cost sharing for Medicare Parts A and B benefits via supplemental benefits. We have the authority to negotiate the level of the supplemental benefits as part of ensuring that the bid is not discriminatory, as described in section 1852(b)(1) of the Act and implemented at proposed § 422.100(f)(2) and § 422.110. Further, in situations where we have questions about the assumptions used for a plan bid, we have the authority to negotiate with the MA organization regarding the appropriate assumptions and the resulting rebate and/or supplemental premiums, to ensure that the supplemental bid reasonably and equitably reflects revenue requirements.

Noninterference

As proposed under § 422.256(a)(2) and in accordance with section 1854(a)(6)(B)(iii) of the Act, we do not have the authority to require—(1) any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under the Act; or (2) a particular price structure for payment under a contract to the extent consistent with our authority. Also, as under current law, we do not have the authority to review or negotiate bids for PFFS plans or any amounts submitted by MSA plans.

Standards of bid review

Proposed § 422.256(b) implements section 1854(a)(6)(B)(ii) and (iii) and section 1854(e)(4) of the Act, which together established three standards for our review of bids. First, the bid and proportions must be supported by the actuarial bases, which we determine based on information provided by the MA organization.

Second, the bid amount and proportions must reasonably and equitably reflect the plan's revenue requirements for providing the benefit package, as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act. We interpreted this reference to mean that the Congress intends for a plan bid to reflect the plan's estimated required revenue in providing coverage (including any profit or retained earnings), and not other factors such as the relative lack of competition in the plan's market area or the level of annual capitation rates and benchmarks in the service area.

Third, proposed § 422.256(b)(3) implemented section 1854(e)(4) of the Act by providing for a limitation on applicable cost-sharing for coordinated care and PFFS plans: the actuarial value of plan cost sharing ''applicable on average'' to plan enrollees cannot exceed the actuarial value of cost sharing ''applicable...on average'' under original Medicare. We interpreted ''applicable'' to mean the level of cost-sharing in effect after any reductions to the level of cost sharing that a plan can make by offering a mandatory supplemental benefit, as specified under section 1852(a)(1)(B) of the Act. That is, we apply this third standard of review, as specified under section 1854(e)(4) of the Act, in light of both the basic A/B bid and the application of any rebate toward reduced cost sharing of Medicare Parts A and B benefits included in the supplemental bid.

We clarified that proposed § 422.254(b)(4), which implements the requirement in section 1852(a)(1)(B)(i) of the Act), that the actuarial value of MA plan cost sharing for Medicare Part A and Part B benefits assumed in constructing the basic A/B bid must equal the actuarial value of original Medicare cost sharing, would affect how MA organizations develop their basic A/B bids. In contrast, the cap on *actual* enrollee cost-sharing liability for Medicare Parts A and B benefits is established at proposed § 422.256(b)(3), which implements the requirement in section 1854(e)(4) of the Act. Before 2006, the sum of applicable plan cost sharing for Part A and Part B services, and any cost sharing for Part A and Part B services that was collected as revenue in the form of a premium or portion of a premium, could not exceed the actuarial value of cost sharing in fee-for-service Medicare (section 1854(e)(1) of the Act). As of 2006, any Medicare cost sharing included in a premium (as well as any cost sharing that is ''bought down'' through the use of rebate dollars) is not counted towards the limit (section 1854(e)(4)of the Act).

We further clarified that, under the new bidding methodology, an MA organization cannot substitute a basic beneficiary premium for some portion of cost sharing under original Medicare. Section 1854(b)(2)(A)(i) of the Act (proposed at § 422.262(a)(1)) mandated that for plans with bids less than benchmarks, the premium for original Medicare benefits must be zero. Our understanding is that Congressional intent was to have the basic A/B bid be for a standardized package. This means MA organizations able to offer plans

with Medicare-covered benefits at a lower cost to the beneficiary than the benchmark will have a plan with zero premium for coverage of benefits under original Medicare.

However, any MA organization can choose to structure the benefit package with a mandatory supplemental benefit that includes a reduction in Medicare Part A and B cost sharing. The premium for this supplemental package, as well as the Part D or Part B premium, can be offset by any rebates for which the plan is eligible. Thus, the aggregate bid would consist of: (1) a basic A/B bid amount for benefits available for either zero premium or a basic premium depending on whether the plan's bid is above or below the benchmark; (2) a mandatory supplemental bid amount for benefits available for a premium or no premium depending on the plan's use of rebates (and an optional supplemental benefit if offered); and (3) a drug bid amount for basic benefits, also available at a premium or no premium depending on use of rebates.

Finally, we clarified that, under the MMA, an MA organization is no longer permitted to reduce the basic beneficiary premium amounts for original Medicare benefits by taking a negative adjustment on additional revenue, as was permitted under the M+C program in the ACRP process. In accordance with section 1854(a)(6)(B)(ii) of the Act, plan bids must reasonably and equitably reflect plan expected revenue requirements. MA organizations cannot submit plan bids that understate their revenue requirements for the basic A/B bid. When the basic A/B bid amount exceeds the benchmark amount, the difference is required to be charged as a basic beneficiary premium. If an MA organization were able to waive the plan's basic beneficiary premium, this would suggest that the MA organization had overstated the plan's expected revenue requirements for basic benefits. In essence, we do not have the authority under the statute to allow MA organizations to waive basic beneficiary premiums for plans with basic A/B bids greater than benchmarks.

Comment: Several commenters requested clarification on how we would interpret the bid review standard that the bid amounts and proportions must ''reasonably and equitably'' reflect the MA plan's revenue requirements for providing the benefit package. Two commenters suggested that we should ensure that adequate flexibility is maintained throughout the bid review and approval process in order to allow MA organizations to pursue legitimate business strategies that promote the availability of viable choices for beneficiaries. One commenter recommended that we consider in its bid review process whether an organization is in a start-up phase and the intensity of the marketplace competition facing the plan. Another commenter suggested that in reviewing the revenue requirements of the plan, we should take into account that a variety of factors may affect anticipated rates of return for MA plans. For example, a new MA organization may reasonably anticipate budget deficits during its early years of operation in order to offer competitive plans while its fixed costs are high in relation to the number of enrollees and its enrollment and revenues grow toward break even. In addition, due to differing marketplace dynamics and other factors, the rates of return may differ for different products. The commenter acknowledged our concern about the integrity of bids from plans lacking competition in their service area, but stated strong opposition to any requirement we may consider that would force plans to have similar ''rates of return'' on Medicare and non-Medicare products as a way to measure bid accuracy. Also, the commenters cautioned against having standards that would skew actual bid amounts in order to avoid the appearance of not operating with maximum efficiency.

Response: In the August 2004 proposed rule, we stated that we believe the Congress used the phrase ''similar to'' in section 1854(a)(6)(B)(i) of the Act (which states that our authority to negotiate bids is similar to OPM's statutory authority to negotiate concerning health plans) to signal an understanding that the FEHBP and MA programs are not identical, but have some similarities. We gave two examples of differences between the programs: (1) MA plans must offer original Medicare benefits, which are defined in law; and (2) the formulas for determining MA rates are established in law. We then gave an example of an area where the OPM-like authority to negotiate bid amounts would be relevant to the MA program: pricing of supplemental bids. We then discussed the three proposed standards of bid review: (1) bids and proportions must be supported by actuarial bases; (2) bids and proportions must reasonably and equitably reflect the plan's revenue requirements for providing the benefit package; and (3) the standard at section 1854(e)(4) of the Act (implemented at proposed 422.256(b)(3)) has been met, which limits enrollees' liability for cost sharing.

In addition to review of bid amounts and proportions under these three standards, we also are mandated to review other aspects of the annual bid submission. We must ensure that all benefits are covered, per the requirements at section 1852(a) of the Act. Section 1852(b)(1) of the Act requires us to review the plan benefit design, particularly the structure of premiums, deductibles, copayments, and coinsurance charged to beneficiaries to ensure it is not discriminatory, as implemented at § 422.110.

With regard to review of bid amounts, we will respond to the commenters' questions by discussing the statutory bases on which we formulated the first two bid review requirements. The first bid review standard, that bids be supported by actuarial bases, is mandated in two places in section 1854(a)(6)(B) of the Act. The first phrase of section 1854(a)(6)(B)(i) of the Act states that subject to the noninterference clause and the exception for PFFS plans, the Secretary has the authority to negotiate bid amounts and proportions under subparagraph (A), including supplemental benefits. Section 1854(a)(6)(A) of the Act (the subparagraph (A) reference), which specifies what information MA organizations should submit with their annual bid submission, includes the requirement that MA organizations submit information demonstrating the actuarial basis for determining the monthly aggregate bid amount. In addition, section 1854(a)(6)(B)(ii) of the Act states that the Secretary can only accept bids if they are supported by the actuarial bases provided under subparagraph (A).

Therefore, under the first review standard we may negotiate whether or not to accept a bid based on our determination that the MA organization submitted sufficient actuarial bases and that the actuarial bases support the submitted bid amounts and proportions. The specific elements for which we will require actuarial bases are not listed as part of the regulatory text, and are incorporated into the bid pricing tool. However, we expect MA organizations to submit the actuarial bases for medical costs and administrative costs (including return on investment) for all components of a plan's aggregate bid (the basic A/B bid, the bid for basic prescription drug coverage, and bids for mandatory and optional supplemental benefits). We will examine the actuarial analyses to ensure that bids have been prepared in accordance with our actuarial guidelines, and properly certified.

The second bid review standard states that bids must reasonably and equitably reflect plan costs. This is also mandated in two places in section 1854(a)(6)(B) of the Act. The latter part of the sentence at section 1854(a)(6)(B)(i) of the Act states that when exercising the requirement to negotiate regarding bid amounts, the Secretary shall have authority similar to the authority the Director of OPM has under Chapter 89 of Title 5 to negotiate with respect to health benefits under the FEHBP program. In addition, section 1854(a)(6)(B)(ii) of the Act states that the Secretary can only accept bids if they reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8) of the Public Health Service Act).

We look to the FEHBP standard in 5 USC 8902(i) to interpret our authority to review bids in a manner similar to OPM's statutory authority. Section 8902(i) gives OPM the authority to require that rates should reasonably and equitably reflect the cost of the benefit provided. We see this provision as imposing upon us the responsibility to evaluate the appropriateness of the overall bid amount and each portion of the aggregate bid. Specifically, we intend to evaluate the reasonableness and appropriateness of the actuarial assumptions made for the aggregate bid. We would examine bids to determine whether the revenue requirements for coverage offered by the plan are reasonable, including examination of administrative costs and return on investment (profit) for reasonableness. (For a discussion of how we will evaluate the reasonableness and accurateness of the prescription drug bid, see subpart F of the preamble in the final rule for the Medicare prescription drug benefit.)

There is no cap on administrative costs under Part C (or Part D) that is similar to the cap in effect for FEHBP experience-rated plans. We assume that competition among plans will generally assure reasonable bids. The Congress, however, did not leave the determination of rates entirely to market forces. We are required to determine that the reasonable and equitable test is met and we are given negotiating authority to assure this result. The initial review of MA bid submissions will focus, in part, on low and high cost outliers, and on bids in areas with little competition. It should be noted however, that bid outliers are not necessarily inappropriate, nor are bids within the measure of central tendency automatically correct. Indeed, an outlier bid may be reasonable and appropriate after additional review and explanation while an ''average'' bid could be based on incorrect actuarial assumptions. In summary, all bids will be reviewed for their reasonableness, whether the bids include outliers or not.

A plan bid submission may meet the first review standard (because there is sufficient actuarial information and it supports the submitted bid amounts), but not meet the second review standard because a bid amount does not reasonably and accurately reflect plan costs.

Finally, the commenters requested that our interpretation of the ''reasonable and equitable'' standard allow enough flexibility for MA organizations to pursue legitimate business strategies. ''Flexibility'' seems to have different meaning for different commenters. We want to clarify that we do not intend to measure bid accuracy by forcing bids for Medicare products to have the same rates of return as non-Medicare products. We do not believe that cross-product line comparisons would be appropriate at this time.

However, we do believe that it would be appropriate to develop criteria for review among Medicare products, such as the following for employer group health plans (EGHPs). We will release separate guidance for EGHP plans.

Comment: Two commenters proposed that the standards of bid review in proposed § 422.256(b), which they see as focusing on the statutory criteria, should be applied to review not only of the basic A/B bid and non-drug portion of the supplemental bid (if any), but also to the Part D basic bid and supplemental drug bid (if any). The commenters' concern is that, although the statutory basis for review and negotiation of bids is the same in Part C and Part D, the discussion in the Part D proposed rule includes broader language suggesting that we may challenge Part D bids with administrative costs (including rates of return) that are higher than those of other sponsors or MA-PD plans. In general, the commenters opposed standards that could lead us to require that MA organizations reduce their bids due to perceptions that their MA products could be operated more efficiently.

Response: See subpart F preamble in the final rule for the Medicare prescription drug benefit, which clarifies that we are not adopting any of the OPM regulations at this time, and we will not apply the FEHBP concept of a Similarly Sized Subscriber Group (SSSG) to review of Part D bids. We believe the preamble discussions on bid review in the final rules for Parts C and D are more clearly aligned.

Comment: One commenter recommended that we revise the language at § 422.256(b)(2) ''as the term revenue requirements is used in section 1302(8) of the Public Health Service Act'' to read ''as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act.'' This tracks the statutory language. In addition, the commenter recommended that we explain in the preamble that the reference to ''revenue requirements'' does not indirectly require that MA organizations need to use the adjusted community rate methodology, which is found in that section of the Public Health Service Act.

Response: We agree with the commenter and have revised the proposed language at § 422.256(b)(2).

Comment: One commenter asked us to clarify that under the MMA bidding methodology, MA organizations will no longer need to include information about commercial pricing.

Response: For the purpose of bid submission, organizations will not be required to submit information about their commercial pricing experiences for purposes of trending. However, it should be noted that we are still statutorily mandated to audit a proportion of MA organizations. Within the scope of an audit, we believe that it is appropriate to request and review an MA organization's allocation of costs between its Medicare and commercial products in order to ensure that a disproportionate share of the expenses is not allocated to the MA line of business.

Comment: One commenter recommended that we prevent MA plans from ''cherry picking'' healthier beneficiaries and to review bids and plan benefit packages to ensure they are not discriminatory against sicker beneficiaries. The commenter cited studies by The Commonwealth Fund and Medpac that confirm that some MA plans have used co-payments and other devices to discourage enrollment of beneficiaries who have high utilization of services.

Response: We will be evaluating bids for their actuarial soundness based on the documentation submitted by plans to support the submitted bid amount and associated proportions. As mandated by the MMA (and earlier statutory provisions), we will also be reviewing the benefit packages of each plan to guard against discrimination. In addition, we will continue to follow the standards described in the M+C final regulation of June 2000 at § 422.110, which prohibit an organization from discriminating against beneficiaries by denying, limiting or conditioning

coverage to beneficiaries or offering of benefits to individuals eligible to enroll in a plan on the basis of any factor that is related to health status (for example, medical history or medical condition, with limited exceptions). We will be concerned about levels of cost sharing for dialysis and chemotherapy drugs, and cost sharing for medical categories (inpatient stays, outpatient facilities, and ambulatory surgical centers).

Negotiation process

Proposed § 422.256(a) would implement section 1854(a)(6)(B)(i) of the Act, which provides us the authority to negotiate with MA organizations. We have the authority to negotiate to ensure that the bid is not discriminatory; and in situations where we have questions about the assumptions used for a plan bid, we will negotiate with the MA organization regarding the appropriate assumptions and the resulting rebate and/or supplemental premiums. We expect that the process of bid negotiation between CMS and an MA organization could result in an agreement to adjust the bid's pricing, utilization, and/or enrollment assumptions. The MA organization would resubmit the bid information for the plan. The bid cannot be changed unless mutually agreed upon by the MA organization's representatives and CMS as a result of our review and negotiation process.

Comment: A few commenters are concerned that we have a uniform process for conducting bid negotiations to ensure that there is consistency across negotiating teams as well as firm deadlines for ending negotiations.

Response: We understand the concerns about the uniformity and timing of bid negotiations. We believe that the bid negotiations will be governed by the specific actuarial review principles that will be contained in the bid pricing tool. Bid negotiations will have to be complete before September in order for plans to have sufficient time to submit their plan benefit package materials for our website.

Comment: One commenter wanted to know how our deadlines for negotiation compare with the deadlines established by OPM for its FEHBP negotiations.

Response: OPM's rate filing and negotiation schedule is similar to that proposed by CMS. Rate proposals are due by May 31 each year, and by mid-August negotiations are generally complete. By law, the filing deadline for the MA program is the first Monday in June, and we expect to conclude negotiations by the end of August or early September.

Comment: Several commenters wanted to confirm that organizations unable to reach agreement with us during the negotiation process will be permitted to withdraw their bids without penalty. The ability to withdraw a bid is significant to avoid an MA organization committing to providing coverage for a year that is not sustainable financially, potentially jeopardizing beneficiary coverage and the MA organization's long term success and viability.

Response: This issue is still under consideration, and we will be issuing subsequent guidance.

Comment: One commenter stated that in the past periodically MA organizations have identified errors in their ACRP after submitting them to us for the filing deadline. The commenter requested that we retain the current policy where MA organizations are allowed to correct these errors after the filing deadline and resubmit the ACRP provided that: (1) the MA organization can demonstrate that the information in fact was in error; (2) it is clear that the error was made inadvertently; and (3) the correction is made within a relatively short period of time following the submission.

Response: We intend to retain the current practice of allowing corrections for inadvertent errors, for example, typographical errors and certain other types of errors that caused the submission to fail the initial front end edits. Guidance on this matter will be published as part of the guidance on filing the new bid pricing tool and Plan Benefit Package.

Comment: One commenter requested clarification of the timeline for bid negotiations and finalizing benchmarks for negotiation with providers.

Response: Regarding negotiations with other contractors, we believe that bidders are developing their bids on what it will cost them to provide the items and/or services in their plan benefit packages and have had discussions and negotiations with potential contractors in order to estimate properly in their bid submission. In most cases where organizations have made good faith efforts to estimate their actual revenue requirements with appropriate supporting documentation, we do not anticipate significant modifications to bid amounts and proportions during the negotiation phase of the process.

Rules for adjustment of rebate dollar allocations.

In addition to other negotiated changes, an MA organization may need to adjust the allocation of rebate dollars in a plan bid, and resubmit the bid. We described several circumstances under which we expect reallocation of rebate dollars.

First, MA organizations must submit their plan bids in June (including the estimated drug premium amount) for both local and regional MA plans before knowing the national average monthly bid amount for basic coverage. Given the preliminary nature of MA organizations' Part D premium submission, we expect that some rebate allocations to Part D premium reductions will be overestimated (excessive allocation) or underestimated (insufficient allocation). These misestimates will mean some portion of the beneficiary rebate has been credited where it is not needed or not enough has been credited to achieve the premium desired. For example, if a plan's monthly drug premium is determined to be $34, which is less than the projected premium of $35 in its initial bid submission, there was an excessive allocation of $1 of the rebate to fund the Part D premium reduction. We would require the MA organization to amend its bid submission to reallocate the excessive $1 of rebate credit to other mandatory supplemental benefits. On the other hand, if the plan monthly drug premium is determined to be $36, which is greater than the projected monthly premium of $35 in the initial bid submission, there is an insufficient allocation of $1. We would give the MA organization the option of reallocating $1 of rebate from another mandatory supplemental benefit toward the Part D premium reduction in order to eliminate the $1 Part D premium and return to the zero premium in the initial bid submission.

For this reason, we anticipated that some MA organizations will make minor technical adjustments to the benefit structures of their non-drug bid amounts (that is, the basic A/B bid and supplemental bid). The adjustments will consist of reallocation of beneficiary rebate dollars among a subset of the categories allowed by law: (1) reduction in the premium for the non-drug portion of the mandatory supplemental package (that is, reduction in cost sharing for Parts A and B benefits or reduction in the cost of additional non-Medicare covered benefits); and (2) reduction in the Part D and Part B premiums. No modifications would be allowed to the cost of the Part D supplemental benefit (reduction in Part D cost sharing or reduction in the cost for coverage of drugs not covered under Part D). Changing the reduction in Part D cost sharing would have a domino effect. It would have implications for projected

reinsurance dollars, which impacts the pricing of the bid for basic Part D benefits, which in turn could affect the national average monthly bid amount and, hence, the basic beneficiary premium, which we would have just previously calculated and published for the year, as required by section 1860D–13(a)(4) of the Act.

Second, we recognized that the June bid submission for regional MA plans will be based on unknown benchmarks not only for the drug premium but also for Medicare Parts A and B benefits. As discussed in § 422.258(c), the region-specific benchmark amount is based, in part, on a weighted average of the plan bids for Medicare Part A and Part B benefits, which we cannot calculate until after the June bid submission. This means that the exact amount of a plan's rebate is unknown and will shift to the extent that the estimated benchmark a plan uses to create its June basic A/B bid amount differs from the region-specific non-drug benchmark we establish based on plan bids. Therefore, regional MA plans will also be allowed to modify the allocation of rebate dollars, other than for Part D benefits, to arrive at the supplemental, Part B, and Part D premiums originally submitted.

We proposed the following rules for the negotiation process concerning reallocation of rebate dollars due to excessive or insufficient allocation.

- MA plans with overestimated allocations to Part D premium reduction must reallocate beneficiary rebate dollars to other mandatory supplemental benefits and can do so only for the purpose of achieving the original Part D premium in their initial bid submission.
- Local MA plans with underestimated allocations to Part D premium reduction have the option of reallocating beneficiary rebate dollars from other mandatory supplemental benefits. However, the plan could only reallocate rebate dollars for the purpose of achieving the Part D premium in the initial bid submission. In this circumstance, plans could choose not to adjust the new premium or reallocate the appropriate amount to achieve the initial premium submitted.

We proposed the following rule for regional plans, which unlike local plans will not know the exact amount of their rebate dollars at the time of the June bid submission.

- Regional MA plans may reallocate beneficiary rebate

dollars to achieve the supplemental, Part B, and Part D premiums in their initial bid submission.

- Local MA plans not offering Part D benefits (these would only be PFFS plans who have elected this option) would have all the necessary information upon which to estimate their bid amounts for their initial June bid submission, and, therefore, the MA organizations would not be allowed to modify their plan benefit structures.

Comment: A few commenters recommended that MA organizations be permitted to reallocate rebate dollars to ensure that dual eligibles would not need to pay a premium for Part D if they enroll or remain enrolled in these MA plans. The commenter believed that the MA plans that would likely use this discretion are MA Special Needs Plans (SNPs). The success of SNPs would be seriously undermined if their Part D premiums exceed the applicable low income Part D subsidy, because their dual eligible enrollment would have an incentive to disenroll from these plans. Because the Part D bids of MA special needs plans are not factored into the national average monthly bid amount and the low-income benchmark premium amount, this adjustment will have an insignificant effect on the bid and payment process.

Response: The proposed requirement is that reallocation of rebate dollars during the negotiation process must result in the supplemental, Part B, and Part D premiums originally submitted in June. We believe the commenter is requesting that this requirement be expanded to allow a change in the Part D premium from that originally submitted in order to allow an MA organization to change the plan premium to match the low income premium subsidy level in effect for the plan's service area. We would allow this. Therefore, when rebate reallocation results in a Part D premium that differs from that originally submitted in June, the new premium must match the low income premium subsidy level. The Part D premium will have to be uniform for every member of the plan.

Comment: One commenter supported our proposal to limit changes to bids to technical changes. The commenter also questioned why MA regional plans would be permitted to make changes in cost sharing that would not be allowed for MA local plans. The commenter believes that allowing more than technical changes from regional plans would destabilize the level playing field of the bidding process.

Response: Because the benchmark is calculated for regional plans after bids are submitted, unlike local plans, regional plans do not have the advantage of knowing the benchmark for estimating their rebate, cost sharing and premium amounts. Therefore, it is necessary to provide additional latitude for regional plans that is not necessary to provide for local plans. Our intent is to allow appropriate redistribution of the estimated amounts so that plans' benchmark estimates can be reconciled with the actual benchmark estimates and the necessary modifications.

5. Calculation of Benchmarks (§ 422.258)

Proposed § 422.258(a) implemented the new section 1853(j) of the Act by providing a description of how benchmarks for local MA plans are calculated. For a service area that is entirely within an MA local area (county), the MA area-specific non-drug monthly benchmark amount is equal to the monthly MA capitation rate for the local area. For a service area that is in more than one MA local area, the benchmark amount is calculated as a weighted average of the local MA monthly capitation rates, using as weights the projected enrollment in each county used to calculate the bid.

Proposed § § 422.258(b) and (c) implemented section 1858(f) of the Act by providing a description of how regional MA plan benchmarks are calculated. Each MA region will have a benchmark amount that consists of two components: (1) the statutory component (based on a weighted average of local area capitation rates in the MA region); and (2) the plan bid component (based on the weighted average of regional plans bids in the MA region). The purpose of the blend will be to be more responsive to market conditions in the region by allowing plan bids to influence the final benchmark amount.

Finally, the statutory component will be multiplied by the statutory national market share, which is the number of MA eligibles in the Nation who were not enrolled in an MA plan during the reference month (the month in the previous year for which the most recent data on MA eligibles is available) divided by the total number of MA eligibles in the nation in the reference month. The plan-bid component will be multiplied by the non-statutory market share, which is the number of MA eligible in the nation who were enrolled in an MA plan during the reference month divided by the total number of MA eligible in the nation. These components will be added to yield the MA regional benchmark.

Comment: One commenter recommended that we revise the first sentence of § 422.258(c)(4) to replace the references to ''plan(s) offered in the region'' with ''regional plans offered in the region'' to clarify the plan-bid component of the regional benchmark is

calculated based only the regional plan bids, not all of the MA plan bids in the region.

Response: We agree and have made this correction. We also made technical corrections in § 422.258(c) along the same lines to further clarify this point. Finally, we made another change to the proposed rule language at § 422.258(c)(5)(i) to clarify further how the plan bid component of the regional benchmark will be calculated. In the final rule at § 422.258(c)(5)(i), we delete the following sentence from the proposed regulatory text because it states a specific calculation for determining a plan's share of enrollment that is not mandated at section 1858(f)(5)(B)(iii) of the Act: ''In that case, each plan's share will be the plan's projected enrollment divided by the total projected enrollment among all plans being offered in the region.'' We delete this sentence to clarify that the statute allows us to apply a factor based on plans' projected enrollment but does not mandate a particular calculation.

6. Beneficiary Premiums (§ 422.262)

Proposed § 422.262(a) would implement section 1854(b)(2)(A) of the Act, and described the new methodology for calculating the MA monthly basic beneficiary premium. This premium will now be determined by comparing the unadjusted statutory non-drug bid amount (basic A/B bid) to unadjusted benchmark amount. For an MA plan with a basic A/B bid that is less than the appropriate unadjusted non-drug benchmark amount, the basic beneficiary premium is zero. For an MA plan with a basic A/B bid that is equal to or greater than the unadjusted non-drug benchmark amount, the basic beneficiary premium is the amount by which the bid amount exceeds the benchmark amount. All approved premiums must be charged; that is, plans are not allowed to waive basic beneficiary premiums.

Proposed § 422.262(b) would implement section 1854(d)(4) of the Act, which specifies that MA enrollees must be charged consolidated monthly premiums. As intended by the Congress and as a part of our efforts to simplify the process for beneficiaries, an MA enrollee will pay a single premium consisting of the sum of all premiums a particular plan charges its enrollees, which will be one or more of the following: (1) the monthly basic beneficiary premium; (2) the monthly supplemental premium; and (3) the MA monthly prescription drug premium. This process will be in addition to the Part B premium payment process already in place.

We clarified that in the case of an Medical Savings Account (MSA) plan, there are no basic beneficiary premiums because we instead make a deposit to the enrollee's MSA. MSA plans are high deductible insurance policies, not managed care plans. The only beneficiary premium for an MSA plan will be a supplemental premium.

Uniformity of premiums and cost-sharing.

The MMA did not change current law regarding uniformity of premiums. Proposed § 422.262(c) would implement section 1854(c) of the Act, which specifies that, with the exception permitted under § 422.106(d), the MA bid amount and beneficiary premiums may not vary among individuals enrolled in the plan. Proposed § 422.262(c) continues current regulations now in subpart G at § 422.304(b) that cost sharing for basic and supplemental benefits may not vary among individuals enrolled in an MA plan.

MA organizations offering local MA plans within segments of service areas must submit separate bids for those segments that may have different premiums and cost sharing. Section 1858(a)(1) of the Act which specifies that regional MA plans may not have segmented service areas.

Proposed § 422.262(f) would implement section 1854(d)(2) of the Act on beneficiary payment options. This provision gives enrollees the option, at their discretion, of paying their MA consolidated premium by: (1) having it deducted directly from their Social Security benefit amount of from their Railroad Retirement Board or the Office of Personnel Management benefit amount in the same manner that Part B premium reductions are handled; (2) setting up an electronic funds transfer; or (3) through other appropriate means CMS may identify, including payment by an employer or under employment-based retiree coverage on behalf of an employee, a former employee, or a dependent. The MA organization may not impose a charge for individuals electing to pay their premiums through a deduction from their Social Security payments. In this final rule, we have consolidated subparagraphs (3) and (4) of § 422.262(f) to clarify that the other methods we may specify for payment of premiums include those listed in the regulation.

Comment: One commenter requested that we allow intra-regional benefit plan adjustments (that is, waiver of the requirement that plan have a uniform benefit package for a service area, including plan premiums and all applicable cost sharing) to ensure that regional PPO plans are not placed at a competitive advantage or disadvantage versus local plans due to rate variations within a plan's regional service area. The commenter stated that overall, the intra-regional benefit waiver would lead to greater participation in the regional PPO program and, at the same time, would ensure local plans can continue participation in areas with traditionally low reimbursement rates, resulting in competition and increased access to health plans for beneficiaries.

Response: We do not have the authority to waive the requirement at section 1854(c) of the Act, which states that plan bids and premiums be uniform for all members of a plan. Moreover, section 1858(a)(1) of the Act explicitly disallows the application of section 1854(h) of the Act to regional plans, which signals Congressional intention that there not be variation in premium and cost sharing across segments within a region. Therefore, at this time, we cannot allow variations in the plan benefit package within the service area of regional MA plan.

Comment: Two commenters recommended that we provide an option for an MA organization to waive the amount of premium that is the difference between the MA-PD premium and the low-income premium subsidy under Part D provided for in § 423.780. The commenter believes that this waiver would fit well within a safe harbor provided for in the federal anti-kick back statute. The ability to waive premium would: (1) allow dual eligibles to be auto-enrolled into their current Medicare Advantage plan without the burden of an added premium that many of these beneficiaries could not afford; and (2) provide more flexibility for dual eligible enrollees to self-enroll into an MA-PD plan of their choosing.

Response: If the commenter's reference to the ''MA-PD premium'' is to the combined basic Part A and Part B beneficiary premium and the Part D beneficiary premium charged by an MA-PD plan, then we must emphasize that these two premiums are determined separately and under different rules. When a plan's basic A/B bid is equal to or below its benchmark, by law the plan is not allowed to charge a basic premium for basic Part A and Part B benefits. When a plan's basic A/B bid is above its benchmark, section 1854(a)(2)(A) of the Act states that this difference is the monthly basic beneficiary premium. The basic beneficiary premium cannot be waived.

Section 1854 of the Act does not provide for waiver of the basic Part A and Part B premium for dual eligibles.

Subsidies for dual eligibles for coverage of medical benefits are set forth under Title XIX of the Act. Moreover, special needs plans are subject to the same bidding rules as other MA plans, in accordance with sections 1854(a)(1)(A) and 1854(a)(6) of the Act. Therefore, we do not have the authority to waive the basic beneficiary premium for dual eligibles.

The Part D premium determination is discussed at § 423.286. We do not have the authority to waive the Part D premium for beneficiaries eligible for a premium subsidy. If those beneficiaries eligible for this subsidy enroll in a Part D plan or MA-PD plan that has a Part D premium higher than the subsidy, then they owe this difference.

Comment: A commenter recommended that during the negotiation process, MA organizations be allowed to reallocate rebate dollars to reduce the Part D premium to the level of the low-income premium subsidy benchmark.

Response: See § 422.256 and the above response to comment in this subpart of the preamble for a discussion on this issue.

Comment: Several commenters recommended that CMS and the Social Security Administration not implement the provision that beneficiaries may opt to have their premiums deducted from their Social Security benefit amounts until the systems are fully in place to ensure that payments will be made to MA organizations correctly and on a timely basis. The concern is that without sufficient operational planning for the development and testing of a new payment system, organizations will not be paid enrollee premiums accurately and timely.

Response: We do not intend to delay the implementation of a statutorily mandated provision that gives beneficiaries the option of paying MA premiums by deducting the amounts from their Social Security benefit amounts. However, we are confident that the development and testing of a new payment system for accurate and timely payment of plans is feasible by January 2006.

Comment: One commenter requested that we make clear that the MMA language at section 1854(d)(2)(C) of the Act only prohibits MA plans from imposing charges pertaining to choice of the premium payment option if beneficiaries choose to have their premiums deducted from their Social Security benefit checks. That is, the commenter wishes that we make clear to beneficiaries that the statute does not prohibit MA plans from imposing charges related to premium payment under other payment options. The commenter therefore requested that we require MA organizations to convey clearly to beneficiaries, and in writing, what are the precise charges that will apply to other premium payment options before the beneficiary makes a choice of how to pay plans premiums.

Response: MA plans may not charge fees for late payment of the plan premium or other types of processing fees because this would violate the uniformity of premiums provision at section 1854(c) of the Act. For example, we interpret the uniform premium provision to mean that plans may not provide incentives to members to pay premiums in a certain manner by offering lower processing fees (per section 1854(d)). See Subpart B for a discussion of administrative remedies for non-payment of premiums.

Comment: One commenter wanted to verify that beneficiaries may still opt to pay their MA plan premiums directly to the plan.

Response: Enrollees in the MA plans may still choose to pay their MA plan premiums directly to the plan.

Comment: Several commenters request that we remove for American Indian/Alaska Natives (AI/AN) Tribes the barriers to paying their Part B premiums under our current group payer rules, specifically rules concerning the size of the group and switching an individual from automatic deduction to group pay. The commenters maintained that without these changes, it is unlikely that AI/AN individuals, who are entitled to health care without cost sharing, will enroll in MA plans.

Response: The issue of payment of Part B premiums under our current group payer rules is beyond the scope of this rulemaking.

7. Calculation of Savings (§ 422.264)

Proposed § § 422.264(a), (c), and (e) would implement sections 1854(b)(3)(A)and (B) of the Act (for local plans) and sections 1854(b)(4)(A) and (B) of the Act (for regional plans) concerning calculation of risk-adjusted basic A/B bids and risk-adjusted benchmarks, which is the first step in determining whether an MA plan has savings. The MMA gave the Secretary flexibility to determine whether the risk adjustment factors to be applied to the benchmarks and bids are determined on a State-wide basis for local plans, a region-wide basis for regional plans, a plan-specific basis, or on the basis of another geographic area.

Proposed § § 422.264(b) and (d) implement sections 1854(b)(3)(C) and (b)(4)(C) of the Act, respectively, on how to determine the amount of savings for each local and regional MA plan (if any) by calculating the amount by which the risk-adjusted benchmark amount exceeds the risk-adjusted bid amount.

Comment: All commenters from the industry agreed plan savings should be related to the risk profile of the enrollees. One important reason for this policy is that the rebate will likely take the form of supplemental benefits or reduced cost sharing and/or premiums. MA plans with enrollees whose average risk score is higher will typically need more revenue to provide the same level of supplemental benefits as a plan whose enrollees have a lower average risk score. To accomplish this objective, the adjustment to the benchmark and the bid that is used for calculating the savings should be based on the risk score of the particular plan.

Response: We agree with the commenters. For both local and regional MA plans, the calculation of savings will be determined by applying the plan average risk adjustment factor to the basic A/B bid and benchmark. We have revised § § 422.264(c) and (e) to reflect this policy, although we have left in regulation our discretion, as provided in the statute, to select a method for calculating savings.

8. Beneficiary Rebates (§ 422.266)

Section 1854 (b)(1)(C) of the Act states that an MA plan with savings (because the basic A/B bid is less than the benchmark) must provide to the enrollee a monthly rebate equal to 75 percent of the savings amount for that plan for the year. The remaining 25 percent of the savings would be retained by the Medicare Trust Funds. If the plan basic A/B bid is equal to or greater than the benchmark, the plan has no savings and, thus, no rebate.

Proposed § 422.266(b) provided, as set forth in section 1854(b)(1)(C)(ii) of the Act, that the beneficiary rebate could be provided in the following forms: (1) some part or all of the rebate can be credited toward the provision of supplemental health care benefits (including additional health benefits not covered under original Medicare; (2) a reduction in cost sharing for Parts A, B, and D benefits, and/or a reduction in the premium for the mandatory supplemental benefits); or (3) credited toward the prescription drug premium or Part B premium.

Proposed § 422.266(b)(1) provided that all rebate dollars must be applied to a mandatory supplemental benefit. We interpret the provision at section 1854(b)(1)(C)(i) of the Act that an MA plan must provide to enrollees a rebate equal to 75 percent of savings to mean

that rebate dollars must be provided to all enrollees in a plan. Therefore, rebate dollars could not be used to fund optional supplemental benefits because this would not guarantee that the plan is providing every enrollee with the rebate dollars.

Although rebate dollars can only be used to fund a mandatory supplemental benefit, a mandatory supplemental benefit may also be funded by beneficiary premium dollars. That is, a plan with a rebate may fund a mandatory supplemental benefit with rebate dollars only or with a mixture of rebate and premium dollars.

The MA plan will be required to inform us about the form and amount of the rebate and/or the actuarial value of the supplemental health care benefits. Adjustments to the structure of the benefit package will occur during the process of negotiating and approving bids detailed in proposed § 422.256.

If an MA organization elects to provide a rebate in the form of a reduction in the beneficiary Part B premium for beneficiaries in a particular plan, we will work with the Commissioner of Social Security to provide the necessary information to the Commissioner to apply a credit (as provided for under section 1840 of the Act) to reduce the amount of the Part B premium to be charged under section 1839 of the Act for each enrollee in that MA plan.

Comment: One commenter recommended that we revise proposed § 422.266 to note that rebate dollars may be used both to pay for the Part D premium and to provide supplemental drug coverage at no cost. The commenter argued that this change is needed to clarify that MA plans have the right to use rebate dollars to fund supplemental prescription drug benefits at no cost to the beneficiary as part of the basic Part D prescription drug benefit offered by the MA plan.

Response: We agree with the commenter, with one clarification. If an MA-PD plan offers basic drug coverage under Part D, by definition at § 423.100, there is no supplemental drug benefit, and thus no supplemental drug premium toward which to apply rebate dollars. If an MA-PD plan offers enhanced alternative coverage under Part D, then the plan must charge a premium for supplemental drug coverage. Per § 422.266(b), supplemental drug coverage may consist of reductions in Part D cost sharing and coverage of drugs not covered under Part D.

Section 1854(b)(2)(C) of the Act refers to the supplemental beneficiary premium that is attributable to the provision of supplemental health care benefits, less the amount of the rebate applied to supplemental benefits. The supplemental beneficiary premium is the estimated revenue required to offer the supplemental package, which may include non-drug or drug supplemental benefits or both. Therefore, when pricing a plan benefit package, MA organizations will distinguish the cost of a Part D supplemental benefit from a non-drug supplemental benefit.

We have changed the language at § 422.266(b)(1) to clarify that rebate dollars may be used to reduce the premium for either the non-drug or drug portions of the supplemental benefit. We also have added language clarifying that plans must distinguish the amount of rebate applied to enhance original Medicare benefits from the rebate applied to enhance Part D benefits. Rebate dollars may also be used to reduce the basic Part D premium and the Part B premium.

Comment: One commenter requested that we allow MA organizations to use rebate dollars to fund stabilization of their provider networks, because recent improvements in provider compensation are not sufficient to ensure stable provider networks.

Response: Proposed § 422.266(b), which implements section 1854(b)(1)(C)(ii) of the Act establishes permissible uses of the beneficiary rebate. The statute does not allow MA organizations to apply rebate dollars to stabilize an MA plan's provider network.

9. Incorrect Collection of Premiums and Cost-Sharing for All Years (§ 422.270)

Proposed § 422.270, which is identical to the previous language in the current MA regulations in subpart G at § 422.309, sets out procedures for situations in which an MA organization collects more than the amount the plan is allowed to charge its enrollees.

Subpart G—Payments to Medicare Advantage Organizations

1. Basis and Scope (§ 422.300)

Proposed § 422.300 set forth the basis and scope for the revised subpart G, stating that it is based on sections 1853, 1854, and 1858 of the Act. It also indicated that the regulations in this subpart set forth the requirements for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), and other payment rules.

2. Monthly Payments (§ 422.304)

The MMA revised the payment methodology for MA plans beginning in 2006. We provided, in proposed § 422.304(a), that, with the exception of payments to MSA plans and payments for ESRD enrollees in all other plans, we will make advance monthly payments to an MA organization for each enrollee for coverage of original FFS benefits in the plan payment area for a month, using a new bidding methodology described in this subpart and subpart F.

The amount of our payment for an MA plan (except an MSA plan) depends on the relationship of the plan basic A/B bid to the benchmark amount. Section 422.304(a) described two payment tracks:

- If the plan's risk-adjusted basic A/B bid is less than the risk-adjusted benchmark, the plan's average per capita monthly savings equals 100 percent of that difference, and the beneficiary is entitled to a rebate of 75 percent of this plan savings amount.
- If the plan's risk-adjusted plan basic A/B bid is equal to the risk-adjusted benchmark, the plan has no savings and thus no rebate, and we pay plans without rebates the benchmark for the geographic service area.
- If the plan's risk-adjusted basic A/B bid is greater than the risk-adjusted benchmark, the plan has no rebate and to meet the plan's revenue needs enrollees must pay a basic beneficiary premium equal to the difference between the unadjusted basic A/B bid and the unadjusted benchmark.

Under section 1853(a)(1)(D) of the Act, implemented in proposed § 422.304(b), MA plans offering qualified prescription drug coverage also receive payments for the direct and reinsurance subsidy payments for basic prescription drug coverage and reimbursement for premium and cost sharing reductions for low-income individuals, described at sections 1860D–14 and 1860D–15 of the Act.

Special rules for enrollees with end-stage renal disease. Proposed § 422.304(c)(1)(i) would implement section 1853(a)(1)(H) of the Act, which instructs us to continue using the ESRD payments rates and risk adjustment methodology in effect before the enactment of the MMA as the basis upon which to determine ESRD payment amounts. We believed the MMA provided us with flexibility for determining ESRD payments because of Congressional recognition that the cost and utilization patterns for ESRD beneficiaries are distinct from aged and disabled beneficiaries.

One option proposed was to pay the State capitation rate for each enrollee,

with the relevant adjustments under this part, including risk adjustment. For plans offering the Part B premium reduction, the amount of that reduction would be subtracted from the capitation payment for ESRD enrollees, too. The second option proposed was to base payment on State capitation rates, as adjusted under MMA adjustments such as the geographic ISAR adjustment at section 1853(a)(1)(F). Accordingly, ESRD enrollees would be fully incorporated into the bid process and payments for all enrollees would reflect the plan's relative weights of ESRD versus non-ESRD enrollee costs. We would consider this sufficient implementation of section 1853(a)(1)(H) of the Act because State capitation rates are the basis of payment. We invited comments on these two approaches.

Special rules for payments to MSA plans. Proposed § 422.304(c)(2) would implement section 1853(a)(1)(B)(iii) of the Act, which contains the same rules for MSA plans that existed under the previous M+C program. The only MMA change in the payment provision is that MSA plans become local MA plans, and we will make payments to MA organizations for MSA enrollees based on the non-drug benchmark amount, less 1/12 of the annual lump sum amount (if any) we deposit to the enrollee's MA MSA, as determined under § 422.314(c). This payment amount is adjusted for enrollee risk, as proposed at § 422.308(c).

RFB plans. Proposed § 422.304(c)(3) on special rules for religious fraternal benefit (RFB) society plan enrollees is unchanged from the current regulations, now in subpart F at § 422.250(a)(2)(iii).

Payment areas. Proposed § 422.304(d) would implement section 1853(d) of the Act, which changes the definition of payment area to account for the new MA regional plan program. Under the previous M+C program, a payment area was defined as a county or equivalent area defined by the Secretary (with the exception of ESRD enrollees, for whom the payment area was a State).

The MMA establishes two general types of payment areas: (1) for MA local plans, the payment area is an MA local area (defined as a county or equivalent specified by CMS); and (2) for MA regional plans, the payment area is an MA region. The payment area for ESRD enrollees continues to be a State.

Proposed § 422.304(e) would implement section 1853(d)(4) of the Act, which permits a State's chief executive to request that we use alternative payment areas. This provision retains the same language as the previous M+C provision, with the exception that the statute specifies this option applies only to local MA plans. No State has availed itself of this option since its enactment in 1998.

Comment: A number of commenters preferred that CMS pay the State rate for each ESRD enrollee, risk adjusted, seeing this approach as linked to their preference not to include ESRD enrollees in bidding. Several commenters did not state a preference for payment, noting that the concept of the second option was not clear, so they are continuing to evaluate CMS's and other options that may merit our consideration.

Response: Beginning in 2007, MA-PD plans will implement a merged bid method where ESRD and non-ESRD costs are combined. This means that MA organizations will submit a single bid for all enrollees, and will be paid according to the relationship of the basic A/B bid and the benchmark.

However, as discussed in the F preamble, for 2006 MA organizations will exclude ESRD costs from plan bids. Accordingly, for 2006 payments, we will apply the ESRD payment method in effect for 2005. For ESRD enrollees on dialysis or transplant status, we will pay the State-level dialysis rate, adjusted by the appropriate individual risk score from the ESRD CMS-HCC risk adjustment model. For functioning graft beneficiaries, we will pay the county risk rate (from the aged/disabled ratebook), adjusted by the appropriate individual risk factor from the ESRD CMS-HCC model.

Finally, as proposed in the August 2004 proposed rule, for any plan offering a Part B premium reduction to MA plan enrollees, the amount of this reduction will be subtracted from the payment for each ESRD enrollee. Future changes to how we make payments for ESRD MA enrollees will be announced in the Advance Notice of Methodological Changes for Calendar Year (CY) Medicare Advantage (MA) Payment Rates.

3. Annual MA Capitation Rates (§ 422.306)

For years before 2004, payments to MA organizations were based on the highest of three amounts: a ''blended rate'' based on a blend of national and local data on Medicare's costs for providing services to beneficiaries not enrolled in an MA plan, a ''floor amount,'' based on an amount specified in statute, subject to an update factor, and an amount representing the previous year's rate updated by a minimum percentage increase.

The MMA replaces the ''highest of three rates'' methodology in several phases. For 2004, the MMA specified a transitional methodology, where the county and State rates were the ''highest of four rates'': the floor amount rate, blend rate, minimum percentage increase rate (which was redefined to be the higher of 102 percent of the previous year's rate or the previous year's rate increased by annual MA growth percentage), or the 100 percent of FFS costs rate introduced by the MMA.

For the next phase, the MMA specified that beginning with 2005, annual capitation rates will be minimum percentage increase rates except for years when we rebase the FFS rate; in rebasing years, the rate is the higher of the minimum percentage increase rate and the FFS rate. The MMA requires us to rebase the FFS rates no less than every 3 years; that is, at least every 3 years a ''higher of two rates'' methodology is in effect. Hence, proposed § 422.306(a) would implement the revised version of section 1853(c)(1)(C) of the Act, which defines the minimum percentage increase rate.

The MMA also provides that no less than every three years, we must assign 100 percent of local per capita FFS costs as the county rate in those counties where this amount is higher than the minimum percentage increase rate. The new FFS rate is defined as the adjusted average per capita cost (AAPCC) for the MA local area, as determined under section 1876(a)(4) of the Act, based on 100 percent of FFS costs for individuals who are not enrolled in an MA plan for the year, with the following adjustments: (1) standardized for the county risk profile relative to the nationally average beneficiary; (2) adjusted to exclude costs of direct graduate medical education; and (3) adjusted to include our estimate of costs for VA and DOD military facility services to Medicare-eligible beneficiaries. We must recalculate the AAPCC rate (which we also call the ''100 percent FFS rate'') no less than once every 3 years. The statute gives us the authority to determine how often to rebase the ratebook within this 3 year window. Rebasing the FFS rates means that the Office of the Actuary retabulates the per capita FFS expenditures for each county (and for ESRD beneficiaries, for each State) so that the FFS rates reflect more recent county growth trends in FFS expenditures.

We intend to announce our decision annually in the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates regarding whether we will rebase the 100 percent FFS rates for the upcoming year.

Comment: Many commenters supported annual rebasing in order to adequately pay MA organizations in

areas where the FFS costs are increasing at a rate faster than the national average. One commenter noted that CMS should rebase annually because of the high degree of volatility in local FFS costs, and stated that CMS recognizes this volatility by using a 5-year moving average when forecasting county level Medicare FFS costs.

Response: As announced in the 2005 Advance Notice of Methodological Changes, the CMS Office of the Actuary believes that it is appropriate to evaluate on an annual basis whether or not it is necessary to recalculate the basis for the 100 percent of FFS costs payment category for MA organizations. By requiring rebasing only every 3 years, the Congress determined there was no need to statutorily mandate an annual retabulation of FFS per capita expenditures for each county. Therefore, CMS will announce each year in the Advance Notice whether it intends to rebase the FFS rate. Interested parties will have the opportunity to comment each year on the announcement before it is finalized.

Comment: A few commenters noted that CMS has not implemented the existing authority for inclusion in the 100 percent FFS rate the costs associated with services provided to eligible Medicare beneficiaries at VA and DOD facilities. Two commenters claimed that the result of taking these costs into account would be a positive adjustment to MA plan payments, and that currently plans serving areas with many VA and DOD facilities were not being fully reimbursed. Commenters recommended that CMS move forward as soon as possible with implementation based on the best data available.

Response: As we previously stated in our Advance Notice of Methodological Changes for 2005, in order to incorporate the costs of services provided at VA/DOD facilities into the MA rates, it is necessary to obtain reliable data on a county level to make the adjustment. We have been unable to obtain these data, so to date the adjustment has been zero. CMS's Office of the Actuary will make an annual determination whether it has been able to obtain sufficient reliable data on the costs of services provided at VA/DOD facilities to make a non-zero adjustment to the 100 percent FFS rates.

4. Adjustments to Capitation Rates, Benchmarks, Bids, and Payments (§ 422.308)

Language proposed in § 422.308(a) remains the same as that currently in subpart F of the current regulations governing payments. Under section 1853(c)(1)(C) of the Act, the MMA makes only one change to how we must apply the national growth percentage each year to increase the minimum percentage increase rate. As we provided in proposed § 422.308(b), no adjustment can be made for changes in prior years' estimates of the national growth percentage for years before 2004.

Risk adjustment. Proposed § 422.308(c) would implement section 1853(a)(1)(C) of the Act, which requires us to adjust the payment amount for an MA plan to take into account the health status of the plan's enrollees. In order to ensure that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees and more for less healthy enrollees), we will apply these adjustment factors to all types of plans (with the exception of MA RFB plans, discussed at § 422.304(c)(3)).

In 2006, 25 percent of our payment to MA organizations for aged and disabled enrollees will be based on current demographic factors, and 75 percent based on the CMS-HCC risk adjustment model. In 2007 the demographic-only payment method will be completely phased-out for MA plans, and 100 percent of payment will be risk-adjusted in 2007 and succeeding years. Note that for ESRD MA enrollees, payments to MA organizations are 100 percent risk adjusted under the CMS-HCC ESRD risk adjustment model, effective January 1, 2005. Also, for PACE organizations and certain demonstrations, the transition payment blends are one year behind that for MA organizations.

The demographic adjustment factors for aged and disabled enrollees are age, sex, institutional status, Medicaid status, and working aged status. The demographic adjustment factors for ESRD enrollees are age and sex.

Under the CMS-Hierarchical Condition Category (HCC) risk adjustment payment methodology, there are CMS-HCC models for three different populations: community-based, long-term institutionalized, and ESRD beneficiaries. Currently, the CMS-HCC factors in these models include age, sex, original reason for entitlement, Medicaid status, and disease factors. The ESRD risk adjustment model distinguishes between an enrollee on dialysis, functioning graft, and transplant status.

The statute continues to provide us the authority to add to, modify, or substitute for risk adjustment factors if the changes will improve the determination of actuarial equivalence. Additional factors would enable us to pay more accurately for different types of beneficiaries, that is, the healthier and less healthy MA enrollees.

Comment: One commenter wanted clarification of how plans that are currently paid under a risk/frailty adjustment model will be paid in 2006 and beyond.

Response: The MMA did not alter the payment methodology transition schedule for MA organizations or other types of plans that are being paid using the current risk/frailty adjustment models (PACE plans and certain demonstrations). Thus, 2006 will be the last year that the demographic method will be used to determine 25 percent of payments for MA plans. In 2006, 75 percent of payment will be based on the risk adjustment method, and from 2007 onward 100 percent of payment will be determined with the risk adjustment method. Hence, PACE organizations are on a transition schedule one year behind MA organizations and certain demonstrations will be paid on the same lagged transition schedule. In 2006, 50 percent of our payments to PACE organizations and certain demonstrations will be based on the current demographic factors and the remaining 50 percent will be based on the appropriate CMS-Hierarchical Condition Category (HCC) risk adjustment model. In 2007, 75 percent of their payment will be based on the current demographic factors and the remaining 25 percent will be based on the CMS-HCC model. In 2008 and beyond, payments to PACE organizations and certain demonstrations will be entirely based on the CMS-HCC model.

Regarding demonstration plans, the MMA did not alter the current protocol for determining a particular demonstration's payment methodology. Therefore, CMS will continue to make decisions on pricing and payment methodology for its demonstrations specific to each demonstration.

Comment: Regarding the current risk adjustment model, one commenter suggested that there are certain conditions like diabetes and cancer that have several different HCC risk adjusters of varying intensity. The concern is that chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), and other HCCs common among frail elderly have only one risk score, when it may be more appropriate to distinguish a late stage or advanced stage of illness for certain conditions to trigger a higher score.

Response: CMS continues to work on improvements to the CMS-Hierarchical Condition Category (HCC) risk adjustment model. For 2006, more diagnoses and HCCs will be included in the CMS-HCC model. We will announce the updates to the CMS-HCC model in

the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates. We believe that this risk adjustment model, on average, accurately pays for Medicare enrollees.

Comment: Several commenters supported the implementation of a frailty adjuster across the MA program, but encouraged CMS to delay implementation of the adjuster for at least two years until the other significant changes to the MA program have been implemented. In light of the likely delayed implementation of a frailty adjuster for all MA organizations, another commenter believed that CMS should pursue a legislative change to pay special needs plans (SNPs) differently, in order to implement a frailty adjuster, from the rest of the MA organizations. In particular, several commenters were concerned about SNPs being paid accurately for their dual eligible enrollees.

Response: We agree that implementation of a frailty adjuster across the MA program would not be appropriate in the near future in the advent of significant changes occurring in the MA program beginning in 2006. We believe that the current risk adjustment model that includes a Medicaid eligibility adjuster pays on average correctly for dual eligible enrollees. In addition, as a part of refining the CMS-HCC model, we intend to recalibrate the current risk adjustment model so that it accurately reflects more current treatment costs. As the MA program continues to stabilize in its new form, we will be able to apply a frailty adjuster across the entire MA program. We do not have the statutory authority to apply a frailty adjuster only to special needs plans because the MMA requires CMS to pay special needs plans using the same methodology it uses for all other MA organizations.

Comment: One commenter requested that CMS encourage MA organizations to include financial incentives in their contracts with providers that are designed to encourage risk adjustment data submission, rather than using financial penalties. The commenter noted the success in California with a pay-for-performance program that includes financial incentives to IPAs and medical groups to encourage quality health care, including incentives for the submission of encounter data.

Response: In principle, we do not object to plans using financial incentives with their physicians to improve their risk adjustment data submission volume to the extent that these financial incentives do not result in MA organizations' encouraging physicians to provide unnecessary or inappropriate services in order to increase diagnosis reporting volumes. MA organizations proposing to offer providers remuneration in exchange for collecting data must ensure that such arrangements do not violate the anti-kickback statute. Parties who desire an advisory opinion about a particular arrangement may request an opinion from the HHS Office of the Inspector General (OIG). The OIG has the authority to audit financial incentives offered to providers.

We believe that physicians who submit diagnoses for purposes of risk adjustment data submission as if they were submitting claims to FFS Medicare for reimbursement will be submitting the appropriate volume.

Comment: One commenter suggested that CMS be less concerned about the burden on MA organizations of submitting risk adjustment data and more concerned about the accuracy of these data. Another commenter echoed this concern by noting that CMS' implementation of an abbreviated dataset might compromise the validity of the data submitted. One commenter praised CMS for reducing the burden on plans by implementing an abbreviated risk adjustment dataset.

Response: In 2000, we implemented a risk adjustment model based on only principal inpatient hospital diagnosis data. The industry voiced concerns that the inpatient hospital model draws on diagnoses from an acute care setting only, and therefore, is less accurate. In 2004, we implemented a more comprehensive model with a more complete list of acute and chronic diagnoses. Diagnosis data are now being collected from three settings: inpatient hospital, outpatient hospital and physician office settings. At the same time as the more accurate, comprehensive model was being implemented, we began requiring an abbreviated set of data elements to be reported in order to reduce any unnecessary administrative burden on the MA organizations. However, this abbreviated dataset does not compromise the validity of the current risk adjustment model because all relevant diagnoses affecting payment still must be submitted. Rather, the fact that we no longer collect a full set of encounters for each MA enrollee means only that we do not have accurate utilization data for future recalibration of risk adjustment models. The fact that we no longer collect a full set of encounters does not affect the validity of the current model for making payments.

Comment: One commenter asked for clarification of risk adjustment data deadlines.

Response: We will provide updated information about risk adjustment data deadlines in the MA organization training materials and other formats such as MA organization user groups designed to provide operational information including data submission deadlines. General guidelines about risk adjustment data submission deadlines can be found at § 422.310(g).

Comment: One commenter stated that any risk adjustment system should take into account the traditionally higher costs and utilization of large employer group health plans.

Response: Regarding the commenter's concern about the accuracy of the risk adjustment model for large employer group plans, data from the Medicare Current Beneficiary Survey indicate that any beneficiaries with supplemental coverage have higher costs. These data do not support the commenter's assertion that the costs and utilization of Medicare Part A and B benefits are higher for enrollees of large employer group plans than for beneficiaries with other types of supplemental coverage.

Adjustment for intra-area variations. Proposed § 422.308(d)(1) would implement section 1853(a)(1)(F)(i) of the Act, which requires us to adjust payments for regional MA plans to account for variations in local payment rates within the region the plan is serving.

Proposed § 422.308(d)(2) would implement section 1853(a)(1)(F)(ii) of the Act, which requires us to adjust payments for a local MA plan serving more than one county to account for variations in local payment rates within the plan's service area.

The proposed rule mentions four methods that could be used to adjust for relative costs in a plan's service area. Each rate reflects a different type of variation.

- *MA rates*: reflect what Congress determined to be appropriate variation in payment rates among counties. (The proposed rule suggests that this option could be used for local plans.)
- *Local average fee-for-service (FFS) costs*: reflect relative price and utilization differences among counties. (MA county rates that are 100% FFS rates also reflect price and utilization differences.)
- *Input prices*: reflect only price differences in certain service categories, for example, physician services, , not variations in practice patterns among counties.
- *Plan-provided (county-specific) factors showing relative revenue needs*

by county (which the MA organizations would provide in their annual bid submission): reflect cost variations unique to each plan.

The proposed rule stated that we may choose to apply different adjustments to local versus regional plans, because there may be different reasons for rate variation. For example, regional MA plans will be required to cover regions at least as large as a State, thereby being compelled to offer the same benefit package to urban and rural areas. This requirement could be the source of significant variation in plan costs because of service area differences in provider practice and beneficiary utilization patterns, wage indices, and other factors.

Comment: Most commenters recommended an adjustment based on the MA rates. One commenter recommended an approach where the cost index would be consistent with the costs MA plans face in their service areas. Several commenters recommended that CMS use the MA rates for a geographic adjustment at least in the initial years of the program, because the industry is familiar with the MA county rates as a means of payment. A number of commenters recommended that the method CMS selects for regional MA plans should be consistent with that for local MA plans so that the adjustment does not advantage one type of plan over the other, thus contributing to a more level playing field for all MA plans—local and regional. Another commenter remarked that the adjustment back to the local county rates is the most consistent with the constraints of the MMA, is the most feasible to implement, and contributes to a level playing field for the different types of private plans. The commenter reasoned that because the different benchmarks are all built upon the county payment rates, and because the local plans can always organize to be paid at the individual county level, payments to all the types of plans should reflect the county payment rates; otherwise, spending on MA plans would likely increase under any geographic adjustment. Finally, one commenter preferred to use county benchmarks as the basis for intra-area adjustments for local plans and an index of county benchmarks for regional plans, but added that the appropriateness of an index-type adjustment method will depend on the basis of the experience underlying the index derivation calculations.

Response: To avoid confusion with the geographic adjustment we use to calculate the 100 percent FFS rates, we will refer to this section 1853(a)(1)(F) adjustment as the geographic ISAR adjustment, reflecting its purpose.

We have chosen to interpret the ISAR adjustment provision broadly. A more narrow interpretation of ''variations in MA local payment rates'' would be that variation refers only to the administratively-set MA rates. A broader interpretation of variation is that the provision denotes underlying variations in local prices. In this sense, ''local payment rates'' means payment rates MA organizations negotiate with providers. We have taken the latter approach because the MMA defines the bid to be an amount that reflects a plan's estimated revenue requirements—that is, the average underlying costs a plan faces in its service area. This approach allows us to consider adjustment methods in addition to those based on MA county rates.

By law, a plan's bid is based on its projected enrollment. The purpose of the ISAR adjustment is to ensure that CMS pays an MA organization what its plan basic A/B bid would have been if the enrollment projections used to estimate the bid were identical to actual plan enrollment. That is, the ISAR adjustment would take into account the difference between the distribution of enrollment across counties in the plan's service area assumed in the plan's bid and the actual geographic mix of enrollment at the time payment is made. Since plan costs are not uniform across the plan's service area, the fact that the distribution of enrollment assumed in the bid is not the same as the plan's actual enrollment distribution would impact on whether the plan receives the revenue it indicated it needed in its bid to provide Medicare Part A and Part B services. The ISAR adjustment uses the distribution of actual enrollment and assumptions about relative costs across counties in the plan's service area to provide a payment amount that reflects actual enrollment.

Regardless of the specific method (whether plan-provided projected costs per county or a relative cost or price index not specific to plans), use of the ISAR adjustment to translate the plan's bid into county-specific rates would mean that if a plan's enrollment distribution turns about to be different than originally estimated in their bid, their aggregate payments would be adjusted automatically to reflect the actual mix of enrollees in of low-cost and high-cost counties. Recall that for plans with bids below benchmarks, the average payment amount is the basic A/B bid (plus the rebate); and for plans with bids greater than or equal to the benchmark, the average payment amount is the benchmark. Conceptually, converting the average payment amount into plan-specific county rates means that the bid (or benchmark)—which is an average for the whole service area—is ''disaggregated'' and allocated to each county in the service area.

For each local and regional plan, we will be using a geographic ISAR adjustment based on the MA payment rates. This approach reflects the method preferred by the majority of commenters. However, since it is our goal to encourage regional bids, we will allow regional MA plans, on a case-by-case basis, to request to have their payments geographically adjusted at the county level using a plan-determined statement of the relative costs the plan faces in different counties for the provision of Medicare-covered services, in the event that the variation in MA rates is not an accurate reflection of the variation in a plan's projected costs in its service area. We would review the plan-provided ISAR factors for reasonableness.

MA organizations would be required to provide support for their factors (such as the projected utilization and cost by service category for each county), with the understanding that we could ask for additional detail (for example, fee schedules) during bid negotiation or during an audit. We would base our determination of whether to use MA rate ISAR factors or plan-provided ISAR factors for a particular regional plan on the comprehensiveness and reasonableness of the MA organization's cost and utilization assumptions and associated documentation, and on an assessment of which approach would best reflect the plan's likely costs throughout the service area.

The rebate, described at § 422.304(a)(3), is for the provision of non-Medicare-covered benefits and is paid separately from the basic A/B bid. The rebate is not subject to geographic adjustment. Further guidance on the calculation of the ISAR adjustment factor will be provided in the Advance Notice of Methodological Changes for 2006 Medicare Advantage Payment Rates, which we expect to release February 18, 2005 on our website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*.

Comment: One commenter remarked that CMS did not clearly explain its proposed method for the ISAR adjustment in the NPRM, and felt that unless we publish a proposed method for establishing regional PPO benchmark levels, participation in the regional PPO program may suffer. Another commenter requested that CMS wait until Medpac releases its report on payment rate variations before

determining how to apply the ISAR adjustment, and that CMS allow industry to comment on the proposed adjustment before implementation.

Response: First, we would like to clarify that the geographic ISAR adjustment does not establish regional benchmarks. The method for calculating regional benchmarks is established by the MMA and implemented at § 422.258. The purpose of the ISAR adjustment is to ensure that we pay an MA organization what its plan basic A/B bid would have been if the enrollment projections used to estimate the bid were identical to actual plan enrollment. Second, although we stated in the August 3, 2004 proposed rule our intention to review Medpac's upcoming study on variations in MA payment rates, we now do not believe we can wait until the final Medpac report is released, because it likely will be presented to the Congress in June 2005. We are required to announce our proposed approach to the ISAR adjustment, and other payment methodologies, in the Advance Notice of Methodological Changes for Calendar Year 2006 MA Payment Rates, which we expect to be released February 18, 2005 on the CMS website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*.

Comment: A few commenters recommended that the ISAR adjustment should be considered by CMS as a tool to use in adjusting the local payment rates in rural markets, where competing with a regional plan would be cost prohibitive. One commenter suggested that the adjustment should result in localized derivations of regional benchmarks, and another commenter suggested that in counties where the local benchmark is significantly lower than the regional benchmark, payment rates to regional plans should be adjusted downward to reduce the significant competitive advantage regional plans would have over local plans, because the latter will have to charge a higher member premium for the same benefit set and cost structure. Finally, a few commenters stated their concern that it has taken many years to narrow the reimbursement gap between rural and urban areas and now is not the time to reinvent that disparity. These commenters felt this could happen under this ISAR provision because it could allow health plans to segregate rural providers within their region and offer them a substantially lower payment rate.

Response: As noted above, the ISAR adjustment will not affect regional or local benchmarks. In addition, the ISAR adjustment is not a tool to increase payments to local versus regional plans or vice versa. The ISAR adjustment is a mechanism to ensure that payments to plans reflect the plans' bids and their actual enrollment distribution.

We have worked within the construct of the statute to provide a level playing field for all plans. The MMA created incentives to encourage participation in the new regional plan program, such as possible funding from a stabilization fund and the use of risk corridors that are only available to MA regional plans, as found at § 422.438 and § 422.458 (and see subpart J). These incentives are specified by statute, so we are unable to expand the types of organization that are eligible for these incentives. It is important to point out, however, that there are special provisions available only to local plans that MA regional plans do not have available, such as the ability to target specific counties and even partial county areas for inclusion in a plan service area, and to have segmented service areas within a local plan, where premiums and cost sharing can vary across segments.

We are not clear exactly what link the commenters are positing between the ISAR adjustment and contract negotiations with rural providers where MA organizations offer payment arrangements that are lower than previous years.

Adjustment relating to risk adjustment: the government premium adjustment. Proposed § 422.308(e) would implement section 1853(a)(1)(G) of the Act, which requires us to adjust payments to plans with basic A/B bids above their benchmarks to ensure that plans are not advantaged or disadvantaged by the method of paying based on bid-to-benchmark comparisons. Under the bidding method, the beneficiary basic premium is the difference between unadjusted (''1.0 beneficiary'') bid and benchmark, yet the payment is the risk adjusted benchmark. If the MA organization received this premium and its risk adjusted payment from CMS, the combined payments would not match its revenue needs since the basic premium is not risk adjusted. Therefore, the impact that risk adjustment would have had on the basic premium will be incorporated into our payment to the organization.

Proposed § 422.308(e)(1) specified that for each regional plan, payments are adjusted so the sum of the monthly payment and any basic beneficiary premium equals the bid adjusted for enrollee risk factors and the adjustment for intra-area variations in payments in proposed § 422.308(d)(1). Note that the formula as stated at section 1853(a)(1)(G)(ii) of the Act also references the adjustment discussed in the previous paragraph—for intra-regional variations in local payment rates.

Proposed § 422.308(e)(2) specified that for each local plan, payments are adjusted so the sum of the monthly payment and any basic beneficiary premium equals the bid adjusted for enrollee risk factors. We note that, in contrast to the language for regional plans at section 1853(a)(1)(G)(ii) of the Act, the formula for local plans does not include a reference to the intra-area variation described in proposed § 422.308(d)(1). We believe this was an unintended omission for local plans, because section 1853(a)(1)(F) of the Act mandates this adjustment for both regional plans and local plans serving more than one county.

The government premium adjustment must be applied after application of the risk adjustment methodology and after taking into account adjustments for intra-area variation in local payment rates under § 422.304(d).

Comment: Two commenters supported CMS' proposal to adjust payment upward or downward to account for the fact that the basic beneficiary premium reflects the revenue needed for a beneficiary with a national average risk profile rather than the MA plan's anticipated mix of enrollees.

Response: We will refer to this adjustment as the ''government premium adjustment,'' in order to distinguish it from other payment adjustments under the MMA.

Section 1854(a)(1)(G) requires CMS to adjust payments to ensure that an MA organization is paid the revenue needed to offer an MA plan in a service area. The government premium adjustment applies to plans that have basic A/B bids greater than their benchmarks, and thus must charge a basic beneficiary premium. As described above, these plans receive their estimated required revenue to offer original Medicare benefits from two sources: capitation payments from CMS and premium payments from enrollees. Because the MMA requires that the basic beneficiary premium is the difference between the unadjusted (standardized ''1.0'') benchmark and unadjusted bid, plans with sicker than average risk profiles will not receive adequate premium payments from enrollees. The government premium adjustment would be an upward adjustment for these plans. Conversely, plans with healthier than average risk profiles will receive more premium payments than required, so they would receive a downward

adjustment. The government premium adjustment will be calculated, at the individual beneficiary level. Details on the payment formula will be provided in the Advance Notice of Methodological Changes for 2006 MA Payment Rates, which we expect to publish February 18, 2005 on the CMS website at *http://www.cms.hhs.gov/healthplans/rates/default.asp*.

Adjustment of payment to reflect the number of enrollees. Proposed § 422.308(f) implemented section 1853(a)(2)(A) of the Act, which is unchanged by MMA. Therefore, we proposed to retain the existing implementing regulatory language currently found in Subpart F. This provision requires us to make retroactive payment adjustments to account for any difference between the actual enrollees and the enrollees upon which we based advanced monthly payment.

Adjustment for national coverage determination (NCD) services and legislative changes in benefits. Section 1853(c)(7) of the Act requires that when a national coverage determination (NCD) or legislative change in benefits is established and we project this will result in a significant increase in costs, we must appropriately adjust payments to reflect these new significant costs. Because all capitation rates under the MMA now automatically build in the annual national MA growth percentage and therefore incorporate the effect of NCDs annually, we proposed to amend § 422.308(g) and remove the NCD adjustment factor.

Section 1858(c) of the Act provides for temporary risk corridors for adjusting payments to regional plans, and proposed § 422.308(h) specified data submission requirements to implement risk corridor payments. At the end of contract year 2006 and/or 2007, and before a date we specify, MA organizations offering regional plans must submit sufficient information for us to calculate risk corridor amounts.

This information includes actual allowable costs for the relevant contract year and the portion of allowable costs that are attributable to administrative expenses incurred in providing these benefits. In addition, the MA organization will be required to provide the total cost for providing rebatable integrated benefits, as well as the portion of rebatable integrated benefits' costs that are attributable to administrative expenses.

5. Risk Adjustment Data (§ 422.310)

Proposed § 422.310 reflected changes we made in the methodology for risk adjusting MA payments, under which we moved from collecting extensive encounter data to collecting targeted risk-adjustment data. The risk-adjustment data referenced in this section are data that are used in the application of the current risk-adjustment model.

We have implemented a streamlined process for MA organizations to submit risk adjustment data. MA organizations may submit risk adjustment data that conform to the requirements for equivalent FFS data. Alternatively, organizations may submit data according to an abbreviated format as specified by us. The purpose of the abbreviated format is to reduce the data submission burden on MA organizations.

In addition, our current practice is to collect data and a sample of medical records, for conducting validation studies of the risk adjustment data we receive. MA organizations will still be required to submit a sample of their medical records in a manner specified by CMS to support the validation studies. We have not and will continue not to use medical records data for any other purpose.

The risk adjustment data must be submitted according to the timeframes specified by CMS. (See the following website for information on the risk adjustment processing system: *http://www.mcoservice.com/*.) A reconciliation process will be allowed to account for late data submissions. Data that we receive after the final deadline for a payment year will not be accepted for purposes of the reconciliation.

We have modified § 422.310(e) to indicate that there may be penalties for submission of false data under the requirement for validation of risk adjustment data.

6. Announcement of Annual Capitation Rates, Regional Benchmarks, and Methodology Changes (§ 422.312)

Proposed § 422.312 would implement section 1853(b) of the Act, which was revised by the MMA to change the date for CMS' announcement of annual capitation rates to no later than the first Monday in April of each year. In addition, we must announce before September the non-drug benchmark amounts for each MA region and MA regional plan for which a bid is submitted. We must announce regional benchmarks after the plan bids are submitted in June, since per the new section 1858(f)(5) of the Act, the regional benchmark calculation includes a plan bid component based on regional plans that bid in June and also participated in the MA program in the previous year.

The deadline for our release of the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates was similarly changed by the MMA to no later than 45 days before the first Monday in April.

Comment: Two commenters requested that CMS include in the Advance Notice of Methodological Changes for Medicare Advantage Payment Rates additional detail on the methodologies we use to develop and refine payment rates. The commenters specifically requested detail on the coding intensity adjustment, issues related to the data lag elimination, and implementation of the frailty adjuster.

Response: The annual Advance Notice is designed to describe the methodological changes we propose in sufficient detail to alert MA organizations to new calculations, new deadlines, and so forth. If the Advance Notice is unclear, the public is invited to request more information during the public comment period, and we then publish further detail in the annual Rate Announcement. We will be sensitive to the commenters' request as we prepare future Advance Notices of Methodological Changes.

7. Special Rules for Beneficiaries Enrolled in MA MSA Plans (§ 422.314)

Proposed § 422.314 would implement section 1853(e)(2) and (3) of the Act, which sets forth special rules for how we should make payments to enrollees' medical savings accounts. The MMA did not amend the payment provisions in section 1853(e) of the Act, so these provisions are similar to the provisions at § 422.262 in subpart F of the current MA regulations. However, we have made a change to conform § 422.314(c) with the statute at section 1853(e)(1) of the Act.

In general, we deposit into the individual's MA MSA account at the beginning of a calendar year a lump sum equal to the annual difference between the monthly MSA premium (analogous to a plan basic A/B bid) and the monthly capitation rate applied under this section for the area. The premium filed by the organization offering the MA MSA plan is uniform for all enrollees enrolled in the MA MSA plan. This results in a uniform amount being deposited into enrollees' MSAs in a given area, because the uniform premium amount will be subtracted from the uniform rate.

The advance monthly payments we make to an MA organization for each enrollee in the plan are risk adjusted under § 422.308(c), as discussed in connection with proposed

§ 422.304(c)(2) on special rules for payments for MSA enrollees.

Comment: One commenter noted a deficiency in the proposed regulations on how payment is made for enrollees in MSA plans, which prevents an MSA plan from being viable option under the MA program. The commenter summarized the problem as follows. Under the statute and proposed regulations, the total CMS payment on behalf of a beneficiary enrolled in an MSA (the sum of the deposit to the enrollee's MSA account and payment to the MSA plan) is not equal to the risk adjusted benchmark amount. Yet section 1853(a)(1)(B)(iii) requires CMS to pay the risk adjusted benchmark amount for each MSA enrollee. This problem arises because the payment to the MSA plan is risk-adjusted and the deposit to the enrollee's MSA is not. The result is that the total payment for an MSA plan enrollee could be substantially higher or lower than the risk adjusted benchmark. Beneficiaries and insurance companies cannot be reasonably sure that the Medicare payment will be adequate to cover the cost of care.

The commenter recommended that the MSA requirements be written so that: (1) the deposit to the MA MSA account is the difference between the risk-adjusted benchmark amount (based on the annual capitation rate) and the risk-adjusted MSA premium; and (2) the payment to the MSA plan is equal to the risk-adjusted MSA premium. This requirement would result in the total payment (deposit plus payment to MSA insurance plan) being equal to the risk-adjusted benchmark. The commenter recognized that this change may require legislation. Specifically, subsection 1853(e) of the Act might need to be amended to provide for risk adjustment to the contribution to the MSA account.

Response: In response to this comment, we have reviewed the proposed regulations text for MSA plans and have made a change to conform § 422.314(c) with the statute at section 1853(e)(1) of the Act. We are continuing to consider how this statutory language should be applied, and this issue will be addressed in the Advance Notice of Methodological Changes for MA Payment Rates, which we expect to release February 18, 2005.

Comment: Several commenters expressed concern about CMS' ability to risk adjust payments for MSA plan enrollees accurately. Given the complexities of risk adjustment and the absence of enrollee incentives to submit claims to their MSA plan, the commenters are concerned that risk scores for many of these enrollees will be artificially low. One commenter is concerned that in the absence of systems and incentives that encourage members to submit medical expenses to be applied against the deductible, it would not be possible to risk adjust accurately the MSA benchmark for individual health status, which is CMS' payment amount to the MSA plan sponsor. As a result, members will exceed deductibles ''prematurely'' and the plan will be responsible for all medical payments without the benefit of risk adjusted revenue.

Response: Section 1853(a)(3)(B) of the statute requires that all MA organizations submit risk adjustment data for their plans, including MSA plans. The MMA did not change this requirement. We are not sure that we understand this comment, because MSA plans are required to track each enrollee's health care expenses in order to track when the deductible has been met and the plan becomes responsible for all covered expenses. Therefore, as an integral part of managing an MSA plan, an MA organization should have access to enrollee claims or ''encounter-like'' data, which should enable them to submit the required data to CMS for risk adjustment payment purposes.

8. Special Payment Rule for Federally Qualified Health Centers (§ 422.316)

At proposed § 422.316 we would implement section 1853(a)(4) of the Act, which provides for a new payment methodology for FQHCs that contract with MA organizations. Under this methodology, the FQHCs will receive a ''wrap-around payment'' from us representing the difference (if any) between what they are paid by an MA organization, including beneficiary cost sharing, and 100 percent of their ''reasonable costs'' of providing care to patients served at the centers who are enrolled in an MA plan.

Section 1857(e)(3) of the Act, also added by MMA, requires that MA organizations that contract with FQHCs pay the FQHCs an amount that is not less than the level and amount of payment they would make for the services if furnished by an entity providing similar services that was not an FQHC. This is designed to avoid an agreement between an MA organization and an FQHC for payment of an artificially low rate, with the knowledge that the FQHC would receive supplemental payments from us resulting in a total of 100 percent cost reimbursement.

Comment: One commenter suggests that § 422.316 be revised to clarify that it applies to both written contracts and any deemed contracts as they exist under the rules that govern PFFS plans. PFFS plans would have to clearly disclose the payment rate in their written terms and conditions of payment. This would avoid discrimination against PFFS plans.

Response: PFFS plans that have ''deemed'' networks must pay what the FFS Medicare program pays to the ''provider in question,'' per § 422.114(a)(2)(i). Therefore, there would be no wrap-around payment for FQHCs treating PFFS patients under a ''deemed'' contract because the FQHC would be receiving full payment from the plan.

9. Special Rules for Coverage That Begins or Ends During an Inpatient Hospital Stay (§ 422.318)

The MMA amended section 1853(g) of the Act, which puts forth special payment rules for situations where a beneficiary's coverage by an MA plan begins or ends while the beneficiary is a hospital inpatient. The MMA amendment expands the list of hospital facilities covered under this provision to include those that have come under a Medicare prospective payment system since the Balanced Budget Act. In addition to ''subsection (d)'' hospitals, three other types of facilities are now included: rehabilitation hospitals, distinct part rehabilitation units, and long-term care hospitals. These changes were proposed at § 422.318, which otherwise retained existing language from subpart F applicable only to subsection (d) hospitals.

Comment: One commenter proposed that CMS include Critical Access Hospitals (CAHs) in the list of facilities to which this provision applies.

Response: Under section 1853(g), this rule applies only to ''subsection (d)'' hospitals and the three types of facilities the MMA specifically added. Because CAHs are not defined under section 1886(d) of the Act, this provision at § 422.318 does not apply to CAHs.

10. Special Rules for Hospice Care (§ 422.320)

Proposed § 422.320 revised the existing MA special rules for hospice care to reflect the new bidding and payment methodology in sections 1853 and 1854 of the Act, and the creation of a prescription drug benefit under Part D. Now the MA organization will be paid the portion of the payment attributable to the beneficiary rebate (minus the amount of the Part B premium reduction, if any) for the MA plan plus the amount of the subsidies related to basic prescription drug coverage for plans that offer prescription drug coverage.

Note that for PACE organizations, PACE enrollees must elect either their PACE organization or the hospice benefit as their provider of Medicare services. An enrollee who elects to enroll in hospice is thereby disenrolled from the PACE benefit. However, PACE organizations provide a service similar to hospice known as ''end-of-life-care.''

Comment: One commenter stated that beneficiaries who choose to enroll in a Medicare hospice program should also assign their Medicare Part D drug benefit to the hospice. The commenter argued that prescription drugs are usually an integral component of hospice care and should be managed by the provider. Once a health plan is not involved in the care management of a patient, then it should not be responsible for the patient's prescription drug management.

Response: When a beneficiary enrolled in an MA plan elects hospice, that beneficiary is still an enrollee in the plan, is still liable for any plan premiums and cost sharing for benefits not covered under hospice. It is possible for an enrollee who has elected hospice to require prescription drugs for conditions not related to hospice care, which are the plan's responsibility. We believe that it is appropriate for Medicare Advantage Prescription Drug (MA-PD) plans to manage the prescription drug coverage of enrollees who have elected hospice, and therefore we will pay MA-PD plans the Part D premium for all enrollees.

Comment: One commenter suggested that CMS conduct a demonstration allowing beneficiaries to elect hospice while still receiving life saving treatment as a means to overcoming the fear and perceived finality of electing hospice. The commenter cites the low rate of hospice election and short duration of services as reasons to develop some innovative approaches to identifying how to better transition beneficiaries with terminal or advanced illness into a care environment that provides needed and appropriate care, while improving quality of life.

Response: It is important to note that the current hospice benefit began as a Medicare demonstration. It was considered successful, and therefore, the Congress added hospice care as a benefit in the Medicare program. In addition, § 409 of the MMA requires CMS to conduct another hospice demonstration. The statute requires CMS to test delivery of hospice care in rural areas under which Medicare eligible individuals, without a caregiver at home, may receive care in a facility of 20 or fewer beds. Such facility will not have to offer hospice services in the community or comply with the 20 percent limit on inpatient days. In the future, we would be interested in considering other innovative ideas for increasing enrollment in hospice care throughout the country. We invite the commenter to submit a proposal on the suggestion.

11. Source of Payment and Effect of MA Plan Election on Payment (§ 422.322)

With the exception of a new provision addressing payments for Part D benefits, proposed § 422.322 is identical to § 422.268 in subpart F of the current MA regulations. Section 422.322(a)(2) was added to reflect the creation of subsidized prescription drug coverage under Part D. As required by section 1853(f) of the Act, subsidy payments to MA-PD organizations for basic drug coverage under this title are included in the payments described in § 422.322(a)(2).

Comment: Two commenters requested clarification on whether an MA organization can authorize that CMS payment be made directly to an agent of the MA organization.

Response: We believe that the commenters may be anticipating a situation under the MA program where an employer directly contracting with CMS to offer an MA plan would contract with an MA organization to manage that plan. However, section 1857(a) of the statute, which was not amended by the MMA, explicitly states that no payment shall be made under section 1853 to an organization unless that organization is under contract with the Secretary. Therefore, we do not have the authority to make any payments from the Medicare Trust Funds under section 1853 to an agent of an MA organization. The existing regulatory language in Subpart F at § 422.268(c) that implements section 1857(a) is found in proposed Subpart G at § 422.322(c).

Comment: One commenter was concerned that the proposed rules are silent with respect to provider recovery of unpaid amounts due from MA plan enrollees. The commenter recommended that CMS allow providers that treat MA enrollees the same recourse for unpaid enrollment amounts that currently exists in the regulations for the FFS program, that is, allow a cost report recovery that follows the Medicare bad debt recovery criteria. Without this recovery mechanism, providers will suffer financial harm because beneficiaries change program status, not because of any change in the service they provide.

Response: The issue of bad debt recovery criteria for providers who submit cost reports is beyond the scope of this rulemaking. We refer the commenter to 42 CFR part 413 for further information about bad debt recovery rules.

12. Payments to MA Organizations for Graduate Medical Education Costs (§ 422.324)

These provisions at proposed § 422.324 were virtually identical to the current MA provisions in subpart F at § 422.270 (we proposed some non-substantive editorial changes), and required us to make payments to MA organizations for direct graduate medical education costs that MA organizations incur in dealings with non-hospital provider settings, under specified conditions.

Comment: One commenter requested that the final rule clarify whether utilization data on MA enrollees should be considered when making determinations about FFS payment adjustments and minimum utilization standards (for example, direct and indirect medical education payment formulas and the disproportionate share payment formula). The commenter also noted that current FFS regulations apply minimum Medicare utilization standards when assigning certain designations such as rural health clinics, sole community provider or rural referral center status, and requested that MA utilization data be included when CMS makes such designations.

Response: The FFS rate determination and provider designation processes are beyond the scope of this rule making. Such decisions could be proposed and finalized in an upcoming rule-making for the relevant prospective payment system.

Subpart I—Organization Compliance with State Law and Preemption by Federal Law

The MMA amended section 1856(b)(3) of the Act and significantly broadened the scope of Federal preemption of State law. We proposed to revise § 422.402 to clearly state that MA standards supersede State law and regulation with the exception of licensing laws and laws relating to plan solvency. In other words, with those exceptions, State laws do not apply to MA plans offered by MA organizations.

We believe that the Conference Report was clear that the Congress intended to broaden the scope of preemption in the MMA. We accordingly believe that the exception for State laws that relate to ''State licensing'' must be limited to State requirements for becoming State licensed, and would not extend to any

requirement that the State might impose on licensed health plans that absent Federal preemption must be met as a condition for keeping a State license.

In addition to outlining the new scope of the preemption, we also proposed the following technical changes:

- We proposed to remove the current § 422.402(c) because

we believed it was no longer relevant given the new MMA provision.

- We clarified that States are expressly prohibited from

imposing a premium tax, or similar type of tax, on premiums paid by beneficiaries or third parties on behalf of beneficiaries to MA organizations.

Below we summarize and respond to the comments we received on Subpart I:

Comment: A commenter expresses concern that the statutory and regulatory language stating that Federal preemption does not extend to State licensing or solvency requirements is vague and may allow States to impose network access requirement on MA plans.

Response: We note that the Conference Report makes it clear that the Congress intended to broaden the scope of Federal preemption with the intention of ensuring that the MA program as a Federal program will operate under Federal rules. We have also clarified (in the preamble to the interim regulation) and we restate here that we believe that State licensing laws under Federal preemption are limited to State requirements for becoming State licensed, and cannot be extended to other requirement that the State might impose on licensed health plans that absent Federal preemption must be met as a condition for keeping a State license. We believe that under current Federal preemption authority States are limited in applying only those requirements that are directly related to becoming State licensed. For example, State-licensing requirements may include requirements such as filing articles of incorporation with the appropriate State agency, or satisfying State governance requirements. However, under Federal preemption, State licensing laws may not be extended to include rules that apply to State licensed health plans which we believe would include network adequacy requirements for MA plans.

Comment: A commenter expresses concern that if all State regulation of MA plans is broadly preempted by Federal law (with the limited exception of licensing and solvency requirements), contracting providers will not have adequate means to ensure prompt payment or access to external review of inappropriate denials of coverage or payment. The commenter recommended that CMS either narrow its interpretation of how State law may be preempted or expand its own Federal requirements for plan-provider contracting standards to include basic provider protections, such as prompt payment.

Response: As previously stated, we believe that with the exceptions of State licensing and solvency requirements the Congress clearly intends and the MMA statute provides that the MA program is to be solely under Federal and not State rules. However, we do recognize concerns regarding the effectiveness of Federal regulation of the MA program. In overseeing the MA Program, CMS will ensure appropriate oversight of MA plans.

With respect to prompt pay requirements, providers and MA organizations may enter into contracts the terms of which are established by the parties. In general the terms of these contracts including payment amounts and prompt payment standards are determined by negotiation between the parties. We specifically require in our regulations at § 422.520(b) that contracts between MA organizations and providers contain prompt payment standards which the parties have both agreed to. In the event an MA organization fails to honor its provider contract(s) in certain circumstances, we may impose intermediate sanctions or even terminate its contract with the MA organization.

Comment: A commenter asks that CMS clarify in its regulations that, with the exception of State laws that relate to State licensing and solvency, Federal preemption extends to any requirement that the State might impose, including requirements imposed as a condition of maintaining State licensure.

Response: We believe our regulations at § 422.402 are clear in regards to the broad extent of Federal preemption authority under the MMA. We have discussed in previous responses that States may not use licensure or solvency requirements as an indirect means to impose health plan regulations on MA plans. Again, we reiterate our understanding of the congressional intent that the MA program, as a Federal program operate solely under Federal rules with the exception of State licensure and solvency requirements.

Comment: A commenter acknowledges the preamble discussion in the proposed rule clarifying that State licensing laws are limited to the requirements for becoming State licensed (for example, filing of articles of incorporation with the appropriate State agency or satisfying State governance requirements) and do not extend to the requirements that a State may impose on licensed health plans that absent preemption must be met as a condition of keeping a State license. The commenter recommended that CMS make this clarification in § 422.402 of the MA regulations.

Response: We believe State licensure requirements cannot be used as an indirect way to regulate MA plans by imposing requirements not generally associated with licensure. For example, we stated that reasonable licensure requirements may include the filing of articles of incorporation with the appropriate State agency or satisfying State governance requirements. However, we chose not to establish the parameters of State licensure in our regulations as there may be other legitimate aspects of State licensure we have not noted.

Comment: A commenter stated that the proposed rule reiterates the MMA and fails to clarify the extent to which State law is preempted. The commenter maintains that the proposed regulation gives no guidance to States in determining which laws they can require Medicare plans to observe. According to the commenter, States do not know which standards they can enforce to protect consumers. As an example, the commenter cites the Knox-Keene Act in California which conditions health plan licensure on several minimum requirements. The commenter maintains that without explanation from CMS on what types of ''licensing'' laws States may enforce, California has no way of determining which parts of the State's broad statutory scheme may apply to Medicare plans and which parts are preempted. The commenter believes that CMS has not provided guidance to States on how financial solvency requirements can be separated from other parts of State licensing law which are intricately interwoven. Instead of clarifying underlying statute and policy, in the commenter's view, the proposed rule injects further confusion regarding the extent of Federal preemption of State law. The commenter requests further explanation and practical guidance on the role of the States in enforcing minimum licensure and financial solvency requirements.

Response: As we stated in the preamble to the proposed rule (69 FR 46904), we believe that under the MMA, States are preempted from applying any regulatory requirements on MA plans with the sole exception of State licensure and solvency requirements. We also believe that licensure and solvency requirements cannot be used

as an indirect method of imposing State regulatory requirements that a State might impose on non MA health plans. We recognize that there still may be questions about the extent of allowable State regulation. As in the case of the pre-MMA pre-emption provisions, we intend to address these specific type of preemption questions in cooperation with States.

Comment: A commenter stated that Federal preemption authority under the MMA means that requirements concerning these matters as fair business practices, plan and physician contracting and prompt payments which have been traditionally under State law, will now be governed by Federal law. The commenter recommended that CMS monitor the effect of Federal preemption and establish strong Federal oversight to ensure that plans are complying with Federal regulatory standards. The commenter is concerned that without strong Federal oversight, patients in MA plans may not have the same protections that apply to other individuals enrolled in health plans, including those in traditional Medicare or those enrolled in private plans governed by State law. The commenter also recommended that since most State laws applicable to health plans will be preempted by Federal law, CMS should ensure that laws and regulatory standards that protect patients and physicians in the traditional Medicare program also be applied by CMS to MA plans.

Response: We are aware of the need for strong consistent oversight of MA plans. As we have done under the previous M+C program, we will ensure that enrollees in MA plans receive the appropriate quality and access to plan covered health care services.

Comment: A commenter stated that in the proposed rule (69 FR 46913 through 46914), CMS takes the position that State contract are ''generally applicable'' to MA organizations and are therefore not preempted. The commenter also indicated that CMS explains (in the preamble to the proposed rule) that State contract and tort law does not specifically apply to health plans, and that the Congress only intended to preempt State standards contained in State statutes and regulations, and that State standards developed through case law (for example, State contract and tort law) are not preempted. The commenter expresses concern that while State contract and tort law principals may have general application, State standards developed through case law based on interpretations of State contract and tort law may be specific to health plans, and may apply State standards that would otherwise be preempted under Section 232(a) of the MMA.

The commenter concludes by stating that they believe that in enacting section 232(a) of the MMA, the Congress intended to draft a clear Federal preemption standard for the MA program, and that the primary motivation for this new preemption standard was to ease the administrative burden caused by the ambiguity in the old § 422.402. The commenter also recommended that CMS make clear that all State standards, including those established through case law, are preempted with respect to the MA program, with exceptions of State licensing and solvency laws.

Response: In response to this comment, we would clarify that all State standards, including those established through case law, are preempted to the extent that they specifically would regulate MA plans, with exceptions of State licensing and solvency laws. Other State health and safety standards, or generally applicable standards, that do not involve regulation of an MA plan are not preepmted.

Comment: A commenter expresses concern that under the rules proposed by CMS, providers who contract with MA plans will be left with virtually no protection because State prompt pay laws will be preempted. The commenter stated that while CMS has proposed adding § 422.520(b)(2), which provides that an MA organization is obligated to pay contracted providers according to the terms of the contract with the MA organization, this language does not provide sufficient protection for contracted providers. The commenter indicated that nearly every State in the country has enacted prompt pay legislation to protect providers who are often unable to negotiate sufficient prompt pay provisions in their contracts with plans. The commenter also suggested that if State prompt pay laws are preempted then CMS should revise the proposed rule to add prompt pay protection for contracted providers that is at least as strong as that given to non-contract providers.

In addition, the commenter believes that preemption of State prompt pay requirements for MA contracting providers will cause hospitals to be less willing to contract with MA plans if they are uncertain whether claims will be paid promptly and fairly.

Response: In our current MA regulations at § 422.520(b), we require that MA organizations include in its contracts with providers a prompt pay provision. However, we allow the providers and MA organization discretion to negotiate the terms of the prompt payment provisions. Since these contracts typically include payment arrangements, we believe it is appropriate and reasonable to leave the parties to the contract discretion to work out mutually agreeable terms of their contract. The contracts may include payment amounts greater than what original Medicare will pay for some services and other payment incentives for contracted providers. If an MA organization fails to honor the terms of its provider contracts under certain conditions, we have the authority to impose intermediate sanctions or even terminate its contract with the MA organization.

Comment: One commenter recommended that CMS develop guidance that builds on the preamble discussion of preemption in subpart I and Subpart M. The Congress provided broad preemption authority to ensure that the program is implemented in a uniform way for beneficiaries in States across the country. The commenter also recommended that CMS interpret the preemption authority, consistent with the Congressional intent, to maximize the uniformity of program implementation nationwide.

Response: We believe that in our previous responses, we have made it clear that our understating of Federal preemption and the Congressional intent is that the MA plans are only subject to Federal regulation with the exception of State licensure and solvency requirements.

Comment: A commenter encourages CMS to clearly communicate the provisions of the new law and regulations relating to both preemption of State law and restrictions on States imposing premium tax on funds collected from enrollees to all States. The commenter states that they have already received questions from States related to premium tax and believe a communication from CMS would help clear up any confusion the States may have.

Response: We believe the MA regulations at § 422.404 are absolutely clear that States cannot levy a premium tax, fee, or any other fee on the payment CMS makes to MA organizations (on behalf of MA enrollees) or payments made by MA enrollees to MA plans or by a third party to a MA plan on a beneficiaries behalf.

Comment: One commenter stated that CMS has not established if its expanded preemption authority applies to cost HMOs that are either: (1) observing the same rules as MA organizations (with respect to grievance and appeals for

example); or (2) offering qualifying Part D coverage. Both the Congress and CMS have stated that cost HMOs offering qualifying Part D coverage should be ''treated'' like local MA-PDs and subject to the same rules as MA-PD plans offered by MA organizations. The commenter maintains that CMS should apply the expanded preemption available to MA organizations to cost HMOs when the latter are carrying out the same programs and are subject to the same rules as the former. The commenter also believes that doing so in the final rule would be consistent with the intent of the Congress, and would ensure consistent application of Medicare managed care rules when those rules are the same for both MA members and cost HMO members. The commenter concludes by noting that without preemption, cost HMOs may be mandated by State law to cover certain drugs, or have certain cost sharing for covered drugs, inconsistent with Part D.

Response: If a cost plan offers the Part D benefit, the Part D provisions that apply under the MA program would apply to the Part D product, including the Federal preemption standards. However, other services offered by the cost plan are not subject to the new Federal preemption authority in the MMA which otherwise only applies to MA plans offered by MA organizations.

Subpart J—Special Rules for MA Regional Plans

Section 1858 of the Act, as amended by section 221 of the MMA, sets forth special rules that apply to new MA regional plans. Although MA regional plans will have many similarities with local MA plans, the Congress provided for a number of unique financial and administrative incentives designed to support the introduction of these types of plans.

These incentives will assist plans as they enter this new line of business and learn the market dynamics of serving beneficiaries across larger geographic areas. In addition, to encourage the formation of regional plans, we establish(at § 422.451) a 2-year moratorium on new local PPO plans from January 1, 2006 until December 31, 2007, unless the plan was offered before the first day of the moratorium, to implement section 221(a)(2) of the MMA.

In the August 3, 2004 rule, we proposed establishing a new subpart J to address many of the special regional PPO requirements. (Bidding and payment provisions for MA regional plans are implemented in subparts F and G of part 422.) We received more than 125 sets of comments on subpart J in response to the proposed rule; most related to the establishment of MA regions. The Secretary of the Department of Health and Human Services announced the establishment of the MA and PDP regions on December 6, 2004. The website address where the MA and PDP regions may be found is *http://www.cms.hhs.gov/medicarereform/mmaregions/*. Below we summarize the proposed provisions and respond to comments.

§ 422.451—2 year Moratorium on Expansion of local PPO plans

To encourage the formation of regional plans, we had proposed at § 422.451 to implement a 2-year moratorium on the offering of new local PPO plans from January 1, 2006 until December 31, 2007. As discussed below, in response to a comment on this final rule, we have revised our interpretation of the moratorium. We now interpret the moratorium as precluding an MA organization from offering a new PPO plan in a service area if the organization did not offer a PPO plan in that area in 2005. As discussed below, an organization that offers a PPO plan in 2005 in a service area will, under our new interpretation, be permitted to offer a different plan in the same area (for example, it could offer both an MA plan and MA-PD plan in the area). Section 221(a)(2) of the MMA provides that we cannot permit the expansion of local PPO plans during 2006 or 2007 unless the PPO was offered as of December 31, 2005. We have determined that a PPO is ''offered'' as of December 31, 2005, for purposes of the moratorium, only if it has actually enrolled beneficiaries into its plan before January 1, 2006.

Comment: A commenter believes that the Congress intended the moratorium to prohibit the expansion of local PPO service areas (for 2006 and 2007) but allow for the introduction of new local PPO plans within those PPO service areas. In support of this view, the commenter believes that the Act permits plans to ''expand enrollment'' during the moratorium, and asserts that product innovation is necessary to do that. The commenter also notes that in order to migrate existing members to new products, MA organizations will need to have several plan offerings, both with and without Part D coverage. In addition, MA organizations may want to offer MA-PD PPO plans with both the standard coverage package and enhanced packages that provide ''donut hole'' coverage. The commenter concluded that if the moratorium were interpreted as freezing the number of plans that a local PPO can offer, the effect would be to greatly restrict choices for current members of local PPO plans. The commenter believes the Congress did not intend such a result.

Response: We agree with the commenter. As noted above, we are now construing the moratorium to apply at the MA Organization level, rather than the plan level. Under this approach, an MA organization that has not offered a local PPO plan in a service area prior to the effective date of the moratorium will be prohibited from doing so, but an organization that did offer a PPO plan in the area could continue to do so, and could add other PPO plan options. We believe this change in interpretation is warranted on several grounds. First, we interpret section 221(a)(2) of the MMA as intended to prevent MA organizations from entering a new service area with a local PPO product in 2006 and 2007, not to preclude an organization already offering a PPO plan in the area from changing its benefit designs. We believe that even though the text of section 221(a)(2) contains the word ''plan,'' Congress used that word in its more colloquial sense—that is, meaning ''health plan'' rather than ''MA plan.'' As the commenter stated, support for this interpretation is found in the Conference Report, which states that MMA section 221(a)(2) establishes the moratorium ''on new local preferred provider organizations to encourage PPOs to operate at the regional level.'' Further support for this interpretation arises from the fact that were we to retain the more restrictive reading, MA organizations would be precluded from offering their enrollees the option of choosing whether to enroll in Part D. Because the organization would be required to offer an MA-PD plan in the service area, if it only offered one PPO plan in 2005, it would have to offer Part D benefits in that plan, as only that plan would be exempted from the moratorium. We believe that the Congress intended to give MA organizations the right to offer a plan without Part D benefits as long as they offered an MA-PD plan in the same area. This right would be thwarted under our earlier interpretation of the moratorium provision. We have revised the regulation accordingly. The effect of the 2006 and 2007 moratorium will be to prevent an MA organization from offering a PPO plan in a service area in 2006 and 2007 if it did not already offer one in the area, and to freeze any service area expansions of existing local PPO plans. However, during the 2-year moratorium, MA organizations offering local PPO plans, may offer additional PPO plans (within the pre-moratorium PPO services areas) to afford beneficiaries reasonable enrollment

options and to allow for the MA organization make changes in order to offer Part D coverage in a local PPO plan.

Comment: A commenter recommended that CMS allow specialized MA plans for special needs individuals or SNPs to offer new local PPO plans and service area expansions (SAEs), even during the moratorium in 2006 and 2007. The commenter believes that this flexibility is warranted because SNPs do not compete with MA regional plans.

Response: As we have discussed above, an MA organization may introduce new local PPO plans within its 2005 service areas where it has offered local PPO plans. However, an MA organization may not expand its service area beyond the boundaries of the local PPO plans the organization has established prior to the moratorium's taking effect. This will allow an organization to offer a SNP (operating as a local PPO) in its pre-moratorium PPO service areas. We think this is consistent with the Congressional intent to allow organizations offering local PPO type plans to expand enrollment within its pre-moratorium service areas.

Comment: A commenter is interested in applying to us in 2006 as a new local HMO that would become operational in 2007. The commenter states that its operational model is as an HMO. However, the commenter is licensed in its State of operation as a ''health care services contractor'' and not as an HMO. The commenter is concerned that because it is not State-licensed as an HMO, it may not fit the definition of a local HMO and will be subject to the 2-year moratorium on local PPOs.

Response: Organizations contracting with us must meet applicable State licensure requirements. Our basic regulatory requirement is that an MA organization must be State licensed to bear risk as described in the MA regulations at § 422.400. Section 422.400 indicates that it is the responsibility of the MA organization to demonstrate to us that it is operating within the scope of its State license or the State authority granted to it under § 422.400(b) (if the entity is not State-licensed as a commercial insurer) authorizes it to offer the type of MA plan or plans it intends to offer in a State. Upon meeting State licensure requirements, the organization offering an MA plan must meet MA regulatory requirements governing the type of plan being offered. As we have previously described, we will approve applications for new local PPO plans for 2006 and 2007 offered by an MA organization within the service area of local PPO plans offered by that MA organization and established prior to January 1, 2006. In addition, MA organizations may introduce other MA plan types without service area restriction (for example, HMOs or PFFS plans) that meet State licensing requirements and MA regulatory requirements.

Comment: The commenter opposes the local PPO 2-year moratorium but recognizes that it is required under the MMA. The commenter states that CMS must set an application deadline that allows for the review and approval of a local PPO application in time for the bidding deadline. Accordingly, the commenter recommends that we consider a plan as ''existing'' before 2006 even though the first effective date will not be until January 1, 2006. An MA local PPO should be considered as ''existing'' when in 2005, has been awarded a contract, has submitted a bid for 2006, and is being marketed during the annual election period which begins in November, 2005.

Response: Under MMA section 221(a)(2), the 2006 and 2007 moratorium prevents the offering of new local PPOs in a service area unless a local PPO plan was offered by that MA organization in that service area as of December 31, 2005. We have determined that this means that local PPO plans must have actually enrolled beneficiaries before January 1, 2006 to be considered ''offered'' and thus in effect before the moratorium begins. The local PPO plans that have enrolled beneficiaries prior to January 1, 2006 will establish the limits of the service area where the MA organization can introduce new local PPO plans during the moratorium.

Establishment of the MA regions (§ 422.455)

At § 422.455, we implement section 1858(a) of the Act, which requires us to establish the regions that will constitute the service areas for the MA regional plans. We were required to establish between 10 and 50 MA regions within the 50 States and the District of Columbia, and an MA regional plan will be required to serve an entire region.

The statute specified that the MA regions should maximize the availability of regional plans for Medicare beneficiaries, particularly those residing in rural areas, regardless of their health status. To assist us in developing the MA regions, we were required to conduct a market survey and analysis, including an examination of current insurance markets.

It is important to note that in accordance with section 1858(a)(2)(B)(ii) of the Act, we may periodically review MA regions and revise as necessary. We implement this provision at § 422.455(b)(2)(ii).

Combined with comments received on Prescription Drug Plan (PDP) regions, we received more than 110 sets of comments on the establishment of MA regions as found in § 422.455(b). The first sets of comments were received in follow-up to a public meeting held in Chicago, Illinois on July 21, 2004 regarding the MA and PDP regions. We also received numerous comments in response to our request for comments in the proposed rule for part 422: Establishment of the MA Program. We also received comments on PDP regions on the part 423 proposed rule: Medicare Prescription Drug Benefit. Comments and responses that relate to the establishment of PDP regions are found in Subpart C of the preamble to the final rule for part 423. Finally, we received written comments following a CMS Special Open Door Forum conference call on ''Factors for Determining MA and PDP Regions to Maximize Beneficiary Choice,'' held on Friday, October 22, 2004.

The majority of MA region comments that specified the size of the region generally favored establishing 50 State-based regions. However, about one-third of all comments supported multistate regions, though few provided the number of multistate regions they would prefer. Issues identified in support of 50 State-based regions included the large assumption of risk with the establishment of larger regions; insufficient time for plans to negotiate and develop networks in larger regions or to renegotiate provider contracts and form partnerships; limitations in capacity and infrastructure issues in the initial years; and potential difficulties in obtaining State licenses and meeting State solvency requirements.

Comment: Some commenters suggested that fewer organizations will participate as regional PPOs if larger regions are established. Commenters who favored multistate regions indicated their belief that larger regions would facilitate plan choices in areas traditionally without a choice of plans. Further, several commenters noted that 50 State-based regions would perpetuate the status quo of not providing choice of plans in certain areas, especially in rural areas. Commenters in favor of multistate regions also cited Congressional intent to provide rural beneficiaries with the same array of choices that beneficiaries in non-rural areas often have. These commenters contend that these choices would not occur with 50 State-based regions. From a market perspective, supporters of multistate regions believe that there

would be a critical mass in larger regions that are necessary to encourage new entrants into the MA market.

One commenter stated that the lack of specificity in the proposed rule made it difficult to envision how the new regional PPO option would work in practice. A number of commenters expressed concern about the compressed timeframe between our announcement of the regions and their deadline for making a decision about whether to apply as a regional PPO. Finally, a number of commenters recommended that CMS make Puerto Rico a freestanding MA region because of the unique cultural factors of Medicare beneficiaries residing in Puerto Rico.

Response: We conducted a market survey and analysis, including an examination of current insurance markets as required in the MMA. Key factors in the survey and analysis included payment rates, eligible population size per region, PPO market penetration, current existence of PPOs, MA plans, or other commercial plans, presence of PPO providers and primary care providers, and not splitting multistate Metropolitan Statistical Areas (MSAs). Additional factors were also considered, for example, solvency and licensing requirements and capacity issues. In response to comments about the lack of specificity in the proposed rule, we have taken several steps (for example, the market survey and extensive public outreach) to ensure that the public could see options for the regions, and factors used in determining these options. We also have sought public input in several contexts before the publication of the regions. The establishment of the MA PPO and PDP regions was announced on December 6, 2004, and can be found at *http://www.cms.hhs.gov/medicarereform/mmaregions/* . We understand the commenters' concerns about Puerto Rico's unique circumstances. However, the statute defines an MA region as one that is within the 50 States and the District of Columbia. Therefore, we are not authorized to include Puerto Rico or any of the other U.S. territories in an MA region. However, pursuant to the requirement to establish PDPs under section 1860D–11(a)(2) of the Act (as implemented at § 423.112), we have established PDP regions for the territories, separate from the 50 States and the District of Columbia. A separate PDP region has been established for each territory.

Risk Sharing (§ 422.458)

Section 1858(c) of the Act provided that we will share risk with MA regional plans for contract years 2006 and 2007, if plan costs are above or below a specific risk corridor. Risk sharing is intended to encourage plans to enter the regional market and to provide assistance to these plans during the start-up phase of their business.

Section 422.258(a) will implement section 1858(c) of the Act by defining the following terms:

- Allowable costs were defined as the total amount of costs incurred in a year in providing benefits covered under the original Medicare FFS program option for all enrollees and in providing rebatable integrated benefits, reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.
- Target amount for an MA regional plan was defined as the total amount of payments made to the organization for enrollees in the plan for the year, reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare FFS program option and rebatable integrated benefits.
- Rebatable integrated benefits were defined as those non-drug supplemental benefits that are funded through beneficiary rebates (described at § 422.266(b)(1)) and that we determine are: (1) additional health benefits not covered under the original Medicare program option; and (2) benefits that require expenditures by the plan.

Section 422.258(b)(2) will implement section 1858(c)(1)(B) of the Act by requiring that MA regional plans notify us, before that date in the succeeding year as we specify, of each plan's total allowable costs. As mentioned above, rebatable integrated benefits (RIBs) are the only supplemental benefits that can be included in a plan's allowable costs. We have discretion to evaluate whether certain rebatable benefits should be included in allowable costs for risk corridor calculations. We asked for comment whether reductions in cost sharing for Parts A and B benefits should be considered RIBs.

Section 422.358(c) will implement section 1858(c)(2) of the Act relating to payment adjustments. There will be no payment adjustment if the allowable costs for the plan are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan. Section 422.358(c) also included the following:

- If allowable costs for the plan are more than 103 percent but not greater than 108 percent of the target amount for the plan for the year, we will increase the total monthly payments made to the organization by 50 percent of the difference between allowable costs and 103 percent of the target amount.
- If allowable costs for the plan are greater than 108 percent of the target amount, we will increase the total monthly payments to the plan by an amount equal to the sum of: (1) 2.5 percent of the target amount; and (2) 80 percent of the difference between allowable costs and 108 percent of the target.
- If the allowable costs for the plan are less than 97 percent, but greater than or equal to 92 percent of the target amount, we will reduce the total monthly payment to the plan by 50 percent of the different between 97 percent of the target amount and the allowable cost.
- If the allowable costs for the plan are below 92 percent of the target, we will reduce the total monthly payments to the organization by the sum of: (1) 2.5 percent of the target amount; and (2) 80 percent of the difference between 92 percent of the target and the allowable costs.

Section 422.358(d) will implement section 1858(c)(3) of the Act relating to disclosure of information. Each contracting MA plan must provide the information that we determine is necessary to carry out this section. Although we have the right to inspect and audit all books and records pertaining to information provided under this section, the information disclosed or obtained for purposes of this section may only be used to carry out this section.

Comment: Two commenters suggested that we clarify how MA regional plans should determine their administrative costs for purposes of determining their allowable costs and target amounts. Both commenters recommended that we develop an administratively straightforward methodology to identify administrative costs. One commenter suggested that we clearly state that the determination of administrative costs for purposes of the MA regional plan risk corridors may differ from the calculation of administrative costs for purposes of the Part D program.

Response: As stated in § 422.254 each bid submission must contain all estimated revenue required by the plan, including administrative costs and return on investment. We interpret the term administrative costs to be the costs associated with administering the program and the expected or retained earnings of health plans. For purposes of this final rule, we use the terms administrative costs and administrative expenses interchangeably. We intend to provide further guidance on defining administrative costs in the instructions

on use of the bid pricing tool. We expect that the guidance will seek to reconcile any differences in how administrative costs are calculated for purposes of Title I and Title II.

Comment: Three commenters recommended that CMS consider cost sharing reductions for Part A and B benefits as plan expenditures, and thus included as rebatable integrated benefits, rather than as foregone revenue that would be excluded from RIBs. One commenter suggested that by doing so, more risk would be shared between a plan and Medicare, thereby encouraging greater plan participation. The commenter believes that this approach would be more intuitive and less likely to result in variable cost estimations than the alternative approach. Another commenter suggested that the MA plan actuary should demonstrate and certify its estimate of the rebatable portion of the cost sharing. Another comment was made recommending that the risk sharing calculation should be modified to include full plan costs (that is, those beyond the rebate funded portion).

Response: We considered several issues when determining which uses of rebate dollars to define as RIBs. As we stated in the August 3, 2004 proposed rule, one approach could be to define RIBs as benefits that will otherwise be covered under original Medicare were it not for the imposition of deductibles, co-pays, coinsurance, and benefit coverage limits. This will exclude, for example, non-Medicare covered benefits from the category of RIBs. However, we concluded that it is difficult to draw a non-arbitrary line between integrated and non-integrated benefits. For this reason, in the proposed rule, we proposed to include additional health benefits not covered by original Medicare in the category of RIBs. In terms of cost sharing reductions for Part A and B benefits, we agree with the commenters that cost sharing reductions for Part A and Part B Benefits can be considered expenses to a plan because when an enrollee pays less, the plan pays more. In other words, when a plan uses the rebate to reduce Part A and B cost sharing, the amount that otherwise would be paid to the provider by the beneficiary must be paid by the plan. Therefore, for the purposes of determining risk-sharing payments to regional plans for 2006 and 2007, cost sharing reductions for Part A and Part B benefits will be considered plan expenditures for purposes of § 422.458(b)(2)(ii). In doing so, this allows cost sharing reductions for Part A and Part B to be considered rebatable integrated benefits provided that these reductions are funded by plan rebate dollars and not by the beneficiary supplemental premium. With regard to extending risk to full plan costs, section 1858(c) of the Act limits the risk sharing arrangement between us and plans to only allowable costs (that is, those incurred in providing Part A and Part B benefits and rebatable integrated benefits). For mandatory supplemental benefits that are non-Medicare benefits and require expenditures by the plan though are partly funded by rebate dollars, we will include only the rebate funded portion of the costs and revenues in the risk corridor calculation.

We note that several applications of rebate dollars are not considered RIBs: (1) reductions in Part D cost sharing since the statute defines RIBS an non-drug supplemental benefits in section 1858(c)(1)(d) of the Act; (2) a Part B or Part D premium reduction does not require expenditure by the plan.

State Licensing Waiver

Section 422.458(e) will implement section 1858(d), of the Act setting forth organizational and financial requirements for regional PPOs, including the provision for a temporary waiver of the MA State licensing requirement. In order to facilitate the offering of MA plans in regions encompassing multiple States, we may temporarily waive State license requirements, for example, to allow sufficient time for the processing of the application by the State or States where an application is pending.

Comment: One commenter stated that under the MMA we have the authority to temporarily waive State licensure requirements to facilitate plans in regions encompassing multiple States when a plan is licensed in at least one State. The commenter asks for clarification whether we can use our authority to grant the same waiver to local plans seeking service area expansion to bordering States. The commenter believes that in providing this authority the Congress intended to facilitate plan choices for beneficiaries. The commenter concludes by noting that the licensure waiver should apply as well to local plans seeking to become another enrollment option for enrollees in neighboring States.

Response: As the commenter indicated, section 1858(d) of the Act provides authority for us to temporarily waive State licensure requirements to facilitate the introduction of regional PPO plans if a region encompasses multiple states. However, under the statute this authority is specific to regional PPO plans. We do not believe we have the authority to extend the State licensure waiver to local plans with a service area encompassing more than one State.

Comment: Another commenter recommended that CMS be as conservative as possible in deciding how to waive State licensing requirements in the States in which regional PPOs are operating. The commenter recommended that CMS ensure regional plans serving beneficiaries in multiple States are held accountable under the State laws under which they are operating.

Response: As specified in the MMA, all MA organizations offering MA plans including regional PPO plans must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which they offer an MA plan. We will temporarily waive the State licensure requirements only in limited circumstances. Specifically, if an MA organization offering an MA regional plan is organized and licensed under State law in at least one State in the region but has not met the licensing requirements in other States in the region, under section 1858(d) of the Act, we may temporarily waive the State licensing requirement in the other States. This waiver will only be extended to allow sufficient time for the processing of the application by the State or States where an application is pending. The statute allows for the waiver to extend for a transition period after denial of a licensure application, but does not permanently excuse a plan from compliance with state licensing requirements. Therefore, if a State denied a regional PPO's application for State licensure, we will not allow the plan to continue operating in that region beyond the transition period, unless the plan obtains licensure in all States in the region.

Comment: A commenter is concerned that organizations that lack sufficient experience in operating a PPO plan or being a capitated Medicare provider will apply to become regional PPO plans. The commenter proposes that we establish minimum requirements (beyond the filing of licensing applications) that an applicant must satisfy before we would consider a temporary waiver of the State licensure requirement. The commenter recommends that CMS impose the following requirements:

- The applicant or a sponsoring organization of the applicant must have operational experience in offering insured PPO plans;
- The applicant or a sponsoring organization of the applicant must have

operational experience with assuming risk under capitated programs;

• CMS should limit the duration of the waiver to one year from the date the waiver is granted.

Response: We anticipate that most State licensure waivers will be for less than 1 year. The exact duration of the waiver will depend on how long a State takes to process the application. In any event, as we indicated in the previous response, all regional PPO plans must become State licensed in each State in which they operate. We do not believe it is necessary for us to impose additional requirements for new PPO applicants. We have considerable experience in reviewing applications from new organizations entering the MA program. New organizations entering the program must meet the operational and regulatory requirements that apply to current plans. If a new applicant has no current experience we invest the necessary time and resources to ensure that the organization offering the plan does in fact have the capacity to offer the proposed plan and meet all regulatory requirements. We expect that we will take the same approach with any new applicant to the MA program.

Comment: A commenter recommends that if CMS do not designate single-State regions, CMS should amend the proposed rules governing preemption of State law to ease the burden of multistate licensure as much as possible. The commenter recommended that CMS apply the Federal waiver and uniform solvency standards applicable to provider sponsored organizations to regional PPO plans to promote greater regional PPO participation and access to potential beneficiaries. Alternatively, the commenter recommends that CMS engage the National Association of Insurance Commissioners and the State departments of Insurance in discussions that will result in the creation of a single, uniform MA PPO licensure application form, procedures, and solvency standards, that maximize the availability of PPO assets for use in providing direct services and care enhancement, and minimize the net worth, reserve, deposit, surplus and related requirements applicable to PPOs.

Response: Under the MMA we do not have the authority to establish regional licensure and solvency standards for regional PPO plans. Under the law, regional PPO plans must meet State licensure and solvency standards in each State in which they operate. We have added language to § 422.458(e)(1) to clarify that regional PPOs must be licensed in each State of the region, except during the period of the temporary waiver.

Comment: A commenter stated that even temporarily waiving State licensure without requiring applicants to satisfy certain minimum requirements could expose the MA program and beneficiaries to insecurity. Waiver of State licensure requirements based on a filing of an application for licensure does not constitute an assurance the organization has the essential capability necessary to operate a multistate PPO potentially serving thousands of beneficiaries. The commenter recommended that CMS establish minimum requirements, such as solvency standards, in addition to the filing of an application that a regional PPO applicant must satisfy before we even evaluates, or approves, a temporary wavier of State licensure. The commenter also recommended that any waiver be limited to 1 year from the date the waiver is granted. The commenter believes that a 1-year limit will promote stability and confidence in the MA program by terminating an unlicensed organization before their withdrawal causes disruption to beneficiaries.

Response: As we have previously discussed, we will grant a temporary State licensure waiver only in circumstances where the organization is State licensed in a least one State in the region and has submitted applications in the others. Under the waiver process, in those State(s) where it has a waiver, the organization will select the licensing rules of one State in the region and apply those rules to the States in which the organization has not met State licensure until the organization is licensed in all the States. We have made a technical change to the regulations at § 422.458(e)(2) to clarify this point. We expect that in most cases the State licensure waiver will be for less than a year. However, we will not specify the time limit, because the length of the waiver will depend on how quickly the State processes the PPO's licensure application. We note that all regional PPO plans entering the MA program (including those with a temporary State licensure waiver) must still be reviewed and approved by us and determined to be capable of meeting all regulatory requirements. We will not approve any MA plan that we have not confirmed through our application review process has the capacity to offer the proposed plan.

Stabilization Fund

Section 422.458(f) will implement the provisions in section 1858(e) of the Act providing for the creation of a Regional Stabilization Fund. The Congress has authorized an MA Regional Plan Stabilization Fund in order to promote greater stability in the regional program and provide us with a tool to respond to market fluctuations.

The Fund can be used to provide incentives for plan entry in each region, as well as for retaining plans that have already entered the market in MA regions with below average MA penetration. Initially, $10 billion will be available for expenditures from the Fund beginning on January 1, 2007, and these start-up funds will only be available until December 31, 2013. The Fund is designed to allow us to respond to market conditions on a temporary basis. If the Fund is used for either plan entry or retention for 2 consecutive years, we will report to the Congress on the underlying market conditions in the regions. These reports will give the Congress time to respond to the market conditions through changes to the regions or the underlying payment system.

The funds will be available in advance of appropriations to MA regional plans in accordance with specified funding limitations. The total amount projected to be expended may not exceed the amount available in the Fund as of the first day of that year. We will only obligate funds if our Chief Actuary, and the appropriate budget officer, certify that there are sufficient funds at the beginning of the year to cover all the obligations for that year. We will take steps to ensure that sufficient funds are available to make the payments for the entire year, which may include computing lower payment amounts or limitations on enrollment in MA regional plans receiving the payments. Expenditures from the Fund will first be made from amounts made available from the initial funding. We have made a change to § 422.458(f)(3)(ii) to conform the provision to our proposal as discussed in the August 2004 proposed rule.

Comment: Several commenters had concerns over the financial incentives made available to MA regional plans and asserted that these would disadvantage local plans by compromising their ability to compete with regional plans or the FFS Medicare program. To encourage the offering of all plan options, commenters recommended that local plans and others should also have access to these risk sharing arrangements. Several commenters proposed that CMS should use the demonstration authority to offer the same financial incentives to local plans as those offered to regional MA plans. Other commenters expressed their support for these incentives, and

asserted that these types of incentives would encourage MA regional plans to enter or re-enter certain markets.

Response: Financial incentives, such as the application of risk corridors and access to the stabilization fund, were designed to encourage new regional plans to enter the MA program and stay in the program over time. Section 1858 of the Act limits these incentives to only MA regional plans. As stated previously, regional plans are defined as those MA preferred provider organization plans available to all MA eligible individuals without regard to health status and are offered throughout the entire region. Because these incentives are provided for in the statute, we are unable to change the types of organizations that could receive them. It is important to note, that there are special provisions available only to local plans that MA regional plans do not have available, for example, the ability to choose the areas they cover, including specific counties and even partial counties, and they are not required to cover an entire region. Further, the MMA contemplated competition between plans so that beneficiaries will have greater choice of high-quality, low-cost regional and local plans. The statute specified the payment methodology for both local and regional plans. Additional responses to bidding and payment comments may be found in the preamble for subparts F and G.

Comment: One commenter stated that the stabilization fund discriminates against local plans because a portion of local plan savings would subsidize the regional plans.

Response: The commenter is incorrect. Seventy-five percent of the savings accrued when an MA plan bid falls below the benchmark, is rebated to the beneficiary in the form of extra benefits. For local plans, the remaining 25 percent of the difference between the bid and the benchmark returns to the Medicare Trust Funds. For regional plans, the remaining 25 percent of the difference is split: 12.5 percent of the difference returns to the Medicare Trust Funds, and 12.5 percent of the difference goes toward supplementing the stabilization fund.

6. Plan Entry Funding

At § 422.458(f), we make available plan entry incentives for either a 1-year national bonus payment or multi-year adjustments in regional payments (but not both). Funding will only be available for a single year, but more than one organization can receive the incentive in the same year.

As found in § 422.458(f)(4)(ii), the national bonus payment will be: (1) available to an organization only if it offers plans in every MA region; (2) available to all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and (3) equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization, subject to funding limitations.

If a national bonus payment is not made, a regional payment adjustment can be made. The regional payment adjustment is an increased payment for an MA regional plan offered in an MA region that did not have any MA regional plans offered in the previous year. The adjusted payment amount will be determined based solely on plans' bids in the region and that the adjusted payment amount be available to all plans offered in the region.

We did not receive any public comments on this section. We are implementing this section as proposed.

7. Regional Payment Adjustment

Subject to funding limitations, we will determine the period of time that funds are available for regional payment changes to encourage plan entry. If funding is provided for a second consecutive year under this provision, we will submit a report to the Congress describing the underlying market dynamics in the region and recommend changes to the payment methodology. Multi-year funding will be made available to all MA plans offered in a region, but if this multi-year increased amount is made available to MA plans in a region, funding will not be available for plan retention in the region in the following year.

We did not receive any public comments on this section. We are implementing this section as proposed.

8. Plan Retention Funding

In addition to using the Fund to encourage plans to enter regions that might otherwise go unserved, we may also use the fund to encourage plans to remain in regions if market conditions are causing plan withdrawals. At § 422.548(f)(5), incentives for plan retention could take the form of an increased payment to plans in regions that meet specific requirements.

We intend to use this provision to ensure that all MA organizations offering regional plans in a region receive appropriate incentives to remain in the region. As specified at § 422.548(f)(5)(ii), the payment will be an amount determined by the Secretary that does not exceed the greater of: (1) 3 percent of the benchmark amount applicable in the region; or (2) an amount that, when added to the benchmark, results in a ratio such that the additional amount plus the benchmark for the region divided by the adjusted average per capita cost (AAPCC) equals the weighted average of benchmarks for all regions divided by the AAPCC.

The payment would be available if: (1) one or more plans inform us that they are going to discontinue service in the region in the succeeding year; (2) we determine that if those plans were not offered, fewer than two MA organizations will be offering MA regional plans in the region in the year; (3) for the previous year, we determine that the proportion of beneficiaries enrolled in MA regional plans in the region is less than the national average of MA regional plan enrollment; and (4) funds have not already been awarded for 2 consecutive years.

We did not receive any public comments on this section. We are implementing this section as proposed.

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

1. Overview

Subpart K sets forth the provisions relating to the application procedures and contract determinations that are entered into by MA organizations including a description of terms that must be included in the contract, the duration of the contract, provisions regarding the nonrenewal or termination of a contract, and minimum enrollment, reporting, and prompt payment requirements of the MMA.

In this final rule, in order to make more clear the requirements for MA plans under part 422 and any additional requirements for MA plans offering a prescription drug benefit under part 423, we have amended section § 422.500 by revising the section heading to read ''Scope and definitions≥; designating the undesignated introductory text as paragraph (b) and adding the heading ''Definitions≥; and adding a new paragraph (a), ''Scope,'' which specifies the scope of the subpart K requirements.

We also incorporated the application requirements and evaluation and determination procedures from subpart A (§ 422.6 and § 422.8) into subpart K at newly redesignated § 422.501 and § 422.502, respectively. As a result we have revised the title of subpart K in this final rule to read as follows ''Application Procedures and Contracts for Medicare Advantage Organizations.''

In addition, we have eliminated the proposed § 422.502(b)(3)(iv)(G), regarding self-reporting requirements.

However, we have specified at § 422.503(b)(vi)(H), that MA-PDPs must follow the requirements in part 423 (the requirements for the Part D prescription drug benefit) concerning a comprehensive fraud and abuse plan. Note that the fraud and abuse requirement in part 423 applies only to the Part D prescription drug benefit offered by the MA organization. Please see our discussion of this requirement at section 4 of this preamble.

The MMA added a new section 1857(e)(3)(A) of the Act, which applies only to Federally Qualified Health Centers (FQHCs)and requires that the contract between CMS and MA organizations include a provision that any written arrangements between an MA organization and an FQHC include a level of payment that would be equal to what the MA organization would pay other providers for similar services. This requirement was codified at proposed § 422.527. We received two comments asking for some clarifications on the reimbursement of FQHCs which we do address here.

We also responded to commenters expressing concern that they would be unable to properly prepare for beneficiary enrollment if the contract process and the bid process were consecutive. Other commenters, for the same reason, asked that we streamline the application and contracting process. We welcomed these suggestions and have made changes accordingly, which we discuss below.

We made a number of technical and clarifying changes. In § 422.502(b)(1), for example, we clarified that the completion of an application is a condition necessary to contract as an MA organization, clarified the distinction between the contract and process for purposes of redeterminations at § 422.501(c)(2), and, at § 422.503(b)(4)(ii), § 422.503(b)(4)(vi)(F), § 422.503(b)(6) and § 422.503(b)(6)(i), made several terminology changes (for example, we changed ''terminated'' to ''non-renew''). We received 25 comments on subpart K. Below we summarize and respond to these comments. Please refer to the proposed rule for additional discussion of the specific provisions of the requirements we proposed for subpart K. Note that public comments on the proposed MA rule and the proposed rule establishing the prescription drug benefit under part 423 are often related and we draw on comments from both proposed rules for our responses here. These comments often lead to changes in both rules and we identify the changes affecting both rules, as appropriate. Because of the similarity of many aspects of both rules and the comments we received related to both we refer interested readers to our final rule establishing the prescription drug benefit.

2. Application Requirements (§ 422.501)

Comment: Several commenter submitted comments on the proposed regulation for MA organizations as well as the proposed rule establishing the Medicare prescription drug benefit asking CMS to make every effort to produce the final regulations as early as possible in January 2005, and to streamline our application process in a way that that does not increase administrative burden for MA plan applicants as well as, specifically, all Part D plan sponsors (which includes MA organizations offering a prescription drug benefit). Several commenters expressed concern that the contract and bid determination processes for MA organizations, as well as, more generally, sponsors of Part D plans, if occurring consecutively, would not leave enough time for plans to be ready for business by January 2006. The commenters requested that CMS permit the contract determination process to run concurrently with the bid application process (subpart F).

Response: We will permit contract applicants to enter into the bid determination process concurrently with the contracting process prior to the execution of a contract. The contract will be pre-qualified and left unsigned until a successful bid negotiation has been approved by us. We are also clarifying at § 422.501(c)(2) that these are distinct processes and, further, that determinations concerning the contract only are appealable under subpart N of part 422 (the bid application requirements are in subpart F). We have made other changes to streamline the contract application process including, for example, the elimination, as a requirement, of a separate notice of incomplete or missing application information which we had proposed in § 422.502(e). Additional ways that we will streamline the contract application process are included in § 422.502(a)(2). We made similar changes to the requirements of part 423. We discuss these and other changes below.

Comment: A commenter recommended that CMS confirm the scope of State licensure requirements that apply to entities offering MA PPO plans, as State licensing laws may restrict an HMO's ability to offer a PPO plan, and sought CMS' confirmation that a State licensed indemnity insurer authorized under State law to provide PDP coverage meets the definition of a Regional Plan provider.

Response: Section 422.400(c) is clear in saying that State law controls whether the MA organization is licensed or authorized to offer the type of MA plan it proposes to offer. As we explained in the preamble discussion in subpart A of the proposed rule, the fact that MA organizations offering local PPOs that are (or are not) licensed as HMOs is pertinent to the MA program solely for purposes of the application of quality improvement standards in section 1852(e) of the Act, and has no specific bearing on whether an MA organization has State authority to actually offer an HMO or PPO under the MA program. Whether an MA organization (licensed either as an HMO or otherwise) can offer a specific type of MA plan continues to rest upon State licensure or authority to offer such a type of MA plan.

3. Evaluation and Determination Procedures (§ 422.502)

Comment: One comment pointed to the differing timelines for evaluation and determination of applications set forth under the Medicare+ Choice rules (and now under MA plans) from those proposed for PDP Sponsors under Part D and requested clarification. Another commenter asked that CMS streamline its application process in a way that does not increase administrative burden for MA organizations wishing to apply to offer MA-PD plans or for other Part D plan sponsor applicants.

Response: We have modified the timeline for evaluation and determination of applications for both applicants to be MA organizations and PDP sponsors at § 422.502 (and made similar changes to the requirements of part 423 for other Part D plan sponsors). We believe that maintaining a single application and evaluation procedure and a single set of contract requirements for both MA and PDP programs brings simplicity, consistency, and reduced administrative burden for those entities that are managing both programs. If an application is determined to be both incomplete, and failing to meet requirements necessary to become an MA organization resulting in an intent to deny issuance, we will notify the applicant concurrently of both determinations. For a notice of intent to deny, based on an incomplete (for example, applicant already received an incompleteness notice and did not provide the required information) or non-responsive application, we will allow applicants 10 days to cure their application before issuing a denial notice, if still justified.

We remain committed to providing successful applicants a reasonable time to begin operations by the first of the year in their selected service area(s). We also want to ensure all potential applicants are given every chance to contract with us. In the event we determine that an application is incomplete, we afford a means for the applicant to ''cure'' the contract application. However, under the MMA with a bidding process added, and the absence of a ''rolling application'' program used under the M+C process, we needed to modify these determination timelines.

In order to respond to concerns that the determination application process as it was set up could compromise a plan's ability to effectively prepare for the beginning of a contract we are consolidating the proposed § 422.502 by removing paragraphs (e), (f), and (g). The change eliminates, as a separate and distinct step in the review process, notification that an application is incomplete. In the final rule, § 422.502 now provides that if an applicant's contract is submitted and found to be both incomplete, as well as unqualified (resulting in the issuance of an Intent to Deny Notice), the period to remedy the application will be 10 days from the date of the notice.

Also, in the final rule in § 422.502(c)(2)(ii), we are changing the amount of time that an applicant has to remedy an application after receiving an intent to deny notice from 60 days suggested in the proposed rule to 10 days. We believe this change is in accordance with the comments we have received to on both rules to streamline the process for each, bring the MA requirements under part 422 and the prescription drug benefit requirements under part 423 in to line, and to reduce confusion and administrative burden. Additionally, if after the initial review of the applications, we determine that an application is missing information necessary for us to make a determination we will attempt to notify the applicant that this is the case. This is not a requirement, however, and we are stating in the preamble of this final rule that applicants receiving notification that their application is incomplete but who have not yet received an intent to deny notice respond back to us with a cured application within two days of receiving the notice. The two days are thus a guide, but ultimately we are constrained by the total amount of time to review applications. As a result, an applicant that takes longer than two days to remedy its incomplete application, risks our issuing a notice of intent to deny before the applicant submits the requested information. We believe that the amount of time given to applicants to furnish information is a procedural rule that is not subject to notice and comment. In addition, applicants will still receive the same 10 days included in the proposed rule to revise their applications if they fail to respond within 2 days, and then receive an intent to deny notice from us.

As discussed above, we are making every effort to accommodate plans in the contract application process. We believe that the availability of choices will enhance opportunities to lower program costs. However, we must balance this goal with the need to ensure that only qualified plans are selected to contract with us.

With the exceptions noted, we are accepting the language from the proposed rule for this section.

4. General Provisions (§ 422.503).

Comment: In the proposed rule at § 422.503(b)(vi)(G)(2), CMS suggested that MA organizations include provisions that would require a MA organization to report misconduct it believes may violate various criminal, civil or administrative authorities. Numerous comments, both for and against, were received regarding these mandatory self-reporting of misconduct requirements. Most of the comments, however, objected that the rule as written was vague and overbroad, with no basis in statute. Other comments directed CMS to eliminate the proposal, stating that current compliance requirements were sufficient.

Response: In response to these comments, we are eliminating from this regulation an explicit requirement that MA organizations report to CMS violations of law, regulation, or other wrongdoing on the part of the organization or its employees/officers. While we are not requiring MA organizations to engage in mandatory self-reporting, we continue to believe that self-reporting of fraud and abuse is a critical element to an effective compliance plan; and we strongly encourage MA organizations to alert CMS, the OIG, or law enforcement of any potential fraud or misconduct relating to the Part D program. If after reasonable inquiry, the MA organization has determined that the misconduct has violated or may violate criminal, civil or administrative law, the MA organization should report the existence of the misconduct to the appropriate Government authority within a reasonable period, that is, within 60 days after the determination that a violation may have occurred.

The failure to disclose such conduct may result in adverse consequences to MA organizations, including criminal prosecution. For example, Title 42 U.S.C. Section 1320a–7b(a)(3) punishes as a felony the knowing failure to disclose an event affecting the initial or continued right to a benefit or payment under the Medicare program. The Federal civil False Claims Act, 31 U.S.C. Section 3729(a)(7) states that any person who knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, is liable to the United States for a civil penalty plus trebled restitution for the damages sustained by the government. In addition, both DOJ and the OIG have longstanding policies favoring self-disclosure.

As discussed earlier, we believe that establishing procedures to ensure prompt responses to potential fraud violations should be one of the elements in an effective compliance plan. While we are eliminating the mandatory self-reporting requirements, we expect all MA organizations offering a Part D plan to comply with the requirement for a comprehensive fraud and abuse plan as found under § 422.503(b)(4)(vi)(H). (Note: we are not reproducing our discussion on the fraud and abuse requirements here as this is a requirement specifically for MA organizations offering a prescription drug benefit. Please see our discussion in our final rule establishing the prescription drug benefit.) In summary, we have elected to recommend reporting fraud and abuse as part of the compliance plan as required as a condition of contracting as an MA organization. Plans that self-report violations will continue to receive the benefits of voluntary self-reporting found in the False Claims Act and Federal sentencing guidelines. In the future, we will examine mandatory self-reporting of health care fraud and abuse across all Medicare providers and contractors.

5. § 422.504 Contract Provisions

Comment: A commenter questioned the need for proposed § 422.504(h) which would require MA organizations to comply with certain specific Federal laws and rules, other laws applicable to recipients of Federal funds, and all other applicable laws and rules. The commenter argued that these requirements were on their face seemingly inconsistent with our regulatory provisions exempting Federal plans from procurement standards and preempting State laws other than those

relating to licensure. Furthermore, nothing suggests a rationale for naming some laws and not others. The same commenter also suggested that the provisions might more appropriately be replace with one focused on plans committing themselves to compliance with Federal standards aimed at preventing or ameliorating waste, fraud, and abuse.

Response: We agree that our efforts are best focused on requirements to prevent fraud, waste, and abuse and on issues that we are responsible for enforcing such as the HIPAA Administrative Simplification rules. We have, therefore, made the suggested changes to reflect this focus at § 422.504(h). These changes are in no way meant to imply that MA organizations need not comply with other Federal laws and regulations as applicable, only that the enforcement of these Federal laws and regulations is the responsibility of Federal agencies other than ours. We have made a similar change in the regulations establishing the prescription drug benefit program under part 423.

Comment: A commenter responding to our proposed rule establishing the prescription drug benefit under part 423 asked us to clarify whether the retention periods all refer to MA organizations offering Part D plans. Another commenter asked that our records retention policy for Part D plan sponsors parallel the statute of limitations that applies to the False Claims Act, that is, a maximum of 10 years from the time of the violation.

Response: We agree with the commenter that our retention requirements should more closely follow the statute of limitations that apply to the False Claims Act. And, in response to the other commenter, we are using this standard for retention requirements under both parts 422 and 423. As a result, in the final rule at § 422.504(e)(4), we are requiring that records be maintained for 10 years from the last contracting period or audit, whichever is latest, to conform to the statute of limitations for the discovery of violations under the False Claims Act.

We recognize that 10 years is the upper limit under the False Claims Act but we believe that this period will best enable us to have access to pertinent records should this be necessary. Also, the 10-year retention policy is in line with requirements concerning the prescription drug rebates under the Medicaid program (see 42 CFR 447.534(h)). We believe, as is the case with the Medicaid rule, that in order to ensure that we have the proper oversight for investigating the complex payment and other relationships associated with the delivery of prescription drugs under a program such as Part D, the 10-year retention requirement is necessary. We are making the change to parts 422 and 423 in order to maintain uniformity between requirements for MA organizations and other Part D sponsors. With the exception noted, we are accepting the language from the proposed for this section.

6. Prompt Payment by MA organization (§ 422.520)

Comment: A commenter recommended that we remove the distinction between contracted and non-contracted providers under § 422.520(a)(3) referring to prompt payment terms for non-contractors, fearing that we relinquish any authority to enforce prompt payment control for contracted providers. A commenter asked that the 60-day period for non-contracted providers to be paid be shortened to 30 days.

Response: In response to the first commenter, we do not believe it is necessary to add language concerning contract and non-contract providers. We believe that § 422.520(b)(2) makes it clear that the MA organization is obligated by the terms of its contract with the provider and that such a contract is the proper vehicle for any prompt payment terms.

In response to the second commenter, we believe that a limit of 60 calendar days strikes a reasonable balance by allowing time for the processing of payment without causing providers hardship.

Comment: We received comments asking that we include Independent Physicians Associations (IPAs) and Medical Groups under the prompt payment standards. Other suggestions included establishing timely payment requirement for capitations paid to IPAs and Medical groups; standards for documentation that should be included with capitation payments and/or deductions; establishment of a 90-day limit on an MA plan's ability to retroactively assign or terminate beneficiaries to or from a capitated IPA or Medical group; establishment of a time limit on how far back an MA plan is allowed to make a capitation deduction (not longer than 12 months; allow capitated IPA and medical groups to renegotiate their capitation rate if new benefits are by law and/or added by an MA plan; requiring MA plans to provide on a quarterly basis a detailed accounting of the status of any risk arrangements or risk pools(for example hospital, and pharmacy) in a mutually agreed to electronic format.

Response: Non-contracted IPAs and Medical Groups are already included in the prompt payment requirements in section 1857(f)(1) of the Act and in § 422.502. The billing ''agent'' or entity is immaterial. We have not specifically regulated the content of contracts between providers and MA organizations. We have long supported the notion that allowing the ''free'' market to determine the contractual terms, including payment amounts and timeliness, as well as related matters was best left to the interested parties (MA organizations and providers), who could best represent their own self-interest. While we support many of the items suggested and would support their inclusion in provider/MA organization contracts, we do not believe it is appropriate to require that they appear there.

We have adopted the language of the proposed rule in this final rule.

7. Agreements with Federally Qualified Health Centers (§ 422.527)

Comment: One commenter recommended that we add language clarifying under § 422.527(b) that payment in full to an FQHC does not preclude the FQHC from receiving the wrap-around payment provided by statute and in § 422.316.

Response: We agree with the commenter that we are responsible for the difference between what the MA plan pays to the FQHC and what its fee for service cost are, described above as a wrap-around. Our proposed language at § 422.527 concerned primarily the contract between CMS and the plan. However, in order to clarify how our payments to FQHCs are determined when a beneficiary in an MA plan receives treatment from an FQHC that has a written agreement with the MA organization offering the plan, we have revised § 422.527 of the final rule by adding new paragraph (c) to specify that financial incentives and withholds are not considered in determining the payments made under § 422.316(a).

Comment: The same commenter asked that we clarify that in the final rule that we will not include a financial incentives, ''such as risk pool payments, bonuses or withholds'' received by a FQHC from an MA—when determining payments made by CMS.

Response: In response to the commenter, we are clarifying in § 422.527(c) that financial incentives such as risk pool payments and bonuses as well as financial withholds are not considered in determining payments made to FQHCs by CMS. The language

at section 1833(a)(3)(B)(ii) of the Act, as added by section 237(a)(B)(ii) of the MMA, specifically excludes these financial incentives or withholds when determining the base amount used to be used in calculating payments by CMS.

With the exception of the changes noted, we are adopting the language of the proposed rule for this section.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

In the proposed rule, we indicated that we would study the modification of existing change of ownership (CHOW) provisions in order to reduce the administrative burden of these requirements and to increase the effectiveness of these provisions. In particular, we requested and received comments regarding situations which constitute a CHOW and how the CHOW provisions should be applied to large companies with multiple business units. These provisions are essentially the same as those requirements found in Title I subpart L for Prescription Drug Plan sponsors. Several commenters specifically requested that we maintain consistency between the provisions for subpart L in Title I and Title II.

After reviewing the comments that we received, we recognize that given the infinite variety of business arrangements and transactions it may be necessary to provide guidance via interpretive documents (for example, FAQs,) and on a case by case basis as to whether a given arrangement constitutes a CHOW and requires an entity to adhere to the CHOW requirements. Contracting organizations should be aware that although we are committed and sensitive to reducing the administrative burden on businesses with multiple legally related entities, we will be alert to situations where these organizations may be looking to avoid compliance with the CHOW provisions so as to evade Medicare liabilities and obligations.

In this final rule we note that contracted MA organizations must adhere to the Privacy Rule on sharing patient health information in the course of a CHOW and novation agreement. MA organizations are not permitted to share protected enrollee health information with a new owner that is not, or will not, become a covered entity absent authorization from its enrollees.

General Provisions (§ 422.550)

Comments: Two commenters requested that CMS clarify that the transfer of the MA line of business from one entity to another constitutes an asset transfer for which CMS will permit a novation agreement.

Response: We agree that the transfer of a MA line of business from one entity to another would constitute a CHOW, such that a novation agreement would be permitted and, in fact, required.

Comment: A commenter recommended that the change of ownership requirements under § 422.550 and § 422.552 exempt change of ownership transactions between two separate subsidiaries of the same parent corporation from the financial information, financial impact and novation agreement requirements of the CHOW provisions. Instead, the commenter suggested that such entities provide written certification detailing that a legally binding transfer of the MA obligations has occurred.

Response: We asked specifically for comments with regard to multiple business units so as to ensure that our rules reflect the realities of today's business world and are not unduly burdensome. While transactions between two subsidiaries of the same parent corporation may not in all cases constitute a CHOW, and, therefore, the business units would not need to adhere to the requirements of the CHOW provisions, we decline to create a separate certification procedure for such business units in the event that a CHOW does occur, as suggested by the commenter. Our ultimate responsibility is to the beneficiaries and objective is to ensure that an entity cannot under any circumstance evade its responsibilities to the Medicare program. What is relevant is whether the transaction leaves the same entity responsible for the MA contract and all inherent responsibilities remain unchanged. Any transfer of functions and/or assets that results in a change of the responsible party or parties for the MA contract must comply with the CHOW provisions under Subpart L.

Asset Sale (§ 422.550(a)(2))

Comment: Two commenters recommended that the title of the subparagraph identified as ''Asset sale,'' be revised to read ''Asset Transfer.''

Response: The suggestion has been adopted in the final regulation. In the proposed rule we were looking for comment on how to best characterize a CHOWs for those businesses with multiple business units, recognizing that a business would not always be selling its assets, but may sometimes simply be transferring a business asset.

Notice Period (§ 422.550(b))

Comments: Two commenters recommended that CMS consider extending the 60 day Notice period that MA organizations are required to provide before a change of ownership. The commenters stated that circumstances may arise when it is not possible to give such notice, for example, State approval pending, and a final determination date by the State is indefinite. Additionally, they recommended adding a good clause exception to the rule when such circumstances occur.

Response: The MMA was passed, in part, to encourage and ease MA plans into the new Medicare market place. Towards that end we will, on a case by case basis, have the flexibility to extend the 60 day notice period if a situation arises that warrants such an exception. We do not feel at this time we need to add a clause that specifies a good cause exception.

Subpart M—Grievances, Organization Determinations, and Appeals

1. Introduction

The MMA did not make any revisions to the statutory requirements in sections 1852(f) and (g) of the Act regarding MA grievances and appeals. Thus, we generally proposed to maintain the existing regulatory requirements in subpart M of part 422, with the inclusion of minor changes needed to conform these subpart regulations to MMA terminology and other provisions. We also reviewed the existing MA grievance and appeal requirements to identify needed refinements. Finally, we proposed changes to the part 417 regulations, which apply only to section 1876 cost contractors and section 1833 health care pre-payment plans (HCPPs) that would establish uniform grievance and appeal procedures for all Medicare managed care plans.

We received 30 comments on subpart M in response to the proposed rule. Below we summarize our proposals and respond to public comments. (For a detailed discussion on our proposals, please refer to the August 3, 2004 proposed rule. (69 FR 46,866, 46,909).

2. Background

Section 1852(f) of the Act provides that an MA organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any other entity or individual through which the organization provides health care services) and enrollees in its MA plans. Section 1852(g) of the Act addresses the procedural requirements concerning coverage (''organization'') determinations and reconsiderations and other appeals for MA organizations. Only disputes concerning ''organization

determinations'' are subject to the reconsideration and other appeal requirements under section 1852(g) of the Act.

In general, organization determinations involve whether an enrollee is entitled to receive a health service or the amount the enrollee is expected to pay for that service. All other disputes are subject to the grievance requirements under section 1852(f) of the Act. For purposes of this regulation, a reconsideration consists of a review of an adverse organization determination by either the MA organization itself or an independent review entity. We use the term ''appeal'' to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Medicare Appeals Council (MAC) and judicial review.

For the grievance, organization determination, and appeal requirements, an MA organization must establish procedures that satisfy these requirements with respect to each MA plan that it offers. These requirements generally are the same for all plan types —including coordinated care plans such as HMOs and PPOs, non-network MSA plans, and PFFS plans. However, note that for MA-PD plans, separate rules apply for drug benefits, as set forth under part 423, subpart M.

Sections 1833(a)(1)(A) and 1876(a)(5)(B) of the Act reference reasonable cost reimbursement contracts for HCPPs and HMO/CMPs. Section 1876(c)(5) of the Act sets forth the procedures HMO/CMP organizations must follow with regard to grievances, organization determinations, and appeals. Section 417.840 of our regulations requires HCPPs to apply the administrative review procedures set forth for HMO/CMPs. Section 1869 of the Act provides the right to a hearing and to judicial review for any individual dissatisfied with a determination regarding his or her Medicare benefits.

3. General Provisions, Grievances, and Organization Determinations (§ 422.560 through § 422.576)

Section 940(b)(2)(A) of MMA amended section 1852(g)(5) of the Act to incorporate the provisions of section 1869(b)(1)(E)(iii) of the Act, which also was added by MMA. This new clause provides for inflation adjustments to the ''amount in controversy'' required to pursue a hearing and judicial review. It makes these provisions applicable in determining the amount in controversy under section 1852(g)(5) of the Act ''in the same manner as they apply to the dollar amounts specified in section 1869(b)(1)(E)(i).'' Therefore, revisions to the provisions in section 1869 of the Act governing the calculation of the amount in controversy apply to MA appeals.

The existing MA regulations incorporate 42 CFR part 405, subparts G and H, and 20 CFR part 404, subparts J and R. Note that in an interim final rule we expect to publish shortly, we intend to create a new subpart I of part 405 to implement significant revisions to section 1869 of the Act. To accommodate these changes, we proposed minor changes to the cross-references for MA appeals at § 422.560(a)(3), § 422.561, and § 422.562 accordingly. We are finalizing these changes in this final rule. We note that under § 422.562(d), the provisions of part 405 apply to the extent that they are appropriate. This means, for example, that the provisions to implement the time and place for a hearing before an ALJ under section 1869 of the Act, if and when finalized, would apply to MA appeals. Thus, we have added a reference to § 422.602(b) that the time and place for a hearing before an ALJ will be set in accordance with § 405.1020. Although that section has not yet been published in final form, we expect that it will be published prior to the effective date of this rule. Readers may refer to 67 FR 69311, 69331 (Nov. 15, 2002) for an explanation of the proposals and a discussion of the possibility of using video-teleconferencing in ALJ hearings. On the other hand, the provisions that are dependent upon qualified independent contractors would not apply since an independent review entity conducts reconsiderations for MA appeals.

We also clarified the definitions of an authorized representative and an enrollee under § 422.561, which are consistent with part 405. We have removed ''authorized representative'' and replaced it with ''representative'' to clarify that a representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the appeal. Unless otherwise stated in this subpart, the representative will have all of the rights and responsibilities of an enrollee or party in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

In accordance with section 1852(g)(1) of the Act, § 422.566 begins by specifying that an MA organization must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive and the amount, if any, that an enrollee must pay for a health service. We clarified at proposed § 422.566(b)(4) that a reduction in services was an action that constituted an organization determination that an enrollee may appeal. Notice requirements would continue to apply whenever an enrollee disputed the reduction, under § 422.568(c).

Standard timeframes and notice requirements for organization determinations (§ 422.568)

The only substantive change we proposed in § 422.568 was the elimination of the practitioner's notice requirement set forth in § 422.568(c). This section required that at each patient encounter with an MA enrollee, a practitioner must notify the enrollee of his or her right to receive, upon request, a detailed written notice from the MA organization regarding any decision to deny services to an enrollee. Instead of requiring practitioners to provide general notices to enrollees at each patient encounter, we proposed instead to require MA organizations to provide specific written notice for MA organization denials. We believed that MA organizations could provide general information about enrollees' rights in physician office settings in the plan's Evidence of Coverage (EOC). Requiring practitioners to issue notices to enrollees has proven to be administratively burdensome and impossible to monitor.

We also proposed conforming changes to § 422.570(d)(2)(ii) and § 422.572(b) to require that an MA organization must inform an enrollee of the right to file an ''expedited'' grievance, if the enrollee disagrees with the MA organization's decision not to expedite a request for an expedited organization determination.

Timeframe and notice requirements for expedited organization determinations.

Under § 422.572(c), we proposed to eliminate the requirement that oral notice of an expedited determination be followed up with written confirmation in cases of fully favorable determinations. Notice would be required only for decisions that are fully or partly adverse to the enrollee, and thus could engender an appeal.

Comment: Several commenters supported the elimination of the practitioner's notice set forth in § 422.568(c). Some commenters agreed that the practitioner's notice was not a practical means of notifying enrollees of their appeal rights; they supported use of the EOC to provide information about enrollee rights in situations where

physicians make coverage determinations in their offices. One commenter contended that the practitioner's notice was burdensome for providers to deliver and in effect absolved plans of any accountability for their utilization review decisions.

Two commenters stated that the EOC was not a viable substitute for communicating appeals information to enrollees. The commenters believe that the EOC would not be as effective as a notice provided in a practitioner's office regarding how an enrollee could get a coverage determination from the plan. These commenters thought our proposal would disadvantage enrollees, because they do not routinely refer to the EOC. In lieu of the requirement to provide a written notice to each enrollee, one commenter recommended that CMS require practitioners to display posters in their offices to inform enrollees about their rights.

Response: In our view, the EOC is an appropriate alternative to requiring practitioners to deliver notices regarding enrollees' rights to receive coverage determinations from their plans. We believe that enrollees have a responsibility to refer to their EOC to obtain general information regarding coverage determinations. Furthermore, we believe that enrollees have relationships with their physicians built on trust, and enrollees often play an active role in the treatment decisions that affect them. Therefore, in the absence of a delegated arrangement, we are not placing the burden on practitioners to deliver notices to enrollees on their right to receive detailed coverage notices at each patient encounter.

We will work with MA organizations to ensure that the EOC contains information on an enrollee's right to receive a detailed explanation if he or she believes that a practitioner has denied care that the enrollee believes he or she is entitled to receive, or care the enrollee believes should continue. For these situations, the EOC will direct the enrollee to request an organization determination. We will also work with consumer advocates to determine other ways to educate enrollees about their rights.

Comment: Four commenters supported CMS' proposal to explicitly specify in § 422.566(b) that a reduction of services constitutes an organization determination that an enrollee may appeal.

Response: We believe that this approach essentially clarifies existing policy, under which a reduction in service is an appealable issue. Thus, if an enrollee disagrees with an MA organization's decision to reduce a course of treatment, the MA organization must consider the disputed reduction of service a new request for an organization determination. A request for a new organization determination allows the enrollee to receive notice, appeal rights, and access to the MA appeals system under § 422.570 and § 422.584.

4. Requests for Reconsiderations (§ 422.582)

The only substantive change we proposed regarding standard reconsiderations pertained to the manner in which a party to an organization determination would request an appeal. Proposed § 422.582(a)(1) and (a)(2) allowed a party to request a standard reconsideration orally or in writing. In addition, proposed § 422.584(e) required an MA organization to give notice in accordance with the broader provision of § 422.590, since there are notice requirements other than those contained in § 422.590(d).

As we proposed for expedited organization determinations under § 422.570(d)(2)(ii), proposed § 422.590(a) and § 422.590(d)(2) required an MA organization to inform an enrollee of the right to file an ''expedited'' grievance if the enrollee disagreed with the MA organization's decision not to expedite a request for an expedited reconsideration. This is a right that already was established under the grievance provision at § 422.564(d)(2) (re-codified under this final rule at § 422.564(f)(2)); thus, we needed to make a conforming change.

Comment: One commenter took exception to the expedited grievance process currently in § 422.564(d) (re-codified in this rule at § 422.564(f)), (and by extension, the conforming changes at proposed § § 422.570(d)(2)(ii) and 422.572(b)), arguing that this process was not beneficial because it allowed the same organization determination to be considered along two separate tracks simultaneously. The commenter stated that an MA enrollee has the right to request an expedited review of a plan's organization determination, and that the review is automatically granted if supported by a physician's assertion that the life or health of an enrollee would be adversely affected by a decision not to expedite the review. Thus, even without the benefit of an expedited grievance process, a decision would still be made by the plan (albeit in a longer period), and the enrollee would not be in jeopardy while waiting for the plan's decision. The commenter recommended that CMS delete this provision from the regulation in its entirety because, in the commenter's view, it is redundant and inefficient. It would also remove the need for conforming changes.

Response: We agree with the commenter that we should not create redundant processes. However, we do not believe that § 422.564(d) (now § 422.564(f)) is duplicative of the appeal procedures. An expedited grievance process provides important protections for enrollees who are unable or prefer not to obtain a physician's certification that applying the standard time frame would have adverse consequences for the enrollee. In addition, an MA plan could determine that it needs an extension to process a standard or expedited organization determination or reconsideration request. By allowing an expedited grievance to proceed under those circumstances, the decision about the grievance would not be the organization determination, but the plan's appropriate use of its discretion to extend the time frame. Thus, we specified at § 422.564(d) (now (f)) that an MA organization must notify the enrollee within 24 hours of receiving a grievance about the MA organization's refusal to expedite a review. Similarly, if an enrollee believes an MA organization's decision to invoke an extension to the organization determination or reconsideration time frames is incorrect, an expedited review would ensure that any inappropriate procedural actions under the appeals process are resolved and that the appeal proceeds without delay. Therefore, we are retaining the provision that in the current § 422.564(d) (now § 422.564(f)), and making the required conforming changes at § 422.570(d)(2)(ii) and § 422.572(b) as previously proposed.

Comment: A commenter supported CMS' decision to revise § 422.572(c) to no longer require MA organizations to provide written notice for fully favorable decisions. The commenter also recommended that the MA organization should communicate fully or partially favorable decisions to the provider, who would then notify the enrollee of the organization's decision.

Response: While we agree that the revision at § 422.572(c) will eliminate the unnecessary burden to issue written notices in cases of fully favorable decisions, we believe that written notifications remain appropriate for partially favorable decisions, which may result in appeals. Moreover, notwithstanding any arrangements an MA organization negotiates with its providers, the MA organization is ultimately responsible for ensuring that its decisions are communicated to

enrollees. We believe that decisions involving whether to initiate a service constitute the majority of an MA organization's communication with enrollees. Therefore, in the absence of a delegated arrangement, we do not believe that it is appropriate or practical to require all individuals or entities that provide health care services to give routine notices to a plan's enrollees.

Comment: Two commenters opposed CMS' proposed revision at § 422.582(a) that would allow a party to request a standard reconsideration orally or in writing. One commenter recommended that CMS delete the proposed provision because oral requests would increase the number of meritless reconsiderations and overburden the reconsideration process. The commenter believed that this provision would lead to confusion and undocumented assertions in the process. The commenter further believed that written requests ensure that MA organizations effectively and efficiently focus on an enrollee's ultimate issue. Additionally, the commenter noted that the MA organization would be required to reduce oral requests to writing, which would transfer the burden of generating a written request from the enrollee to the MA organization. If the provision for oral appeal requests is retained, the commenter recommended that they be allowed only in person. Another commenter believed that MA organizations would need guidance on how to process oral requests, particularly in the case of a request from a purported authorized representative. Finally, a commenter stated that CMS should not permit oral requests in order to be consistent with private sector regulatory requirements.

Response: Based on our review of the comments, we agree with the commenters that oral appeal requests could present problems for both MA organizations and the appealing parties, particularly when one individual attempts to translate an oral request into writing on behalf of another. We believe that an unintended consequence of our proposed change is the potential for essential information to get misconstrued. Thus, rather than requiring MA organizations to accept oral requests, we will continue to provide guidance on how an MA organization may choose to accept an oral request for reconsideration, and the steps it can take to validate the request. This will enable plans the flexibility to create such a process if they choose to do so. Therefore, we have revised the text at § 422.582(a) to reflect that an MA organization may adopt a policy under which it accepts oral requests for standard reconsiderations. We would expect that MA organizations would accept oral requests in instances where there is a clear and compelling reason to do so. An example of a clear and compelling reason to accept an oral request would be in the case of an illiterate or an incapacitated enrollee on the basis that they would not be able to request a reconsideration in writing.

5. Administrative Law Judge (ALJ) Hearings, Appeals to the Medicare Appeals Council, Judicial Review, and Provisions Affected by Part 405 (§ 422.600 through § 422.612)

Section 931 of the MMA requires that the ALJ hearing function now conducted by the Social Security Administration (SSA) be transferred to the Department of Health and Human Services by no later than October 1, 2005. In light of this impending change, we are revising § 422.582 and § 422.602 to eliminate any reference to SSA as a location for enrollees to file appeals. If an enrollee inadvertently files an appeal request with SSA after the transfer, its field offices will ensure that the request is transferred to the appropriate appeals entity. We have modified § 422.602(a) to require that a party must file a written request for an ALJ hearing with the entity specified in the independent review entity's (IRE's) reconsideration notice.

6. Noncoverage of Inpatient Hospital Care—Notice and QIO Review (§ 422.620 and § 422.622)

We proposed at § 422.620(b) to specify that an MA organization (or an entity delegated by the organization) must obtain the concurrence of the physician responsible for the enrollee's in-patient care before discharging an enrollee. This provision would clarify an omission in our April 4, 2003 final rule where we inadvertently failed to include a corresponding change that physician concurrence is necessary for discharging the enrollee rather than for issuing the notice. Therefore, an MA organization's obligation to provide a notice of non-coverage when an enrollee objects to a discharge would not be contingent upon a physician concurrence because the discharge decision already would have been made.

We also proposed to revise § 422.620(c) to require that if an MA organization lowers the enrollee's level of care in an inpatient hospital setting, for example, from acute to skilled, but the enrollee is not discharged from the facility, the MA organization must specify the enrollee's new level of care in the notice. This change would be consistent with § 422.620(a)(1)(ii), which requires the MA organization to provide a notice to the enrollee when it no longer intends to continue coverage of the inpatient hospital stay, but is not ''discharging'' the enrollee from the facility.

Comment: Several commenter recommended that CMS clarify that an enrollee's right to receive a notice of non-coverage is linked to physician concurrence to the extent that the physician must concur with the MA organization's decision to discharge the enrollee or change the enrollee's level of care. Several commenters continued to believe that an MA organization could not issue a notice without the physician's concurrence. One commenter thought that the propose rule suggested that it is the MA organization rather than the physician that ultimately discharges the enrollee. The commenter maintained that since a hospital cannot discharge an enrollee without physician concurrence, CMS should prohibit an MA organization from ending coverage without a physician's concurrence. Another commenter stated that the final rule should prevent MA organizations from shifting financial liability to hospitals without securing the attending physician's concurrence to discharge the enrollee.

One commenter stated that a benefit determination based on medical necessity guidelines to discontinue unnecessary inpatient coverage does not require physician concurrence. Another commenter thought that if physician concurrence were required to issue the notice of non-coverage, then enrollees would be unable to initiate the appeals process in a timely manner. This commenter recommended that CMS delete the entire provision and only require plans to issue a notice of non-coverage to the enrollee when it decides to no longer pay for acute care.

Another commenter, concerned about a hospitalized enrollee's reaction to receiving a notice of non-coverage from the MA organization, thought that CMS should withdraw the proposal, citing the trauma, confusion and stress to the enrollee. Instead, the commenter believed that the hospital staff familiar with the specific medical circumstances related to the enrollee's confinement should provide the notice.

Response: Medical guidelines alone cannot substitute for a physician's judgment about the medical condition of the patient under the physician's care. We agree with the commenters that physicians ultimately have the authority to discharge enrollees or change the level of care in hospital settings.

However, the MA organization is required to issue a notice of non-coverage if an enrollee objects to the discharge decision, or when an enrollee's level of care changes in an acute facility. Since the attending physician must agree to the discharge or the change in level of care, the MA organization can provide the notice without further physician involvement. Thus, we are merely clarifying under § 422.620(b) that a physician concurrence is required before discharging an individual or changing the level of care in an inpatient setting.

We disagree with the commenter that argued if a physician concurrence were required to issue the notice, then enrollees would be unable to initiate timely appeals. The timeframe for filing does not begin until the enrollee receives the notice. We further disagree that we should delete the entire provision at § 422.620 and only require plans to issue notices when they decide to no longer pay for acute care. If an enrollee disagrees with being discharged from the hospital, then the enrollee is entitled to a notice explaining his or her appeal rights under the law.

Finally, if an MA organization believes that its provision of the notice to an enrollee in an acute facility would create stress, trauma and confusion, then the MA organization has the option to delegate to the hospital the responsibility to provide the notice of non-coverage on behalf of the MA organization.

Advance Beneficiary Notices in the MA Program

In the August 3, 2004 proposed rule, we solicited comments on whether to permit or require network and non-network providers to furnish enrollees advance beneficiary notices (ABNs) when they access non-Medicare covered services, or when they face potential liability for out of network services that would be otherwise payable by the MA plan if proper referral were obtained.

Comment: Several commenters vehemently opposed requiring providers to furnish ABNs to enrollees who wish to obtain non-Medicare covered services. They stated that CMS could not enforce any requirements on non-network providers to advise enrollees of potential liability. The commenters believed that ABNs would be burdensome for physicians, providers and MA organizations, and could lead to delays in care for enrollees. Another commenter stated that CMS, instead, should educate providers about their responsibility to contact the MA organization when enrollees seek out of network or non-Medicare covered services.

Several commenters stated that ABNs in original Medicare have inherent problems, such as providers that issue blanket ABNs, which then become meaningless to the enrollee. A commenter noted that although the ABN was only a one-page document, there were 30 pages of instructions for the provider to complete the form, thus the use of ABNs would be confusing.

One commenter indicated that it was premature to propose the use of ABNs in managed care. Instead, CMS should establish a database with information, so that physicians could have access to coverage information for each plan. Otherwise, it would be too burdensome for physicians to know the different benefits and coverage of each plan. The commenter further recommended that if CMS determined that ABNs were necessary, then we should ensure that MA organizations provide clear information to physicians' offices on the appropriate use of ABNs.

Another commenter recommended that CMS should allow providers to issue ABNs only after they have requested and received an adverse organization determination from the MA organization. If an enrollee waived the right to have the provider request an organization determination, nothing would preclude the enrollee from appealing the MA organization's denial for the service.

Other commenters, however, were in favor of CMS allowing the use of ABNs in managed care. One commenter reported that not all providers of MA organizations have contracted networks, and even among those that do, enrollees still utilize non-network providers. The commenter stated that the MA organization could be unaware that the enrollee received any services until he or she presents a claim. ABNs would inform enrollees about potential costs at the time the enrollee seeks services, thereby providing protection from unintended liability. Another commenter thought ABNs should be required when enrollees access non-Medicare covered services, and that an out of network provider should be required to get an organization determination prior to providing services.

Response: We will continue to study this issue and will pursue subsequent notice and comment rulemaking before implementing any standard use of ABNs under the MA program. In addition, we will work with interested parties to determine how best to educate enrollees and providers on financial liability matters, including the possibility of permitting optional use of an ABN-like notice.

8. Appeal Procedures for Cost Plans and HCPPs.

We proposed under § 417.600(b) that the same rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to organizations offering Medicare cost plans. In proposing this change, we took into account that a key difference between cost plans and MA plans is that virtually all organizations offering cost plans employ a billing option available under § 417.532(c)(1) that reduces a cost plan's financial liability for certain Medicare-covered services. Under this billing methodology, hospitals and SNFs that furnish services to cost plan members can obtain direct reimbursement from Medicare fiscal intermediaries for these services. For services paid for under this methodology, the claims appeal procedures available under original Medicare regulations in part 405 would be the appropriate recourse when a Medicare fiscal intermediary denies a claim. However, for other services, including any service or payment denial resulting from an organization determination under a cost plan, as defined in § 417.606, enrollees would appeal through the cost plan's appeals process. The plan's appeal procedures would also apply in the rare situation when a fiscal intermediary approved a claim for hospital or SNF services, but the cost plan refused to pay the covered portion of the enrollee's cost sharing associated with the services.

As noted above, the cost plan appeals process would follow the same rules that apply to MA organizations, as set forth in subpart M of part 422. Although the appeal procedures set forth in part 417 and part 422 are largely similar, it is important to note that the part 422 grievance provisions and recent changes to the notice and appeal requirements for inpatient hospital, SNF, home health agency (HHA) and comprehensive outpatient rehabilitation facility services would apply to cost plans for the first time. These changes primarily involve § 422.564, § 422.620, § 422.622, § 422.624 and § 422.626 which were set forth in the April 4, 2003 final rule, Improvements to the Medicare+Choice Appeals and Grievance Procedures.'' (See 68 FR 16,652). The effect of those changes would be that plans would have more specific guidelines for processing grievances, and enrollees would be entitled to the same notice and appeal rights in cases of terminations of Medicare services

furnished by hospitals, SNFs, HHAs and CORFs.

Comment: Commenters generally supported CMS' proposal to require cost plans and HCPPs to follow the Medicare Advantage grievance and appeal requirements, particularly in light of the unique billing arrangement utilized by the majority of cost plans. One commenter stated that CMS should reflect in its final rule that cost plans may elect billing option one, a payment methodology where a fiscal intermediary pays certain Part A services instead of the cost plan. Another commenter wanted CMS to make sure that the cost plan's appeals process would apply in the unusual circumstance where a fiscal intermediary approved a claim, but the cost plan denied payment of the enrollee's cost sharing portion. Other commenters wanted CMS to allow sufficient time for cost plans that do not have MA experience to transition to the MA rules. Some commenters recommended an effective date of January 2006. Another commenter requested that the transition to MA rules apply as of the first day of the contract year following publication of the final rule.

Response: We did not receive any comments on the applicability of the notice and appeal requirements to cost plans when Medicare services end in SNFs, HHAs and CORFs, under § 422.624 and § 422.626. Nevertheless, we agree with the commenters that there should be one managed care appeals process for all plan types. As proposed, all part 422 rules now apply to cost plans and HCPPs. Thus, we have deleted all part 417 grievance, organization determination, and appeal provisions, and replaced them with § 417.600(b) and § 417.840 to require cost plans and HCPPs to apply the MA procedures under part 422, subpart M. Additionally, we have made a conforming change to § 417.832(c) dealing with representation of parties, and added a new provision at § 417.832(d) dealing with administrative law judge hearings, Medicare Appeals Council review, and judicial review that references part 405, as applicable to those provisions. However, for those cost plans that elect to bill under original Medicare, any denied claim by the fiscal intermediary or carrier must be subject to the appeals process under original Medicare. We also agree that if a plan denies payment of an enrollee's cost sharing amount, then the enrollee must file an appeal under the MA appeal procedures.

As recommended by commenters, we will require that cost plans and HCPPs must transition to the MA grievance and appeals processes under part 422 no later than January 1, 2006. This should give plans, providers and original Medicare contractors an ample opportunity to make a seamless transition.

9. Federal Preemption of Grievances and Appeals

Section 232(a) of the MMA changes the presumption from one in which State laws are not preempted unless they conflict with Federal laws or fall into specified categories to one in which State standards are presumed preempted unless they are licensing or solvency laws. In light of the comprehensive nature of the appeals process already established, we did not believe that the new preemption standard would have any effect on coverage appeals provisions. Our regulations would continue to defer to State law on the issue of authorized representatives of enrollees in the organization determination, grievance and appeals processes. We were concerned, however, with State grievance requirements now preempted, and believed that we needed to reexamine our Federal grievance requirements. Therefore, we solicited comments on whether we should adopt the grievance provisions proposed in our January 24, 2001 proposed rule that would require MA organizations to establish notice and timeliness procedures. (See 66 FR 7593.) Alternatively, we asked whether we should impose, as a Federal MA requirement, that MA organizations meet State grievance requirements.

Comment: Most commenters, including both those representing MA organizations and consumers, favored adopting the specific grievance requirements first proposed in the January 2001 proposed rule. They indicated that establishing national standards would eliminate confusion for plans, particularly regional PPOs, and protect beneficiary interests. They indicated that plans should not be subject to multiple and conflicting State laws governing grievances. One commenter generally supported the grievance rules but recommended that CMS make two changes. The first modification would be that MA organizations must process grievances ''as expeditiously as the enrollee's health requires, but no later than 60 days.'' The second change would prohibit plans from taking extensions to the timeframes.

Two commenters thought that CMS should not only require the originally proposed standards for grievances, but also require plans to adhere to individual State grievance processes as well. One of the commenters believed that requiring plans to follow State processes would restore the status quo before enactment of MMA, while the other commenter thought that beneficiaries would have better protections by having access to both Federal and State grievance procedures.

Response: We agree with the commenters that establishing a uniform set of grievance standards would reduce confusion and burden for MA organizations. We also believe that one set of rules will ensure greater beneficiary understanding of their grievance rights and achieve consistency among plan operations. Thus, we are implementing at § 422.564 the specific Federal requirements for grievance procedures that basically mirror those set forth in our January 2001 proposed rule. We disagree with the commenter that MA organizations should be required to follow both State and Federal grievance processes. We believe that such an approach would be inconsistent with section 232(a) of the MMA, which preempts State grievance requirements.

Under MA grievance requirements, organizations must notify enrollees of decisions as expeditiously as the enrollee's case requires, but no later than 30 calendar days after receiving a complaint. MA organizations may extend the timeframe by up to 14 calendar days if the enrollee requests the extension, or if the organization justifies a need for additional information and the delay is in the interest of the enrollee. We believe that the timeframes should be according to the enrollee's case as opposed to the enrollee's health since not all grievances involve medical care. For example, an enrollee may complain that a network physician does not offer convenient hours for office visits. In addition, we believe that most MA organizations will be able to respond to most grievances within 30 days. Even if an MA organization needs to extend the timeframe, we believe that a 60-day standard is too long for an MA organization to respond to an enrollee's grievance.

If an enrollee makes a grievance orally, the MA organization may respond to it orally or in writing, unless the enrollee requests a written response. If an enrollee files a written grievance, then the MA organization must respond in writing. In addition, an MA organization must provide information to enrollees on their right to request a review by a Quality Improvement Organization (QIO) if the grievance

involves a quality of care issue. For any complaint involving a QIO, the MA organization must comply with the requirement at § 422.564(c), and cooperate with the QIO in resolving the complaint. MA organizations must establish a 72–hour expedited grievance process for complaints involving certain procedural matters in the appeals process. Finally, MA organizations must create a system to track and maintain records on all grievances.

We note that under MMA, enrollees would still have access to various State remedies available in cases in which an issue is unrelated to the MA organization's status as a health plan. As noted above, cost plans and HCPPs must follow the grievance, organization determination and appeal procedures under MA. However, general preemption rules continue to apply to cost plans and HCPPs.

10. Employer Sponsored Benefits and Appeals

When an employer, by contracting with an MA plan, provides health benefits in addition to those covered under Part C of Title XVIII of the Social Security Act to their retirees, such employer may have established a group health plan governed by both title I of the Employee Retirement Income Security Act of 1974 (ERISA), as amended, and State law (to the extent such State law is not preempted by ERISA). In addition, when MA plans offer benefits covered under Part C, they also fall under the requirements of part 422 with respect to Part C benefits. Therefore, we solicited comments on whether, and to what extent, the application of parallel appeal procedures in this context might be a problem for plans, employers and/or eligible individuals.

Comment: Almost all commenters supported utilizing only the MA procedures for claims involving integrated ERISA and MA benefits. One commenter noted that enrollees probably do not distinguish between ERISA and CMS approved benefits when they are integrated, and therefore, a single appeals process would be less confusing. Another commenter agreed, recommending that to the extent any benefits received by an individual are part of an underlying MA, MA-PD, or PDP group plan, including benefits separately negotiated between the MA, MA-PD or PDP organization and an employer or labor organization, those benefits should be governed by the MA or PDP regulations on grievances, organization determinations, and appeals rather than subjecting the beneficiary to two separate processes. Commenters also noted that although the ERISA and MA rules contain some differences, they generally provide similar enrollee protections.

Three commenters agreed that adopting and applying a single, uniform MA appeals process for all benefits would be easier for the enrollee to understand. Other commenters stated that parallel appeal processes for enrollees with Medicare and ERISA benefits were costly, redundant, and burdensome to administer, with the potential for conflicting determinations. Only one commenter promoted a continuation of parallel appeal procedures, but only to the extent that parallel procedures afforded enrollees with more protection than would be available in the absence of parallel procedures.

One commenter argued that the benefits under the two separate programs must be adjudicated according to the rules for each program. The commenter stated that it was not clear whether the outcome of a CMS decision would preclude an enrollee from filing an ERISA appeal, and that a decision made by CMS could affect the need for appeal under ERISA when the ERISA plan had secondary payer status. The commenter added that given that the benefits provided to the Medicare beneficiary in this instance involve two different laws, there is no statutory authority for us to adjudicate appeals relating to an ERISA plan, just as there is no statutory authority for the DOL to adjudicate appeals relating to Medicare benefits. This commenter recommended that DOL and CMS work together to develop a process that would allow the plan sponsor of a retiree health plan to delegate its authority for appeals to the same entity considering Medicare appeals, provided that DOL is satisfied that this process would satisfy ERISA claims and appeal procedures.

Response: After reviewing the public comment and conferring with representatives of DOL, we have concluded that changes (not only to the CMS regulations but also to the DOL regulations) are needed to properly address this issue. Accordingly, we have added § 422.560(c), which is intended to give ERISA plans the option, according to regulations of the Secretary of Labor, of electing the MA process rather than the procedures under 29 CFR § 2560.503–1 for claims involving supplemental benefits provided by contract with an MA organization. In this regard, DOL has agreed to work with CMS to develop such regulations. The language in § 422.560 is intended to demonstrate our commitment to make the entire MA process available in this context. The provision in § 422.560 would not take effect in the absence of regulations by the Secretary of Labor.

Subpart N. Medicare Contract Determinations and Appeals

1. Overview

Subpart N ''Medicare Contract Determinations and Appeals'' went into effect under Part C of Title XVIII, and as such was not part of the proposals in the proposed rule of August 3, 2004. However, we found that we needed to make a change to the requirements under Title II subpart N.

Section 1860D–12(b)(3)(F) of the Act directs that the ''procedures for termination'' in section 1857(h) of the Act be incorporated into requirements for PDP sponsors. Therefore, we proposed under Title I that a single set of procedures relating to contract determinations and appeals would apply to both MA organizations and PDP sponsor contractors and that the requirements in § 423.641 through § 423.669 (applicable to PDP sponsors) would mirror the requirements at § 422.641 through § 422.698 for the MA program. We asked for comments on this proposal and did not receive any negative comments. Whenever practicable the regulations mirror each other. We assume that commenters believed that it should be simpler to adhere to a uniform set of contract requirements.

We found that in order to maintain one set of contract requirements—and be responsive to commenters asking for a streamlined application process and a single timeline—we needed to add a cutoff date to the contract determination process under subpart N. This new rule clarifies the timeline for valid contracts, in the event of a redetermination, and we have added this provision at § 422.654(c). This provision specifies that in the case of a favorable redetermination, including favorable decisions as the result of a hearing or Administrative review, that such determinations be made by July 15 for the contract in question to be effective on January of the following year. We have made a corresponding change to the PDP sponsor regulations by adding § 423.647(c).

Subpart O—Intermediate Sanctions

In the proposed rule, we proposed a technical correction to § 422.752(a)(8). The word ''entity'' was inadvertently left out of the regulations text of that amendment. We proposed revising paragraph (a)(8) to read ''[e]mploys or contracts with an individual or entity who is excluded from participation in

Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an individual or entity) for the provision of any of the following.'' We did not receive any comments on these clarifications and will adopt them in this final rule.

We note that while we did not propose other changes to the requirements at § 422.750 through § 422.760, an interim final rule with comment period was issued at the end of December, 2004 to correct technical errors in the regulatory text made in a final rule for MA plans that was issued on August 22, 2003 and that was entitled ''Modifications to Medicare Rules'' (68 FR 50840).

In addition, in the course of reviewing and responding to comments that we received regarding the corresponding regulatory provisions for Title I and the Part D program, we discovered that while we did not need to propose changes to the substance of the regulatory provisions, we needed to make certain revisions to the regulatory text at this subpart in the interests of clarity and accuracy. We are, therefore, making the following changes in this final rule:

At § 422.752(b), we are deleting the references to § 422.756(c)(1) and (c)(3) that are listed under procedures for imposing sanctions. We are replacing them with references to § 422.750(a)(2) and (a)(4). The purpose of this correction is to include a reference to the provision that details the kinds of sanctions that we may impose, rather than the provision that details the procedures for imposing sanctions.

At § 422.752(a) we clarified our authority to impose more than one sanction at a time by deleting the word ''any'' and replacing it with the phrase ''one, or more''. Therefore, § 422.752(a) will now read as follows: ''All intermediate sanctions. For the violations listed in this paragraph (a), we will impose one, or more, of the sanctions. . .''

Also, at § 422.752(a)(8) we have added the word ''excluded'' to the parenthetical clause in the interest of clarity. The parenthetical will now read, ''or with an entity that employs or contracts with an excluded individual or entity.''

At § 422.756(f)(2) a reference to ''part 1005 of this chapter'' was incorrect and we have replaced with a reference to ''part 1003 of this chapter,'' since part 1003 is the correct reference to the OIG procedures for imposing sanctions whereas part 1005 includes the appeal procedures for sanctions.

At § 422.756(f)(3) we have deleted the clause ''in accordance with the provisions of part 1005 of this chapter'' of this chapter. Since this subparagraph discusses our authority to impose CMPs, as opposed to the OIG's authority, we realized that this reference was incorrect.

At § 422.758, in the introduction and at paragraph (c), we made some editorial changes to better clarify the basis for civil money penalties issued by CMS.

IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the proposed rule. Those provisions of this final rule that differ from the proposed rule are as follows:

Effective Date of Initial Regulations (§ 417.402)

In paragraph (c)(2) we have added the word ''calendar'' prior to ''year'' to clarify our intent.

Applicability of Requirements and Procedures (§ 417.832)

We have made a conforming change to paragraph (c) of § 417.832 to reflect that the provisions of subpart I of part 405 dealing with the representation of parties apply to organization determinations and appeals.

We have added a new paragraph (d) at § 417.832 to indicate that the provisions of subpart I of part 405 dealing with administrative law judge hearings, Medicare Appeals Council review, and judicial review are applicable, unless otherwise provided.

Definitions (§ 422.2)

We have amended the definitions of ''prescription drug plan (PDP)'' and ''Prescription drug plan (PDP) sponsor'' to make them consistent with the Medicare Prescription Drug Benefit Program proposed rule.

We have revised the definition of ''service area'' to clarify that CMS may consider whether a contracting provider network meets the access and availability standards set forth in § 422.112 for all MA coordinated care plans and network MA MSA plans.

We have clarified the definition of ''institutionalized'' for the purpose of SNPs to provide information on what is meant by a long term care facility (SNFs, ICF, ICF/MR and Inpatient Psychiatric hospitals). We have also expanded the definition to include a special needs individual who is expected to reside in a long-term care facility for 90-days or longer based on as assessment of the potential for such a stay as long as the assessment is of a type approved by CMS .

We have defined a SNP that enrolls a disproportionate percentage of special needs individuals as one that enrolls a greater proportion of the target group than occur nationally in the Medicare population.

We have included in its definition that a SNP is required to provide Part D coverage.

We further clarified the definition of a SNP as a plan that has been designated by CMS as meeting the requirements of a MA SNP for institutionalized or dual eligible individuals or those individuals with a severe or disabling chronic condition as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population

Additionally, we have added a technical amendment to correct the term ''Religious and Fraternal Benefit (RFB) Society'' to read ''Religious Fraternal Benefit (RFB) Society''.

Types of Plans (§ 422.4)

We have amended paragraph (a)(1)(iv) to clarify the types of MA plans and Part D prescription drug coverage.

We have also added a new paragraph (c) regarding rules for MA plans' Part D coverage. This paragraph clarifies the requirements for MA coordinated care plans, MA MSAs, and MA PFFS plans. In addition, a new paragraph (c)(2) states the MSAs cannot offer drug coverage, other than that required under Parts A and B of Title XVIII of the Act. Finally, in paragraph (c)(3), we have added language that MA organizations offering private fee for service plans can choose to offer qualified Part D coverage meeting the requirements in § 423.104.

Eligibility to Elect an MA Plan (§ 422.50)

In § 422.50, we have added a new paragraph (a)(2)(iii) to allow SNPs to serve ESRD individuals.

We have amended paragraph (a)(5) to provide that beneficiaries may make elections by completing an enrollment form by completing another CMS approved election mechanism offered by the MA organization.

Coordination of Enrollment and Disenrollment through MA Organizations (§ 422.66)

We have revised § 422.66(d)(5) to allow us to offer, as an option in the future, the ability of an MA plan to process a ''seamless'' enrollment upon an individual's entitlement to Medicare.

Disenrollment by the MA Organization (§ 422.74)

We have added a new paragraph (b)(2)(iv) to show that in certain cases, loss of special needs status is a basis for required disenrollment from a SNP that enrolls only special needs individuals.

We have amended paragraph (d)(1)(i) by adding paragraphs (d)(1)(i)(A), (B), and (C) to clarify what ''reasonable efforts'' to collect unpaid premiums must be taken in prior to the disenrollment of an individual from an MA plan.

We have revised the definition of ''disruptive behavior'' in paragraph (d)(2)(i) to focus on the behavior that substantially impairs the plan's ability to arrange or provide care for the individual or other plan members.

We have added a new paragraph (d)(2)(ii) ''Basis of disenrollment for disruptive behavior.

We have amended paragraph (d)(2)(iii) to require the MA organization to provide reasonable accommodations for individuals with mental or cognitive conditions.

We have amended paragraph (d)(2)(iv) ''Documentation'' to provide an MA organization the option to decline future enrollment of an individual who has been disenrolled for disruptive behavior.

We have revised proposed paragraph (d)(2)(v) ''CMS review of the proposed disenrollment'' to also require MA organizations to provide a ''reasonable accommodation'' to individuals in exceptional circumstances.

We have removed proposed paragraph (d)(2)(vi) ''Reenrollment in the MA organization'' and paragraph (d)(2)(vii) ''Expedited process''.

Requirements Related to Basic Benefits (§ 422.101)

We have revised paragraph (b)(4) to clarify its intent.

We have added a new paragraph (b)(5) to require MA organizations that elect to apply local coverage policies uniformly across a local MA plan's service area, or across an MA regional plan's service area, to inform enrollees and potential providers of the applicable local coverage policy that applies to the MA plan enrollees.

We have modified § 422.101(d)(4) to indicate that notification to providers, as well as members, of enrollee status related to a deductible (if any) and catastrophic caps is required.

Special Rules for Self-Referral and Point of Service Option (§ 422.105)

We have renamed the title of this section and reorganized the section in order to clarify its scope and applicability.

Coordination of Benefits with Employer or Union Group Health Plans and Medicaid (§ 422.106)

We have modified § 422.106 to clarify the intent.

Disclosure Requirements (§ 422.111)

To be consistent with language elsewhere in this regulation, we have added a conforming amendment, revising paragraph (b)(9) to change references to ''Quality assurance program'' to ''Quality improvement program.

We have amended paragraph (e) by reinserting the word ''written'', as its removal was unintentional.

We have corrected the language in § 422.111(f)(10) to clarify our initial intent.

We have added a requirement at § 422.111(f)(11) requiring all MA organizations to make uniform coverage policies related to an MA plan readily available to members and providers, including through the Internet.

We have also added a new paragraph (f)(12) requiring MA organizations that have Internet web-sites to post the Evidence of Coverage, the Summary of Benefits, and information on the network of contracted providers.

Access to Service (§ 422.112)

In paragraph (a) introductory text, we removed obsolete terminology from both heading and introductory text.

We have revised paragraph (b) introductory text related to ''continuity of care.''

We have removed the instructions that would have removed paragraph (b)(4)(i) and redesignated paragraphs (b)(4)(ii) and (b)(4)(iii). The inclusion of this amendment in the proposed rule was an error.

We have amended paragraph (c) introductory text by adding ''noncontracting'' before ''hospital''.

We have amended paragraph (c)(1) to clarify the types of hospitals that are eligible to be designated an ''essential hospital''.

We have amended paragraph (c)(3) to clarify ''good faith''.

We have added a new paragraph (c)(4) in order to include ''competition text'' in regulation, where no MA organization will be permitted to designate a hospital as an ''essential hospital'' where there is a ''competing hospital'' in the area.

We have added a new paragraph (c)(7), under which we will evaluate the continued applicability of ''essential hospital'' status on an annual basis at the time of annual contract renewal.

Compliance Deemed on the Basis of Accreditation (§ 422.156)

We revised paragraph (b)(1) to change the term ''Quality assurance Program'' to ''Quality improvement program'', in order to be consistent with changes elsewhere in this regulation.

Terminology (§ 422.252)

We have made a clarifying change to the definition of MA local area to be consistent with the intent of § 422.308.

Submission of Bids (§ 422.254)

We amended paragraph (a)(1) by adding ''and, for plans with rebates as described at § 422.266(a), the MA organization must provide the information required in paragraph (d) of this section.''

We have added a new paragraph (a)(3), to retain language from the current MA regulations at § 422.306(a)(2), which says if the bid submission is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

We have revised paragraph revise (b)(2) to read ''as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act'' to track the statutory language.

We have amended paragraph (b)(3) by removing the proposed sentence stating that plan assumptions about revenue requirements must include adjustments for the utilization effects of cost sharing reductions.

We have revised paragraph (b)(4) to conform the regulation to the statutory provision.

We have made a clarifying change to paragraph (c)(5) to reflect the statutory requirement that in the bid submission, MA organizations provide the actuarial bases for determining the amount of cost sharing for a plan.

We have added a new paragraph (c)(9) to address information requirements resulting from our policy decision on the geographic ISAR adjustment, presented in the G preamble discussion of § 422.308(d).

We have added paragraph (f) to clarify that separate bids must be submitted for Part A and Part B enrollees and Part B-only enrollees for each MA employer group health plan offered.

Review, Negotiation, and Approval of Bids (§ 422.256)

We have amended paragraph (b)(2) for clarity and to better reflect the statutory language on standards of bid review.

Calculations of Benchmarks (§ 422.258)

We have corrected paragraph (c)(4) to clarify the plan-bid component of the regional benchmark is calculated based only on regional plan bids, not an all of the MA plan bids in the region.

We made an additional change to the proposed paragraph (c)(5)(i) to clarify further how the plan bid component of the regional benchmark will be calculated.

Calculation of Beneficiary Premiums (§ 422.262)

We have amended paragraph (f)(1) to add the Railroad Retirement Board and the Office of Personnel Management.

We consolidate paragraphs (f)(3) and (f)(4) to clarify that the other methods CMS may specify for payment of premiums include those listed in the regulation.

Calculation of Savings (§ 422.264)

We have amended paragraphs (c) and (e) to more accurately reflect the policy that for both local and regional MA plans, the calculation of savings will be determined by applying the plan average risk adjustment factor to the basic A/B bid and benchmark, although we have left in regulation the statutorily mandated discretion for CMS to select a method for calculating savings.

Beneficiary Rebates (§ 422.266)

We have changed the language in paragraph (b)(1) to clarify that rebate dollars may be used to reduce the premium for either the non-drug or drug portions of the supplemental benefit. We also add language clarifying that plans must distinguish the amount of rebate applied to enhance original Medicare benefits from the rebate applied to enhance Part D benefits.

We have amended paragraph (c) by adding ''MA organizations must distinguish, for each MA plan, the amount of rebate applied to enhance original Medicare benefits fro the amount of rebate applies to enhance Part D benefits.''

Adjustments to Capitation Rates, Benchmarks, Bids, and Payments (§ 422.308)

We have amended the language in paragraph (e) to refer to the adjustment as the ''government premium adjustment,'' in order to distinguish it from other payment adjustments under the MMA.

Risk Adjustment Data (§ 422.310)

We have modified § 422.310(e) to indicate that there may be penalties for submission of false data under the requirement for validation of risk adjustment data.

Special Rules for Payments to Federally Qualified Health Centers (§ 422.316)

We have amended (a) to clarify what amount CMS will pay an FQHC by adding ''less the amount the FQHC would receive for the MA enrollee from the MA organization and taking into account the cost sharing amount paid by the enrollee.''

Moratorium on New Local Preferred Provider Organization Plans (§ 442.451)

We have revised this section to better reflect Congressional intent to give MA organizations the option of introducing new PPO plans in those service areas where they have already established a local PPO plan prior to the start of the local PPO moratorium of 2006 & 2007.

Risk Sharing with Regional MA Organizations for 2006 and 2007 (§ 422.458)

We have added language to § 422.458(e)(1) to clarify that regional PPOs must be licensed in each State of the region, except during the period of the temporary waiver.

We have also made a technical change in paragraph (e)(2) to clarify what State licensing rules an organization must apply until the organization is licensed in all states, under the waiver process.

Scope (§ 422.500)

This section sets forth application requirements for entities seeking a contract as a Medicare Organization offering, an MA plan. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of 42 CFR part 423 specifically related to the prescription drug benefit.

Application Requirements (§ 422.501)

We have added a new § 422.501(c)(2) to clarify that a CMS determination that an entity is qualified to act as an MA sponsor is distinct from the bid negotiation that occurs under subpart F of part 422.

Evaluation and Determination Procedures (§ 422.502)

In paragraph (c)(2)(ii), we are changing the amount of time that an applicant has to remedy an application after receiving an Intent to Deny Notice from 60 days to 10 days.

We have eliminated paragraphs (e), (f) and (g

General Provisions (§ 422.503)

In § 422.503, we have eliminated the mandatory self reporting requirements that we proposed, but we have added a new requirement at § 422.503(b)(4)(vi)(H) that MA-PDPs have a comprehensive fraud and abuse plan.

Contract Provisions (§ 422.504)

We have made changes in paragraph (h) to reflect our focus on requirements to prevent fraud, waste and abuse and on issues that we are responsible for enforcing, such as the HIPAA administrative simplification rules.

Agreements with Federally Qualified Health Centers (§ 422.527)

We have amended paragraph (c) to clarify that financial withholds are not considered in determining payments made to FQHCs by CMS.

General Provisions (§ 422.550)

We have added an amendment to amend § 422.550(a)(2) by revising the heading to read, ''Asset Transfer'' instead of ''Asset Sale''.

Basis and Scope (§ 422.560)

In response to comments on whether and to what extent, the application of parallel appeal procedures might be a problem for plans, employers, and eligible individuals, we have added a new paragraph (c) related to ERISA standards.

Definitions (§ 422.561)

We have clarified the definitions of ''Enrollee'' and ''Authorized representative'' in this section. We have removed ''Authorized representative'' and replaced it with ''Representative'' to clarify that a representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in an appeal.

Grievance Procedures (§ 422.564)

We have added new paragraphs (d) and (e) related to the method for filing a grievance and the grievance disposition and notification process and we have redesignated the existing sections.

Timeframes and notice requirements for expedited organization determinations.

We have made a conforming change in paragraph (b) of § 422.572 to reflect the enrollee's right to file an expedited grievance if he or she disagrees with an MA organization's decision not to expedite an organization determination.

Request for a Standard Reconsideration (§ 422.582)

We have revised the text in paragraph (a) to denote that an MA organization may adopt a policy under which it accepts oral requests for standard considerations. Additionally, in accordance with part 405, subpart I, we have removed paragraph (a)(2) to eliminate the SSA as a filing location for standard reconsideration requests.

Timeframes and Responsibility for Reconsideration (§ 422.5900)

We have made a conforming change in paragraph (a) of § 422.590 to reflect the enrollee's right to file an expedited grievance if he or she disagrees with an MA organization's decision not to expedite a request for an expedited reconsideration.

We have revised paragraph (a) of § 422.602 that previously read that a party must file a written request with ''the appropriate ALJ hearing office'' to read that a party must file a written request for a hearing with ''the entity specified in the IRE's reconsideration notice'' in accordance with part 405, subpart I that eliminates alternate filing locations.

Reconsideration: Applicability (§ 422.648)

We have added a new paragraph (c) to § 422.648. This provision specifies that in the case of a favorable determination, including favorable decisions as a result of a hearing or Administrative review, that such

determinations be made by July 15 for the contract in question to be effective in January of the following year.

Basis for Imposing Sanctions (§ 422.752)

We have amended paragraph (a) in § 422.752 to clarify CMS' authority to impose more than one sanction at a time.

We have also amended paragraph (b), by deleting references to § 422.756 (c)(1) and (c)(3) and replacing them with references to § 422.750(a)(2) and (a)(4). This clarifies that we are cross referencing the basis for sanctions with the kind of sanctions that could result, not the procedure for imposing sanctions.

Procedures for Imposing Sanctions (§ 422.756)

We have amended paragraph (f)(2) to corrected a reference to ''part 1005 of this chapter'' to correctly reference ''part 1003 of this chapter,'' since 1003 includes the OIG procedures for imposing sanctions whereas 1005 are appeal procedures.

Maximum Amount of Civil Money Penalties Imposed by CMS (§ 422.758)

At § 422.758 we added some language that better clarifies the basis for Civil monetary penalties (CMPS) issued by CMS. At § 422.758(a) we added language that clarifies the existing basis for the Office of the Inspector General to support the imposition of this CMP. At § 422.752(a)(8) we added the word ''excluded'' for clarification.''

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The collection requirements referenced in sections one and two below are currently approved under OMB approval number 0938–0753 (CMS–R–0267, Medicare Plus Choice Program Requirements Referenced in 42 CFR 422.000 through 422.700), with a current expiration date of October 31, 2005.

Section one below outlines the collection requirements referenced in this regulation that have not been modified by the proposed regulatory changes. Section number two references requirements in this regulation that have been technically revised, but do not affect the currently approved burden estimates. Table three below references new collection requirements.

It should be noted that all of the collection requirements summarized and discussed below are open for public comment and will be submitted to OMB for approval.

1. Currently Approved Collection Requirements Not Affected By Proposed Regulation:

Section 422.54 Continuation of enrollment for MA local plans

(b) The intent by an enrollee to no longer reside in an area and permanently live in another area must be verified by the plan through documentation that establishes residency, such as a driver's license, voter registration.

(c)(2) The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

Section 422.60 Election process

(b)(1) MA organizations may submit information on enrollment capacity of plans.

(c)(1) The plan election must be completed by the MA eligible individual (or the individual who will soon become eligible to elect an MA plan) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the MA organization. Persons who assist beneficiaries in completing forms must sign the form, or through other approved mechanisms, indicate their relationship to the beneficiary.

(e)(3) The MA organization must give the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(e)(4) If the MA plan is enrolled to capacity, it must explain the procedures that will be followed when vacancies occur to the potential enrollee.

(e)(5) Upon receipt of the election, or for an individual who was accepted for future enrollment from the date a vacancy occurs, the MA organization transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary to its records as an enrollee of the MA organization.

(f)(3) Upon receipt of the election from the employer, the MA organization must submit the enrollment within timeframes specified by CMS.

Section 422.66 Coordination of enrollment and disenrollment through MA organizations

(f)(2) Upon receipt of the election from the employer, the MA organization must submit a disenrollment notice to CMS within timeframes specified by CMS.

Section 422.80 Approval of marketing materials and election forms

(a)(i) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in paragraph (c).

Section 422.506 Nonrenewal of contract

(a)(2)(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, and original Medicare and must receive CMS approval prior to issuance.

Section 422.564 Standard timeframes and notice requirements for organization determinations

(e)(3)(ii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO.

Based on the results of prior sampling of managed care enrollees, we extrapolate that approximately 17 percent of MA enrollees would likely experience some dissatisfaction with their MA organizations. Since we estimate that there would be approximately 6.7 million MA enrollees in 450 plans, we estimate that approximately 1,139,000 enrollees likely would experience some dissatisfaction with their MA organizations in a given year.

Based on previous grievance requirements analysis (See 66 FR 7593 through 7600), we estimate that approximately 455,600 enrollees, that is,

40 percent of the total number of dissatisfied enrollees, will file an oral or written grievance. We further estimate that another 60 percent will request a grievance orally, that is, 273,360. Of those requests, we believe that approximately 10 percent of enrollees will request a follow-up written response, that is 27,336 enrollees.

We estimate that it will take MA organizations 15 minutes to prepare and furnish each written response, and that MA organizations will be required to provide an estimated 27,336 written notices following oral requests. The total annual burden associated with this requirement is 6,834 hours.

Section 422.568 Standard timeframes and notice requirements for organization determinations

(a) When a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination.

(c) If an MA organization decides to deny service or payment in whole or in part, or if an enrollee disagrees with an MA organization's decision to discontinue or reduce the level of care for an ongoing course of treatment, the organization must give the enrollee written notice of the determination.

Section 422.590 Timeframes and responsibility for reconsiderations

(d)(2) When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

Section 422.600 Right to a hearing

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

Section 422.608 Medicare Appeals Council (MAC) review

Any party to the hearing, including the MA organization, who is dissatisfied with the ALJ hearing decision, may request that the MAC review the ALJ's decision or dismissal.

Section 422.612 Judicial review

(b) Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) In order to request judicial review, a party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405 of this chapter for a description of the procedures to follow in requesting judicial review.

2. Currently Approved Collection Requirements Technically Modified By Proposed Regulation: Not Affecting Burden:

Section 422.50 Eligibility to elect an MA plan

(a)(5) Completes and signs an election form or completes another CMS approved election method offered by the MA organization and provides information required for enrollment.

Section 422.66 Coordination of enrollment and disenrollment through MA organizations

(b)(1)(i)Elect a different MA plan by filing the appropriate election with the MA organization.

(b)(1)(ii) Submit a request for disenrollment to the MA organization in the form and manner prescribed by CMS or file the appropriate disenrollment request through other mechanisms as determined by CMS.

(b) (3) (ii) Provide enrollee with notice of disenrollment in a format specified by CMS.

(b) (3) (iii) In the case of a plan where lock-in applies, include in the notice a statement.

(d) (5) The individual who is converting must complete an election as described in § 422.60(c)(1), unless otherwise provided in a form and manner approved by CMS.

Section 422.74 Disenrollment by the Medicare Advantage Organization

(c)(1) A notice must be provided to the individual before submission of the disenrollment transaction to CMS.

(d)(1)(i) The MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount that meets the requirements of this section.

(d)(1)(ii)The MA organization provides the enrollee with notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(d)(2)(ii)An organization may disenroll an individual whose behavior is disruptive as defined in 422.74(d)(2)(1)(i)only after it meets the requirements described in this section and CMS reviews and approves the request.

(d)(2)(iii) The beneficiary has a right to submit any information or explanation that he or she may wish to submit to the MA organization.

(d)(2)(iv) The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraphs (d)(2)(i) through (d)(2)(ii) of this section and any extenuating circumstances. The MA organization may request from CMS the ability to decline future enrollment by the individual if the organization obtains approval from CMS.

Section 422.111 Disclosure requirements

(d)(2) For changes that take effect on January 1, the plan must notify all enrollees 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

(e) The MA organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

Section 422.112 Access to services

(a)(1)(i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(a)(1)(ii) MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.

Section 422.152 Quality improvement program

(b)(3)(i) Plans must measure performance using the measurement tools required by CMS, and report its performance to CMS. The standard

measures may be specified in uniform data collection and reporting instruments required by CMS.

(b)(3)(ii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

(d)(5) The organization must report the status and results of each project to CMS as requested.

(e)(2)(i) MA organizations offering an MA regional plan or local PPO plan as defined in this section must measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(f)(i) and (iii) For all types of plans that it offers, an organization must maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program and make all collected information available to CMS.

Section 422.570 Expediting certain organization determinations

(d)(2)(ii) The plan must inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite.

Section 422.572 Timeframes and notice requirements for expedited organization determinations

(c) If the MA organization first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

Section 422.582 Request for a standard reconsideration

(a) A party to an organization determination must ask for a reconsideration of the determination by making an oral or written request to the MA organization that made the organization determination or to an SSA office.

(c)(2) If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination may file a request for reconsideration with the MA organization.

Section 422.602 Request for an ALJ hearing

A party must file a written request for a hearing with the appropriate ALJ office, which meets the requirements of this section.

Section 422.620 How enrollees of MA organizations must be notified of noncovered inpatient hospital care

(c) When appropriate, a written notice of non-coverage must be issued no later than the day before hospital coverage ends. The written notice must include the elements set forth in this section.

As noted above, while the requirements in this section have been modified, the associated burden has not changed.

3. New/Revised Collection Requirements Proposed In This Regulation: Affecting burden:

Section 422.80 Approval of marketing materials and election forms

(a)(3) The MA plan meets the performance requirements established by CMS The MA plan may distribute the designated marketing materials 5 days following their submission to CMS with an certification that the marketing materials meet the model language guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for the plan to submit the designated marketing materials to CMS five days prior to distribution.

We estimate it will take 350 plans approximately 12 hours to provide the materials to CMS on an annual basis.

Section 422.101 Requirements relating to basic benefits

(b)(5) An MA organization an MA local plan or regional MA plan as described in this section must make information on the selected local coverage policy readily available to the enrollees and health care providers.

The burden associated with this requirement is the time and effort necessary for the plan to make information on the selected local coverage policy readily available to the enrollees and health care providers. We estimate that it will require 350 MA plans 1 hour each on annual basis to make the necessary information available.

(d)(4) MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) of this section based on incurred out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the deductible (if any) or a limit has been reached.

The burden associated with this requirement is the time and effort necessary for the plan to notify members when the deductible (if any) or a limit has been reached. While this requirement is subject to the PRA, we believe this requirement meets the requirements of 5 CFR 1320.3(b)(2), and as such, the burden associated with this requirement is exempt from the PRA.

Section 422.106 Coordination of benefits with employer group health plans and Medicaid

(d)(1) To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof), of the labor organizations, those MA plans may request, in writing, from CMS, a waiver or modification of those requirements in this part that hinder the design of, the offering of, or the enrollment in, those plans by those individuals.

The burden associated with this requirement is the time and effort necessary for the plan to submit a waiver to CMS. We estimate that on an annual basis it will take plans 2 hours to submit the waiver to CMS. However, we do not anticipate more then nine waiver requests on an annual basis. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Section 422.111 Disclosure requirements

(f)(10) The names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other areas.

The burden associated with this requirement is the time and effort necessary for the plan to notify member of the names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other areas. While this requirement is subject to the PRA, we believe this requirement meets the requirements of 5 CFR 1320.3(b)(2), and as such, the burden associated with this requirement is exempt from the PRA.

Section 422.112 Access to services

(c) An MA regional plan may seek, upon application to CMS, to designate a noncontracting hospital as an essential hospital as defined in section 1858(h) of the Act that meets the conditions set forth in this section.

The burden associated with this requirement is the time and effort necessary for the plan to submit the required materials to CMS. We estimate

that on an annual basis it will take 100 plans 8 hours to submit the materials to CMS.

Section 422.254 Submission of bids and rebate information

(a)(1) No later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section and, for plans with rebates as described at 422.266, the MA organization must provide the information required in this section.

The burden associated with this requirement is the time and effort necessary for the plan to submit the required bid materials and rebate information to CMS. 350 MA organizations offering 400 plans 100 hours per plan bid and rebate submission to CMS for a total annual burden of 40,000 hours.

(b) For MSA plans, MA organizations must submit the following information: the monthly MSA premium, the plan deductible amount, and the beneficiary supplemental premium, if any. Since CMS does not review or approach MSA plan submissions, we estimate that the submission burden is half that for other MA plans. Under the M+C program, no MSA plans were offered. We estimate that under the MA program 5 organizations will offer an MSA plan and require 50 hours for submission of the above information, for a total annual burden of 250 hours.

Section 422.270 Incorrect collections of premiums and cost-sharing

(b) An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

The burden associated with this requirement is the time and effort necessary for the MA organization to provide written assurance to CMS that they will refund all amounts incorrectly collected from its Medicare enrollees or representatives. We estimate that on an annual basis it will take 350 MA organizations 30 minutes to submit a written agreement to CMS.

Section 422.304 Monthly payments

(e)(2) A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas, as outlined in this section, for MA local plans for the following calendar year.

The burden associated with this requirement is the time and effort necessary for a State to provide a written request for geographic adjustment to CMS. Under the M+C program, we received inquiries from 2 states and requests from none. Thus, we estimate that on an annual basis we may receive 2 State submissions. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Section 422.310 Risk adjustment data

(b) Each MA organization must submit to CMS (in accordance with CMS instructions) all data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required risk adjustment data to CMS. We estimate that on an annual basis it will take 350 MA organizations 121 hours each to submit the required data to CMS.

(d)(1) MA organizations must electronically submit data that conform to the requirements for equivalent data for Medicare FFS when appropriate, and to all relevant national standards. Alternatively, MA organizations may submit data according to an abbreviated format, as specified by CMS and which meet the requirements of (d)(2) and (d)(3) of this section.

The burden associated with this requirement is the time and effort necessary for a plan to gather the required data and submit the required risk adjustment data to CMS. The estimate for submission of the abbreviated format data is included in the above estimate.

(e) MA organizations and their providers and practitioners will be required to submit medical records for the validation of risk adjustment data, as required by CMS.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required validation data to CMS. We estimate that on average 350 MA organizations will each submit 29 medical records to CMS, requiring 1 hour per record, for a total annual burden of 9800 hours.

Section 422.314 Special rules for beneficiaries enrolled in MA MSA plans

(b) An entity that acts as a trustee for an MA MSA must Register with CMS, certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the IRS Code, agree to comply with the MA MSA provisions of section 138 of the IRS Code of 1986; and provide any other information that CMS may require.

The burden associated with this requirement is the time and effort necessary for an entity to certify and submit the required materials to CMS as outlined in this section. We estimate 5 MA organizations will submit the required information on an annual basis. As such, this requirement is not subject to the PRA as stipulated under 5 CFR 1320.3(c).

Section 422.320 Special rules for hospice care

(a) An MA organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 about the availability of hospice care if a Medicare hospice program is located within the plan's service area, or it is common practice to refer patients to hospice programs outside that area.

The burden associated with this requirement is the time and effort necessary for a plan to disclose to each Medicare enrollee about the availability of hospice care. We estimate that on an annual basis it will take 350 plans 1.14 hours to distribute the required materials to enrollees. While this estimate may appear low, we believe that this disclosure requirement will be standardized and incorporated into the plans marketing material routinely disseminated to enrollees.

Section 422.458 Risk sharing with regional MA organizations for 2006 and 2007

(d)(1) Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required information to CMS. We estimate that on an annual basis it will take 30 to 100 plans, 40 hours to submit the required information to CMS.

(d)(2) Pursuant to the existing § 422.502(d)(1)(iii) (section 1857(d)(2)(B) of the Act), CMS has the right to inspect and audit any books and records of the organization that pertain

to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

This requirement is exempt from the PRA as stipulated under 5 CFR 1320.4.

Section 422.501 Application requirements

(b)(1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete and submit a certified application, in the form and manner required by CMS, that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for a plan to submit the required application to CMS. We estimate that on an annual basis it will take 350 plans 40 hours to submit the required application to CMS.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare and Medicaid Services

Office of Strategic Operations and Regulatory Affairs,

Attn: John Burke (CMS–4069–P)

Room C5–13–28, 7500 Security Boulevard,

Baltimore, MD 21244–1850;

and

Office of Information and Regulatory Affairs,

Office of Management and Budget,

Room 10235, New Executive Office Building,

Washington, DC 20503,

Attn: Christopher Martin, CMS Desk Officer,

[CMS–4069–F],

Christopher_Martin@omb.eop.gov.

Fax (202) 395–6974.

VI. Regulatory Impact Analysis

We received comments on the proposed rule regulatory impact analysis in six subject areas. The comments pertained to (1) our not having examined the impact of the Comparative Cost Adjustment program under section 241 of the MMA, set to begin in 2010; (2) an error in our projection of the value of extra benefits that enrollees of MA plans will receive; (3) a question regarding the number of insurers licensed to operate nationally or in multiple states; (4) the manner in which we classify entities as being either regional plans or local plans; (5) concerns about the competitive advantages that regional plans may have over local plans; and (6) our not having discussed the effect of these rules on American Indian and Alaska Native populations. Our responses to those comments are addressed in the appropriate sections below. None of these comments suggested the need for major changes in our analysis, and we have accordingly modified it primarily to reflect final decisions and to use updated economic projections (in addition to correcting the projection error pointed out in public comments).

A. Overall Impact

We have examined the impacts of this rule under Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and Executive Order 13132 on Federalism.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impact and equity). A regulatory impact analysis (RIA) must be prepared for any rule with an effect on the economy of $100 million or more in any one year. Since this rule will be the most significant step in implementing the MA program, we are classifying it as an economically ''significant'' rule for purposes of E.O. 12866 and as a ''major'' rule for purposes of the Congressional Review Act (5 U.S.C., section 804(2)). Accordingly, we have prepared this RIA in accordance with OMB Circular A–4, combined with a Final Regulatory Flexibility Analysis (FRFA), pursuant to the Regulatory Flexibility Act), in which we analyze the overall effects of the Medicare Advantage program, including effects not addressed in this rulemaking (for example, rate increases that went into effect in March, 2004). Although the MMA is a highly detailed statute that delineates most important provisions of the MA program, there are alternatives available to us in implementing several important provisions of the statute. We analyze in detail those areas for which regulatory alternatives are available.

Although we have included or summarized most of the required analysis in this section of the preamble, the explanation of the basis for the rule and analysis of some regulatory options are presented elsewhere in the preamble. We note that the preamble to the companion rulemaking concerning the Part D drug benefit also contains an RIA and a FRFA, and some effects of the legislation (for example, on Medigap plans) are analyzed in more detail in that preamble.

The MMA provides for increasing the role of private plans in providing Medicare benefits to beneficiaries. The statute made changes to the payment system that increase Medicare payment rates to private plans as of 2004, and for subsequent years. A new private plan option is introduced, the regional Medicare Advantage plan, structured as a PPO, which will be required to offer services over a wide geographic area. To encourage the formation of such plans, the MMA provides financial incentives above and beyond the payment rate increases applicable to all plans. There are other financial incentives discussed in what follows and elsewhere in the preamble. In addition to increased payments to plans, the MMA will provide benefits to beneficiaries and to entities (such as employers and States) that would otherwise be financially responsible for the cost of beneficiaries' medical care. The benefits to beneficiaries and plans are the result of transfer payments from the Federal Government which we project will total $18.3 billion in the period 2004 to 2009 (as a result solely of the Title II provisions of the MMA), as described in more detail in what follows.

The main purpose of this rule is to implement the statutory provisions of Title II of the MMA, which deal with the Medicare Advantage program. Insofar as the rule implements provisions of the law, we are providing a general discussion of the impact of the law and our basis for projections of the impact. These impact projections reflect the statutory scheme in its entirety, not just the relatively minor effects attributable to discretionary provisions in the regulations. Although the statute prescribes Medicare Advantage rules and procedures in considerable detail, it specifically affords CMS discretion to make decisions on a number of issues regarding how the law will be implemented. The preamble and this impact analysis discuss these types of issues in greater detail. The rule also introduces changes to Medicare private health plan requirements that, in most cases, are intended to streamline the administration of the program and make contracting less burdensome for health plans while not impinging on the rights of enrollees. (Note that this analysis does not extend beyond the year 2009; that is, the Comparative Cost Adjustment (CCA) demonstration program of subtitle E of the MMA is not

discussed. The CCA regulations will be proposed at a later date.)

Comment: One commenter expressed disappointment in the approach of dealing with the impact of the law and regulations only through 2009, without discussing the Comparative Cost Adjustment (CCA) program set to begin in 2010 (under section 241 of the MMA). The commenter is interested in knowing what our thinking is with regard to the CCA program.

Response: As discussed in the notice of proposed rule making, any necessary regulations for the CCA program will appear sometime in the future as proposed rules, at which time there will be opportunity for public comment. We would also note that our experience with the bidding system that begins in 2006 will help inform our thinking about the CCA program when we begin active planning for it.

1. Objectives of the Final Rule

The primary goal of the MMA is to expand the health plan choices available to Medicare beneficiaries, allowing beneficiaries to meet their medical needs at a lower cost. There is also the expectation that Medicare health plan enrollment will increase. The expansion of health plan choice is envisioned as occurring at many levels: areas of the country that previously did not have private plans available should see new plans enter the market; areas where there are plans should see an increase in the number of competing plans; and beneficiary choice should be enhanced by the introduction of new types of plans, including specialized plans, and, most importantly, regional plans that are structured as preferred provider organizations. In keeping with the overall objectives of the law, the rule seeks to implement the law in ways that will promote plan participation (and, as a consequence, lead to increased enrollment in private plans). The introduction of regional plans and the choice of the PPO model for such plans are designed to lead to greater plan participation. The rationale for the introduction of regional plans and the use of the PPO model are discussed in the impact analysis of the August 3, 2004 proposed rule (69 FR 46919).

General Impact. In general, the law and regulations will have a positive impact on beneficiaries and private health plans. Transfer payments from the Federal Government will go towards the provision of additional health benefits to enrollees of health plans and reduced out-of-pocket costs, including reduced Part B and Part D premiums for these enrollees. The law will result in increased revenue for participating private plans for the provision of the basic Medicare benefit and the provision of additional health benefits. We also anticipate a positive impact for employers and unions as sponsors of retiree coverage, as discussed in more detail below.

There are revenue effects on States arising directly from the law (the prohibition on premium taxes) and arising indirectly as a result of beneficiary movement towards private plans and away from traditional FFS Medicare with Medigap coverage. The latter effect is relevant to Medigap insurers. The effects on States and insurers are discussed more fully in what follows.

2. Provisions of the Law

The MMA introduces major changes in the payment rules for private plans. These changes are discussed in detail in the preamble text for subparts F and G of these regulations. For local plans, the MMA increased MA payment rates beginning in 2004, by using county FFS rates (minus direct medical education payments) as a minimum payment level and rebasing the rates periodically, by removing a budget neutrality limitation on payment at a national/local blended rate, and by providing for higher yearly payment rate increases (while maintaining minimum payment rate increases).

Payment to plans are risk adjusted for health status (in addition to risk adjustment for demographic factors such as age), with 30 percent of payment being subject to health status risk adjustment in 2004, 50 percent in 2005, 75 percent in 2006, and 100 percent in 2007 and thereafter. When payments are risk-adjusted, a greater proportion of such payments are directed to chronically ill and older beneficiaries with predictably high costs. Note that CMS is currently implementing health status risk adjustment in a ''budget-neutral'' manner, with savings re-invested in plan payments. That is, the difference in payment between the total health status-adjusted payment rates and the rates adjusted only by demographic factors is paid to the health plan ''sector,'' in 2006, but the funds are distributed among plans based on the relative health status of each plan's enrollees.

Through 2005, there is no change to the payment rules related to how plans must use any excess funds (Medicare payments greater than the amount a health plan requires to provide the Medicare benefit). Currently such funds must be returned to enrollees in the form of reduced cost sharing, or the provision of extra (non-Medicare) benefits. Plans also have the option of using the excess funds to reduce all or a portion of an enrollee's Part B premium, but in that case, the Government retains 20 percent of the reduction in plan payments while reducing the Part B premium that is usually collected through a beneficiary's Social Security payment. Another option for the disposition of excess funds is to make deposits to a ''stabilization fund'' to be used in a subsequent contract year for reductions in cost sharing or for financing of extra benefits-an option that the MMA eliminates as of the end of the 2005 contract year.

Currently and through 2005, the determination of whether there are excess funds is done through the ''adjusted community rate'' approval process (a CMS review of proposed benefits and premiums and the revenue required to provide the benefit package). The MMA does away with the ACR review process and instead institutes a bidding process. As of 2006, plans will present bids that are to be compared against benchmarks to determine whether enrollees will receive rebates or be required to pay a premium to the health plan. For local plans, the benchmark is based on what today are county payment rates. For regional plans, the benchmark represents a weighting of these same county rates and the actual plan bids. CMS will evaluate the bids for reasonableness and actuarial soundness, and can negotiate over the bid amounts and proposed supplemental benefits. In 2006 and thereafter, to the extent that the bid is less than the benchmark, that difference (comparable to the current ''excess funds'') determines plan rebates. The Government retains 25 percent of this difference, and the remaining 75 percent is to be used for beneficiary ''rebates,'' which can take the form of extra benefits, reduced cost sharing, reduced health plan premiums for mandatory supplemental benefits, or reduced Part B and/or Part D premiums. To the extent that the plan bid is greater than the benchmark, that difference becomes the premium the plan must charge enrollees for ''basic'' benefits.

The limitation on cost sharing for Medicare services that previously existed is modified in the MMA. Prior to the MMA, for coordinated care plans, the combination of the actuarial value of cost sharing for Medicare-covered services, plus any premium or portion of a premium representing a charge in lieu of Medicare cost sharing, could not exceed the average level of cost sharing that beneficiaries face in FFS Medicare. As of 2006, premium amounts that are in lieu of cost sharing are not counted

in determining whether the limit is exceeded (which is the rule as it is currently applied to PFFS plans). In addition, the comparison is made to local values of cost sharing in FFS Medicare rather than to the current use of national values. (The cost sharing for Medicare Part A and B services that enrollees of MA regional plans obtain from non-network providers is not counted in determining whether the cost sharing limit on Medicare services has been exceeded.)

The MMA also makes structural changes in the Medicare private plan contracting program. The most important of these statutory changes is the introduction of regional MA plans that will be structured as PPOs, and which would first become available in 2006. While local plans may choose the counties in which they wish to operate as MA plans, regional plans must cover an entire region. On December 6, 2004, we designated 26 regions for MA regional plans and 34 regions for PDP plans. Information on the regions and the basis for their selection can be found at www.cms.hhs.gov/medicarereform/mmaregions. To facilitate the ability of regional plans to operate in multiple States, plans that are licensed in at least one State in the region can qualify for a waiver of the licensing requirements in the other States in the region for a period of time pending an organization's becoming licensed in each State (see the preamble text for subpart J). In the first 2 years of formation of regional plans, there is a moratorium imposed on the formation or expansion of local PPOs.

Regional plans have various statutory incentives to participate, including:

- Sharing risk with the Government in 2006 and 2007,
- Access, beginning in 2007 through the end of 2013, to a ''stabilization fund'' of $10 billion (plus half of the 25 percent of regional plan rebate dollars that would otherwise go to the Government). The stabilization fund will be used to encourage plan entry (including a bonus for plans operating in the entire Nation) or to prevent plans from discontinuing contracts; and
- Access to additional funding payable to ''essential'' hospitals (as described in the subpart G preamble text).

As described elsewhere in this regulation, we are also taking other regulatory steps to support regional plan participation, such as allowing plan payments to be adjusted based on geographic variations in a plan's costs within a region, and providing flexibility in network adequacy standards (as outlined in the preamble discussion of subpart G).

Other structural changes affecting Medicare health plans include provisions for plans that can exclusively or disproportionately serve special needs individuals, special treatment of enrollees with ESRD (paid outside of the bidding system in 2006–see subpart G), authority for direct contracting between CMS and employers or unions for coverage of retirees (see § 422.106), and removal of certain limitations that had been imposed on medical savings account plans. There are also provisions calling for the termination of cost-reimbursed contracts with health plans if certain conditions are met (see discussion of changes to part 417).

In the following section we list those areas in which we will exercise discretion, either because the law entails a choice of options or because we have elected to exercise regulatory discretion.

3. Discretion Resulting from Statutory Provisions

Designation of Regions. The most important feature of the MA program that the statute leaves to the discretion of the Secretary is to determine the boundaries for the regions in which regional MA plans will operate. As permitted by the statute, the regions for MA are different from the PDP regions, as explained in the announcement of the regional configurations and as discussed in the impact analysis for Title I of the MMA (concerning PDPs). The biggest difference between the two sets of regions is that the size of the eligible population necessary to support economic viability is somewhat larger for MA than PDP plans. All PDP regions are ''nested'' within (included in) MA regions to simplify planning and administration. Some of the issues relating to the configuration of regions were discussed in the alternatives considered section of the proposed rule (see 69 FR 46937). The estimates contained in the analysis found in the proposed rule (see 69 FR 46928, Table 2, for example) were for illustrative purposes and were based on an assumption that there would be 15 regions. The projected numbers in this final rule are based on the MA regions designated by CMS. The configuration of the regions affects the projections because of the expected benchmark levels in each region and the projected bids from health plans in the regions.

Statewide Versus Plan-Specific Risk Adjustment. CMS is given the authority to use a statewide, area-wide, or a plan-specific, risk adjustment methodology for determining rebates. The effects of each and the factors to consider in choosing one or the other approach were discussed in the alternatives considered section of the proposed rule (see 69 FR 46942). The consequence of choosing the option of the plan-specific approach is briefly discussed below, in the alternatives considered section of this final rule.

4. Regulatory Discretion

The statute spells out in detail most major and many minor parameters of Medicare reform. However, in certain matters, the statute describes a structure or uses terminology that is open to interpretation but which is a necessary component of the statutory scheme. There are also other areas where we believe further interpretation is needed, or where there appear to be internal inconsistencies in the statute that need to be resolved. The following issues are of this nature, and each is noted here briefly, with some of the issues discussed in further detail in the section on alternatives considered.

Actuarial Value of Medicare Cost Sharing. When plans present bids for Medicare-covered services the bid may include only Medicare-covered services and must reflect cost sharing at Medicare levels or with ''actuarially equivalent'' cost sharing. The options for defining ''actuarially equivalent'' in this context are discussed in detail in the preamble text of subsection F in this final rule and in the proposed rule (where the uniform, plan-specific, and proportional amount methods of determining actuarial equivalence are discussed).

Treatment of Induced Demand as a Supplemental Cost. As was discussed in the proposed rule, to the extent that we were to use the ''plan-specific'' approach to determining cost sharing that is actuarially equivalent to that of traditional Medicare, an additional issue arises, having to do with the additional expenditures arising from ''induced demand'' (higher utilization because of lower cost sharing). We have decided not to use the plan-specific approach, relying instead on a proportional approach to determining cost sharing as a component of the bid for Medicare A and B services. Therefore we are unable to quantify any induced demand that may exist (that is, any difference in A and B expenditures between the bid and actual utilization under a plan's benefit design which is attributable to reduced cost sharing). In the alternatives considered section, below, we discuss the consequence of this choice.

Prohibiting Use of Rebate Dollars for the Purchase of Optional Supplemental Benefits. This final rule prohibits rebate dollars from being used for the purchase of optional supplemental benefits, as

explained in the preamble text for subpart F.

Intra-Area Geographic Adjustment to Payments. The statute specifies that ''if applicable'' (1853(a)(1)(B)(i)), CMS ''shall adjust'' payments ''in a manner to take into account variations in MA local payment rates'' (1853(a)(1)(F) for regional plans and for local plans operating in more than one local payment area. This issue is discussed in more detail in the ''alternatives considered'' section. We will be using a geographic adjustment based on MA county payment rates, but in exceptional situations, for regional plans, we will allow the use of a plan-determined statement of the variation in the relative cost to the plan of providing Medicare-covered services.

5. Provisions Of The Rule Not Based On Specific MMA Changes

As discussed throughout the preamble of this final rule and the proposed rule, we have made a concerted effort to improve, and wherever possible simplify and reduce the burden of, existing regulations. In general, as previously noted, these provisions reduce the burden on health plans while enhancing beneficiary protections or not adversely affecting the rights of enrollees. Among the changes that are being made that are not a result of the MMA statutory provisions are (a) new beneficiary protections related to coverage of services when network providers can see patients on a ''point-of-service'' basis (§ 422.105); (b) revisions to the rules limiting beneficiary cost sharing related to emergency episodes (§ 422.113); (c) the elimination of requirements on MA plans that are duplicative of activities already conducted by CMS regarding information about beneficiary health care coverage options (elimination of § 422.111(f)(4) and (f)(6), and portions of (f)(7)); (d) the elimination of certain access to care provisions (changes made at § 422.112); (e) use of alternative election mechanisms other than forms (§ 422.50(a)(5)), and alternative notice options (§ 422.60(e)); (f) allowing MA organizations to submit requests to restrict enrollment for capacity reasons at any time during the year (§ 422.60(b)); (g) providing more flexibility in the procedures for disenrolling beneficiaries for failure to pay premiums (§ 422.74(d)(1)) and rules related to disenrollment due to disruptive behavior (§ 422.74(d)(2)); (h) formal adoption of a ''file and use'' approach to approval of marketing materials (§ 422.80) for contractors that have demonstrated a record of compliance with marketing rules; (i) changes in requirements regarding information plans provide to enrollees about participating providers (§ 422.111(b)(3), for example); and, in § 422.133 , extending the right under section 1852(l) of the Act for admission to a ''home skilled nursing facility'' in the event that a health plan admits an enrollee to a skilled nursing facility without a prior qualifying hospital stay. In addition, various changes are made in subpart D that are consistent with a ''quality improvement'' approach to quality standards.

B. Basis for Estimating Impacts

The extent of the impact of the MMA will depend on whether the goals of the law are realized. We believe that the payment changes and structural changes of the MMA will lead to higher levels of plan participation, and, as a consequence, enrollment in coordinated care plans will increase over the next several years and over the longer term. We expect the absolute level of Medicare health plan enrollment to increase because of the greater availability of plans, and we expect the rate of enrollment in such plans (''penetration'') to increase because plans will be able to offer plan designs that will allow beneficiaries to meet their medical needs at a lower cost, and MA organizations will be able to offer generous benefit packages that Medicare beneficiaries will find attractive. However, there is a great deal of uncertainty involved in making projections of plan participation and beneficiary enrollment levels. The factors contributing to uncertainty include uncertainty about market decisions health plans might make, how changes in health care markets and costs will affect plan participation and beneficiary enrollment, whether MA plan offerings will satisfy the enrollment preferences of Medicare beneficiaries, how MA plans will fare in competition with the new PDP plans, and other factors. For the MMA, the designation of MA regions and how the marketplace will react to the regional designations is also a factor contributing to uncertainty.

We have revised the enrollment, expenditure, and distribution of funds estimates contained in the proposed rule (summarized in the proposed rule, in Tables 2, 4, and 12, found at 69 FR 46928, 46930, and 46951). The revisions reflect revised bid and benchmark estimates based on the designation of regions; and revised enrollment estimates based in part on the results of discussions with the Technical Review Panel on the Medicare Trustees Reports (information about the panel and its findings can be found at *http://aspe.hhs.gov/health/medpanel/2004/*, in particular the minutes of the October 15, 2004 meeting). The enrollment estimates (and associated expenditures for MA) were revised downward for the 2004 to 2009 period that is the subject of the projections contained in this final rule. While enrollment in MA had been projected to reach 33 percent of the Medicare population by 2009 in our proposed rule projections, we are revising the penetration projection to be lower in 2009–it is now projected to be about 24 percent-but we continue to expect enrollment to reach 33 percent by 2016, with enrollment in 2016 being evenly divided between local MA plans and regional plans.

The proposed rule contained a lengthy discussion of the history and current state of the MA program (and its predecessor programs, such as Medicare+Choice). The discussion contained data on beneficiary access to MA plans over the years and penetration levels in the past, the types of beneficiaries who currently enroll in such plans (for example, lower-income individuals are more likely to enroll in MA), the categories of beneficiaries less likely to enroll; and a discussion of any conclusions that can be drawn from the history of the program in terms of health plan decisions to participate in the program and beneficiary decisions on enrollment in Medicare health plans (69 FR 46921 through 46925 of the proposed rule). The discussion was intended to provide historical and anecdotal evidence to support the enrollment projections found in the proposed rule. For this final rule, we are providing an update of some of the data.

As of January 2005 there are 174 MA coordinated care plans (CCPs), and such plans were available to 65 percent of the Medicare population (compared to 61 percent of the population at the end of 2004, and compared to a historical high of 74 percent). There are applications pending for 19 additional CCPs. Including PFFS plans, if all pending new contract applications and service area expansion requests are approved, 86 percent of Medicare beneficiaries will have access to at least one Medicare private plan.

The current data demonstrate a significant increase in plan participation in MA, associated with an increase in enrollment in CCP plans of about three percent between January and December of 2004 (to 4.7 million). (In addition, enrollment in PPO demonstration plans increased 34 percent to 111,000; and enrollment in PFFS plans increased 93 percent, to 51,000.)

With regard to MSA plans, we remain uncertain, as noted in the proposed rules, about participation and enrollment in MSAs. The MMA changed the MSA provisions of the BBA with a view towards facilitating the offering of such plans. However, we are unable to determine whether the MMA provisions will result in such plans being introduced and the extent to which beneficiaries might enroll in such plans.

Comment: Several commenters remarked that the impact analysis showed that very little of the additional payments to health plans resulting from the MMA would be used to fund extra benefits for plan enrollees.

Response: The commenters have pointed out what is an error in the impact analysis published in the notice of proposed rule making of August 3, 2004. We are correcting the error in this final rule. While the projections of Tables 2 and 4 of the proposed rule (69 FR 46928 and 46930, respectively) show that only about six percent of total new expenditures arising from the MMA would be used to fund extra benefits, the correct percentage, over the period 2004 through 2009, should be a much higher figure-in the range of 50 percent, as explained below in the section on effect on beneficiaries. The remainder of the payment increases will support maintaining and enhancing provider networks and stabilization of the plans' financial status in Medicare. (The erroneous projected percentage was based on the percentage of total MA payments in 2004 through 2009 that we project will be used for extra benefits, not the percentage of only the incremental dollars that plans will receive in 2004 through 2009 because of the MMA provisions.)

Comment: One comment questioned a statement in the impact analysis of the proposed rule to the effect that there were a number of insurers that are licensed as insurers in every State in the Nation, or which are licensed in multiple States. The commenter noted that they were aware of several national and multi-state insurers but inquired whether CMS had in mind any other insurers beyond the ones named in the comment.

Response: The CMS information on the number of insurers that are multi-state or national insurers was based on information available at the web site of the National Association of Insurance Commissioners (www.naic.org), showing the licensure status, by State, of health insurance companies. We have not done an exhaustive analysis to determine the total number of such companies. Our purpose was merely to point out, as the commenter noted, that there are a number of organizations that are potential MA regional plan contractors.

Projections Provided in the Impact Analysis. The methodology used to project the impact of the law and regulations is partly explained in the section on effects on beneficiaries. The projections in this final rule, which are different from those in the proposed rule, are based on the CMS designation of 26 MA regions. For projection purposes, a model is used that assumes three regional plans in each region, with each plan at a different level of efficiency (though this is not to suggest that this would be the number of regional/national plans in each region). With regard to the number of MA local plans, the projections of enrollment do not involve assumptions about any specific number of local plans. Instead a certain level of enrollment is assumed for local plans based on the benefits they are expected to offer. It was assumed that there would be sufficient capacity among local plans to enroll all beneficiaries that are expected to join such plans. The estimates of plan bids are based on the proprietary information submitted to CMS by current Medicare Advantage plans (coordinated care plans as well as demonstration PPO plans). Beneficiary behavior is modeled with utility functions that predict the choices they will make among available health plan options. As previously mentioned, we recognize the high degree of uncertainty entailed in such projections. The projections represent our best estimate of the impact given the assumptions stated.

C. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies identify any Federal mandates resulting from rules that may result in the expenditure by State, local, and tribal governments of $100 million or more (adjusted for inflation and currently about $110 million). If this threshold is met, a detailed analysis is required. This rule does not contain any such mandate, and other direct effects on State, local, and tribal governments will be minimal. There will, however, be an indirect effect on State premium tax revenues due to the increased enrollment in MA plans and reduced enrollment in certain Medigap policies. These indirect effects, however, are not the result of these rules, but of increased plan payments and prohibitions on sale of those Medigap policies implemented independently of these regulations.

Title II of the MMA contains several provisions that have a direct impact on States. Section 232(a) of the MMA amends section 1856(b)(3) to preempt all State standards other than licensure and solvency as they apply to MA plans. Section 232(b) of MMA amends section 1854(g) to expand a prohibition on State taxes for MA plans to apply to both CMS' payments to MA plans and to enrollee premium payments to MA plans. In addition, section 221(c) of MMA allows for temporary waiver of State licensure in States covered by regional MA plans where those plans cover a multi-State area.

Medicare law prohibiting State taxes on section 1853 payments to M+C organizations, that is, payments made by CMS to health plans contracting with Medicare, was established by the Balanced Budget Act 1997. That prohibition did not apply to enrollee premium payments made to M+C plans.

Section 232(b) of the MMA has expanded the prohibition on State taxes for MA plans, addressed in statute at section 1854(g), to apply to both section 1853 payments to MA plans and to section 1854 enrollee premium payments to MA plans. This provision was effective on the date of enactment of the MMA and is, therefore, not subject to the Regulatory Accountability provisions of the UMRA, which apply only to effects resulting from promulgation of rules. Section 422.404(a) is revised to reflect this change. We do not anticipate that the added prohibition on taxation of enrollee premiums to have a significant cost impact on States. Enrollee premiums to Medicare health plans are a small proportion of total payments to health insurers. Thus, State loss of tax revenue from Medicare enrollee premiums would also be small. Therefore, even if it were subject to UMRA, the prohibition of taxation by States of Medicare enrollee premiums would not approach the UMRA threshold.

We also recognize, however, that there is an indirect effect of the MMA law because of the expected enrollment shift from taxable Medigap insurance, and employer-sponsored private supplemental coverage, to non-taxable MA plans. This indirect effect would vary by State and would be dependent on a variety of factors, including the State's tax rate on health insurance premiums, the extent of Medigap enrollment in a State, the extent that Medigap enrollees choose to shift to MA plans in that State, as well as other resulting factors such as changes in Medigap premiums that could result from enrollment shifts. Due to these

factors, estimates of the indirect effect of enrollment shifts away from taxable Medigap and employer-sponsored supplemental plans combined with the prohibition on State taxation of Medicare enrollee premiums would involve great uncertainty and would necessarily be speculative.

D. Federalism

MMA provisions may have qualitative impacts on how States regulate and interrelate with health insurers serving Medicare enrollees due to the expanded preemption of State laws and possible temporary waiver of State licensure for multi-State MA regional plans. Law relating to Federal preemption of State standards for Medicare-contracting health plans has undergone several revisions in recent years. While Federal preemption of State standards was initially established into Medicare law by the Balanced Budget Act of 1997, a general preemption authority existed under Executive Order prior to that time. Federal preemption of State standards for Medicare-contracting health plans was expanded by Congress in 2000 and expanded again by Congress in 2003.

Prior to 1997, Federal law did not contain specific preemption requirements for Medicare-contracting health plans. However, section 1876 Federal requirements could preempt a State law or standard if State provisions were inconsistent with Federal standards based on general constitutional Federal preemption principles, consistent with the provisions of Executive Order 12612 on Federalism, since superseded by Executive Order 13132. Section 1876 requirements did not preempt a State law or standard unless the State law or standard was in direct conflict with Federal law. See the June 26, 1998 **Federal Register** notice (63 FR 35012) for further discussion on the history of general Federal preemption of State law prior to the BBA.

The BBA established for the M+C program at section 1856(b)(3) of the Act a general preemption authority in which State laws or standards would be preempted when they were inconsistent with M+C standards in the same manner that the previous Executive Order applied, and this law also established a specific preemption of State laws and standards in three areas: benefit requirements, requirements relating to inclusion or treatment of providers, and coverage determinations (including related appeals and grievance procedures). This meant that a general preemption applied if State laws, regulations, or other standards were inconsistent with Federal standards and, furthermore, in the specifically preempted areas, meant that State standards were preempted regardless of whether or not those standards were inconsistent with Federal standards.

In 2000, section 614 of BIPA maintained the general preemption authority and expanded specific preemption requirements by amending benefit requirements to include cost-sharing requirements and by adding a fourth specific preemption for requirements relating to marketing materials and summaries and schedule of benefits regarding a M+C plan. Thus, the list of areas of specific preemption effective since 2001 were: benefit requirements (including cost-sharing requirements), requirements relating to inclusion or treatment of providers, coverage determinations (including related appeals and grievance procedures), and requirements relating to marketing materials and summaries and schedule of benefits.

In 2003, section 232(a) of the MMA amended section 1856 for MA plans by eliminating the general and specific preemption distinctions from section 1856 and expanded Federal preemption of State standards to broadly apply preemption to all State law or regulation (other than State licensing laws or State laws relating to plan solvency). Section 422.402 of the regulation is thus revised. Note that State laws on secondary payer are also preempted by Federal law and a change is made in regulation at § 422.108(f) to reflect that States are prohibited from limiting the amount that MA organizations can recover from liable third parties under Medicare Secondary Payer provisions. The Congress indicated its intention to fully preempt State laws in the Conference Report for the MMA emphasizing that Medicare is a Federal program and that State laws should not apply. Section 232(a) of MMA was effective on enactment.

We do not perceive that there will be a significant cost impact on States from section 232(a) of MMA to broaden Federal preemption authority to preempt all State law and regulation (other than State licensing laws or State laws relating to plan solvency). The specific preemptions already in effect were broad areas where States were most likely to have enacted laws or developed other regulations or standards for health insurance. Apart from those specific preemptions, general preemption already applied where State provisions were inconsistent with Federal standards such that other State standards in conflict with Federal standards were also already preempted.

Areas of State law that will newly be preempted by full preemption of State laws (other than licensing and solvency) do exist, however, and will affect State residents who are Medicare beneficiaries. State governments will be affected in that State governments will no longer be responsible for enforcing preempted laws, which will likely reduce costs to States. A discussion of the diverse types of State laws that previously fell under general preemption is addressed in some detail in the response to public comments in the preamble to a June 29, 2000 final rule implementing the BBA's preemption law. (See 65 FR 35012 through 35014 of the June 29, 2000 **Federal Register** for a further discussion of the types of State laws that may be affected, which includes grievances and quality complaint reviews conducted by State governments.)

In reality, determinations of which State laws have been subject to general preemption often has not been made unless specific questions or disputes have arisen that resulted in a court review of applicability of law to specific cases. The MMA revision relieves uncertainty of which State laws are preempted by ''preempting the field'' of State laws other than State laws on licensing and solvency.

As required by Executive Order 13132, because of the implications for the States of the Federal preemption of State laws enacted in the MMA, we will consult with the States regarding the effect of the preemption provision on the role the States will play with respect to the regulation of Medicare plans, and the effect the preemption will have on State agencies and on beneficiaries enrolled in Medicare health plans. As noted in the preamble discussion of subpart I, there are issues to resolve with the States in order to clarify the breadth of preemption provisions with respect to State licensure laws, and which State statutory and regulatory provision may be considered licensing standards which are not preempted by the MMA provision. The comments and responses presented earlier in this preamble make clear that the role of State regulation of these plans is severely circumscribed. Some State-specific questions may subsequently arise, and some of these may be common across several States. In such cases we will undertake appropriate consultations with the States and, if necessary, issue interpretive guidance.

E. Effect on Beneficiaries

The MMA increases the value of benefits that enrollees of MA plans have and will increase the availability of such

benefits. When MA plans can bid at levels below the relevant benchmark, they can offer Medicare enrollees coverage of benefits beyond what Medicare covers (such as eyeglasses, hearing aids, or dental care), reduction in out-of-pocket expenditures for covered services (either as reduced cost sharing, on average, compared to FFS Medicare, or reduced expenditures for supplemental premiums compared to Medigap, for example), and reductions in expenditures for the Medicare Part B and Part D premiums. As a result of the MMA provisions, we project that in the period 2004 through 2009, Medicare beneficiaries enrolling in MA plans will see benefits beyond basic Medicare Parts A and B coverage which represent approximately 50 percent of the incremental dollars that are the government transfers to plans listed in Table 1. We are unable to provide a more precise figure because of the type of modeling used to determine projected expenditures and enrollment. The 50 percent estimate is based on the disposition of the incremental MMA dollars that MA plans received in March of 2004, at which time plans were asked to resubmit adjusted community rate proposals to CMS to account for the extra money received mid-year. We analyzed the benefit changes resulting from these mid-year filings and found that, for non-employer-sponsored plans, 58 percent of the additional funds were used to provide enrollees with extra benefits (or were deposited in a stabilization fund to be used for that purpose in 2005). Remaining funds were used to strengthen MA benefits in other ways, for example, maintaining or enhancing provider networks or financial stability for the MA plan. Expressed in dollars per enrollee, of the $38 per enrollee per month that was added to plan payments by the MMA in March of 2004, $22 was used to finance extra benefits or reduce out-of-pocket costs, and most of the remainder was used for provider networks (which will be particularly important to create attractive PPO plans). Employer group plans, which represent a little under 20 percent of MA enrollment, had a higher proportion of incremental dollars used for extra benefits-about 80 percent of the incremental dollars were used for that purpose-but, unlike non-group plans, a substantial proportion of the incremental dollars (over three-fourths of the funds) were deposited for use in 2005 (compared to five percent for non-group enrollees), and are included in the 80 percent figure. On average, therefore, across both types of coordinated care plans (employer group plans and plans for individual Medicare enrollees), about 60 percent of the 2004 MMA incremental dollars were used to finance extra benefits for MA enrollees. We assume that in future years this percentage will decrease slightly (a) because of the 2006 provision whereby the Government retains 25 percent of savings generated by local plans, and (b) because regional plans will incur relatively higher costs for the provision of Medicare A and B services (for example, because of higher out-of-network costs) and will consequently have less money available to return to enrollees in the form of rebates.

Because of the MMA payment increases effective March 2004, beneficiaries enrolled in private plans have already seen reduced out-of-pocket expenditures and increased benefits. Our analysis of MA benefit packages in 2004 after the MMA payment increases shows that enrollees of MA plans had out-of-pocket costs (including Medigap premiums) that were $700 less per year than for an individual in traditional FFS. This corresponds to a 14 percent savings for MA enrollees, relative to traditional Medicare. Individuals in poorer health had estimated savings in out-of-pocket costs of up to $1,909 a year in comparison to the alternative of traditional Medicare without Medigap coverage. (Savings are also substantial for MA relative to traditional Medicare with Medigap, average $1,647 per year).

F. Effect on Health Plans and Insurers

Health plans will see significant increases in transfer payments from the Federal Government as a result of the MMA. Plan payments will increase significantly, allowing plan revenues and profits to rise as enrollment increases with the offering of better benefits, better networks, and more stable plan availability. Organizations that currently contract with Medicare will have new market opportunities as regional plans and opportunities to expand their participation as local plans (other than as PPOs at a local level, which are prohibited from being newly formed, or expanding into a new service area, for an interim transition period, 2006 and 2007). Organizations that are not currently participating in Medicare will have a more favorable market environment for participating as local or regional plans.

The Federal Government transfer payments to health plans over and above what would have been paid in the absence of the law, as a result of the Title II provisions of the MMA, are expected to total $18.3 billion. To determine the administrative costs associated with these expenditures, we have relied on the adjusted community rate proposals of current MA coordinated care plans and demonstration PPOs, which report administrative cost figures as a percentage of Medicare payments. On average, ten percent of total plan revenues-consisting of Government payments and member premiums-will be used for plan administration in each type of plan (local and regional). The benefits to health plans will vary geographically, depending on benchmarks and the cost of doing business for the plans. The administrative cost figure cited here for the plans includes projected start-up costs for new organizations becoming Medicare contractors. The estimates of benefits related to MA plans for 2004 through 2009 are shown in Table 1. The data in the table reflect projections we have made about the number of plans participating, their bids and (consequently) their level of benefits, and the level of expected beneficiary enrollment. These projections are based on (a) what we know about the expected benchmarks in each of the 26 MA regions; (b) the current premium and benefit packages of MA plans and PPO demonstration plans, and their costs for the packages as submitted to CMS; and (c) the current patterns of enrollment in health plans in Medicare and the commercial sector. As noted previously, projections are based on a model that assumes three regional plans in each region, and that there will be a sufficient number of local plans to meet beneficiary demand for enrollment in local plans. In general, in terms of the proportion of funds used to provide extra benefits to enrollees, we expect local MA plans to be able to have more revenue available than regional PPO plans for the provision of extra benefits and reduced out-of-pocket expenditures. This is due to the cost of doing business in the areas where the regional PPOs will draw much of their enrollment (for example, the higher costs in rural areas), and the PPO structure, which involves the use of network providers as well as non-network providers. However, we would also expect that in many areas, there will only be regional plans available, and no local MA coordinated care plans. In addition, some beneficiaries will prefer the availability of out-of-network options in the regional PPOs, as is the case for many non-elderly Americans who prefer PPOs. As noted elsewhere, areas where there are only regional plan options and no coordinated care MA plans are likely to have higher benchmarks that are a vestige of the ''floor'' payment status of

such counties. Although PPO plans may face higher costs in operating in such areas, the higher benchmarks will enable them to offer enriched benefit packages (compared to traditional FFS Medicare). The projections of Table 1 show the distribution of dollars to all plans. The distribution is subject to regional variation (as is currently the case), so that in some areas, for example, beneficiaries will have more offerings and better benefit packages available to them as a result of plans having more funds to provide extra benefits, reduced cost sharing, lower premiums, or more extensive networks. Some plans may offer very few extra benefits but would still be attractive to enrollees and would be viewed by beneficiaries as more advantageous than FFS Medicare with Medigap coverage, for example.

The dollar figures shown in Table 1 reflect the projected additional Medicare Part A and B expenditures incurred solely as a result of the MMA provisions. That is, the expenditures are the incremental program expenditures that are incurred because of the MMA provisions, including any difference in expenditures that result when beneficiaries enroll in a private plan rather than receiving care in FFS Medicare.

Comment: Several commenters stated that the impact analysis projections are misleading in how types of plans are classified-that is, the basis for determining whether a plan is a regional plan or a local plan, and what kinds of organizations will be receiving payments as MA plans. The commenters noted that some local plans cannot become regional plans because they are not able to provide services across an entire region, while some local plans are sponsored by organizations that would also be (or could become) regional plans. The commenters believe that payments to local plans that are operated by organizations that operate regional plans (or could operate such plans) should be classified as payments to regional plans rather than payments to local plans. *Response:* While we acknowledge that the commenters' observations reflect the situation in the health care market-which is that not all organizations can be regional plans-we have provided separate projections for regional and local plans on the basis of the statutorily defined differences between the two types of MA contractors. In addition, we separated the two categories because we believe there is a value to the public in knowing what our expectations are with respect to the new types of plans-MA regional plans-introduced by the MMA.

The Congress recognized that it is not feasible for some organizations that are current MA contractors to become regional plans, and Congress did not preclude regional plan sponsors from also operating local plans. In various sections of the conference report it is noted that regional plans were designed to be able to provide services over a wide geographic area, and in particular to provide choices in rural areas that historically have not had coordinated care plans available to Medicare beneficiaries (see pages 96 through 98 of the MMA Conference Agreement, for example). It is recognized that regional plans would be larger-scale plans than some current local plans. We would also note that the possibility envisioned in the statute of a national plan eligible for stabilization fund payments demonstrates that Congress was aware that there could be plans that operate on a much larger scale than many local plans.

TABLE 1: PROJECTED PAYMENTS TO MA PLANS RESULTING FROM TITLE II PROVISIONS OF THE MMA, YEARS 2004 TO 2009, IN MILLIONS (INCREMENTAL AMOUNTS IN ABSENCE OF MMA TITLE II PROVISIONS); PROJECTED TOTAL PLAN ENROLLMENT, 2004 TO 2009, IN THOUSANDS (TOTALS MAY NOT SUM DUE TO ROUNDING)

	Year 2004	Year 2005	Year 2006	Year 2007	Year 2008	Year 2009	TOTAL, Years 2004–2009
Enrollment Projection, Local Plans	4,752	4,855	4,980	5,648	6,234	6,539	
Enrollment Projection, Regional Plans			1,686	2,637	3,097	3,604	
Total Value of Transfer Payments, Local Plans	1,738	2,618	2,143	1,632	1,259	1,023	10,414
Total Value of Transfer Payments, Regional Plans			746	2,498	2,372	2,312	7,928
Total Value of Transfer Payments to Plans, Both Types of Plans	1,738	2,618	2,889	4,130	3,631	3,335	18,342

As between regional and local plans, and the choice that an organization can make, regional plans, as described elsewhere, have a number of financial incentives. Local plans have the advantage of being able to selectively market to Medicare beneficiaries in that they can make decisions on a county basis. Local MA plans can choose whether or not to serve a particular county, and they can also vary benefits and premiums by county under one contract by segmenting larger service areas to as small a unit as a single county. The uniform benefit requirement applies to local plans at the service area or segment level, while regional MA plans, as previously noted, must have a uniform benefit in the entire region (for each of the plans that an MA regional organization offers in a region, each of which must be offered on a region-wide basis). One organization may offer both local and regional plans.

Although we have emphasized the additional benefits that we expect plans to be able to offer, the transition to a competitive bidding process more similar to that used by FEHB and large employers to obtain high-quality, stable plan participation should also help provide broader plan participation. As part of this process, Medicare has replaced the adjusted community rate process and its requirement that plan profit levels must be the same as for a plan's commercial product, and has

eliminated the limit on premiums related to reducing cost sharing for Medicare-covered benefits, plans can potentially manage their profit levels by developing more competitive benefit packages at a lower cost. Plans with bids exceeding the benchmark can also be assured of having adequate revenue to operate as Medicare plans (though they must offer sufficient additional benefits or quality to attract beneficiaries despite their higher premium). These provisions may also lend stability to the program in allowing plans to make adjustments to revenue needs from one year to the next without facing statutorily imposed limits on their ability to generate needed revenue.

There are a number of statutory and regulatory provisions which reduce burden on Medicare plans while maintaining and strengthening beneficiary protections, including the statutory changes that eliminated the reporting requirements relating to physician incentive plans, and the major changes in the quality assurance standards for plans. As discussed elsewhere, this rule also has several administrative changes that will reduce plan burden, including elimination of plan disclosure requirements that are redundant, and provisions that streamline the appeals procedure as regards notices to beneficiaries.

In terms of estimating the impact of these changes, the physician incentive plan (PIP) burden reduction was previously codified in the final rule entitled ''Medicare Program: Modifications to Managed Care Rules'' on August 22, 2003 and effective September 22, 2003. In the regulatory impact statement of that rule (68 FR 50853 and 50854) we stated: ''We find that overall the economic impact of this final rule is positive, due to...the reductions in regulatory burden due to...the reduction of the physician incentive reporting requirements...The data available do not allow us to determine the distributional effects...We have not considered alternatives to lessen the economic impact or regulatory burden of this final rule because the regulatory burden is reduced...'' We have no new data at this time that would alter the analysis and conclusions drawn in the prior rule.

With regard to the ''file and use'' policy, we are codifying in regulation a previously existing program tolerance which has been successful. The ''burden reduction'' actually associated with ''File and Use'' is minimal for two reasons. The first is that it represents a ''tolerance'' already in use; so additional burden reduction is non-existent. Second, File and Use is simply permission to publish (or use) certain marketing materials prior to CMS review and approval. To the extent that MA plans ''earn'' (or qualify for) File and Use status, the advantage gained and the burden reduction available to them is that MA plans qualifying for File and Use will not need to wait for CMS approval prior to using specific marketing materials. Finally, CMS does not currently collect data nor does it have information on the distributional impact of the currently existing File and Use program, so it is impossible to project the precise impact that File and Use will have on organizations qualifying for it.

We remove certain plan disclosure requirements from § 422.111(f). These disclosure requirements all are information that MA organizations must provide ''upon request.'' We have no data that would help us quantify the actual level of burden reduction. Therefore, the level of administrative burden mitigation is likely negligible.

Other Effects. Although most Medicare health plans and organizations that can participate as MA plans stand to benefit from the MA provisions, Medigap insurers may face price pressures and see declining enrollment if MA enrollment increases to the level that CMS projects. It should be noted that many of the insurers that offer Medigap coverage are companies that also operate health plans and are already, or can become, local or regional MA plans.

Medicare Advantage PFFS plans are another class of insurer that may see changes in the competitive environment. To date, such plans have operated primarily in ''floor'' counties (counties in which, because of the BBA and BIPA payment rules, health plan payment rates are higher than estimated FFS Medicare costs). PFFS plans generally have not competed directly against coordinated care plans. PFFS plans offer generally less generous benefit packages than MA coordinated care plans (involving higher levels of cost sharing and premiums), but they do offer some level of supplemental coverage for individuals (including drug coverage in many such plans), and they offer an advantage that some beneficiaries prefer, which is that there is not a limited network of providers that must be used to obtain covered care. As a consequence of the MMA, where there are regional MA plans, regional plans are likely to have a competitive advantage over Medicare PFFS plans that had usually targeted areas in which there were no MA local plans. MA regional plans must offer coverage for out-of-network care, and they are likely to be able to offer a significant level of extra benefits because of the financial incentives in the MMA. (As stated elsewhere in the preamble, regional MA plans may not be PFFS plans; regional plans must operate as a PPO model.)

G. Effects on States

States may see benefits from Title II of the MMA if more Medicaid beneficiaries who are also entitled to Medicare A and B coverage (the dual eligible population) enroll in private Medicare plans. Because MA enrollees are likely to receive non-Medicare-covered benefits (such as vision care) as well as lower copayments for Medicare-covered benefits, dual eligible enrollees would receive benefits that the States would otherwise have had to pay for. States may benefit from reduction of the Part B premium which the State would otherwise pay for dual eligibles. It should be noted that to date, the enrollment level of dual eligibles in Medicare plans is not as high as it could be (see Edith G. Walsh and William D. Clark, ''Managed Care and Dually Eligible Beneficiaries: Challenges in Coordination,'' Health Care Financing Review, fall 2002, volume 24, number 1). A number of factors could contribute to greater enrollment of dual eligibles in MA plans: the extension of plan availability across an entire State (as part of a regional plan), the likelihood of Part B premium rebates (which the State would be entitled to), and the designation in the law of dual eligibles as a category for purposes of determining whether an MA plan is a specialized plan. Dual eligible individuals do not have the same incentives to enroll in MA plans as other low-income Medicare beneficiaries. In certain circumstances, a State may require the enrollment of dual eligibles in MA plans (if, for example, the plan is also a Medicaid health plan and the State has a waiver permitting mandatory health plan enrollment for Medicaid beneficiaries).

The direct effect on the States of the expansion of the premium tax prohibition is discussed in the section on unfunded mandates. The MMA changed the law to exempt from State premium taxes the premiums paid by beneficiaries, as well as Federal payments to plans (which the law already exempted). This provision by itself has a relatively minor effect on State revenues, given the prevalence of zero-premium MA plans and given the expected trend in MA benefit packages towards more zero-premium products. However, an indirect effect of the premium tax prohibition is that, to the

extent that there are reductions in the number of beneficiaries who hold Medigap policies, States may lose premium tax revenue that would have been derived from Medigap policies (the entire premium of which is generally taxed). As previously discussed, it is unclear what the impact will be if there is such an effect, given the trend of greater numbers of beneficiaries with Medigap coverage and rising Medigap premiums.

H. Effect on Employers and Unions as Sponsors of Retiree Coverage

Historically, Medicare-contracting health plans that contracted with employer or union groups to provide benefits had to comply with the same Medicare regulatory requirements that apply to all Medicare-contacting health plans. In 2000, section 617 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) added a new authority at section 1857(i) of the Act, effective 2001, that provided CMS broad authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in M+C plans under contracts between M+C organizations and employers, labor organizations, or the trustees of a fund established to furnish benefits to an employer's current or former employees or to a labor organization's current or former members.

Three types of waivers have been approved under the BIPA authority which are discussed in an August 22, 2003 **Federal Register** notice (68 FR 50845). The three types of waivers are: (1) M+C organizations are allowed to offer employer-only plans that are not open to individuals and plan marketing materials do not have to be submitted for CMS review and approval; (2) M+C organizations are allowed to ''swap'' benefits not covered by Medicare of approximately equal value when an employer asks for a benefit package different from what is offered on the individual market; and (3) M+C organizations are allowed to raise the co-payments for certain benefits but to provide a higher benefit level or a modification to the premium charged as long as projected beneficiary liability is actuarially equivalent. These waiver authorities also will continue for MA organizations.

Section 222(j) of the MMA adds another authority for employer or union sponsored plans, effective 2006, at section 1857(i)(2) of the Act CMS may waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered directly by an employer, a labor organization, or the trustees of a fund established by employers or labor organizations to furnish benefits to current or former employees or to current or former members of labor organizations. This authority is added in the rule at § 422.106(d). We have received a number of inquiries from employers and labor organizations expressing interest in this direct contracting option.

We believe that there is likely to be a significant increase in the number of retirees whose employer or union provides retiree coverage through an MA plan because of the additional payments MA plans will receive (so that benefits that otherwise would have been financed by the employer or union can be financed by Medicare payments), and because regional plans will be available that can cover wider geographic areas and meet the needs of employers with retirees residing throughout a large geographic area, or dispersed across many geographic areas.

As of January 2002, about 18 percent of enrollees in Medicare+Choice plans were employer- or union-sponsored retirees (see Geoffrey R. Hileman, Kerry E. Moroz, C. William Wrightson, and Suhn K. Kim, ''Medicare+Choice Individual and Group Enrollment: 2001 and 2002,'' Health Care Financing Review, fall 2002, volume 24, number 1). There are 1.1 million beneficiaries residing in counties in which only employer-sponsored retirees or dependents may enroll in MA plans operating in those counties. MA plans may find this particular market segment attractive for a number of reasons, including: the efficiency of marketing to a large group; the advantage of having a group will have been previously insured; and the ability of offering enrollees a seamless continuation of coverage between active worker status and retiree status. The regional PPO model may also facilitate the ability of plans to serve this population to the extent that retirees no longer reside near their place of work.

According to a 2003 Hewitt-Kaiser Family Foundation survey of large employers, 21 percent of employers with 1000 or more employees require new Medicare-eligible retirees to pay 100 percent of the plan premium. The survey also found that, with regard to future trends, ''Serious consideration is also being given to only providing access to health benefits and asking retirees to pay 100 percent of costs; 26 percent of firms said that they are very or somewhat likely to make such a change.'' (Frank B. McArdle, et al., ''Large Firms' Retiree Health Benefits Before Medicare Reform: 2003 Survey Results.'' Health Affairs, web exclusive, January 14, 2004.) MA plans are a likely vehicle for employers to offer health plans under these circumstances. In fact, the 2004 Kaiser/Hewitt Survey on Retiree Health Benefits report indicates the continuing trend of having retirees pay 100 percent of their premiums and also shows that, among the changes large private sector employers made in 2004, ten percent of such employers are offering MA plans (the report is available at *http://www.kff.org/medicare/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=49652*; see in particular exhibit 22, at page 53). These trends would suggest that we will see an increase in MA enrollment of retirees with employer group or union-sponsored coverage (for beneficiaries of both types, those for whom the sponsor contributes to the cost of the coverage and those whose coverage involves only an offering of coverage).

I. Effect on the Federal Government

The benefits to beneficiaries and private health plans are the result of transfer payments from the Federal Government to plans, or, in the case of reductions in the Part B and Part D premiums, transfer payments to beneficiaries. For the period 2004 through 2009, the total amount of such transferred funds is projected to be $18.3 billion above what would otherwise have been incurred in the absence of the Title II provisions of the law. The preceding figure assumes a private plan penetration rate of 24 percent by 2009. The total expenditure figure assumes that $5.1 billion of the stabilization fund dollars for regional MA plans are used in the period 2004 through 2009. We have not separately projected an administrative cost to the Government for the administration of Title II of the MMA separate from administration of all portions of the MMA taken together.

There were several issues with a potential budgetary impact that were discussed in the notice of proposed rule making. The section on alternatives considered in the proposed rule examined the impact on expenditures in choosing between statewide and plan-specific risk adjustment to determine rebate amounts (beginning at page 46942). The conclusion of that analysis was that expenditures under either approach (plan-specific or area-wide) depended on the risk profile of plan enrollees, and that it was not possible to quantify the effect: ''Wide swings in the level of rebate dollars are possible under either method, but we cannot quantify the effect at this time without knowing the risk distribution of enrollees for

2006 and the respective bids of the health plans.'' As discussed in the preamble, in part as a reflection of comments received, CMS has chosen the plan-specific option. (See the preamble of the final rule and the alternatives considered section of the proposed rule, previously cited, for a discussion of the considerations that led to this decision.)

Another issue that has an effect on expenditures is the payment adjustment relating to risk adjustment for bids that exceed the benchmark. The regulatory text at § 422.308(e), discussed in subpart G of the preamble, would implement section 1853(a)(1)(G) of the Act, which requires CMS to make certain plan payment adjustments to take into account the health status of a plan's enrollees. For plans bidding above the benchmark, this provision would allow the total revenue a plan receives for its actual enrollees to more closely match the plan's required revenue. The 1853(a)(1)(G) provision requires CMS to adjust plan payments in recognition of the amount that a health plan receives as a basic premium from its enrollees. The basic member premium that plans actually will charge is the premium for a ''1.0'' beneficiary-that is, it is determined based on the revenue needs for a person with average health status. For a plan with a risk score above 1.0 (that is, the plan has enrollees that are sicker than average and utilize more services), there would be an additional payment from Medicare to provide the plan with revenue that covers the shortfall between the basic premium determined for a 1.0 enrollee, and the actual revenue necessary from member premiums. (Under the current system, but not after 2005, in such a case enrollees would be charged a higher plan premium to cover the needed revenue that matches their enrollees' actual utilization patterns.)

A similar adjustment would be made for plans with risk scores below 1.0. A plan with a risk score below 1.0 would have determined its basic premium for a 1.0 person, and enrollees will be charged that level of premium. This provides the plan with more revenue than it needs. Consequently, the section 1853(a)(1)(G) provision would call for a reduction in Medicare's payment to the plan in recognition of the additional revenue that comes from member premiums that are determined for a 1.0 beneficiary.

The budgetary impact of this provision depends on the number of plans that would have bids above the benchmark, and the health status of enrollees in such plans. One would assume that the majority of organizations deciding to enter the Medicare market would like to be able to offer extra benefits at no cost, or at little cost, to prospective enrollees. Therefore there may be few plans that bid above the benchmark, and those that do so would try to limit the basic premium to an amount that would attract a sufficient number of beneficiaries. However, bids above the benchmark may arise (a) in certain areas-for example, in areas where there may be only one or two plans, or (b) in certain competitive situations-for example, when the reason for a bid above the benchmark is that the plan offers coverage that is expensive but has features that appeal to beneficiaries (such as a wide network of providers, particular ''marquee'' providers in the network, especially lower copayments, or generous out-of-network coverage).

With respect to the risk profile of plans that may be bidding above the benchmark, currently private plan enrollees are somewhat healthier on average than Medicare beneficiaries in traditional FFS. If plans bidding above the benchmark have healthier-than-average enrollees, the budgetary impact of the 1853(a)(1)(G) provision would actually be net program savings as beneficiaries bear some extra cost in their plan premium. If today's patterns of enrollment continue, there may be such program savings: looking at the subset of plans that currently charge a premium for Medicare-covered services compared to plans that have no premium charge for Medicare-covered services (a rough type of proxy for determining whether a bid will be above the benchmark), the risk status of enrollees of plans in which there is no premium is below 1.0 but closer to 1.0 than among plans charging a premium. The latter group of plans have risk scores that are also below 1.0, but the risk scores are about 10 percent lower-that is, risk scores show that enrollees are healthier-than the risk scores of plans that have no premium charge for Medicare-covered services.

On the other hand, as Medicare increases the proportion of plan payments that are risk-adjusted to 100 percent, plans will have even greater financial incentives to offer benefit packages that appeal to less healthy beneficiaries. Consequently, moving to full risk adjustment would be expected to lead to a reduction of any differences in health status in MA plans, including the higher-premium plan.

In summary, the 1853(a)(1)(G) risk adjustment provision, which may have limited applicability if few plans bid above the benchmark, may result in program savings.

J. Administrative Costs

The expenditures shown in Table 1 include administrative costs for MA plans. For both local and regional plans, administrative costs are assumed to comprise ten percent of the total incremental expenditures shown in Table 1. This includes both costs to administer the program and the profit or retained earnings of health plans. Administrative costs for local plans and regional plans are considered to be roughly the same based on the reported administrative costs of current MA plans that are PPOs and HMOs.

K. Analysis of Effects on Small Entities

The Regulatory Flexibility Act (RFA) requires us to determine whether a rule will have a ''significant economic impact on a substantial number of small entities.'' If so, the RFA requires that a Final Regulatory Flexibility Analysis (FRFA) be prepared. Under the RFA, a ''small entity'' is defined as either a small business (as defined by the size standards of the Small Business Administration, or SBA), a non-profit entity of any size that is not dominant in its field, or a small governmental jurisdiction. The SBA size standard for ''small entity'' health insurance plans is annual revenue of $6 million or less.

The direct effects of Medicare Advantage fall primarily on insurance firms and on individual enrollees. The competitive market created by Medicare Advantage is likely to have long run indirect effects on health care providers, such as hospitals, physicians, and pharmacies, depending on the extent to which MA plans attract enrollees. However, those effects will result from the workings of market choices made by enrollees, plans, and providers, not from specific provisions of this rule. (There is an MMA provision for paying certain ''essential hospitals'' higher rates for participation in the MA program, which we analyze below.) Therefore, we primarily analyze effects on the insurance industry (including HMOs as insurers) in this FRFA.

We do not believe that these rules will create a significant economic impact on a substantial number of small entities. We have prepared the following analysis in part to provide a factual basis for our beliefs regarding the impact of this regulation on small entities; we also consider this analysis a voluntary FRFA. Under longstanding HHS policy we prepare a FRFA if significant impacts of a rule on small entities are positive rather than negative. We also prepare a FRFA if we cannot be certain of a conclusion of no ''significant impact'' on less than a

''substantial number.'' In this case, the statutory reform is so major and the number of regulatory changes so large that we cannot be certain of our conclusion. Finally, we generally prepare a FRFA if there is likely to be substantial interest on the part of small entities. Essentially all of the insurance firms affected by the statute and this final rule exceed size standards for ''small entities'' within the meaning of the RFA and implementing SBA guidelines, which state that an insurance firm is ''small'' only if its revenues are below $6 million annually. We note that under prior law (continued unchanged for Medicare Advantage), no health insurance plan is normally eligible to participate in Medicare Advantage unless it already serves at least 5,000 enrollees, or 1,500 enrollees if it primarily serves rural areas. At the 5,000–enrollee level, no plan would fall below the SBA revenue cutoff assuming, very conservatively, yearly revenue of $2,000 per enrollee. While a very small rural plan could fall below the threshold, we do not believe that there are more than a handful of such plans. In the InterStudy Competitive Edge HMO Directory for 2000, discussed below, we found only one rural HMO with a continuing enrollment level below 1,500. Therefore, the statutory limits generally prevent any insurance firm defined as ''small'' pursuant to the RFA's size standards from participating in the program. However, a substantial fraction of the insurance firms affected by this final rule are ''small entities'' by virtue of their non-profit status. The analysis in this section, taken together with the other regulatory impact sections, and the preamble as a whole, constitute our FRFA for the Medicare Advantage provisions of Title II of the MMA. We note that there is a related FRFA in the companion final rule on the Part D Drug Program of Title I of the MMA.

1. The Health Insurance Industry

The 1997 Economic Census: Finance and Insurance (the latest available edition when the proposed rule was being developed) states that there were 944 firms classified as ''Health and Medical Insurance Carriers'' under the North American Industry Classification System. Of these, 851 firms operated the entire year. Using Census data, these firms had total revenue of $203 billion, operated through about 3,200 establishments, and had about 328,000 employees. Of the 851 firms that operated the entire year, 342 had revenues of less than $5 million. Taking into account subsequent inflation, this corresponds closely to the $6 million threshold established by the SBA as the current cutoff for small businesses in this insurance category. Thus, approximately 40 percent of the industry as counted by the Census is ''small'' using the SBA definition. These small firms had total revenue of about $440 million, rather less than one half of one percent of total health insurance revenue. As discussed below, we do not believe that any of these small firms underwrite comprehensive health insurance policies, or are actual or potential participants in the Medicare Advantage market.

In contrast, the Census found that the largest 50 firms, or 6 percent, accounted for 75 percent of all health insurance revenue. While these data cannot be reconciled directly with other statistics on numbers and size of health insurance companies, they clearly indicate that the market for comprehensive health insurance policies, covering the lives of about 200 million Americans, is dominated by several hundred companies, few of which, and most likely none of which, are ''small'' by SBA revenue standards.

Another source of industry data, much richer in detail, is found in the InterStudy Competitive Edge. This annual report covers only HMOs. The discussion that follows uses the 2000 edition as reflecting most of the changes of the 1990s, but still close enough in time to the Census information to be roughly comparable. In 2000, there were 560 HMOs. While these were all separately incorporated, many were subsidiaries of larger corporations. For example, the report lists 40 United HealthCare plans, 22 Aetna and 32 Prudential plans (all owned by Aetna), 31 Cigna plans, 10 Humana plans, and 9 Kaiser plans. Ninety-seven of these HMOs enrolled 200,000 or more people (enrollment is a standard industry measure of size). The InterStudy data, using an enrollment cutoff of 3,000 to correspond roughly to the SBA $6 million threshold, shows that only 5 HMOs were continually operating entities (not entering or exiting the industry) with revenues below the SBA small entity threshold.

Of the approximately 200 contracts under the current MA program (this figure excludes demonstration contracts), only a handful have enrollment of fewer than one thousand or annual Medicare revenue of under $6 million assuming, conservatively, revenues of $6,000 per enrollee (Medicare enrollees cost, and are reimbursed, more than double working age persons). Of course, these plans have other revenues from non-Medicare clients, and we are unaware of any current MA organizations with revenues below the SBA threshold. (Note that the number of current MA contracts includes separate Medicare contracts held by a single firm in different parts of the country-as in the case of PacifiCare, for example, which has ten contracts in eight States.)

These data show that few, if any, health insurance firms with revenues of $6 million or less underwrite comprehensive insurance in the national insurance market. Furthermore, discussions with Bureau of the Census staff indicate many and probably most of the small firms classified as insurers do not underwrite health care costs (that is, provide comprehensive health insurance), but are firms offering dental or medical discounts through small provider networks or offering indemnity-type policies paying, for example, a few hundred dollars a day for each day spent in a hospital. They would not even be licensed by States to offer comprehensive or group insurance policies. Therefore, we have no reason to believe that the changes to the Medicare Advantage program that will take effect for the 2006 contract year will have any positive or negative effect on ''small'' insurance firms, with the possible exception of Medigap insurers.

Some of these small firms may be Medigap insurers. For this limited group, the MMA has major consequences. Specifically, existing categories of Medigap policy that cover prescription drugs will become illegal to sell to new enrollees, and several new Medigap categories will be created. (These changes, however, are specified in the statute and are not subject to regulatory discretion.) Furthermore, Medigap insurance is a unique type of product that does not involve accepting insurance risk for the full cost of health benefits, since Medicare itself remains the primary insurer. Therefore, it is unlikely that any consequential number of firms operating solely in the Medigap market would expect to operate in the Medicare Advantage market. Effects of the MMA on Medigap are discussed in more detail the economic effects analysis in the companion Title I rule.

The definition of small entities under the RFA also encompasses not-for-profit organizations that are not ''dominant'' in their field. (HHS interprets ''dominant'' to mean national dominance.) There are many large HMO companies that are non-profit. As of 2000, about 37 percent of HMO enrollment was in non-profit firms, and 152 of 558 HMOs, or 27 percent, were non-profit (InterStudy Competitive Edge HMO Industry Report for 2000). None of these firms is nationally ''dominant'' in

the health insurance industry although many firms achieve large market share in particular health care markets.

About half of these firms already compete in the Medicare MA market, and most are potential entrants or re-entrants as Medicare Advantage plans. According to the InterStudy data, about one third of HMOs currently participating in MA are non-profit. Some HMOs, profit or non-profit, may be potential entrants in the new regional MA markets. This will partly depend on how rapidly the non-profit firms grow by merger or make other market adaptations, such as adding PPO networks. However, relatively few HMO plans (in contrast to parent company or linked HMOs), operating through local HMO networks, are likely to be able to compete in a region encompassing large areas or several States and multiple health care markets.

2. The Local Medicare Advantage Market and Small Entities

Under MA, there are two distinct (though overlapping) markets: local and regional. All existing MA HMO plans participate on a local area basis, typically covering the several counties encompassed in a metropolitan area. Because HMOs are most common in metropolitan areas, and especially in the largest metropolitan areas, existing plan availability and enrollment is concentrated in these areas. As discussed previously in this analysis, only about one fifth of U.S. counties, though over 60 percent of the eligible population, have an MA coordinated care plan available. The MMA makes one major change for local plans by significantly improving payment rates. This statutory change is already in effect and is not addressed in these rules. These rules will have beneficial effects on local plans, by reducing some administrative burdens, but the changes in this final rule, singly and collectively, do not rise to the level of ''significant economic impact'' on local HMOs (though the payment increases in 2004, already in effect as a result of the statute, did have an effect of that magnitude).

The other major changes of Medicare Advantage include the creation of a new regional plan structure to become operational in 2006, designed for and limited to PPO plans. The regional structure is intended to ensure that the entire beneficiary population, not just those residing in major urban centers, has access to alternative plans. As discussed elsewhere in this analysis, we assume that as a result of these changes private plans may attract as much as one-third of all Medicare enrollment by 2016.

Starting in 2006, local HMOs will face two new sources of competition. First, they will find themselves seeking to attract enrollees from a pool of eligible applicants who will now have Part D drug benefits as enrollees in FFS Medicare. Second, they will be competing against regional MA plans serving their areas. Regional plans will have some advantages specified in the statute, including access to the stabilization fund and, temporarily, to risk sharing with the government. It is possible that some existing local plans will lose some enrollment. The local HMOs will, however, have important assets including integrated benefit packages (as compared to free-standing PDPs), quite likely drug benefits at premiums lower than PDP premiums, and extra benefits (including rebates of the Parts B and D premiums) not available in FFS and possibly more generous than those available in regional MA plans. The local plans will have an existing customer base and pre-existing networks in the areas where most beneficiaries live. Most compete in major metropolitan areas where Medicare payment rates are higher than in other areas that a region would encompass. Finally, many and perhaps most local plans are subsidiaries of large insurance firms that offer multiple product lines. These firms retain the ability to ''mix and match'' their product offerings to best advantage. Regardless, whether and how much any given plan loses or gains will primarily depend on its overall attractiveness (benefits, services, provider panels, out of network benefits, and premiums) compared to its competitors. Nothing in these rules, as such, either favors or disfavors local plans when competing against regional plans.

While it is impossible to predict the precise situations that these HMOs will face, or their responses, there are some lessons available from the FEHB Program experience. In that program, about 200 local HMOs co-exist in competition with about a dozen national PPO plans. Most HMOs compete in big city markets against 15 or 20 plans, both PPO and HMO. While HMO enrollment in the program has declined slightly in recent years, and almost half of all HMOs have left the program since their peak participation in the early 1990s (reflecting mainly industry consolidations), HMOs currently enroll about 35 percent of all Federal employees, and 9 percent of retirees, down only slightly from the peak levels of 39 percent and 10 percent, respectively, a decade ago.

3. The Regional Medicare Advantage Market and Small Entities

Starting in 2006, health insurance firms both profit and non-profit (and hence ''small entities'' under the RFA) will be able to compete as regional plans. A firm may compete in as many regions as it chooses, up to and including the entire nation. The chief constraint is that a plan must demonstrate that it has a region-wide network of providers.

We know of one group of potential regional competitors who may be affected by regional boundary decisions-insurance plans that operate on a state-specific basis, notably Blue Cross/Blue Shield plans. In recent years many Blue Cross/Blue Shield plans have merged within and across State lines. However, there still remain several dozen of these plans that operate on a state-delineated basis. The regional MA boundaries established in December, 2004 attempt to accommodate these and other plans that face significant practical constraints in operating across state line. Of course, many considerations affected decisions on regional boundaries, including beneficiary access, viable economic size, and existing medical and PPO markets. Our primary objectives were to give all Medicare beneficiaries the opportunity to enroll in an MA plan, to give them the greatest amount of choice by encouraging competition, and as a result to provide price competition and affordable costs for enrollees. These considerations, and the resulting boundary decisions, are described on the CMS Web site at *www.cms.hhs.gov/medicarereform/mmaregions*.

A local plan may encompass all or most of a State, and/or operate in more than one State if it so chooses. Of course, regional plans have some advantages, but local plans have others. Since the statute preempts State standards for benefits, coverage, and provider networks, leaving effectively only licensure and solvency standards as State-imposed requirements, we anticipate no important problems for plans (though regional plans may have to seek licensure in States in which they currently do not operate, or would have to seek a waiver as permitted by the MMA). There is another problem that could be important to a plan far larger than the SBA size standard but nonetheless smaller than the plans serving hundreds of thousands or millions of enrollees. Organizing the full resources needed to compete effectively in the Medicare context will require substantial investments in acquiring and maintaining actuarial expertise, legal expertise, effective marketing, network

building, benefit design, cost-control, disease management, formulary design, claims processing, financing, and so forth. There are economies of scale in health insurance (like many other businesses), and these presumably favor larger firms, all other things equal, up to some point. We are not aware of any industry studies that seek to measure the minimum size necessary for health insurance firms to compete effectively in local, regional, or national markets and request information on this question. However, to the best of our understanding any such barriers to entry or cost competitiveness are likely to fall well within the size of most firms competing today in such large systems as M+C, the FEHB Program, or the private employer market. In summary, the MA program, by having both a regional and local model, provides opportunity for health insurance entities of all types and most sizes (but probably not below the ''small'' insurance entity cutoff level defined by the SBA, which is lower than appears viable for a comprehensive, risk-bearing insurance plan), and offering many different kinds of plans, to participate. That participation is more likely to take the form of local plans in the case of smaller and non-profit entities. However, the overriding objective of the regional plan model is to give beneficiaries access to and choice among integrated private plans that can offer comprehensive health insurance encompassing Medicare parts A, B, and D. This model is dictated in almost all its important details in the statute.

Comment: Several commenters felt that the impact analysis did not discuss the negative impact on local MA plans of having to compete with regional plans, which have various financial incentives to ensure participation. For example, local plans operating in a rural area would be at a disadvantage because their benchmarks could be lower than the benchmarks applying to regional plans. The commenters also suggested that CMS work with the Department of Justice and the Federal Trade Commission to ensure that anti-competitive practices are not permitted, given that the MMA creates new health insurance markets with participating plans that, the commenters state, would have the market power to unfairly limit competition.

Response: As we noted above in response to another comment regarding how to classify plans as local or regional, in order to address the issue of limited access to coordinated care plans in rural areas, the MMA has created the MA regional plan option, which is likely to be an option that is primarily offered by larger health plans or insurers. In the year 2003, only about 13 percent of Medicare beneficiaries residing in rural areas had access to a Medicare coordinated care plan. That is, only 13 percent of the rural population was served by a local coordinated care plan. If the MMA is successful in the goal of expanding access to rural areas, ideally 100 percent of rural enrollees will have access to a coordinated care plan because of new regional MA option.

The manner in which the MMA seeks to expand access to coordinated care plans in rural areas involves certain incentives for plans willing to participate under the terms set out by the law, and it involves certain ''trade-offs'' that were felt necessary to ensure participation. One such trade-off is the willingness of the Congress to increase payments through the use of the stabilization fund in order to ensure maximum access to MA plans across a wide geographic area. Only plans that are willing to serve a wide geographic area have access to the stabilization fund. Local plans do not have access to the fund, unless they are willing to participate as regional plans. Similarly, regional benchmarks may be higher than local benchmarks in certain areas. However, organizations for which a regional benchmark applies are assuming risk for a large population across a wide geographic area, must offer a uniform benefit package across the entire area, and cannot selectively discontinue contracting on a county-by-county basis (or even selectively drop portions of counties, as local plans are permitted to do under certain circumstances). Regional plans are required to operate as preferred provider organizations throughout a large service area. Requiring plans to operate under such a model, as opposed to a more tightly knit network model, would tend to raise costs for the plan and would result in a lower level of extra benefits for enrollees. The PPO model also adds to the level of risk assumed by the health plans because of the uncertainty surrounding the utilization and costs for out-of-network services that such plans must reimburse.

As we have stated above, we would hope that there is room for competition to occur in all types of areas of the country between local plans and regional plans. With regional and local plans each having some advantages, and open competition among multiple plans of each type expected in most areas, we cannot predict likely ''winners.'' Our expectation is that plans of both types will succeed in most areas.

With respect to anti-competitive practices, CMS has worked with the Department of Justice and Federal Trade Commission in the past on competition issues in the provider and health plan markets, and we will continue to work with those agencies in the future.

4. Hospitals

An additional program under Medicare Advantage directly affects hospitals. HHS has long taken the approach of treating all hospitals as presumptive ''small entities'' within the meaning of the RFA, mainly because of the dominance of the non-profit model in the hospital industry (about 80 percent) and also because most of the rest have revenues under the $29 million SBA size threshold for hospitals.

The MMA facilitates the inclusion of hospitals in regional networks in cases in which a plan and a hospital cannot reach agreement regarding the hospital's provision of services under the plan. As described in more detail under the Subpart C preamble section, if the hospital's participation is ''essential'' to meeting a plan's network adequacy requirement, and the hospital can demonstrate to us that its costs are higher than the normal Part A payment it receives, then the MA plan can pay the normal amount and the network adequacy fund will pay the difference. The total amount available nationally for this purpose is $25 million in 2006 (rising annually at the hospital market basket rate).

This provision will most likely apply to small towns and rural areas, particularly if such areas are served by only one hospital. It is impossible at this time to predict the frequency with which this situation will arise, since that depends on future bargaining among plans and hospitals, and on hospitals' ability to demonstrate excess costs. Since the hospitals benefiting would otherwise serve Medicare enrollees at Medicare rates, the financial effects of this program on hospitals should never be negative, and qualifying hospitals will obtain higher payments. Likewise, by allowing regional plans to meet their network requirements at a reasonable cost the effects on them are positive. We note that over 700 rural hospitals are already paid at rates somewhat higher than would otherwise be applicable under Medicare's hospital payment rules. Some of these would be candidates for ''essential'' hospital payments (although the eligibility criteria are different). Although there are 700 such hospitals, they are small hospitals in sparsely inhabited rural areas and account for only about one

percent of Medicare hospital payments. The pattern under the essential hospital program is likely to be similar.

5. Medical Savings Accounts

These regulations also change the rules for Medical Savings Accounts (MSAs), which are high deductible plans. This provides new opportunities for insurance firms to participate in Medicare Advantage. High deductible plans are increasingly being offered in the under age 65 market by large insurance firms. As discussed previously in this Preamble, we are implementing the statutorily defined changes (at section 233 of the MMA), which are intended to make MSAs a viable option for beneficiaries. We are also amending the existing rules in several places to remove requirements that would be inappropriate if applied to MSAs.

6. Employer Sponsored Plans

The MMA adds new authority for employers and unions to sponsor plans for their employees and former employees, or members. Previously they could sponsor plans through an M+C organization; the statute gives them the flexibility to sponsor plans directly. The statute and the regulation provide for waiver or modification of any requirement under Part C or Part D that would hinder the design of, the offering of, or the enrollment in employer or union-sponsored plans.

7. Other Requirements in the Regulatory Flexibility Act

The RFA lists five general requirements for a FRFA and four categories of burden reducing alternative to be considered. It also defines as a small entity a ''small governmental jurisdiction'' whose area has a population of less than fifty thousand. We anticipate no consequential effects of these regulations on small governmental jurisdictions. We know of no relevant Federal rules that duplicate, overlap, or conflict with the rule (which in any event amends an existing rule that is not duplicated or overlapped by other rules). The analysis above, taken together with the rest of this preamble, addresses all these general requirements.

We have also sought both to avoid imposing new burdens, and to ameliorate existing burdens, as discussed throughout this analysis. Throughout this preamble we identify a number of changes that would lessen the burden of the existing MA rules.

Comment: In response to our desire to know of any small businesses or entities affected by these regulations whose concerns might not have been addressed, a number of commenters stated that CMS failed to address issues related to the health care needs of AI/AN.

Response: This concern is addressed in various sections of the preamble language dealing with specific issues as they relate to AI/AN (specifically in subparts A, B, C and F). As noted in those sections, where the statute permits us to do so, we have taken into consideration issues raised by commenters having to do with the special needs of AI/AN populations, their use of IHS providers and the reimbursement rules and cost sharing requirements for such providers, and outreach issues related to such populations.

The preamble to subpart A addressed the comments asking (1) that IHS services be included within the definition of basic services; (2) that we include as SNPs those plans that would enroll only AI/AN beneficiaries; and (3) that we recognize that IHS, I/T/U Programs will face high costs related to outreach, education and enrollment because of the MMA. As stated in the preamble, we are unable to accept the commenters suggestions for the first two issues because there is no statutory authority to expand the definition of basic services as suggested, and there is no statutory authority for establishing AI/AN special needs plans. With regard to the third issue, we recognize this concern and state that we will continue to work with the IHS and other partners in identifying effective outreach and education strategies appropriate to AI/AN populations.

Comments on subpart B asked that (1) we make exceptions for AI/AN beneficiaries when plans are closed for enrollment because of capacity waivers; (2) allow AI/AN beneficiaries to switch among types of plans outside of open enrollment periods; (3) have plans contact I/T/U if a plan intends to involuntarily disenroll an AI/AN enrollee; and (4) specify that outreach workers employed by IHS or tribal organizations not be prohibited from going door-to-door to assist AI/AN individuals in making health plan choices because of the prohibition on door-to-door marketing. With regard to the first item, we do not believe it is appropriate to have exceptions to capacity waivers for particular categories of individuals because of the nature of capacity waivers, which are granted when an organization establishes that its provider network capacity is such that enrollment must be limited to a certain number of individuals. With respect to SEPs, the subpart B preamble language explains that specific SEPs are included in regulations if they are based on statutory provisions. Periodically, we establish SEPs based on special circumstances, and there may arise situations in which AI/AN populations may be subject to SEPs. On the question of involuntary disenrollment, the preamble states that the notification is to the individual who is the subject of the proposed disenrollment, and that to bring in other parties would be beyond the scope of the statutory provision. With regard to the prohibition on door-to-door marketing, the preamble notes that we understand this concern and will work with the IHS and tribal organizations to address the concern.

Subpart C comments included requests that there be rules requiring ''full reimbursement'' of IHS facilities and that there be a blanket waiver of cost sharing requirements for AI/AN enrollees of MA plans. Neither of these requests is possible within the scope of the statute. However, the rules that apply, for example, to non-network providers and the amount that must be paid to such providers, apply to IHS providers. With regard to cost sharing, although blanket waivers are not permissible, under current law and regulations cost sharing can be waived in individual cases under certain circumstances.

The subpart C preamble also discusses a comment asking that we use the waiver authority of section 1857(i)(2) of the Act, as expanded by section 222(j)(2) of the MMA, to permit direct contracting with I/T/Us to sponsor MA plans exclusively designed for AI/AN beneficiaries. As stated in the subpart C discussion, the waiver authority applies only to employer- or union-sponsored health plans.

In the subpart F preamble we note that we are considering possible options to facilitate the ability of AI/AN Tribes to use the option of allowing groups to pay the part B premium for individuals, which is suggested as a means of making it more likely that AI/AN beneficiaries will enroll in MA plans.

L. Alternatives Considered

In this section we discuss the impact of several issues in which we have made a choice among various policy options. We refer readers to the Notice of Proposed Rule Making, and other documents available from CMS, for a fuller discussion on the issue of the designation of regions. Readers are referred to the NPRM for a discussion of the effect of our decision to use a plan-specific versus statewide, area-wide or region-wide risk adjustment to

determine plan rebates, and the effect of the payment adjustment relating to risk adjustment for bids that exceed the benchmark. Below is a discussion of the impact of our decision regarding the determination of the actuarial value of Medicare cost sharing as part of a health plan's bid, as well as a discussion of the potential impact of different approaches to intra-area geographic adjustment of payments when plans serve more than one county.

Designation of Regions

The impact analysis for the proposed rule of August 3, 2004, noted that a major area in which CMS was given discretion was in the matter of designating the configuration of MA and PDP regions. The proposed rule impact analysis included a discussion of some of the issues related to the designation of MA regions (69 FR 46937). On December 6, 2004, CMS announced the MA and PDP regions. The listing of the regions and material discussing the rationale for choosing the regions can found at *http://www.cms.hhs.gov/medicarereform/mmaregions/*. That site also contains links to sites containing research findings related to the designation of regions, and information concerning public meeting that were held on the subject of the regions (for example, *http://www.cms.hhs.gov/medicarereform/mmaregions/All_Info_Materials.pdf*). The impact analysis of the companion Title I final regulations contain an explanation of why there is a larger number of PDP regions than MA regions.

As we have discussed in the explanation of projections, the enrollment and expenditure figures of Table 1 represent our best estimate of the effects of the law and regulations based on the regions as they have now been designated. The proposed rule assumed 15 regions, but with a greater number of MA regions, there is likely to be a smaller level of enrollment in regional plans.

Plan-Specific Versus Statewide, Area-Wide or Region-Wide Risk Adjustment to Determine Plan Rebates; Payment Adjustment Relating To Risk Adjustment For Bids That Exceed The Benchmark

As noted previously in section I (Effect on the Federal Government), these issues were discussed at length in the proposed rule, with the conclusion being that the impact could not be quantified without knowing the risk distribution among the plans and their bids. Another issue that has an effect on expenditures is the payment adjustment relating to risk adjustment for bids that exceed the benchmark, previously discussed in section I, Effect on the Federal Government.

Actuarial Value of Medicare Cost Sharing as Part of Bid

As explained in the preamble of this final rule in the discussion of subpart F, a number of alternatives were considered in determining how to compute an actuarially equivalent value of Medicare cost sharing as a component of a plan's bid for the basic Medicare benefit package (coverage of Medicare A and B services). Under the provisions of section 1854(a)(6)(A)(ii)(I) of the Act, one component of the bid is the proportion of ''such bid amount.attributable to.the provision of benefits under the original Medicare fee-for-service program option (as defined in section 1852(a)(1)(B)).'' Under section 1852(a)(1)(B), ''benefits under the original Medicare fee-for-service program'' are defined as ''those items and services (other than hospice care) for which benefits are available under parts A and B to individuals entitled to benefits under part A and enrolled under part B, with cost-sharing for those services as required under parts A and B or an actuarially equivalent level of cost-sharing as determined in this part.'' A number of alternatives are discussed in the preamble of the final rule and the proposed rule under subpart F.

One alternative discussed would use a plan-specific determination of cost sharing which would have included a computation of any induced demand resulting from reduced cost sharing. That is, for purposes of comparison to the benchmark, a bid would have been made based on the cost sharing structure of FFS Medicare. To the extent that the Medicare cost sharing structure acts as a limit on utilization, a plan would require less revenue to provide Medicare A and B services as compared to a benefit package with a cost sharing structure less restrictive than that of FFS Medicare (the extreme case being, for example, a benefit package with no cost sharing on Part A and B benefits). The former, lower amount-the bid based on Medicare cost sharing-would be the amount to be compared to the benchmark to determine whether there were any savings that would be retained by the Government (25 percent of the savings, for local plans) or which would have to be passed on to the plan's enrollees (75 percent of the savings). If an organization decided to offer a benefit package with, for example, no cost sharing for Medicare-covered services, the proposed rule suggested that the supplemental benefits associated with such a benefit package would include not only the dollar value of reduced cost sharing (that is, the charges that would otherwise be the responsibility of the beneficiary are borne by the health plan), but also the dollar value of any additional utilization of Part A and B services which would not have arisen if there had been a Medicare-like cost sharing structure. In other words, because the benefit package being offered is ''richer'' or more costly than the benefit package that the Government asks plans to bid on (the Medicare Part A and B package with a specified level of cost sharing), one hundred percent of that cost must be borne by the plan and/or its enrollees. The cost to the beneficiary of such a package could be reduced by available rebate dollars, but the computation of the total rebate dollars would be based on a comparison between the benchmark and the plan-specific determination of the presumably lower-cost ''benefits under part A and.part B, with cost-sharing for those services as required under Parts A and B.''

The alternative chosen-which is to use a proportional method to determine the actuarial value of cost sharing for Part A and B services associated with a bid-does not involve a determination of induced utilization. The proportional method assigns cost sharing values to a bid in manner that is intended to closely approximate Medicare FFS cost sharing with respect to the expenditures for services that would be plan expenditures versus those (the cost sharing) that are beneficiary expenditures. It is not entirely clear whether having chosen this method rather than the plan-specific approach has the effect of reducing the amount of savings the Government would have retained. And if there is such a difference, we do not believe we are able to provide a reasonable dollar estimate of the effect.

With regard to whether induced demand is an issue that would affect the determination of Government savings as just described, a number of commenters stated that induced demand does not arise in managed care plans because utilization is limited to necessary and appropriate services through the plan's utilization management practices. That is, changes in cost sharing would neither reduce nor increase utilization; they would only shift the source of provider revenue from the plan to the enrollee. As discussed in the preamble, this argument may be clearer for hospital services received through a plan, when discretionary hospitalizations may be limited because physicians admit patients, but for other service such as specialist physician services in ''open access'' plans there

would presumably be a utilization effect if, for example, copayments for specialist physician visits are far higher than copayments for primary care providers and a beneficiary is making a choice between visiting a specialist versus a primary care provider.

As we note in the preamble, CMS will continue to examine the issue of the relationship between cost sharing and plan bids, and we may refine our approach in the future.

Geographic Adjustment of Payments

Subpart G of the preamble contains a discussion of the manner in which we will implement the geographic adjustment of payments called for in section 1853(a)(1)(F) of the Act ''to take into account variations in MA local payment rates under this part among the different MA local areas.'' Under the bidding system effective in 2006, variations in payment rates among counties have to be taken into account through an adjustment process that is somewhat different from what occurs today when Medicare Advantage plans operate in more than one county. As previously noted, we will be using a geographic adjustment based on county-level MA payment rates, but will allow regional MA plans, on a case-by-case basis, to request to have their payments geographically adjusted at the county level using a plan-determined statement of the relative costs the plan faces in different counties for the provision of Medicare-covered services. What follows is a general discussion of the two methods and the possible budget implications of one method versus another.

Under the system in use in 2005 (as in prior years), the ''geographic adjustment'' consists simply of paying the county MA rate adjusted by the demographic and risk characteristics of the individual beneficiary. To the extent that a plan's health care expenditures vary by county, this method of ''geographic adjustment'' entails a certain level of risk for a health plan with respect to any unanticipated costs incurred for (a) the provision of Medicare A and B benefits, to the extent that the plan's costs of providing A and B benefits vary from county to county, and (b) the provision of required extra benefits to the extent that the cost of such benefits vary by county, or-what is more likely-to the extent that the Medicare A and B cost and revenue projections, which form the basis of the determination of savings and the valuation of extra benefits, vary from actual A and B costs and revenues because of the actual enrollment distribution. The geographic adjustment system of 2006 and thereafter will have a different budgetary impact because of the manner in which rebates are paid for, and the impact may differ from today's methodology depending on the method used to accomplish the geographic adjustment.

Today's method of ''geographic adjustment'' is illustrated in Table 2. In this example, an organization is operating in three counties with the same benefit package offered in all counties. The first section of Table 2 shows the plan's projected enrollment, revenue needs, and ability to provide extra benefits based on the projected enrollment (the kind of information contained in the adjusted community rate proposal the plan submits to CMS under today's system). Although in one county, County A of the example, the plan's projected cost of providing the Medicare A and B benefit package exceeds the Medicare payment level ($520 in costs versus a payment of $500), the ability of the plan to provide the Medicare A/B benefit package in other counties at a ''cost'' below the level of the MA payment rate in the county enables the organization to provide extra benefits to each of its expected enrollees. That is, enrollees in one county are cross-subsidizing the costs of enrollees in other counties. Had this organization only contracted for County C, residents of that county would have received $100 in extra benefits. However, because there are three counties involved, and a certain enrollment distribution is assumed, County C enrollees will receive less in extra benefits, but they will receive the same amount as any other enrollee of the plan in the three-county area. This geographic cross-subsidization enables residents of some counties (in this case, the first two counties listed in Table 2) to receive extra benefits financed by revenues generated in a different county (County C, which enables County A residents to receive extra benefits, and enables County B enrollee to receive better benefits than they would otherwise receive under a single-county contract).

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Table 2: "Geographic Adjustment" of MA Payments in 2005 and Plan Benefit Package Obligations

I. Plan Adjusted Community Rate Submission Under 2005 Rules: $40 in Savings = $40 in Extra Benefits

	MA Rates	Projected Enrollment	Projected Medicare Payment	Plan A/B Per Capita Revenue Needs in County for A/B Benefits	Total Plan Revenue Needs for A/B Benefits	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $40 Per Enrollee)	Total CMS Payment for A/B Benefits and Extra Benefits = MA Rate in County
County A	$500	4	$2,000	$520	$2,080	$2,240	$2,000
County B	$500	3	$1,500	$480	$1,440	$1,560	$1,500
County C	$800	5	$4,000	$700	$3,500	$3,700	$4,000
Totals:		12	$7,500		$7,020	$7,500	$7,500
Per Capita:			$625		$585	$625	$625
Plan Savings for Extra Benefits, Per Capita (Difference Between Projected Payments and A/B Revenue Need):					$40		

IIa. Plan Payment with MA-Based Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with Higher Margin

	MA Rates	Projected Enrollment	Actual Plan Enrollment	Plan A/B Per Capita Revenue Needs in County for A/B Benefits	Total Plan Revenue Needs for A/B Benefits	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $40 Per Enrollee)	Total CMS Payment for A/B Benefits and Extra Benefits = MA Rate in County
County A	$500	4	1	$520	$520	$560	$500
County B	$500	3	1	$480	$480	$520	$500
County C	$800	5	10	$700	$7,000	$7,400	$8,000
Average	$600	Totals:	12		$8,000	$8,480	$9,000
Weighted Average	$750	Per Capita:			$667	$707	$750
					Plan excess revenue per capita:		$43

IIb. Plan Payment with MA-Based Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with No Margin (Counties Where Plan Revenue Need for Medicare A/B Coverage Exceeds Payment)

	MA Rates	Projected Enrollment	Actual Plan Enrollment	Plan A/B Per Capita Revenue Needs in County for A/B Benefits	Total Plan Revenue Needs for A/B Benefits	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $40 Per Enrollee)	Total CMS Payment for A/B Benefits and Extra Benefits = MA Rate in County
County A	$500	4	10	$520	$5,200	$5,600	$5,000
County B	$500	3	1	$480	$480	$520	$500
County C	$800	5	1	$700	$700	$740	$800
Average	$600	Totals:	12		$6,380	$6,860	$6,300
Weighted Average	$525	Per Capita:			$532	$572	$525
					Plan revenue shortfall per capita:		-$47

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Table 2 serves to illustrate the ''risk'' to the Government, and the risk to the plan, in the current system. If the actual enrollment had turned out to be the distribution in section II.a. of Table 2, the Government would have paid the plan more money because of the actual enrollment distribution coming from each county. In this example, the plan would have had excess revenue beyond that needed to provide the Medicare A and B benefits and the promised level of extra benefits. Had the plan predicted this enrollment distribution going into the contract year in its ACR submission, beneficiaries would have been entitled to extra benefits valued at $83 per month. (Under the current system, there is a limit to the Goverment's ''risk exposure'' in the case just described because county level payments for any enrollee cannot exceed the MA payment rate in each county.)

Section II.b. of Table 2 shows a situation in which, because of the actual enrollment distribution, the plan incurs a loss both in the provision of A and B benefits and in providing the promised level of extra benefits. Plans can seek to protect themselves from this kind of risk by reducing their obligation to provide extra benefits. The plan can have an adjusted community rate filing showing that its required revenue matches the MA payment rates in each county, for example (though the stated inability to provide extra benefits may dampen enrollment, and the statement of revenue needs might be challenged in the ACR audit process). However, even with that approach to minimizing risk, if the figures in section II.b. of Table 2 accurately represent the plan's costs in each county, the plan will incur a loss just in providing Medicare A and B benefits, with the enrollment mix shown in the example. To avoid that kind of risk, what the MA organization might do is either not include the first county in its service area, or segment that county. Segmenting the county-establishing a separate ''plan'' for the county-enables the organization to exclude the county's enrollees from the computation of extra benefits for the other counties and to have a separate determination of the Medicare benefit package to be offered in the individual county. (Such service area segmentation is not available to regional plans in the competitive bidding system, but the approach can still be used by MA local plans in 2006 and thereafter.)

The examples of Table 2 show extreme cases in which the actual enrollment ends up being significantly different from the projected distribution of enrollment by county. Once a plan has at least one year's experience as a contractor, there is a better basis for reviewing the enrollment projections of a plan to ensure that the projections are reasonable and that the plan is appropriately determining the level of benefits it should be providing to its enrollees. This will also be true in the new system as of 2006, when one aspect of the bid review process will be an evaluation of the reasonableness of a plan's projections. However, there is always likely to be some level of uncertainty in predicting a plan's enrollment distribution by county. The issue of geographic adjustment is especially important for regional plans that will be required to have a uniform benefit package and premium in a large region.

The purpose of the equivalent of a bid under the ''old'' system was solely to determine whether there were any extra benefits available to beneficiaries, and what their Medicare premium would be. A bid under the new system serves that same purpose but it also can be thought of as the primary basis of payment for the provision of Medicare A and B services. Any rebate, for the provision of non-Medicare-covered benefits, is paid separately from the bid, and is not subject to geographic adjustment In the competitive bidding system of 2006 and thereafter, the Government is ''at risk'' for the cost of the rebate to the extent that the rebate amount would have been higher or lower because a plan's projected enrollment mix does not match its actual enrollment mix. Under the prior system, plans could be said to be at risk for the promised value of extra benefits incorporated in their bid: even though there might be significant changes in the county of residence of their actual enrollment compared to their projected enrollment, only the county-based Government payments could change. When the Government payments changed in tandem with the relative change in costs faced by the plan, the plan would remain whole with respect to its revenue needs for the provision of Medicare A and B benefits and, potentially, for the provision of any additional benefits. (Whether the plan would remain whole would also depend on the types of additional benefits being provided-for example, a fixed cost benefit such as a dollar reduction of the Part B premium, or a benefit with variable costs, such as the buy-down of cost sharing that can take the form of reduced coinsurance. Under the new system, the Government also limits its risk exposure by retaining 25 percent of plan savings.)

For geographic adjustment in 2006, one of the alternatives considered, an adjustment based on the MA payment rates, is similar to today's system. This method allows us to adjust the service area-wide bid to arrive at the county MA rate, less the value of any rebate when a rebate is required. The rebate value that reduces the MA rate is ''apportioned'' across all counties based on the plan's projected enrollment and based on the overall expected revenue that enabled the plan to offer a rebate (which is a function of the MA payment rate totaled across all counties, based on the enrollment projected in each county). When a plan provides a rebate, this method pays a percentage (always less than 100 percent) of the county MA payment rate, even though in a particular county the plan's costs of providing the Part A and B benefit might exceed the county MA payment. In that respect, this method is similar to the current method, which limits the Government's risk exposure to the level of the MA payment, or benchmark, in a given county.

This adjustment is illustrated in Table 3. The bid is adjusted by the county-level, enrollment-weighted MA factors shown in Table 3. This operation ''returns'' the bid to the appropriate MA rate for that county, taking into account the level of rebate dollars determined on a plan-wide basis. (Note that unless the plan projects the same level of enrollment in each county of its service area, the MA factors for the plan are not the same as the simple relationship among MA payment levels in the plan's service area.)

Under this method of geographic adjustment based on MA payment rates, the Government never pays more than the MA rate in a given county for the provision of Medicare A and B benefits. However, it is possible under the competitive bidding system for the Government to have higher per capita expenditures for an MA enrollee in a given county as compared to today's MA payment methodology, because of the manner in which rebate dollars are paid. In the competitive system of 2006 and thereafter, the bid to benchmark comparison-a comparison based on projected enrollment-determines the rebate dollars (in the same manner that savings were determined in 2005, by comparing projected payment rates to projected revenue needs for Medicare A and B services). In 2006 and thereafter, regardless of the plan's actual enrollment distribution by county, the Government is obligated to pay the per capita amount of rebate dollars directly to the plans as a separate payment stream (or the Government withholds the amount for reduction of the Part B premium). That is, the rebate amount, as determined based on projected

numbers, is a fixed amount and is not geographically adjusted. In 2005 and earlier years, there was no separate payment of savings dollars. Savings were financed out of the county MA rate, with plans receiving 100 percent of the MA payment rate as the payment for the provision of both A and B benefits. The MA payment also financed the provision of any extra (non-Medicare) benefits the plan was obligated to provide if its projected average MA payment rate exceeded its adjusted community rate for the provision of Medicare A and B benefits. (For simplicity, these examples represent the situation of a multi-county local plan with enrollment of beneficiaries with a 1.0 risk score. A similar methodology would also apply to regional plans.)

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Table 3: Geographic Adjustment of MA Payments in 2006 Based on County MA Rates

Ia. Plan Bid: $30 in Extra Benefits (75% of $40 in Savings)

	MA Rates	Unweighted MA Index (or Index at Equal Enrollment Distribution in All Counties)	Projected Enrollment	Enrollment-Weighted MA Index	Medicare Advantage Service Area Benchmark Computation	Plan A/B Per Capita Revenue Needs in County for A/B Benefits	Total Plan Revenue Needs for A/B Benefits = Plan Bid	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	0.83	4	0.80	$2,000	$520	$2,080	$2,200
County B	$500	0.83	3	0.80	$1,500	$480	$1,440	$1,530
County C	$800	1.33	5	1.28	$4,000	$700	$3,500	$3,650
Average	$600	Totals:	12		$7,500		$7,020	$7,380
Weighted Average	$625	Per Capita:			$625		$585	$615
						Savings Per Enrollee:	$40	
						Rebate:	$30	

Ib. Plan Payment with MA-Based Geographic Adjustment, Enrollment as Projected

	MA Rates	Per Capita Bidj-Based Payment for A/B Services (MA Rate Times Bid/Benchmark Ratio)	Actual Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in this County	Total Plan Revenue Needs for A/B Benefits = Plan Bid	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$468.00	4	$30	$498.00	$1,992	$2,080	$2,200
County B	$500	$468.00	3	$30	$498.00	$1,494	$1,440	$1,530
County C	$800	$748.80	5	$30	$778.80	$3,894	$3,500	$3,650
Totals						$7,380	$7,020	$7,380
Per Capita:						$615	$585	$615

IIa. Plan Payment with MA-Based Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with Higher Margin

	MA Rates	Per Capita Bidj-Based Payment for A/B Services (MA Rate Times Bid/Benchmark Ratio, or Bid Times Enrollment-Weighted MA Index)	Actual Plan Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in Each County	Total Plan Revenue Needs for A/B Benefits, Based on Actual Enrollment	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$468.00	1	$30	$498.00	$498	$520	$550
County B	$500	$468.00	1	$30	$498.00	$498	$480	$510
County C	$800	$748.80	10	$30	$778.80	$7,788	$7,000	$7,300
Average	$600	Totals:	12			$8,784	$8,000	$8,360
Weighted Average	750	Per Capita:				$732.00	$666.67	$696.67
						Plan excess revenue per capita:		$35.33

IIb. Plan Payment with MA-Based Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with No Margin (Counties Where Plan Revenue Need for Medicare A/B Coverage Exceeds Payment)

	MA Rates	Per Capita Bidj-Based Payment for A/B Services (MA Rate Times Bid/Benchmark Ratio, or Bid Times Enrollment-Weighted MA Index)	Actual Plan Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in Each County	Total Plan Revenue Needs for A/B Benefits, Based on Actual Enrollment	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$468.00	10	$30	$498.00	$4,980.00	$5,200	$5,500
County B	$500	$468.00	1	$30	$498.00	$498.00	$480	$510
County C	$800	$748.80	1	$30	$778.80	$778.80	$700	$730
Totals:			12			$6,256.80	$6,380	$6,740
Per Capita:						$521.40	$531.67	$561.67
						Plan revenue shortfall per capita:		-$40.27

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A different alternative method for geographic adjustment that was mentioned in the impact analysis of the NPRM, would emphasize the bid-based nature of the new system (that is, plans are to be paid their bids for the provision of Medicare A and B services) and would recognize variation in plan costs among counties, as stated by the plans, for the provision of Medicare A and B benefits. Under this method, illustrated in Table 5, we would adjust the bid by a county-level cost factor to arrive at the payment for each plan in each county. Under either system, the MA-based system or the plan-determined cost factor system, total payments to a plan in a given year would be the same to the extent that the plan's actual enrollment distribution across counties matched the projected enrollment distribution that formed the basis of any rebate determination. When the actual enrollment distribution differs from the projection, the Government payment to a plan might exceed the MA rate in a given county if the plan states that its costs in the county exceed the MA rate. However, in at least one county, we would pay less than the MA rate (and less than the MA-rate-based geographically adjusted amount of the alternative previously described, given that there has to be at least one county below the MA rate in order for the plan to have a rebate). This bid-based method of payment based on plan-determined relative costs makes plans whole with respect to their revenue needs for the provision of Medicare A and B services, unlike the MA-based system which can pay more or less than the plan needs for the provision of A and B services. With regard to rebate dollars, either method results in the plan being paid the stated cost of providing the required rebate, which should make the plan whole with respect to these expenditures unless there is geographic variation in the cost of providing the rebate (for example, cost sharing reductions as a rebate).

Table 4: Geographic Adjustment of MA Payments in 2006 Using Plan-Determined A/B Cost Factors

Ia. Plan Bid: $30 in Extra Benefits (75% of $40 in Savings)

	MA Rates	Enrollment-Weighted MA Index (Included for Comparison to Plan A/B Revenue Need Index)	Projected Enrollment	Medicare Advantage Service Area Benchmark	Plan A/B Per Capita Revenue Needs in County for A/B Benefits	Plan-Specified A/B Revenue Need Index (Ratio of County Revenue Needed to Bid)	Total Plan Revenue Needs for A/B Benefits = Plan Bid	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	0.80	4	$2,000	$520	0.89	$2,080	$2,200
County B	$500	0.80	3	$1,500	$480	0.82	$1,440	$1,530
County C	$800	1.28	5	$4,000	$700	1.20	$3,500	$3,650
Average	$600	Totals:	12	$7,500			$7,020	$7,380
Weighted Average	$625		Per Capita	$625	$585		$585	$615
						Savings Per Enrollee:	$40	
						Rebate:	$30	

Ib. Plan Payment with Plan Revenue Need Index Geographic Adjustment, Enrollment as Projected

	MA Rates	Per Capita Bid-Based Payment for A/B Services (Bid Times Plan A/B Revenue Need Index)	Actual Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in this County	Total Plan Revenue Needs for A/B Benefits = Plan Bid	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$520.00	4	$30	$550.00	$2,200	$2,080	$2,200
County B	$500	$480.00	3	$30	$510.00	$1,530	$1,440	$1,530
County C	$800	$700.00	5	$30	$730.00	$3,650	$3,500	$3,650
Totals						$7,380	$7,020	$7,380
Per Capita:						$615	$585	$615

IIa. Plan Payment with Plan Revenue Need Index Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with Higher Margin

	MA Rates	Per Capita Bid-Based Payment for A/B Services (Bid Times Plan A/B Revenue Need Index)	Actual Plan Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in Each County	Total Plan Revenue Needs for A/B Benefits, Based on Actual Enrollment	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$520.00	1	$30	$550.00	$550	$520	$550
County B	$500	$480.00	1	$30	$510.00	$510	$480	$510
County C	$800	$700.00	10	$30	$730.00	$7,300	$7,000	$7,300
Average	$600	Totals:	12			$8,360	$8,000	$8,360
Weighted Average	$750	Per Capita:				$696.67	$666.67	$696.67
						Plan excess revenue per capita:		$0.00

IIb. Plan Payment with Plan Revenue Need Index Geographic Adjustment, Enrollment Different from Projection; More Enrollment from County with No Margin (Counties Where Plan Revenue Need for Medicare A/B Coverage Exceeds Payment)

	MA Rates	Per Capita Bid-Based Payment for A/B Services (Bid Times Plan A/B Revenue Need Index)	Actual Plan Enrollment	Rebate Dollars to Plan, Per Enrollee	Payment Per Capita with Rebate Dollars	Total Plan Payment in Each County	Total Plan Revenue Needs for A/B Benefits, Based on Actual Enrollment	Total Plan Revenue Needs for A/B Benefits and Extra Benefits (at $30 Per Enrollee)
County A	$500	$520.00	10	$30	$550.00	$5,500.00	$5,200	$5,500
County B	$500	$480.00	1	$30	$510.00	$510.00	$480	$510
County C	$800	$700.00	1	$30	$730.00	$730.00	$700	$730
Totals:			12			$6,740.00	$6,380	$6,740
Per Capita:						$561.67	$531.67	$561.67
						Plan revenue shortfall per capita:		$0.00

Table 5 below summarizes the examples of Tables 2, 3 and 4. The two different possible methods of geographic adjustment for 2006 discussed above have different results, but in each case there is a divergence only when the actual enrollment differs from the projected enrollment distribution, as previously noted. In certain cases, the plan-determined index produces higher total Government expenditures than the MA payment-based index, while in other cases the opposite is true. Only the plan-determined index makes a plan whole with respect to its reported cost of providing benefits on a county-by-county basis. As is the case with today's payment system, enrollment distributions different from those projected in advance result in either revenue gains or revenue shortfalls. Compared to the current system of payment, the plan-determined index would appear to be particularly advantageous to plans in ensuring the avoidance of risk based on errors in enrollment projections. As previously noted, however, the MA-based index prevents Government payments in any county which would exceed the benchmark-which is a possibility for the plan-specified approach. Again, as previously noted, for there to be any projected rebate, there has to be at least one county in which plans costs (whether revealed or not) are below the benchmark, with such margins being used to cross-subsidize other counties.

One concern with the plan-specified system is the issue of whether it is more subject to gaming than the MA index approach. Either approach is gameable based on misstatements of enrollment projections in order to maximize profits. However, manipulation of the enrollment distribution, if it occurs, would likely be an issue only in the first year of contracting.

Table 5: Summary of Results in Tables A, B, and C

	Government Expenditures	Plan Excess Revenue or Shortfall Per Capita (Shortfall Is Negative Number)	Difference in Government Payments Compared to Plan-Specified Index Adjustment (If Negative Number, Government Expenditures Lower for Row Category)	Plan Index Pays More?	Difference in Government Payments Compared to MA Index Adjustment (If Negative Number, Government Expenditures Lower for Row Category)	MA Index Pays More?
Plan-Determined Index Results						
Projected Payment Using Plan-Determined Cost Index	$ 7,380.00	$ -				
Plan-Determined Index, More Enrollment Coming from Higher Margin Counties	$ 8,360.00	$ -			$ (424.00)	yes
Plan-Determined Index, More Enrollment Coming from Lower (Negative) Margin County	$ 6,740.00	$ -			$ 483.20	no
MA Geographic Index Results						
Projected Payment Using MA Geographic Index	$ 7,380.00	$ -				
MA Geographic Index, Enrollment Coming from Higher Margin Counties	$ 8,784.00	$ 35.33	$ 424.00	no		
MA Geographic Index, More Enrollment Coming from Negative Margin County	$ 6,256.80	$ (40.27)	$ (483.20)	yes		
Year 2005 Payment System Results (No 25 Percent Reduction of Savings; Savings Amount Not Paid Separately)						
Year 2005 MA Payments, Enrollment Coming from Higher Margin Counties	$ 9,000.00	$ 43.33	$ 640.00	no	$ 216.00	no
Year 2005 MA Payments, Enrollment Coming from Negative Margin County	$ 6,300.00	$ (46.67)	$ (440.00)	yes	$ 43.20	no, but plan shortfall is less with 2006 MA index

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The public comments on the method of geographic adjustment almost without exception favored the use of the MA rates as the basis for adjustment. Commenters stated that they favored using the MA rates because it promotes a level playing field among plans and because current plans are familiar with adjustments made on this basis (which is similar to today's method of adjustment). While we have accepted these comments and have decided to use the MA rates for geographic adjustment, we also believe that it is important to provide the option to regional plans, on a case-by-case basis, of using a plan-determined index for geographic adjustment. The purpose of allowing this is to encourage regional bids. As we have noted, local plans can fashion their own service areas and can pick and choose which counties they want to serve. In most cases, local plans are operating as Medicare plans in areas in which they have commercial operations and are therefore familiar with the market conditions that they face. This enables local plans to be able to project their costs (in relation to MA rates) and to make more reliable projections of enrollment in a given area. For regional plans, the law requires that they assume risk over a wide geographic area, because a regional plan must serve an entire MA region and not a subset of counties in the region. Regional plans are likely to be entering areas in which they have not had any Medicare involvement and may not have had any significant commercial presence (for example, in rural areas, where fewer people have employer group coverage).

M. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a–4.pdf*), in Table 6 we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of Title II of the MMA that are the subject of this regulation. The table provides our best estimate of the dollar amount of these transfers, expressed in 2001 dollars, at three percent and seven percent discount rates.

All expenditures are classified as transfers to health plans. As previously explained, a large share of these expenditures would be used for the provisions of extra

benefits and reduced cost sharing for beneficiaries enrolled in private plans. (Note that this information, as it appeared in Table 12 of the August 3, 2004 proposed rule did not contain annualized figures. The figures were total figures for the 2004 to 2009 period.)

TABLE 6. ACCOUNTING STATEMENT: CLASSIFICATION OF EXPENDITURES, 2004 THROUGH 2009 (2001 DOLLARS, IN MILLIONS)

Three Percent Annual Discount Rate	
TRANSFERS	
Annualized Monetized Transfers	2,742
From Whom To Whom?	Federal Government To Private Plans
Seven Percent Annual Discount Rate	
TRANSFERS	
Annualized Monetized Transfers	2,711
From Whom To Whom?	Federal Government To Private Plans

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 417–HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: Sec. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e 9), and 31 U.S.C. 9701.

Subpart J—Qualifying Conditions for Medicare Contracts

■ 2. Amend § 417.402 by—

A. Revising paragraph (b).

B. Adding paragraph (c).

The revision and addition read as follows:

§ 417.402 Effective date of initial regulations.

* * * * *

(b) No new cost plan contracts are accepted by CMS. CMS will, however, accept and approve applications to modify cost plan contracts in order to expand service areas, provided they are submitted on or before September 1, 2006, and CMS determines that the organization continues to meet regulatory requirements and the requirements in its cost plan contract. Section 1876 cost plan contracts will not be extended or renewed beyond December 31, 2007, where conditions in paragraph (c) of this section are present.

(c) *Mandatory HMO or CMP and contract non-renewal or service area reduction.* CMS will non-renew all or a portion of an HMO's or CMP's contracted service area using procedures in § 417.492(b) and § 417.494(a) for any period beginning on or after January 1, 2008, where-

(1) There were two or more coordinated care plan-model MA regional plans in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section; or

(2) There were two or more coordinated care plan-model MA local plans in the same service area or portion of a service area for the entire previous calendar year meeting the conditions in paragraph (c)(3) of this section.

(3) *Minimum enrollment requirements.* (i) With respect to any service area or portion of a service area that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to the Metropolitan Statistical Area, 5,000 enrolled individuals.

(ii) With respect to any service area or portion of a

service area that is not within a Metropolitan Statistical Area described in paragraph (c)(3)(i) of this section, 1,500 individuals.

Subpart Q—Beneficiary Appeals

■ 3. Section 417.600 is revised to read as follows:

§ 417.600 Basis and scope.

(a) *Statutory basis.* (1) Section 1869 of the Act provides the right to a redetermination, reconsideration, hearing, and judicial review for individuals dissatisfied with a determination regarding their Medicare benefits.

(2) Section 1876 of the Act provides for Medicare payments to HMOs and CMPs that contract with CMS to enroll Medicare beneficiaries and furnish Medicare-covered health care services to them.

(3) Section 234 of the MMA requires section 1876 contractors to operate under the same provisions as MA plans where two plans of the same type enter the cost plan contract's service area.

(b) *Applicability.* (1) The rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

(2) In applying those provisions, references to section 1852 of the Act must be read as references to section 1876 of the Act, and references to MA organizations as references to HMOs and CMPs.

§ 417.602 through § 417.638 [Removed]

■ 4. Sections 417.602 through 417.638 are removed.

Subpart U—Health Care Prepayment Plans

■ 5. Amend § 417.832 by-

A. Revising paragraph (c).

B. Adding paragraph (d).

The revision and addition read as follows:

§ 417.832 Applicability of requirements and procedures.

* * * * *

(c) The provisions of part 405 dealing with the representation of parties apply to organization determinations and appeals.

(d) The provisions of part 405 dealing with administrative law judge hearings, Medicare Appeals Council review, and judicial review are applicable, unless otherwise provided.

■ 6. Section 417.840 is revised to read as follows:

§ 417.840 Administrative review procedures.

The HCPP must apply § 422.568 through § 422.619 of this chapter to

organization determinations that affect its Medicare enrollees, and to reconsiderations, hearings, Medicare Appeals Council review, and judicial review of those organization determinations.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 7. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 8. Revise the heading of part 422 to read as set forth above.

Subpart A—General Provisions

■ 9. Amend § 422.1(a) by adding the following statutory basis in numerical order:

§ 422.1 Basis and scope.

(a) * * *

1858—Special rules for MA Regional Plans.

* * * * *

■ 10. Amend § 422.2 by-

A. Removing the definitions of ''ACR,'' ''Additional benefits,'' ''Adjusted community rate,'' and ''M+C.''

B. Revising the definitions of ''Basic benefits,'' ''Benefits,'' ''Mandatory supplemental benefits,'' and ''Service area.''

C. Adding the definitions of ''Institutionalized,''

''MA,'' ''MA local area,'' ''MA local plan,'' ''MA-Prescription drug plan,'' ''MA regional plan,'' ''Prescription drug plan (PDP),'' ''Prescription drug plan (PDP) sponsor,'' ''Special needs individual,'' and ''Specialized MA plans for special needs individuals.''

D. In the definitions of ''M+C eligible individual,'' ''M+C organization,'' ''M+C plan,'' and ''M+C plan enrollee,'' ''M+C'' is removed each place it appears and ''MA'' is added in its place.

E. Amending the definition of ''Religious and Fraternal Benefit (RFB) Society'' by removing the words ''Religious and Fraternal'' and by adding the words ''Religious Fraternal'' in their place.

■ The revisions and additions read as follows:

§ 422.2 Definitions.

* * * * *

Basic benefits means all Medicare-covered benefits (except hospice services).

Benefits means health care services that are intended to maintain or improve the health status of enrollees, for which the MA organization incurs a cost or liability under an MA plan (not solely an administrative processing cost). Benefits are submitted and approved through the annual bidding process.

* * * * *

Institutionalized means for the purpose of defining a special needs individual, an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care facility which is a skilled nursing facility (SNF) nursing facility (NF); SNF/NF; an intermediate care facility for the mentally retarded (ICF/MR); or an inpatient psychiatric facility.

* * * * *

MA stands for Medicare Advantage.

MA local area is defined in § 422.252.

MA local plan means an MA plan that is not an MA regional plan.

MA-Prescription drug (PD) plan means an MA plan that provides qualified prescription drug coverage under Part D of the Social Security Act.

MA regional plan means a coordinated care plan structured as a preferred provider organization (PPO) that serves one or more entire regions. An MA regional plan must have a network of contracting providers that have agreed to a specific reimbursement for the plan's covered services and must pay for all covered services whether provided in or out of the network.

Mandatory supplemental benefits means health care services not covered by Medicare that an MA enrollee must accept or purchase as part of an MA plan. The benefits may include reductions in cost sharing for benefits under the original Medicare fee for service program and are paid for in the form of premiums and cost sharing, or by an application of the beneficiary rebate rule in section 1854(b)(1)(C)(ii)(I) of the Act, or both.

* * * * *

Prescription drug plan (PDP). PDP has the definition set forth in § 423.272 of this chapter.

Prescription drug plan (PDP) sponsor. A prescription drug plan sponsor has the definition set forth in § 423.2 of this chapter.

* * * * *

Service area means a geographic area that for local MA plans is a county or multiple counties, and for MA regional plans is a region approved by CMS within which an MA-eligible individual may enroll in a particular MA plan offered by an MA organization. Each MA plan must be available to all MA-eligible individuals within the plan's service area. In deciding whether to approve an MA plan's proposed service area, CMS considers the following criteria:

(1) For local MA plans:

(i) Whether the area meets the ''county integrity rule'' that a service area generally consists of a full county or counties.

(ii) However, CMS may approve a service area that includes only a portion of a county if it determines that the ''partial county'' area is necessary, nondiscriminatory, and in the best interests of the beneficiaries. CMS may also consider the extent to which the proposed service area mirrors service areas of existing commercial health care plans or MA plans offered by the organization.

(2) For all MA coordinated care plans, whether the contracting provider network meets the access and availability standards set forth in § 422.112. Although not all contracting providers must be located within the plan's service area, CMS must determine that all services covered under the plan are accessible from the service area.

(3) For MA regional plans, whether the service area consists of the entire region.

Special needs individual means an MA eligible individual who is institutionalized, as defined above, is entitled to medical assistance under a State plan under title XIX, or has a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan.

Specialized MA Plans for Special Needs Individuals means a MA coordinated care plan that exclusively enrolls or enrolls a disproportionate percentage of special needs individuals as set forth in § 422.4(a)(1)(iv) and that, beginning January 1, 2006, provides Part D benefits under part 423 of this chapter to all enrollees; and which has been designated by CMS as meeting the requirements of a MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population.

■ 11. Amend § 422.4 by-

A. Revising the section heading.

B. Revising paragraph (a)(1)(iii).

C. Redesignating paragraph (a)(1)(iv) as paragraph

(a)(1)(v).

D. Adding a new paragraph (a)(1)(iv).

E. Revising newly redesignated paragraph (a)(1)(v).

F. Removing paragraph (a)(2)(ii).

G. Redesignating paragraph (a)(2)(iii) as paragraph (a)(2)(ii).

H. Adding a new paragraph (c).

■ The revisions and additions read as follows:

§ 422.4 Types of MA plans.

(a) * * *

(1) * * *

(iii) Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), regional or local preferred provider organizations (PPOs) as specified in paragraph (a)(1)(v) of this section, and other network plans (except MSA and PFFS plans).

(iv) A specialized MA plan for special needs individuals (SNP) includes any type of coordinated care plan that meets CMS'SNP requirements and either—

(A) Exclusively enrolls special needs individuals as defined in § 422.2; or

(B) Enrolls a greater proportion of special needs individuals than occur nationally in the Medicare population as defined by CMS.

(v) A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and, only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO.

* * * * *

(c) *Rule for MA Plans' Part D coverage.*

(1) Coordinated care plans. In order to offer an MA coordinated care plan in an area, the MA organization offering the coordinated care plan must offer qualified Part D coverage meeting the requirements in § 423.104 of this chapter in that plan or in another MA plan in the same area.

(2) *MSAs.* MA organizations offering MSA plans are not permitted to offer prescription drug coverage, other than that required under Parts A and B of Title XVIII of the Act.

(3) *Private Fee-For-Service.* MA organizations offering private fee-for-service plans can choose to offer qualified Part D coverage meeting the requirements in § 423.104 in that plan.

§ 422.6 [Removed]

■ 12. Remove § 422.6.

§ 422.8 [Removed]

■ 13. Remove § 422.8.

§ 422.10 [Redesignated as § 422.6]

■ 14. Redesignate § 422.10 as § 422.6 and amend newly redesignated § 422.6 by-

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b).

D. Revising paragraph (d)(2)(ii).

E. Revising paragraph (e).

F. Revising paragraph (f)(1).

G. Revising paragraph (f)(2)

H. Revising paragraph (f)(3).

■ The revisions read as set forth below:

§ 422.6 Cost-sharing in enrollment-related costs (MA user fee).

(a) *Basis and scope.* This section implements that portion of section 1857 of the Act that pertains to cost-sharing in enrollment-related costs. It sets forth the procedures that CMS follows to determine the aggregate annual ''user fee'' to be contributed by MA organizations and PDP sponsors under Medicare Part D and to assess the required user fees for each MA plan offered by MA organizations and PDP sponsors.

(b) *Purpose of assessment.* Section 1857(e)(2) of the Act authorizes CMS to charge and collect from each MA plan offered by an MA organization its pro rata share of fees for administering section 1851 of the Act (relating to dissemination of enrollment information), and section 4360 of the Omnibus Budget Reconciliation Act of 1990 (relating to the health insurance counseling and assistance program) and section 1860D–1(c) of the Act (relating to dissemination of enrollment information for the drug benefit).

* * * * *

(d) * * *

(2) * * *

(ii) For fiscal year 2006 and each succeeding year, $200 million, the applicable portion (as defined in paragraph (e) of this section) of $200 million.

(e) *Applicable portion.* In this section, the term ''applicable portion'' with respect to an MA plan means, for a fiscal year, CMS's estimate of Medicare Part C and D expenditures for those MA organizations as a percentage of all expenditures under title XVIII and with respect to PDP sponsors, the applicable portion is CMS's estimate of Medicare Part D prescription drug expenditures for those PDP sponsors PDP sponsors as a percentage of all expenditures under title XVIII.

(f) *Assessment methodology.* (1) The amount of the applicable portion of the user fee each MA organization and PDP sponsor must pay is assessed as a percentage of the total Medicare payments to each organization. CMS determines the annual assessment percentage rate separately for MA organizations and for PDPs using the following formula:

(i) The assessment formula for MA organizations (including MA-PD plans):

C divided by A times B where—

A is the total estimated January payments to all MA organizations subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year MA organization user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(ii) The assessment formula for PDPs:

A is the total estimated January payments to all PDP sponsors subject to the assessment;

B is the 9-month (January through September) assessment period; and

C is the total fiscal year PDP sponsor's user fee assessment amount determined in accordance with paragraph (d)(2) of this section.

(2) CMS determines each MA organization's and PDP sponsor's pro rata share of the annual fee on the basis of the organization's calculated monthly payment amount during the 9 consecutive months beginning with January. CMS calculates each organization's monthly pro rata share by multiplying the established percentage rate by the total monthly calculated Medicare payment amount to the organization as recorded in CMS's payment system on the first day of the month.

(3) CMS deducts the organization's fee from the amount of Federal funds otherwise payable to the MA organization or PDP sponsor for that month.

* * * * *

Subpart B—Eligibility, Election, and Enrollment

■ 15. Amend § 422.50 by-

A. Revising the section heading.

B. Adding introductory text.

C. Amending paragraph (a)(2)(i) by removing the word ''and'' from the end of the paragraph.

D. Amending paragraph (a)(2)(ii) by removing the period from the end of the paragraph and by adding ''; and'' in its place.

E. Adding paragraph (a)(2)(iii).

F. Revising paragraph (a)(5).

■ The revisions and addition read as follows:

§ 422.50 Eligibility to elect an MA plan.

For this subpart, all references to an MA plan include MA-PD and both MA local and MA regional plans, as defined

in § 422.2 unless specifically noted otherwise.

(a) * * *

(2) * * *

(iii) An individual with end-stage renal disease may elect an MA special needs plan as defined in § 422.2, as long as that plan has opted to enroll ESRD individuals.

* * * * *

(5) Completes and signs an election form or completes another CMS-approved election method offered by the MA organization and provides information required for enrollment; and

* * * * *

■ 16. Add § 422.52 to read as follows:

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

(a) *General rule*. In order to elect a specialized MA plan for a special needs individual (Special Needs MA plan, or SNP), the individual must meet the eligibility requirements specified in this section.

(b) *Basic eligibility requirements*. Except as provided in paragraph (c) of this section, to be eligible to elect an SNP, an individual must:

(1) Meet the definition of a special needs individual, as defined at § 422.2;

(2) Meet the eligibility requirements for that specific SNP; and

(3) Be eligible to elect an MA plan under § 422.50.

(c) *Exception to § 422.50*. CMS may waive § 422.50(a)(2) concerning the exclusion of persons with ESRD.

(d) *Deeming continued eligibility*. If an SNP determines that the enrollee no longer meets the eligibility criteria, but can reasonably be expected to again meet that criteria within a 6-month period, the enrollee is deemed to continue to be eligible for the MA plan for a period of not less than 30 days but not to exceed 6 months.

(e) *Restricting Enrollment*. An SNP must restrict future enrollment to only special needs individuals as established under § 422.2.

(f) *Exceptions*. (1) As specified in § 422.4, CMS may designate certain MA plans that disproportionately serve special needs individuals, as defined in § 422.2 as SNPs.

(2) Individuals already enrolled in an MA plan that CMS subsequently designates as an SNP may continue to be enrolled in the plan and may not be involuntarily disenrolled because they do not meet the definition of special needs individuals in § 422.2.

■ 17. Amend § 422.54 by-

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b).

D. Revising paragraph (c)(1)(ii).

E. Revising paragraph (c)(2).

F. Revising paragraph (d)(3).

■ The revisions read as follows:

§ 422.54 Continuation of enrollment for MA local plans.

(a) *Definition*. *Continuation area* means an additional area (outside the service area) within which the MA organization offering a local plan furnishes or arranges to furnish services to its continuation-of-enrollment enrollees. Enrollees must reside in a continuation area on a permanent basis. A continuation area does not expand the service area of any MA local plan.

(b) *Basic rule*. An MA organization may offer a continuation of enrollment option to MA local plan enrollees when they no longer reside in the service area of a plan and permanently move into the geographic area designated by the MA organization as a continuation area. The intent to no longer reside in an area and permanently live in another area is verified through documentation that establishes residency, such as a driver's license or voter registration card.

(c) * * *

(1) * * *

(ii) Describe the option(s) in the member materials it offers and make the option available to all MA local plan enrollees residing in the continuation area.

(2) An enrollee who moves out of the service area and into the geographic area designated as the continuation area has the choice of continuing enrollment or disenrolling from the MA local plan. The enrollee must make the choice of continuing enrollment in a manner specified by CMS. If no choice is made, the enrollee must be disenrolled from the plan.

(d) * * *

(3) Reasonable cost sharing. For services furnished in the continuation area, an enrollee's cost-sharing liability is limited to the cost-sharing amounts required in the MA local plan's service area (in which the enrollee no longer resides).

* * * * *

■ 18. Amend § 422.56 by-

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b).

■ The revisions read as follows:

§ 422.56 Enrollment in an MA MSA plan.

(a) *General*. An individual is not eligible to elect an MA MSA plan unless the individual provides assurances that are satisfactory to CMS that he or she will reside in the United States for at least 183 days during the year for which the election is effective.

(b) *Individuals eligible for or covered under other health benefits program*. Unless otherwise provided by the Secretary, an individual who is enrolled in a Federal Employee Health Benefit plan under 5 U.S.C. chapter 89, or is eligible for health care benefits through the Veteran's Administration under 10 U.S.C. chapter 55 or the Department of Defense under 38 U.S.C. chapter 17, may not enroll in an MA MSA plan.

* * * * *

■ 19. Amend § 422.60 by-

A. Revising paragraph (b)(1).

B. Revising paragraph (b)(3).

C. Revising the heading of paragraph (c).

D. Revising paragraph (c)(1).

E. Revising paragraph (d).

F. Revising paragraph (e).

G. Revising paragraph (f)(1).

H. Revising paragraph (f)(3).

■ The revisions read as follows:

§ 422.60 Election process.

* * * * *

(b) *Capacity to accept new enrollees*. (1) MA organizations may submit information on enrollment capacity of plans.

* * * * *

(3) CMS considers enrollment limit requests for an MA plan service area, or a portion of the plan service area, only if the health and safety of beneficiaries is at risk, such as if the provider network is not available to serve the enrollees in all or a portion of the service area.

(c) *Election forms and other election mechanisms*. (1) The election must comply with CMS instructions regarding content and format and be approved by CMS as described in § 422.80. The election must be completed by the MA eligible individual (or the individual who will soon become eligible to elect an MA plan) and include authorization for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services and its designees and the MA organization. Persons who assist beneficiaries in completing forms must sign the form, or through other approved mechanisms, indicate their relationship to the beneficiary.

* * * * *

(d) *When an election is considered to have been made*. An election in an MA plan is considered to have been made on the date the completed election is received by the MA organization.

(e) *Handling of elections*. The MA organization must have an effective system for receiving, controlling, and processing elections. The system must

meet the following conditions and requirements:

(1) Each election is dated as of the day it is received in a manner acceptable to CMS.

(2) Elections are processed in chronological order, by date of receipt.

(3) The MA organization gives the beneficiary prompt notice of acceptance or denial in a format specified by CMS.

(4) If the MA plan is enrolled to capacity, it explains the procedures that will be followed when vacancies occur.

(5) Upon receipt of the election, or for an individual who was accepted for future enrollment from the date a vacancy occurs, the MA organization transmits, within the timeframes specified by CMS, the information necessary for CMS to add the beneficiary to its records as an enrollee of the MA organization.

(f) *Exception for employer group health plans.* (1) In cases in which an MA organization has both a Medicare contract and a contract with an employer group health plan, and in which the MA organization arranges for the employer to process elections for Medicare-entitled group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 422.250(b), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

* * * * *

(3) Upon receipt of the election from the employer, the MA organization must submit the enrollment within timeframes specified by CMS.

■ 20. Amend § 422.62 by-

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b) introductory text.

D. Revising the heading of paragraph (d).

E. Revising paragraph (d)(1).

F. Removing paragraph (d)(2)(i)(A).

G. Redesignating paragraph (d)(2)(i)(B) as paragraph (d)(2)(i)(A).

H. Redesignating paragraph (d)(2)(i)(C) as paragraph (d)(2)(i)(B).

■ The revisions and addition read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) *General: Coverage election periods*—(1) *Initial coverage election period for MA.* The initial coverage election period is the period during which a newly MA-eligible individual may make an initial election. This period begins 3 months before the month the individual is first entitled to both Part A and Part B and ends on the later of—

(i) The last day of the month preceding the month of entitlement; or

(ii) If after May 15, 2006, the last day of the individual's Part B initial enrollment period.

(2) *Annual coordinated election period.* (i) Beginning with 2002, the annual coordinated election period for the following calendar year is November 15th through December 31st, except for 2006.

(ii) For 2006, the annual coordinated election period

begins on November 15, 2005 and ends on May 15, 2006.

(iii) During the annual coordinated election period, an individual eligible to enroll in an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan. If an individual changes his or her election to original Medicare, he or she may also elect a PDP.

(3) *Open enrollment and disenrollment opportunities through 2005.* Through 2005, the number of elections or changes that an MA eligible individual may make is not limited (except as provided for in paragraph (d) of this section for MA MSA plans). Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an individual eligible to elect an MA plan may change his or her election from an MA plan to original Medicare or to a different MA plan, or from original Medicare to an MA plan.

(4) *Open enrollment and disenrollment during 2006.* (i) Except as provided in paragraphs (a)(4)(ii), (a)(4)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan, but who is eligible to elect an MA plan in 2006, may elect an MA plan only once during the first 6 months of the year.

(A) An individual who is enrolled in an MA-PD plan may elect another MA-PD plan or original Medicare and coverage under a PDP. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. Such an individual may not elect an MA-PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible during 2006 may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 6th month of the entitlement, or on December 31, whichever is earlier, subject to the limitations in paragraphs (a)(4)(i)(A) and (a)(4)(i)(B) of this section.

(iii) The limitation to one election or change in paragraphs (a)(4)(i) and (a)(4)(ii) of this section does not apply to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(5) *Open enrollment and disenrollment beginning in 2007.* (i) For 2007 and subsequent years, except as provided in paragraphs (a)(5)(ii), (a)(5)(iii), and (a)(6) of this section, an individual who is not enrolled in an MA plan but is eligible to elect an MA plan may make an election into an MA plan once during the first 3 months of the year.

(A) An individual who is enrolled in an MA-PD plan may elect another MA-PD plan or original Medicare and coverage under a PDP. An individual who is in original Medicare and has coverage under a PDP may elect a MA-PD plan. Such an individual may not elect an MA plan that does not provide qualified prescription drug coverage.

(B) An individual who is enrolled in an MA plan that does not provide qualified prescription drug coverage may elect another MA plan that does not provide that coverage or original Medicare. An individual who is in original Medicare and does not have coverage under a PDP may elect an MA plan that does not provide qualified prescription drug coverage. Such an individual may not elect an MA-PD plan or coverage under a PDP.

(ii) *Newly eligible MA individual.* An individual who becomes MA eligible during 2007 or later may elect an MA plan or change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the 3rd month of the entitlement, or on December 31, whichever is earlier subject to the limitations in paragraphs (a)(5)(i)(A) and (a)(5)(i)(B) of this section.

(iii) The limitation to one election or change in paragraph (a)(5)(i) and (a)(5)(ii) of this section does not apply to elections made or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section or during a special election period specified in paragraph (b) of this section.

(6) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to

elect an MA plan and who is institutionalized, as defined by CMS, is not limited (except as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make. Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to original Medicare, to a different MA plan, or from original Medicare to an MA plan.

(b) *Special election periods.* An individual may at any time (that is, not limited to the annual coordinated election period) discontinue the election of an MA plan offered by an MA organization and change his or her election, in the form and manner specified by CMS, from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

* * * * *

(d) *Special rules for MA MSA plans*—(1) *Enrollment.* An individual may enroll in an MA MSA plan only during an initial coverage election period or annual coordinated election period described in paragraphs (a)(1) and (a)(2) of this section.

* * * * *

■ 21. Amend § 422.66 by-

A. Revising the section heading.

B. Revising paragraph (b)(1)(i).

C. Revising paragraph (b)(1)(ii).

D. Revising paragraph (b)(3)(ii).

E. Revising paragraph (b)(3)(iii) introductory text.

F. Revising paragraph (d)(5).

G. Revising paragraph (e).

H. Revising paragraph (f)(2).

■ The revisions and additions read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(b) * * *

(1) * * *

(i) Elect a different MA plan by filing the appropriate election with the MA organization.

(ii) Submit a request for disenrollment to the MA organization in the form and manner prescribed by CMS or file the appropriate disenrollment request through other mechanisms as determined by CMS.

* * * * *

(3) * * *

(ii) Provide enrollee with notice of disenrollment in a format specified by CMS; and

(iii) In the case of a plan where lock-in applies, include in the notice a statement explaining that he or she—

* * * * *

(d) * * *

(5) *Election.* The individual who is converting must complete an election as described in § 422.60(c)(1) unless otherwise provided in a form and manner approved by CMS.

* * * * *

(e) *Maintenance of enrollment.* (1) An individual who has made an election under this section is considered to have continued to have made that election until either of the following, which ever occurs first:

(i)The individual changes the election under this section.

(ii)The elected MA plan is discontinued or no longer serves the area in which the individual resides, as provided under § 422.74(b)(3), or the organization does not offer or the individual does not elect the option of continuing enrollment, as provided under § 422.54.

(2) An individual enrolled in an MA plan that becomes an MA-PD plan on January 1, 2006, will be deemed to have elected to enroll in that MA-PD plan.

(3)An individual enrolled in an MA plan that, as of

December 31, 2005, offers any prescription drug coverage will be deemed to have elected an MA-PD plan offered by the same organization as of January 1, 2006.

(4) An individual who has elected an MA plan that does not provide prescription drug coverage will not be deemed to have elected an MA-PD plan and will remain enrolled in the MA plan as provided in paragraph (e)(1) of this section.

(5) An individual enrolled in an MA-PD plan as of December 31 of a year is deemed to have elected to remain enrolled in that plan on January 1 of the following year.

(f) * * *

(2) Upon receipt of the election from the employer, the MA organization must submit a disenrollment notice to CMS within timeframes specified by CMS.

■ 22. Amend § 422.68 by revising paragraph (b) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(b) *Annual coordinated election periods.* For an election or change of election made during the annual coordinated election period as described in § 422.62(a)(2)(i), coverage is effective as of the first day of the following calendar year except that for the annual coordinated election period described in § 422.62(a)(2)(ii), elections made after December 31, 2005 through May 15, 2006 are effective as of the first day of the first calendar month following the month in which the election is made.

* * * * *

■ 23. Amend § 422.74 by-

A. Revising the section heading.

B. Revising paragraph (b)(1)(ii).

C. Adding paragraph (b)(2)(iv).

D. Revising paragraph (c)(1).

E. Revising paragraph (d)(1).

F. Revising paragraph (d)(2).

■ The revisions and addition read as follows:

§ 422.74 Disenrollment by the MA Organization.

* * * * *

(b) * * *

(1) * * *

(ii) The individual has engaged in disruptive behavior specified at paragraph (d)(2) of this section.

* * * * *

(2) * * *

(iv) Individuals enrolled in a specialized MA plan for special needs individuals that exclusively serves and enrolls special needs individuals who no longer meet the special needs status of that plan (or deemed continued eligibility, if applicable).

(c) * * *

(1) Be provided to the individual before submission of the disenrollment to CMS; and

* * * * *

(d) *Process for disenrollment*—(1) *Monthly basic and supplementary premiums are not paid timely.* An MA organization may disenroll an individual from the MA plan for failure to pay basic and supplementary premiums under the following circumstances:

(i) The MA organization can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount, including:

(A) Alerting the individual that the premiums are delinquent;

(B) Providing the individual with a grace period, that is, an opportunity to pay past due premiums in full. The length of the grace period will be, at minimum, one month and will begin on the first day of the month for which the premium is unpaid.

(C) Advising the individual that failure to pay the premiums by the end of the grace period will result in termination of MA coverage.

(ii) The MA organization provides the enrollee with notice of disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) If the enrollee fails to pay the premium for optional supplemental benefits but pays the basic premium and any mandatory supplemental premium, the MA organization has the option to discontinue the optional supplemental benefits and retain the individual as an MA enrollee.

(2) Disruptive Behavior. (i) *Definition of disruptive behavior.* An MA plan enrollee is disruptive if his or her behavior substantially impairs the plan's ability to arrange for or provide services to the individual or other plan members. An individual cannot be considered disruptive if such behavior is related to the use of medical services or compliance (or noncompliance) with medical advice or treatment.

(ii) *Basis of disenrollment for disruptive behavior.* An organization may disenroll an individual whose behavior is disruptive as defined in 422.74(d)(2)(i) only after it meets the requirements described in this section and CMS has reviewed and approved the request.

(iii) *Effort to resolve the problem.* The MA organization must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities. In addition, the MA organization must inform the individual of the right to use the organization's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to the MA organization.

(iv) *Documentation.* The MA organization must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (iii), and any extenuating circumstances. The MA organization may request from CMS the ability to decline future enrollment by the individual. The MA organization must submit this information and any documentation received by the beneficiary to CMS.

(v) *CMS review of the proposed disenrollment.* CMS will review the information submitted by the MA organization and any information submitted by the beneficiary (which the MA organization must forward to CMS) to determine if the MA organization has fulfilled the requirements to request disenrollment for disruptive behavior. If the organization has fulfilled the necessary requirements, CMS will review the information and make a decision to approve or deny the request for disenrollment, including conditions on future enrollment, within 20 working days. During the review, CMS will ensure that staff with appropriate clinical or medical expertise review the case before making the final decision. The MA organization will be required to provide a reasonable accommodation, as determined by CMS, for the individual in such exceptional circumstances that CMS deems necessary. CMS will notify the MA organization within 5 working days after making its decision.

(vi) *Effective date of disenrollment.* If CMS permits an MA organization to disenroll an individual for disruptive behavior, the termination is effective the first day of the calendar month after the month in which the MA organization gives the individual notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section, unless otherwise determined by CMS.

* * * * *

■ 24. Amend § 422.80 by-

A. Revising paragraph (a).

B. Revising paragraph (e)(1)(ii).

C. Revising paragraph (e)(1)(iii).

D. Revising paragraph (e)(1)(iv).

E. Revising paragraph (e)(1)(v).

F. Adding paragraph (e)(1)(ix).

■ The revisions and additions read as follows:

§ 422.80 Approval of marketing materials and election forms.

(a) *CMS review of marketing materials.* (1) Except as provided in paragraph (a)(2) of this section, an MA organization may not distribute any marketing materials (as defined in paragraph (b) of this section), or election forms, or make such materials or forms available to individuals eligible to elect an MA organization unless—

(i) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution the MA organization has submitted the material or form to CMS for review under the guidelines in paragraph (c); and

(ii) CMS does not disapprove the distribution of new material or form.

(2) The MA organization may distribute the marketing materials 5 days following their submission to CMS if—

(i)The MA organization is deemed by CMS to meet certain performance requirements established by CMS; or

(ii)The MA organization certifies that in the case of certain marketing materials designated by CMS, it followed all applicable marketing guidelines or used model language specified by CMS without modification.

* * * * *

(e) * * *

(1) * * *

(ii) Engage in any discriminatory activity, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization. The MA organization may not claim it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the MA plan. It may, however, explain that the organization is approved for participation in Medicare.

(v) Distribute marketing materials for which, before expiration of the 45-day period (or 10 days as provided in paragraph (a)(1) of this section), the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the MA organization, its marketing representatives, or CMS.

* * * * *

(ix) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

* * * * *

Subpart C—Benefits and Beneficiary Protections

§ 422.100 [Amended]

■ 25. Amend § 422.100 by-

A. Revising paragraph (b)(2).

B. Revising paragraph (c)(1).

C. Removing paragraph (e).

D. Redesignating paragraph (f) as paragraph (e).

E. Redesignating paragraph (g) as paragraph (f).

F. Redesignating paragraph (h) as paragraph (g).

G. Redesignating paragraph (i) as paragraph (h).

H. Redesignating paragraph (j) as paragraph (i).

I. Revising newly redesignated paragraph (f) introductory text.

J. Revising newly redesignated paragraph (f)(2).

■ The revisions read as follows:

Subpart C—Benefits and Beneficiary Protections

§ 422.100 General requirements.

* * * * *

(b) * * *

(2) An MA plan (and an MA MSA plan, after the annual deductible in § 422.103(d) has been met) offered by an MA organization satisfies paragraph (a) of this section with respect to benefits for services furnished by a noncontracting provider if that MA plan provides payment in an amount the provider would have received under original Medicare (including balance billing permitted under Medicare Part A and Part B).

(c) ***

(1) Basic benefits are all Medicare-covered services, except hospice services.

* * * * *

(f) *CMS review and approval of MA benefits*. CMS reviews and approves MA benefits using written policy guidelines and requirements in this part and other CMS instructions to ensure that—

* * * * *

(2) MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services; and

* * * * *

■ 26. Amend § 422.101 by-

A. Revising paragraph (b)(2).

B. Revising paragraph (b)(3) introductory text.

C. Adding paragraph (b)(4).

D. Adding paragraph (b)(5).

E. Adding paragraph (d).

F. Adding paragraph (e).

■ The revision and additions read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(b) * * *

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by regulations in this part or related instructions; and

(3) Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan. If an MA plan covers geographic areas encompassing more than one local coverage policy area, the MA organization offering such an MA plan may elect to apply to plan enrollees in all areas uniformly the coverage policy that is the most beneficial to MA enrollees. MA organizations that elect this option must notify CMS before selecting the area that has local coverage policies that are most beneficial to enrollees as follows:

* * * * *

(4) Instead of applying rules in paragraph (b)(3) of this section, and to the extent it exercises this option, an organization offering an MA regional plan in an MA region that covers more than one local coverage policy area must uniformly apply all of the local coverage policy determinations that apply in the selected local coverage policy area in that MA region to all parts of that same MA region. The selection of the single local coverage policy area's local coverage policy determinations to apply throughout the MA region is at the discretion of the MA regional plan and is not subject to CMS pre-approval.

(5) If an MA organization offering an MA local plan elects to exercise the option in paragraph (b)(3) of this section related to a local MA plan, or if an MA organization offering an MA regional plan elects to exercise the option in paragraph (b)(4) of this section related to an MA regional plan, then the MA organization must make information on the selected local coverage policy readily available, including through the Internet, to enrollees and health care providers.

* * * * *

(d) *Special cost-sharing rules for MA regional plans*. In addition to the requirements in paragraph (a) through paragraph (c) of this section, MA regional plans must provide for the following:

(1) *Single deductible*. MA regional plans, to the extent they apply a deductible, are only permitted to have only a single deductible related to combined Medicare Part A and Part B services (to the extent they have a deductible). Applicability of the single deductible may be differential for specific in-network services and may also be waived for preventative services or other items and services.

(2) *Catastrophic limit*. MA regional plans are required to provide for a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the original Medicare fee-for-service program (Part A and Part B benefits).

(3) *Total catastrophic limit*. MA regional plans are required to provide a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the original Medicare fee-for-service program. This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under original Medicare, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section.

(4) *Tracking of deductible and catastrophic limits and notification*. MA regional plans are required to track the deductible (if any) and catastrophic limits in paragraphs (d)(1) through (d)(3) of this section based on incurred out-of-pocket beneficiary costs for original Medicare covered services, and are also required to notify members and health care providers when the deductible (if any) or a limit has been reached.

(e) *Other rules for MA regional plans*. (1) MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within or outside of the network of contracted providers.

(2) In applying the actuarially equivalent level of cost-sharing with respect to MA bids related to benefits under the original Medicare program option as set forth at § 422.256(b)(3), only the catastrophic limit on out-of-pocket expenses for in-network benefits in paragraph (d)(2) of this section will be taken into account.

■ 27. Amend § 422.102 by-

A. Revising paragraph (a)(1).

B. Revising paragraph (a)(3).

C. Adding paragraph (a)(4).

■ The revisions and addition read as follows:

§ 422.102 Supplemental benefits.

(a) * * *

(1) Subject to CMS approval, an MA organization may require Medicare enrollees of an MA plan (other than an MSA plan) to accept or pay for services in addition to Medicare-covered services described in § 422.101.

* * * * *

(3) CMS approves mandatory supplemental benefits if the benefits are designed in accordance with CMS' guidelines and requirements as stated in this part and other written instructions.

(4) Beginning in 2006, an MA plan may reduce cost sharing below the actuarial value specified in section 1854(e)(4)(A) of the Act only as a mandatory supplemental benefit.

* * * * *

■ 28. Amend § 422.103 by—

A. Revising the section heading.

B. Revising paragraph (a).

■ The revisions read as follows:

§ 422.103 Benefits under an MA MSA plan.

(a) General rule. An MA organization offering an MA MSA plan must make available to an enrollee, or provide reimbursement for, at least the services described in § 422.101 after the enrollee incurs countable expenses equal to the amount of the plan's annual deductible.

* * * * *

■ 29. Amend § 422.105 by-

A. Revising the section heading.

B. Revising paragraph (a).

C. Revising paragraph (b).

■ The revisions read as follows:

§ 422.105 Special rules for self-referral and point of service option.

(a) *Self-referral.* When an MA plan member receives an item or service of the plan that is covered upon referral or pre-authorization from a contracted provider of that plan, the member cannot be financially liable for more than the normal in-plan cost sharing, if the member correctly identified himself or herself as a member of that plan to the contracted provider before receiving the covered item or service, unless the contracted provider can show that the enrollee was notified prior to receiving the item or service that the item or service is covered only if further action is taken by the enrollee.

(b) *Point of service option.* As a general rule, a POS benefit is an option that an MA organization may offer in an MA coordinated care plan to provide enrollees with additional choice in obtaining specified health care services. The organization may offer A POS option—

(1) Before January 1, 2006, under a coordinated care plan as an additional benefit as described in section 1854(f)(1)(A) of the Act;

(2) Under a coordinated care plan as a mandatory supplemental benefit as described in § 422.102(a); or

(3) Under a coordinated care plan as an optional supplemental benefit as described in § 422.102(b).

(4) An MA regional plan or local MA PPO is permitted to offer a POS–LIKE benefit as described in paragraphs (b)(2) or (b)(3) of this section as a supplemental benefit. An MA regional plan or local MA PPO may offer a POS–LIKE option as a supplemental benefit where cost sharing for out-of-network services is reduced, in a limited manner, for services obtained from out-of-network providers. Offering a POS–LIKE supplemental benefit does not affect the MA regional plan's or local MA PPO's responsibility to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within the network of contracted providers.

* * * * *

■ 30. Amend § 422.106 by-

A. Revising the paragraph (c) heading.

B. Revising paragraph (c)(2).

C. Adding paragraph (d).

■ The revisions and addition read as follows:

§ 422.106 Coordination of benefits with employer or union group health plans and Medicaid.

* * * * *

(c) *Waiver or modification of contracts with MA organizations.*

* * * * *

(2) Approved waivers or modifications under this paragraph granted to any MA organization may be used by any other similarly situated MA organization in developing its bid.

(d) *Employer sponsored MA plans for plan years beginning on or after January 1, 2006.* (1) CMS may waive or modify any requirement in this part or Part D that hinders the design of, the offering of, or the enrollment in, an MA plan (including an MA-PD plan) offered by one or more employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof), or that is offered, sponsored or administered by an entity on behalf of one or more employers or labor organizations, to furnish benefits to the employers' employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations. Any entity seeking to offer, sponsor, or administer such an MA plan described in this paragraph may request, in writing, from CMS, a waiver or modification of requirements in this part that hinder the design of, the offering of, or the enrollment in, such MA plan.

(2) An MA plan described in this paragraph may restrict the enrollment of individuals in that plan to individuals who are beneficiaries and participants in that plan.

(3) Approved waivers or modifications under this paragraph granted to any MA plan may be used by any other similarly situated MA plan in developing its bid.

■ 31. Amend § 422.108 by revising paragraph (f) to read as follows:

§ 422.108 Medicare secondary payer (MSP) procedures.

* * * * *

(f) *MSP rules and State laws.* Consistent with § 422.402 concerning the Federal preemption of State law, the rules established under this section supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to MA plans. A State cannot take away an MA organization's right under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. The MA organization will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations in subparts B through D of part 411 of this chapter.

■ 32. Amend § 422.109 by-

A. Revising paragraph (a)(2).

B. Revising paragraph (c)(2)(iv).

C. Revising paragraph (c)(3).

■ The revisions read as follows:

§ 422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits.

(a) * * *

(2) The estimated cost of Medicare services furnished as a result of a particular NCD or legislative change in benefits represents at least 0.1 percent of the national average per capita costs.

* * * * *

(c) * * *

(2) * * *

(iv) Any services, including the costs of the NCD service or legislative change in benefits, to the extent the MA organization is already obligated to cover it as a supplemental benefit under § 422.102.

(3) Costs for significant cost NCD services or legislative changes in benefits for which CMS fiscal intermediaries and carriers will make payment are those Medicare costs not listed in paragraphs (c)(2)(i) through (c)(2)(iv) of this section.

* * * * *

■ 33. Amend § 422.110 by-

A. Revising paragraph (b).

B. Removing paragraph (c).

■ The revision reads as follows:

§ 422.110 Discrimination against beneficiaries prohibited.

* * * * *

(b) *Exception.* An MA organization may not enroll an individual who has been medically determined to have end-stage renal disease. However, an enrollee who develops end-stage renal disease while enrolled in a particular MA organization may not be disenrolled for that reason. An individual who is an enrollee of a particular MA organization, and who resides in the MA plan service area at the time he or she first becomes MA eligible, or, an individual enrolled by an MA organization that allows those who reside outside its MA service area to enroll in an MA plan as set forth at § 422.50(a)(3)(ii), then that individual is considered to be ''enrolled'' in the MA organization for purposes of the preceding sentence.

§ 422.111 [Amended]

■ 34. Amend § 422.111 by-

A. Revising paragraph (b)(2) introductory text.

B. Redesignating paragraph (b)(3) introductory text as paragraph (b)(3)(i) and revising it.

C. Adding new paragraph (b)(3)(ii).

D. Revising paragraph (b)(9).

E. Adding paragraph (b)(11).

F. Revising paragraph (c)(1).

G. Revising paragraph (d)(2).

H. Revising paragraph (e).

I. Removing paragraph (f)(4).

J. Removing paragraph (f)(6).

K. Redesignating paragraph (f)(5) as paragraph (f)(4).

L. Redesignating paragraph (f)(7) as paragraph (f)(5).

M. Redesignating paragraph (f)(8) as paragraph (f)(6).

N. Redesignating paragraph (f)(9) as paragraph (f)(7).

O. Redesignating paragraph (f)(10) as paragraph (f)(8).

P. Redesignating paragraph (f)(11) as paragraph (f)(9).

Q. Revising newly redesignated paragraph (f)(5)(iv).

R. Removing newly redesignated paragraph (f)(5)(v).

S. Redesignating paragraph (f)(5)(vi) as paragraph (f)(5)(v).

T. Redesignating paragraph (f)(5)(vii) as paragraph (f)(5)(vi).

U. Redesignating paragraph (f)(5)(viii) as paragraph (f)(5)(vii).

V. Revising newly redesignated paragraph (f)(9).

W. Adding new paragraph (f)(10).

X. Adding new paragraph (f)(11)

Y. Adding new paragraph (f)(12)

■ The revisions and addition read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(2) *Benefits*. The benefits offered under a plan, including applicable conditions and limitations, premiums and cost-sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits; and to the extent it offers Part D as an MD-PD plan, the information in § 423.128 of this chapter; and for purposes of comparison-

* * * * *

(3) *Access*. (i) The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services; any out-of network coverage; any point-of-service option, including the supplemental premium for that option; and how the MA organization meets the requirements of § 422.112 and § 422.114 for access to services offered under the plan.

(ii) The process MA regional plan enrollees should follow to secure in-network cost sharing when covered services are not readily available from contracted network providers.

* * * * *

(9) *Quality improvement program*. A description of the quality improvement program required under § 422.152.

* * * * *

(11) *Catastrophic caps and single deductible*. MA organizations sponsoring MA regional plans are required to provide enrollees a description of the catastrophic stop-loss coverage and single deductible (if any) applicable under the plan.

(c) * * *

(1) The information required in paragraph (f) of this section.

* * * * *

(d) * * *

(2) For changes that take effect on January 1, notify all enrollees at least 15 days before the beginning of the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

* * * * *

(e) *Changes to provider network*. The MA organization must make a good faith effort to provide written notice of a termination of a contracted provider at least 30 calendar days before the termination effective date to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must be notified.

(f) * * *

(5) * * *

(iv) In the case of an MA MSA plan, the amount of the annual MSA deposit.

* * * * *

(9) *Supplemental benefits*. Whether the plan offers mandatory and optional supplemental benefits, including any reductions in cost sharing offered as a mandatory supplemental benefit as permitted under section 1852(a)(3) of the Act (and implementing regulations at § 422.102) and the terms, conditions, and premiums for those benefits.

(10) The names, addresses, and phone numbers of contracted providers from whom the enrollee may obtain in-network coverage in other parts of the service area.

(11) If an MA organization exercises the option in § 422.101(b)(3) or (b)(4) related to an MA plan, then it must make the local coverage determination that applies to members of that plan readily available to providers, including through a web site on the Internet.

(12) To the extent an MA organization has a web site or provides MA plan information through the Internet, then it must also post copies of its Evidence of Coverage, Summary of Benefits and information (names, addresses, phone numbers, specialty) on the network of contracted providers on an Internet web site. Such posting does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees.

§ 422.112 [Amended]

■ 35. Amend § 422.112 by-

A. Revising the heading of paragraph (a) and paragraph (a) introductory text.

B. Revising paragraph (a)(1).

C. Removing paragraph (a)(4).

D. Redesignating paragraph (a)(5) as paragraph (a)(4).

E. Redesignating paragraph (a)(6) as paragraph (a)(5).

F. Redesignating paragraph (a)(7) as paragraph (a)(6).

G. Redesignating paragraph (a)(8) as paragraph (a)(7).

H. Redesignating paragraph (a)(9) as paragraph (a)(8).

I. Redesignating paragraph (a)(10) as paragraph (a)(9).

J. Revising the heading of paragraph (b) and paragraph (b) introductory text.

K. Adding paragraph (c).

■ The revisions and addition read as follows:

§ 422.112 Access to services.

(a) *Rules for coordinated care plans*. An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the MA organization must meet the following requirements:

(1) *Provider network*. (i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.

(ii) *Exception*: MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.

* * * * *

(b) *Continuity of care*. MA organizations offering coordinated care plans must ensure continuity of care and integration of services through

arrangements with contracted providers that include-

* * * * *

(c) *Essential hospital.* An MA regional plan may seek, upon application to CMS, to designate a noncontracting hospital as an essential hospital as defined in section 1858(h) of the Act under the following conditions:

(1) The hospital that the MA regional plan seeks to designate as essential is a general acute care hospital identified as a ''subsection(d)'' hospital as defined in section 1886(d)(1)(B) of the Act.

(2) The MA regional plan provides convincing evidence to CMS that the MA regional plan needs to contract with the hospital as a condition of meeting access requirements under this section.

(3) The MA regional plan must establish that it made a ''good faith'' effort to contract with the hospital to be designated as an essential hospital and that the hospital refused to contract with it despite its ''good faith'' effort. A ''good faith'' effort to contract will be established to the extent that the MA regional plan can show it has offered the hospital a contract providing for the payment of rates in an amount no less than the amount the hospital would have received had payment been made under section 1886(d) of the Act.

(4) The MA regional plan must establish that there are no competing Medicare participating hospitals in the area to which MA regional plan enrollees could reasonably be referred for inpatient hospital services.

(5) The hospital that is to be designated as an essential hospital provides convincing evidence to CMS that the amounts normally payable under section 1886 of the Act (and which the MA regional plan has agreed to pay) will be less than the hospital's actual costs of providing care to the MA regional plan's enrollee.

(6) If CMS determines the requirements in paragraphs (c)(1) through (c)(5) of this section have been met, it will make payment to the essential hospital in accordance with section 1858(h)(2) of the Act based on the order in which claims are received, as limited by the amounts specified in section 1858(h)(3) of the Act.

(7) If CMS determines the requirements in paragraphs (c)(1) through (c)(4) of this section have been met, (and if they continue to be met upon annual renewal of the CMS contract with the MA organization offering the MA regional plan), then the hospital designated by the MA regional plan in paragraph (c)(1) of this section shall be ''deemed'' to be a network hospital to that MA regional plan based on the exception in paragraph (a)(1)(ii) of this section and normal in-network inpatient hospital cost sharing levels (including the catastrophic limit described in § 422.101(d)(2)) shall apply to all plan members accessing covered inpatient hospital services in that hospital.

■ 36. Amend § 422.113 by-

A. Revising paragraph (b)(2)(v).

B. Revising paragraph (c)(2)(iv).

■ The revisions read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(2) * * *

(v) With a limit on charges to enrollees for emergency department services of $50 or what it would charge the enrollee if he or she obtained the services through the MA organization, whichever is less.

* * * * *

(c) * * *

(2) * * *

(iv) Must limit charges to enrollees for post-stabilization care services to an amount no greater than what the organization would charge the enrollee if he or she had obtained the services through the MA organization. For purposes of cost sharing, post-stabilization care services begin upon inpatient admission.

* * * * *

■ 37. Amend § 422.114 by—

A. Revising the section heading to read as set forth below.

B. Adding paragraph (c) to read as follows:

§ 422.114 Access to services under an MA private fee-for-service plan.

* * * * *

(c) *Contracted network.* Private fee-for-service plans that meet network adequacy requirements for a category of health care professional or provider by meeting the requirements in paragraph (a)(2)(ii) of this section may provide for a higher beneficiary copayment in the case of health care professionals or providers of that same category who do not have contracts or agreements to provide covered services under the terms of the plan.

■ 38. Amend § 422.133 by adding paragraph (b)(4) to read as follows:

§ 422.133 Return to home skilled nursing facility.

* * * * *

(b) * * *

(4) If an MA organization elects to furnish SNF care in the absence of a prior qualifying hospital stay under § 422.101(c), then that SNF care is also subject to the home skilled nursing facility rules in this section. In applying the provisions of this section to coverage under this paragraph, references to a hospitalization, or discharge from a hospital, are deemed to refer to wherever the enrollee resides immediately before admission for extended care services.

* * * * *

Subpart D—Quality Improvement

■ 39. In subpart D, remove ''quality assurance'' wherever it appears and add in its place ''quality improvement.''

■ 40. Revise § 422.152 to read as follows:

§ 422.152 Quality improvement program.

(a) *General rule.* Each MA organization (other than MA private-fee-for-service and MSA plans) that offers one or more MA plans must have, for each of those plans, an ongoing quality improvement program that meets the applicable requirements of this section for the services it furnishes to its MA enrollees. As part of its ongoing quality improvement program, a plan must—

(1) Have a chronic care improvement program that meets the requirements of paragraph (c) of this section concerning elements of a chronic care program;

(2) Conduct quality improvement projects that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, and meet the requirements of paragraph (d) of this section; and

(3) Encourage its providers to participate in CMS and HHS quality improvement initiatives.

(b) *Requirements for MA coordinated care plans (except for regional MA plans) and including local PPO plans that are offered by organizations that are licensed or organized under State law as HMOs.* An MA coordinated care plan's (except for regional PPO plans and local PPO plans as defined in paragraph (e) of this section) quality improvement program must—

(1) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(2) Have in effect mechanisms to detect both underutilization and overutilization of services.

(3) Measure and report performance. The organization offering the plan must do the following:

(i) Measure performance under the plan, using the measurement tools required by CMS, and report its performance to CMS. The standard

measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64(c)(10).

(4) Special rule for MA local PPO-type plans that are offered by an organization that is licensed or organized under State law as a health maintenance organization must meet the requirements specified in paragraphs (b)(1) through (b)(3) of this section.

(c) *Chronic care improvement program requirements*. Develop criteria for a chronic care improvement program. These criteria must include—

(1) Methods for identifying MA enrollees with multiple or sufficiently severe chronic conditions that would benefit from participating in a chronic care improvement program; and

(2) Mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program.

(d) *Quality improvement projects*. (1) Quality improvement projects are an organization's initiatives that focus on specified clinical and nonclinical areas and that involve the following:

(i) Measurement of performance.

(ii) System interventions, including the establishment or alteration of practice guidelines.

(iii) Improving performance.

(iv) Systematic and periodic follow-up on the effect of the interventions.

(2) For each project, the organization must assess performance under the plan using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status and enrollee satisfaction, or valid proxies of those outcomes.

(3) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(4) Interventions must achieve demonstrable improvement.

(5) The organization must report the status and results of each project to CMS as requested.

(e) *Requirements for MA regional plans and MA local plans that are PPO plans as defined in this section*—(1) *Definition of local preferred provider organization plan*. For purposes of this section, the term local preferred provider organization (PPO) plan means an MA plan that—

(i) Has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(ii) Provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and

(iii) Is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(2) MA organizations offering an MA regional plan or local PPO plan as defined in this section must:

(i) Measure performance under the plan using standard measures required by CMS and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.

(ii) Evaluate the continuity and coordination of care furnished to enrollees.

(iii) If the organization uses written protocols for utilization review, the organization must—

(A) Base those protocols on current standards of medical practice; and

(B) Have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation.

(f) *Requirements for all types of plans*—(1) *Health information*. For all types of plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to CMS.

(2) *Program review*. For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality improvement program.

(3) *Remedial action*. For each plan, the organization must correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

§ 422.154 [Removed]

■ 41. Remove § 422.154.

■ 42. Amend § 422.156 by-

A. Revising paragraph (b)(1).

B. Adding paragraph (b)(7).

■ The revision and addition read as follows:

§ 422.156 Compliance deemed on the basis of accreditation.

* * * * *

(b) * * *

(1) Quality improvement.

* * * * *

(7) Part D prescription drug benefit programs that are offered by MA programs.

* * * * *

Subpart E—Relationships With Providers

§ 422.202 [Amended]

■ 43. In § 422.202, amend paragraph (b) introductory text by removing ''quality assurance'' and adding ''quality improvement'' in its place.

§ 422.204 [Amended]

■ 44. In § 422.204, amend paragraph (b)(2)(ii) by removing ''quality assurance'' and adding ''quality improvement'' in its place.

■ 45. In § 422.208, the following changes are made:

A. Paragraph (c)(2) is revised.

B. Paragraph (h) is removed.

C. Paragraph (i) is redesignated as paragraph (h).

■ The revision reads as follows:

§ 422.208 Physician incentive plans: Requirements and limitations.

* * * * *

(c) * * *

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section and conduct periodic surveys in accordance with paragraph (h) of this section.

* * * * *

■ 46. Section 422.210 is revised to read as follows:

§ 422.210 Assurances to CMS.

Each organization will provide assurance satisfactory to the Secretary that the requirements of § 422.208 are met.

■ 47. In 422.214, the following changes are made:

A. Paragraph (a)(1) is revised.

B. Paragraph (b) is revised.

■ The revisions read as follows:

§ 422.214 Special rules for services furnished by noncontract providers.

(a) * * *

(1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not

have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

* * * * *

(b) Services furnished by section 1861(u) providers of service. Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts (less any payments under § 412.105(g) and § 413.86(d) of this chapter) that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.86(d) concerns calculating payment for direct medical education costs.)

■ 48—49. Subpart F is revised to read as follows:

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

Secs.
422.250 Basis and scope.
422.252 Terminology.
422.254 Submission of bids.
422.256 Review, negotiation, and approval of bids.
422.258 Calculation of benchmarks.
422.262 Beneficiary premiums.
422.264 Calculation of savings.
422.266 Beneficiary rebates.
422.270 Incorrect collections of premiums and cost sharing.

Subpart F-Submission of Bids, Premiums, and Related Information and Plan Approval

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from section 1853 and section 1858 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, and negotiation and approval of bids by CMS.

§ 422.252 Terminology.

Annual MA capitation rate means a county payment rate for an MA local area (county) for a calendar year. The terms ''per capita rate'' and ''capitation rate'' are used interchangeably to refer to the annual MA capitation rate.

MA local area means a payment area consisting of county or equivalent area specified by CMS.

MA monthly basic beneficiary premium means the premium amount an MA plan (except an MSA plan) charges an enrollee for benefits under the original Medicare fee-for-service program option (if any), and is calculated as described at § 422.262.

MA monthly MSA premium means the amount of the plan premium for coverage of benefits under the original Medicare program through an MSA plan, as set forth at § 422.254(e).

MA monthly prescription drug beneficiary premium is the MA-PD plan base beneficiary premium, defined at section 1860D–13(a)(2) of the Act, as adjusted to reflect the difference between the plan's bid and the national average bid (as described in § 422.256(c)) less the amount of rebate the MA-PD plan elects to apply, as described at § 422.266(b)(2).

MA monthly supplemental beneficiary premium is the portion of the plan bid attributable to mandatory and/or optional supplemental health care benefits described under § 422.102, less the amount of beneficiary rebate the plan elects to apply to a mandatory supplemental benefit, as described at § 422.266(b)(2)(i).

MA-PD plan means an MA local or regional plan that provides prescription drug coverage under Part D of Title XVIII of the Social Security Act.

Monthly aggregate bid amount means the total monthly plan bid amount for coverage of an MA eligible beneficiary with a nationally average risk profile for the factors described in § 422.308(c), and this amount is comprised of the following:

(1) The unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits;

(2) The amount for coverage of basic prescription drug benefits under Part D (if any); and

(3) The amount for provision of supplemental health care benefits (if any).

Plan basic cost sharing means cost sharing that would be charged by a plan for benefits under the original Medicare FFS program option before any reductions resulting from mandatory supplemental benefits.

Unadjusted MA area-specific non-drug monthly benchmark amount means, for local MA plans serving one county, the county capitation rate CMS publishes annually, and for local MA plans serving multiple counties it is the weighted average of county rates in a plan's service area, weighted by the plan's projected enrollment per county.

Unadjusted MA region-specific non-drug monthly benchmark amount means, for MA regional plans, the amount described at § 422.258(b).

Unadjusted MA statutory non-drug monthly bid amount means a plan's estimate of its average monthly required revenue to provide coverage of original Medicare benefits to an MA eligible beneficiary with a nationally average risk profile for the risk factors CMS applies to payment calculations as set forth at § 422.308(c).

§ 422.254 Submission of bids.

(a) *General rules.* (1) Not later than the first Monday in June, each MA organization must submit to CMS an aggregate monthly bid amount for each MA plan (other than an MSA plan) the organization intends to offer in the upcoming year in the service area (or segment of such an area if permitted under § 422.262(c)(2)) that meets the requirements in paragraph (b) of this section. With each bid submitted, the MA organization must provide the information required in paragraph (c) of this section and, for plans with rebates as described at § 422.266(a), the MA organization must provide the information required in paragraph (d) of this section.

(2) CMS has the authority to determine whether and when it is appropriate to apply the bidding methodology described in this section to ESRD MA enrollees.

(3) If the bid submission described in paragraphs (a)(1) and (2) of this section is not complete, timely, or accurate, CMS has the authority to impose sanctions under subpart O of this part or may choose not to renew the contract.

(b) *Bid requirements.* (1) The monthly aggregate bid amount submitted by an MA organization for each plan is the organization's estimate of the revenue required for the following categories for providing coverage to an MA eligible beneficiary with a national average risk profile for the factors described in § 422.308(c):

(i) The statutory non-drug bid amount, which is the MA plan's estimated average monthly required revenue for providing benefits under the original Medicare fee-for-service program option (as defined in § 422.252).

(ii) The amount to provide basic prescription drug coverage, if any (defined at section 1860D–2(a)(3) of the Act).

(iii) The amount to provide supplemental health care benefits, if any.

(2) Each bid is for a uniform benefit package for the service area.

(3) Each bid submission must contain all estimated revenue required by the plan, including administrative costs and return on investment.

(4) The bid amount is for plan payments only but must be based on plan assumptions about the amount of revenue required from enrollee cost-sharing. The estimate of plan cost-sharing for the unadjusted MA statutory non-drug monthly bid amount for coverage of original Medicare benefits must reflect the requirement that the level of cost sharing MA plans charge to enrollees must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare program option. The actuarially equivalent level of cost sharing reflected in a regional plan's unadjusted MA statutory non-drug monthly bid amount does not include cost sharing for out-of-network Medicare benefits, as described at § 422.101(d).

(c) *Information required for coordinated care plans and MA private fee-for-service plans.* MA organizations' submission of bids for coordinated care plans, including regional MA plans and specialized MA plans for special needs beneficiaries (described at § 422.4(a)(1)(iv)), and for MA private fee-for-service plans must include the following information:

(1) The plan type for each plan.

(2) The monthly aggregate bid amount for the provision of all items and services under the plan, as defined in § 422.252 and discussed in paragraph (a) of this section.

(3) The proportions of the bid amount attributable to-

(i) The provision of benefits under the original Medicare fee-for-service program option (as defined at § 422.100(c));

(ii) The provision of basic prescription drug coverage (as defined at section 1860D–2(a)(3) of the Act; and

(iii) The provision of supplemental health care benefits (as defined § 422.102).

(4) The projected number of enrollees in each MA local area used in calculation of the bid amount, and the enrollment capacity, if any, for the plan.

(5) The actuarial basis for determining the amount under paragraph (c)(2) of this section, the proportions under paragraph (c)(3) of this section, the amount under paragraph (b)(4) of this section, and additional information as CMS may require to verify actuarial bases and the projected number of enrollees.

(6) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of the deductibles, coinsurance, and copayments.

(7) For qualified prescription drug coverage, the information required under section 1860D–11(b) of the Act with respect to coverage.

(8) For the purposes of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit the following information developed using the appropriate actuarial bases.

(i) Projected allowable costs (defined in § 422.458(a)).

(ii) The portion of projected allowable costs attributable to administrative expenses incurred in providing these benefits.

(iii) The total projected costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of costs that is attributable to administrative expenses.

(9) For regional plans, as determined by CMS, the relative cost factors for the counties in a plan's service area, for the purposes of adjusting payment under § 422.308(d) for intra-area variations in an MA organization's local payment rates.

(d) *Beneficiary rebate information.* In the case of a plan required to provide a monthly rebate under § 422.266 for a year, the MA organization offering the plan must inform CMS how the plan will distribute the beneficiary rebate among the options described at § 422.266(b).

(e) *Information required for MSA plans.* MA organizations intending to offer MA MSA plans must submit—

(1) The enrollment capacity (if any) for the plan;

(2) The amount of the MSA monthly premium for basic benefits under the original Medicare fee-for-service program option;

(3) The amount of the plan deductible; and

(4) The amount of the beneficiary supplemental premium, if any.

(f) Separate bids must be submitted for Part A and Part B enrollees and Part B-only enrollees for each MA plan offered.

§ 422.256 Review, negotiation, and approval of bids.

(a) *Authority.* Subject to paragraphs (a)(2), (d), and (e) of this section, CMS has the authority to review the aggregate bid amounts submitted under § 422.252 and conduct negotiations with MA organizations regarding these bids (including the supplemental benefits) and the proportions of the aggregate bid attributable to basic benefits, supplemental benefits, and prescription drug benefits.

(1) When negotiating bid amounts and proportions, CMS has authority similar to that provided the Director of the Office of Personnel Management for negotiating health benefits plans under 5 U.S.C. chapter 89.

(2) *Noninterference.* (i) In carrying out Parts C and D under this title, CMS may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services.

(ii) CMS may not require a particular price structure for payment under such a contract, with the exception of payments to Federally qualified health centers as set forth at § 422.316.

(b) *Standards of bid review.* Subject to paragraphs (d) and (e) of this section, CMS can only accept bid amounts or proportions described in paragraph (a) of this section if CMS determines the following standards have been met:

(1) The bid amount and proportions are supported by the actuarial bases provided by MA organizations under § 422.254.

(2) The bid amount and proportions reasonably and equitably reflects the plan's estimated revenue requirements for providing the benefits under that plan, as the term revenue requirements is used for purposes of section 1302(8) of the Public Health Service Act.

(3) *Limitation on enrollee cost sharing.* For coordinated care plans (including regional MA plans and specialized MA plans) and private fee-for-service plans (other than MSA plans):

(i) The actuarial value of plan basic cost sharing, reduced by any supplemental benefits, may not exceed—

(ii) The actuarial value of deductibles, coinsurance, and copayments that would be applicable for the benefits to individuals entitled to benefits under Part A and enrolled under Part B in the plan's service area with a national average risk profile for the factors described in § 422.308(c) if they were not members of an MA organization for the year, except that cost sharing for non-network Medicare services in a regional MA plan is not counted under the amount described in paragraph (b)(2)(i) of this section.

(c) *Negotiation process.* The negotiation process may include the resubmission of information to allow MA organizations to modify their initial bid submissions to account for the

outcome of CMS' regional benchmark calculations required under § 422.258(b) and the outcome of CMS' calculation of the national average monthly bid amount required under section 1860D–13(a)(4) of the Act.

(d) *Exception for private fee-for-service plans.* For private fee-for-service plans defined at § 422.4(a)(3), CMS will not review, negotiate, or approve the bid amount, proportions of the bid, or the amounts of the basic beneficiary premium and supplemental premium.

(e) *Exception for MSA plans.* CMS does not review, negotiate, or approve amounts submitted with respect to MA MSA plans, except to determine that the deductible does not exceed the statutory maximum, defined at § 422.103(d).

§ 422.258 Calculation of benchmarks.

(a) The term ''MA area-specific non-drug monthly benchmark amount'' means, for a month in a year:

(1) *For MA local plans with service areas entirely within a single MA local area,* 1/12th of the annual MA capitation rate (described at § 422.306) for the area, adjusted as appropriate for the purpose of risk adjustment.

(2) *For MA local plans with service areas including more than one MA local area*, an amount equal to the weighted average of annual capitation rates for each local area (county) in the plan's service area, using as weights the projected number of enrollees in each MA local area that the plan used to calculate the bid amount, and adjusted as appropriate for the purpose of risk adjustment.

(b) For MA regional plans, the term ''MA region-specific non-drug monthly benchmark amount'' is:

(1) The sum of two components: the statutory component (based on a weighted average of local benchmarks in the region, as described in paragraph (c)(3) of this section; and the plan bid component (based on a weighted average of regional plan bids in the region as described in paragraph (c)(4) of this section).

(2) Announced before November 15 of each year, but after CMS has received the plan bids.

(c) *Calculation of MA regional non-drug benchmark amount.* CMS calculates the monthly regional non-drug benchmark amount for each MA region as follows:

(1) *Reference month.* For all calculations that follow, CMS will determine the number of MA eligible individuals in each local area, in each region, and nationally as of the reference month, which is a month in the previous calendar year CMS identifies.

(2) *Statutory market share.* CMS will determine the statutory national market share percentage as the proportion of the MA eligible individuals nationally who were not enrolled in an MA plan.

(3) *Statutory component of the region-specific benchmark.* (i) CMS calculates the unadjusted region-specific non-drug amount by multiplying the county capitation rate by the county's share of the MA eligible individuals residing in the region (the number of MA eligible individuals in the county divided by the number of MA eligible individuals in the region), and then adding all the enrollment-weighted county rates to a sum for the region.

(ii) CMS then multiplies the unadjusted region-specific non-drug amount from paragraph (c)(3)(i) of this section by the statutory market share to determine the statutory component of the regional benchmark.

(4) *Plan-bid component of the region-specific benchmark.* For each regional plan offered in a region, CMS will multiply the plan's unadjusted region-specific non-drug bid amount by the plan's share of enrollment (as determined under paragraph (c)(5) of this section) and then sum these products across all plans offered in the region. CMS then multiples this by 1 minus the statutory market share to determine the plan-bid component of the regional benchmark.

(5) *Plan's share of enrollment.* CMS will calculate the plan's share of MA enrollment in the region as follows:

(i) In the first year that any MA regional plan is being offered in an MA region, and more than one MA regional plan is being offered, CMS will determine each regional plan's share of enrollment based on one of two possible approaches. CMS may base this factor on equal division among plans, so that each plan's share will be 1 divided by the number of plans offered. Alternatively, CMS may base this factor on each regional plan's estimate of projected enrollment. Plan enrollment projections are subject to review and adjustment by CMS to assure reasonableness.

(ii) If two or more regional plans are offered in a region and were offered in the reference month: The plan's share of enrollment will be the number of MA eligible individuals enrolled in the plan divided by the number of MA eligible individuals enrolled in all of the plans in the region, as of the reference month.

(iii) If a single regional plan is being offered in the region: The plan's share of enrollment is equal to 1.

§ 422.262 Beneficiary premiums.

(a) Determination of MA monthly basic beneficiary premium. (1) For an MA plan with an unadjusted statutory non-drug bid amount that is less than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is zero.

(2) For an MA plan with an unadjusted statutory non-drug bid amount that is equal to or greater than the relevant unadjusted non-drug benchmark amount, the basic beneficiary premium is the amount by which (if any) the bid amount exceeds the benchmark amount. All approved basic premiums must be charged; they cannot be waived.

(b) Consolidated monthly premiums. Except as specified in paragraph (b)(2) of this section, MA organizations must charge enrollees a consolidated monthly MA premium.

(1) The consolidated monthly premium for an MA plan (other than a MSA plan) is the sum of the MA monthly basic beneficiary premium (if any), the MA monthly supplementary beneficiary premium (if any), and the MA monthly prescription drug beneficiary premium (if any).

(2) *Special rule for MSA plans.* For an individual enrolled in an MSA plan offered by an MA organization, the monthly beneficiary premium is the supplemental premium (if any).

(c) *Uniformity of premiums*—(1) *General rule.* Except as permitted for supplemental premiums pursuant to § 422.106(d), for MA contracts with employers and labor organizations, the MA monthly bid amount submitted under § 422.254, the MA monthly basic beneficiary premium, the MA monthly supplemental beneficiary premium, the MA monthly prescription drug premium, and the monthly MSA premium of an MA organization may not vary among individuals enrolled in an MA plan (or segment of the plan as provided for local MA plans under paragraph (c)(2) of this section). In addition, the MA organization cannot vary the level of cost-sharing charged for basic benefits or supplemental benefits (if any) among individuals enrolled in an MA plan (or segment of the plan).

(2) *Segmented service area option.* An MA organization may apply the uniformity requirements in paragraph (c)(1) of this section to segments of an MA local plan service area (rather than to the entire service area) as long as such a segment is composed of one or more MA payment areas. The information specified under § 422.254 is submitted separately for each segment. This provision does not apply to MA regional plans.

(d) *Monetary inducement prohibited.* An MA organization may not provide for cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

(e) *Timing of payments.* The MA organization must permit payments of MA monthly basic and supplemental beneficiary premiums and monthly prescription drug beneficiary premiums on a monthly basis and may not terminate coverage for failure to make timely payments except as provided in § 422.74(b).

(f) *Beneficiary payment options.* An MA organization must permit each enrollee, at the enrollee's option, to make payment of premiums (if any) under this part to the organization through-

(1) Withholding from the enrollee's Social Security benefit payments, or benefit payments by the Railroad Retirement Board or the Office of Personnel Management, in the manner that the Part B premium is withheld;

(2) An electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account);

(3) According to other means that CMS may specify, including payment by an employer or under employment-based retiree health coverage on behalf of an employee, former employee (or dependent), or by other third parties such as a State.

(i) Regarding the option in paragraph (f)(1) of this section, MA organizations may not impose a charge on beneficiaries for the election of this option.

(ii) An enrollee may opt to make a direct payment of premium to the plan.

§ 422.264 Calculation of savings.

(a) *Computation of risk adjusted bids and benchmarks.*

(1) *The risk adjusted MA statutory non-drug monthly bid amount* is the unadjusted plan bid amount for coverage of original Medicare benefits (defined at § 422.254), adjusted using the factors described in paragraph (c) of this section for local plans and paragraph (e) of this section for regional plans.

(2) The *risk adjusted MA area-specific non-drug monthly benchmark amount* is the unadjusted benchmark amount for coverage of original Medicare benefits by a local MA plan (defined at § 422.258), adjusted using the factors described in paragraph (c) of this section.

(3) The *risk adjusted MA region-specific non-drug monthly benchmark amount* is the unadjusted benchmark for coverage of original Medicare benefits amount by a regional MA plan (defined at § 422.258) adjusted using the factors described in paragraph (e) of this section.

(b) *Computation of savings for MA local plans.* The average per capita monthly savings for an MA local plan is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted area-specific non-drug monthly benchmark amount (described in paragraph (a)(2) of this section). Plans with bids equal to or greater than plan benchmarks will have zero savings.

(c) *Risk adjustment factors for determination of savings for local plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (c)(1) or (c)(2) of this section determined for the purpose of calculating savings amounts for MA local plans.

(1) For the purpose of calculating savings for MA local plans CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Statewide average risk adjustment factors, or factors determined on a basis other than plan-specific factors or Statewide average factors.

(2) In the event that CMS applies Statewide average risk adjustment factors, the statewide factor for each State is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA local plans in that State in the previous year. In the case of a State in which no local MA plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable States or applied on a national basis.

(d) *Computation of savings for MA regional plans.* The average per capita monthly savings for an MA regional plan and year is 100 percent of the difference between the plan's risk-adjusted statutory non-drug monthly bid amount (described in paragraph (a)(1) of this section) and the plan's risk-adjusted region-specific non-drug monthly benchmark amount (described in paragraph (a)(3) of this section), using the risk adjustment factors described in paragraph (e) of this section. Plans with bids equal to or greater than plan benchmarks will have zero savings.

(e) *Risk adjustment factors for determination of savings for regional plans.* CMS will publish the first Monday in April before the upcoming calendar year the risk adjustment factors described in paragraph (e)(1)and (e)(2) of this section determined for the purpose of calculating savings amounts for MA regional plans.

(1) For the purpose of calculating savings for MA regional plans, CMS has the authority to apply risk adjustment factors that are plan-specific average risk adjustment factors, Region-wide average risk adjustment factors, or factors determined on a basis other than MA regions.

(2) In the event that CMS applies region-wide average risk adjustment factors, the region-wide factor for each MA region is the average of the risk factors calculated under § 422.308(c), based on all enrollees in MA regional plans in that region in the previous year. In the case of a region in which no regional plan was offered in the previous year, CMS will estimate an average and may base this average on average risk adjustment factors applied to comparable regions or applied on a national basis.

§ 422.266 Beneficiary rebates.

(a) *General rule.* An MA organization must provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in § 422.264(b) for MA local plans and § 422.264(d) for MA regional plans.

(b) *Form of rebate.* The rebate required under this paragraph must be provided by crediting the rebate amount to one or more of the following:

(1) *Supplemental health care benefits.* MA organizations may apply all or some portion of the rebate for a plan toward payment for non-drug supplemental health care benefits for enrollees as described in § 422.102, which may include the reduction of cost sharing for benefits under original Medicare and additional health care benefits that are not benefits under original Medicare. MA organizations also may apply all or some portion of the rebate for a plan toward payment for supplemental drug coverage described at § 423.104(f)(1)(ii), which may include reduction in cost sharing and coverage of drugs not covered under Part D. The rebate, or portion of rebate, applied toward supplemental benefits may only be applied to a mandatory supplemental benefit, and cannot be used to fund an optional supplemental benefit.

(2) *Payment of premium for prescription drug coverage.* MA organizations that offer a prescription drug benefit may credit some or all of the rebate toward reduction of the MA monthly prescription drug beneficiary premium.

(3) *Payment toward Part B premium.* MA organizations may credit some or all of the rebate toward reduction of the

Medicare Part B premium (determined without regard to the application of subsections (b), (h), and (i) of section 1839 of the Act).

(c) *Disclosure relating to rebates.* MA organizations must disclose to CMS information on the amount of the rebate provided, as required at § 422.254(d). MA organizations must distinguish, for each MA plan, the amount of rebate applied to enhance original Medicare benefits from the amount of rebate applied to enhance Part D benefits.

§ 422.270 Incorrect collections of premiums and cost-sharing.

(a) *Definitions.* As used in this section-

(1) Amounts incorrectly collected-

(i) Means amounts that-

(A) Exceed the limits approved under § 422.262;

(B) In the case of an MA private fee-for-service plan, exceed the MA monthly basic beneficiary premium or the MA monthly supplemental premium submitted under § 422.262; and

(C) In the case of an MA MSA plan, exceed the MA monthly beneficiary supplemental premium submitted under § 422.262, or exceed permissible cost sharing amounts after the deductible has been met per § 422.103; and

(ii) Includes amounts collected from an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled.

(2) *Other amounts due* are amounts due for services that were—

(i) Emergency, urgently needed services, or other services obtained outside the MA plan; or

(ii) Initially denied but, upon appeal, found to be services the enrollee was entitled to have furnished by the MA organization.

(b) *Basic commitments.* An MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf.

(c) *Refund methods*—(1) *Lump-sum payment.* The MA organization must use lump-sum payments for the following:

(i) Amounts incorrectly collected that were not collected as premiums.

(ii) Other amounts due.

(iii) All amounts due if the MA organization is going out of business or terminating its MA contract for an MA plan(s).

(2) *Premium adjustment or lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the MA organization may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(3) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the MA organization must make the refund in accordance with State law.

(d) *Reduction by CMS.* If the MA organization does not make the refund required under this section by the end of the contract period following the contract period during which an amount was determined to be due to an enrollee, CMS will reduce the premium the MA organization is allowed to charge an MA plan enrollee by the amounts incorrectly collected or otherwise due. In addition, the MA organization would be subject to sanction under subpart O of this part for failure to refund amounts incorrectly collected from MA plan enrollees.

■ 50–51. Subpart G is revised to read as follows:

Subpart G—Payments to Medicare Advantage Organizations

Sec.
422.300 Basis and scope.
422.304 Monthly payments.
422.306 Annual MA capitation rates.
422.308 Adjustments to capitation rates, benchmarks, bids, and payments.
422.310 Risk adjustment data.
422.311 Announcement of annual capitation rate, benchmarks, and methodology changes.
422.314 Special rules for beneficiaries enrolled in MA MSA plans.
422.316 Special rules for payments to Federally qualified health centers.
422.318 Special rules for coverage that begins or ends during an inpatient hospital stay.
422.320 Special rules for hospice care.
422.322 Source of payment and effect of MA plan election on payment.
422.324 Payments to MA organizations for graduate medical education costs.

Subpart G—Payments to Medicare Advantage Organizations

§ 422.300 Basis and scope.

This subpart is based on sections 1853, 1854, and 1858 of the Act. It sets forth the rules for making payments to Medicare Advantage (MA) organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), and other payment rules.

See § 422.458 in subpart J for rules on risk sharing payments to MA regional organizations.

§ 422.304 Monthly payments.

(a) *General rules.* Except as provided in paragraph (b) of this section, CMS makes advance monthly payments of the amounts determined under paragraphs (a)(1) and (a)(2) of this section for coverage of original fee-for-service benefits for an individual in an MA payment area for a month.

(1) *Payment of bid for plans with bids below benchmark.* For MA plans that have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays:

(i) The unadjusted MA statutory non-drug monthly bid amount defined in § 422.252, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262; and

(ii) The amount (if any) of the rebate described in paragraph (a)(3) of this section.

(2) *Payment of benchmark for plans with bids at or above benchmark.* For MA plans that do not have average per capita monthly savings (as described at § 422.264(b) for local plans and § 422.264(d) for regional plans), CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount specified at § 422.258, risk-adjusted as described at § 422.308(c) and adjusted (if applicable) for variations in rates within the plan's service area (described at § 422.258(a)(2)) and for the effects of risk adjustment on beneficiary premiums under § 422.262.

(3) *Payment of rebate for plans with bids below benchmarks.* The rebate amount under paragraph (a)(1)(ii) of this section is the amount of the monthly rebate computed under § 422.266(a) for that plan, less the amount (if any) applied to reduce the Part B premium, as provided under § 422.266(b)(3)).

(b) *Separate payment for Federal drug subsidies.* In the case of an enrollee in an MA-PD plan, defined at § 422.252, the MA organization offering such a plan also receives-

(1) Direct and reinsurance subsidy payments for qualified prescription drug coverage, described at section 1860D–15(a) and (b) of the Act (other than payments for fallback prescription drug plans described at section 1860D–11(g)(5) of the Act); and

(2) Reimbursement for premium and cost sharing reductions for low-income individuals, described at section 1860D–14 of the Act.

(c) *Special rules*—(1) *Enrollees with end-stage renal disease.* (i) For enrollees determined to have end-stage renal

disease (ESRD), CMS establishes special rates that are actuarially equivalent to rates in effect before the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(ii) CMS publishes annual changes in these capitation rates no later than the first Monday in April each year, as provided in § 422.312.

(iii) CMS applies appropriate adjustments when establishing the rates, including risk adjustment factors.

(iv) CMS reduces the payment rate for each renal dialysis treatment by the same amount that CMS is authorized to reduce the amount of each composite rate payment for each treatment as set forth in section 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.

(2) *MSA enrollees*. In the case of an MSA plan, CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount for the service area, determined in accordance with § 422.314(c) and subject to risk adjustment as set forth at § 422.308(c), less 1/12 of the annual lump sum amount (if any) CMS deposits to the enrollee's MA MSA.

(3) *RFB plan enrollees*. For RFB plan enrollees, CMS adjusts the capitation payments otherwise determined under this subpart to ensure that the payment level is appropriate for the actuarial characteristics and experience of these enrollees. That adjustment can be made on an individual or organization basis.

(d) *Payment areas*—(1) *General rule*. Except as provided in paragraph (e) of this section—

(i) An MA payment area for an MA local plan is an MA local area defined at § 422.252.

(ii) An MA payment area for an MA regional plan is an MA region, defined at § 422.455(b)(1).

(2) *Special rule for ESRD enrollees*. For ESRD enrollees, the MA payment area is a State or other geographic area specified by CMS.

(e) *Geographic adjustment of payment areas for MA local plans*—(1) *Terminology*. ''Metropolitan Statistical Area'' and ''Metropolitan Division'' mean any areas so designated by the Office of Management and Budget in the Executive Office of the President.

(2) *State request*. A State's chief executive may request, no later than February 1 of any year, a geographic adjustment of the State's payment areas for MA local plans for the following calendar year. The chief executive may request any of the following adjustments to the payment area specified in paragraph (c)(1)(i) of this section:

(i) A single statewide MA payment area.

(ii) A metropolitan-based system in which all non-metropolitan areas within the State constitute a single payment area and any of the following constitutes a separate MA payment area:

(A) All portions of each single Metropolitan Statistical Area within the State.

(B) All portions of each Metropolitan Statistical Area within each Metropolitan Division within the State.

(iii) A consolidation of noncontiguous counties.

(3) *CMS response*. In response to the request, CMS makes the payment adjustment requested by the chief executive. This adjustment cannot be requested or made for payments to regional MA plans.

(4) *Budget neutrality adjustment for geographically adjusted payment areas*. If CMS adjusts a State's payment areas in accordance with paragraph (d)(2) of this section, CMS at that time, and each year thereafter, adjusts the capitation rates so that the aggregate Medicare payments do not exceed the aggregate Medicare payments that would have been made to all the State's payments areas, absent the geographic adjustment.

§ 422.306 Annual MA capitation rates.

Subject to adjustments at § 422.308(b) and § 422.308(g), the annual capitation rate for each MA local area is determined under paragraph (a) of this section for 2005 and each succeeding year, except for years when CMS announces under § 422.312(b) that the annual capitation rates will be determined under paragraph (b) of this section.

(a) *Minimum percentage increase rate*. The annual capitation rate for each MA local area is equal to the minimum percentage increase rate, which is the greater of—

(1) 102 percent of the annual capitation rate for the preceding year; or

(2) The annual capitation rate for the area for the preceding year increased by the national per capita MA growth percentage (defined at § 422.308(a)) for the year, but not taking into account any adjustment under § 422.308(b) for a year before 2004.

(b) *Greater of the minimum percentage increase rate or local area fee-for-service costs*. The annual capitation rate for each MA local area is the greater of—

(1) The minimum percentage increase rate under paragraph (a) of this section; or

(2) The amount determined, no less frequently than every 3 years, to be the adjusted average per capita cost for the MA local area, as determined under section 1876(a)(4) of the Act, based on 100 percent of fee-for-service costs for individuals who are not enrolled in an MA plan for the year, with the following adjustments:

(i) Adjusted as appropriate for the purpose of risk adjustment;

(ii) Adjusted to exclude costs attributable to payments under section 1886(h) of the Act for the costs of direct graduate medical education; and

(iii) Adjusted to include CMS' estimate of the amount of additional per capita payments that would have been made in the MA local area if individuals entitled to benefits under this title had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.

§ 422.308 Adjustments to capitation rates, benchmarks, bids, and payments.

CMS performs the following calculations and adjustments to determine rates and payments:

(a) *National per capita growth percentage*. The national per capita growth percentage for a year, applied under § 422.306, is CMS' estimate of the rate of growth in per capita expenditures under this title for an individual entitled to benefits under Part A and enrolled under Part B. CMS may make separate estimates for aged enrollees, disabled enrollees, and enrollees who have ESRD.

(b) *Adjustment for over or under projection of national per capita growth percentages*. CMS will adjust the minimum percentage increase rate at § 422.306(a)(2) and the adjusted average per capita cost rate at § 422.306(b)(2) for the previous year to reflect any differences between the projected national per capita growth percentages for that year and previous years, and the current estimates of those percentages for those years. CMS will not make this adjustment for years before 2004.

(c) *Risk adjustment*—(1) *General rule*. CMS will adjust the payment amounts under § 422.304(a)(1), (a)(2), and (a)(3) for age, gender, disability status, institutional status, and other factors CMS determines to be appropriate, including health status, in order to ensure actuarial equivalence. CMS may add to, modify, or substitute for risk adjustment factors if those changes will improve the determination of actuarial equivalence.

(2) *Risk adjustment: Health status*—(i) *Data collection*. To adjust for health status, CMS applies a risk factor based on data obtained in accordance with § 422.310.

(ii) *Implementation*. CMS applies a risk factor that incorporates inpatient hospital and ambulatory risk adjustment data. This factor is phased as follows:

(A) 100 percent of payments for ESRD MA enrollees in 2005 and succeeding years.

(B) 75 percent of payments for aged and disabled enrollees in 2006.

(C) 100 percent of payments for aged and disabled enrollees in 2007 and succeeding years.

(3) *Uniform application*. Except as provided for MA RFB plans under § 422.304(c)(3), CMS applies this adjustment factor to all types of plans.

(d) *Adjustment for intra-area variations*. CMS makes the following adjustments to payments.

(1) *Intra-regional variations*. For payments for an MA regional plan for an MA region, CMS will adjust the payment amount specified at § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the region.

(2) *Intra-service area variations*. For payments to an MA local plan with a service area covering more than one MA local area (county), CMS will adjust the payment amount specified in § 422.304(a)(1) and (a)(2) to take into account variations in local payment rates among the different MA local areas included in the plan's service area.

(e) *Adjustment relating to risk adjustment: the government premium adjustment*. CMS will adjust payments to an MA plan as necessary to ensure that the sum of CMS' monthly payment made under § 422.304(a) and the plan's monthly basic beneficiary premium equals the unadjusted MA statutory non-drug bid amount, adjusted for risk and for intra-area or intra-regional payment variation.

(f) *Adjustment of payments to reflect number of Medicare enrollees*—(1) *General rule*. CMS adjusts payments retroactively to take into account any difference between the actual number of Medicare enrollees and the number on which it based an advance monthly payment.

(2) *Special rules for certain enrollees*. (i) Subject to paragraph (f)(2)(ii) of this section, CMS may make adjustments, for a period (not to exceed 90 days) that begins when a beneficiary elects a group health plan (as defined in § 411.1010) offered by an MA organization, and ends when the beneficiary is enrolled in an MA plan offered by the MA organization.

(ii) CMS does not make an adjustment unless the beneficiary certifies that, at the time of enrollment under the MA plan, he or she received from the organization the disclosure statement specified in § 422.111.

(g) *Adjustment for national coverage determination (NCD) services and legislative changes in benefits*. If CMS determines that the cost of furnishing an NCD service or legislative change in benefits is significant, as defined in § 422.109, CMS will adjust capitation rates, or make other payment adjustments, to account for the cost of the service or legislative change in benefits. Until the new capitation rates are in effect, the MA organization will be paid for the significant cost NCD service or legislative change in benefits on a fee-for-service basis as provided under § 422.109(b).

(h) *Adjustments to payments to regional MA plans for purposes of risk corridor payments*. For the purpose of calculation of risk corridors under § 422.458, MA organizations offering regional MA plans in 2006 and/or 2007 must submit, after the end of a contract year and before a date CMS specifies, the following information:

(1) Actual allowable costs (defined in § 422.458(a)) for the previous contract year.

(2) The portion of the costs attributable to administrative expenses incurred in providing these benefits.

(3) The total costs for providing rebatable integrated benefits (as defined in § 422.458(a)) and the portion of the costs that is attributable to administrative expenses in addition to the administrative expenses described in paragraph (h)(2) of this section.

§ 422.310 Risk adjustment data.

(a) *Definition of risk adjustment data*. Risk adjustment data are all data that are used in the application of a risk adjustment payment model.

(b) *Data collection: Basic rule*. Each MA organization must submit to CMS (in accordance with CMS instructions) the data necessary to characterize the context and purposes of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. CMS may also collect data necessary to characterize the functional limitations of enrollees of each MA organization.

(c) *Sources and extent of data*. (1) To the extent required by CMS, risk adjustment data must account for the following:

(i) Services covered under the original Medicare program.

(ii) Medicare covered services for which Medicare is not the primary payer.

(iii) Other additional or supplemental benefits that the MA organization may provide.

(2) The data must account separately for each provider, supplier, physician, or other practitioner that would be permitted to bill separately under the original Medicare program, even if they participate jointly in the same service.

(d) *Other data requirements*. (1) MA organizations must submit data that conform to the requirements for equivalent data for Medicare fee-for-service when appropriate, and to all relevant national standards. Alternatively, MA organizations may submit data according to an abbreviated format, as specified by CMS.

(2) The data must be submitted electronically to the appropriate CMS contractor.

(3) MA organizations must obtain the risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the services.

(4) MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.

(e) *Validation of risk adjustment data*. MA organizations and their providers and practitioners will be required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data.

(f) *Use of data*. CMS uses the data obtained under this section to determine the risk adjustment factor used to adjust payments, as required under § 422.304(a)(1), (a)(2), and (a)(3). CMS may also use the data for other purposes except for medical records data.

(g) *Deadlines for submission of risk adjustment data*. Risk adjustment factors for each payment year are based on risk adjustment data submitted for services furnished during the 12-month period before the payment year that is specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag that may be changed or eliminated as appropriate.

(1) The annual deadline for risk adjustment data submission is the first Friday in September for risk adjustment data reflecting services furnished during the 12-month period ending the prior June 30, and the first Friday in March for data reflecting services furnished during the 12-month period ending the prior December 31.

(2) CMS allows a reconciliation process to account for late data submissions. CMS continues to accept risk adjustment data submitted after the

March deadline until December 31 of the payment year. After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary. Risk adjustment data that are received after the annual December 31 late data submission deadline will not be accepted for the purposes of reconciliation.

§ 422.312 Announcement of annual capitation rate, benchmarks, and methodology changes.

(a) *Capitation rates*—(1) *Initial announcement*. Not later than the first Monday in April each year, CMS announces to MA organizations and other interested parties the following information for each MA payment area for the following calendar year:

(i) The annual MA capitation rate.

(ii) The risk and other factors to be used in adjusting those rates under § 422.308 for payments for months in that year.

(2) CMS includes in the announcement an explanation of assumptions used and a description of the risk and other factors.

(3) *Regional benchmark announcement*. Before the beginning of each annual, coordinated election period under § 422.62(a)(2), CMS will announce to MA organizations and other interested parties the MA region-specific non-drug monthly benchmark amount for the year involved for each MA region and each MA regional plan for which a bid was submitted under § 422.256.

(b) *Advance notice of changes in methodology*. (1) No later than 45 days before making the announcement under paragraph (a)(1) of this section, CMS notifies MA organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates.

(2) The MA organizations have 15 days to comment on the proposed changes.

§ 422.314 Special rules for beneficiaries enrolled in MA MSA plans.

(a) *Establishment and designation of medical savings account (MSA)*. A beneficiary who elects coverage under an MA MSA plan—

(1) Must establish an MA MSA with a trustee that meets the requirements of paragraph (b) of this section; and

(2) If he or she has more than one MA MSA, designate the particular account to which payments under the MA MSA plan are to be made.

(b) *Requirements for MSA trustees*. An entity that acts as a trustee for an MA MSA must—

(1) Register with CMS;

(2) Certify that it is a licensed bank, insurance company, or other entity qualified, under sections 408(a)(2) or 408(h) of the Internal Revenue Code of 1986, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the MA MSA provisions of section 138 of the Internal Revenue Code of 1986; and

(4) Provide any other information that CMS may require.

(c) *Deposit in the MA MSA*. (1) The payment is calculated as follows:

(i) The monthly MA MSA premium is compared with 1/12 of the annual capitation rate applied under this section for the area determined under § 422.306.

(ii) If the monthly MA MSA premium is less than 1/12 of the annual capitation rate applied under this section for the area, the difference is the amount to be deposited in the MA MSA for each month for which the beneficiary is enrolled in the MSA plan.

(2) CMS deposits the full amount to which a beneficiary is entitled under paragraph (c)(1)(ii) of this section for the calendar year, beginning with the month in which MA MSA coverage begins.

(3) If the beneficiary's coverage under the MA MSA plan ends before the end of the calendar year, CMS recovers the amount that corresponds to the remaining months of that year.

§ 422.316 Special rules for payments to Federally qualified health centers.

If an enrollee in an MA plan receives a service from a Federally qualified health center (FQHC) that has a written agreement with the MA organization offering the plan concerning the provision of this service (including the agreement required under section 1857(e)(3) of the Act and as codified in § 422.527)—

(a) CMS will pay the amount determined under section 1833(a)(3)(B) of the Act directly to the FQHC at a minimum on a quarterly basis, less the amount the FQHC would receive for the MA enrollee from the MA organization and taking into account the cost sharing amount paid by the enrollee; and

(b) CMS will not reduce the amount of the monthly payments under this section as a result of the application of paragraph (a) of this section.

§ 422.318 Special rules for coverage that begins or ends during an inpatient hospital stay.

(a) *Applicability*. This section applies to inpatient services in a ''subsection (d) hospital'' as defined in section 1886(d)(1)(B) of the Act, a psychiatric hospital described in section 1886(d)(1)(B)(i) of the act, a rehabilitation hospital described in section 1886(d)(1)(B)(ii) of the Act, a distinct part rehabilitation unit described in the matter following clause (v) of section 1886(d)(1)(B) of the Act, or a long-term care hospital (described in section 1886(d)(1)(B)(iv)).

(b) *Coverage that begins during an inpatient stay*. If coverage under an MA plan offered by an MA organization begins while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) Payment for inpatient services until the date of the beneficiary's discharge is made by the previous MA organization or original Medicare, as appropriate;

(2) The MA organization offering the newly-elected MA plan is not responsible for the inpatient services until the date after the beneficiary's discharge; and

(3) The MA organization offering the newly-elected MA plan is paid the full amount otherwise payable under this subpart.

(c) *Coverage that ends during an inpatient stay*. If coverage under an MA plan offered by an MA organization ends while the beneficiary is an inpatient in one of the facilities described in paragraph (a) of this section—

(1) The MA organization is responsible for the inpatient services until the date of the beneficiary's discharge;

(2) Payment for those services during the remainder of the stay is not made by original Medicare or by any succeeding MA organization offering a newly-elected MA plan; and

(3) The MA organization that no longer provides coverage receives no payment for the beneficiary for the period after coverage ends.

§ 422.320 Special rules for hospice care.

(a) *Information*. An MA organization that has a contract under subpart K of this part must inform each Medicare enrollee eligible to select hospice care under § 418.24 of this chapter about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the MA organization or a related entity) if—

(1) A Medicare hospice program is located within the plan's service area; or

(2) It is common practice to refer patients to hospice programs outside that area.

(b) *Enrollment status*. Unless the enrollee disenrolls from the MA plan, a

beneficiary electing hospice continues his or her enrollment in the MA plan and is entitled to receive, through the MA plan, any benefits other than those that are the responsibility of the Medicare hospice.

(c) *Payment.* (1) No payment is made to an MA organization on behalf of a Medicare enrollee who has elected hospice care under § 418.24 of this chapter, except for the portion of the payment attributable to the beneficiary rebate for the MA plan, described in § 422.266(b)(1) plus the amount of the monthly prescription drug beneficiary premium (described at § 422.252). This no-payment rule is effective from the first day of the month following the month of election to receive hospice care, until the first day of the month following the month in which the election is terminated.

(2) During the time the hospice election is in effect, CMS' monthly capitation payment to the MA organization is reduced to the sum of—

(i) An amount equal to the beneficiary rebate for the MA plan, as described in § 422.304(a)(3) or to zero for plans with no beneficiary rebate, described at § 422.304(a)(2); and

(ii) The amount of the monthly prescription drug beneficiary premium (if any).

(3) In addition, CMS pays through the original Medicare program (subject to the usual rules of payment)—

(i) The hospice program for hospice care furnished to the Medicare enrollee; and

(ii) The MA organization, provider, or supplier for other Medicare-covered services to the enrollee.

§ 422.322 Source of payment and effect of MA plan election on payment.

(a) *Source of payments.* (1) Payments under this subpart for original fee-for-service benefits to MA organizations or MA MSAs are made from the Federal Hospital Insurance Trust Fund or the Supplementary Medical Insurance Trust Fund. CMS determines the proportions to reflect the relative weight that benefits under Part A, and benefits under Part B represents of the actuarial value of the total benefits under title XVIII of the Act.

(2) Payments to MA-PD organizations for statutory drug benefits provided under this title are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

(b) *Payments to the MA organization.* Subject to § 412.105(g) and § 413.86(d) of this chapter and § 422.109, § 422.264, and § 422.266, CMS' payments under a contract with an MA organization (described in § 422.304) with respect to an individual electing an MA plan offered by the organization are instead of the amounts which (in the absence of the contract) would otherwise be payable under original Medicare for items and services furnished to the individual.

(c) *Only the MA organization entitled to payment.* Subject to § 422.314, § 422.318, § 422.320, and § 422.520 and sections 1886(d)(11) and 1886(h)(3)(D) of the Act, only the MA organization is entitled to receive payment from CMS under title XVIII of the Act for items and services furnished to the individual.

§ 422.324 Payments to MA organizations for graduate medical education costs.

(a) MA organizations may receive direct graduate medical education payments for the time that residents spend in non-hospital provider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs.

(b) MA organizations may receive direct graduate medical education payments if all of the following conditions are met:

(1) The resident spends his or her time assigned to patient care activities.

(2) The MA organization incurs ''all or substantially all'' of the costs for the training program in the non-hospital setting as defined in § 413.86(b) of this chapter.

(3) There is a written agreement between the MA organization and the non-hospital site that indicates the MA organization will incur the costs of the resident's salary and fringe benefits and provide reasonable compensation to the non-hospital site for teaching activities.

(c) An MA organization's allowable direct graduate medical education costs, subject to the redistribution and community support principles specified in § 413.85(c) of this chapter, consist of—

(1) Residents' salaries and fringe benefits (including travel and lodging where applicable); and

(2) Reasonable compensation to the non-hospital site for teaching activities related to the training of medical residents.

(d) The direct graduate medical education payment is equal to the product of—

(1) The lower of—

(i) The MA organization's allowable costs per resident as defined in paragraph (c) of this section; or

(ii) The national average per resident amount; and

(2) Medicare's share, which is equal to the ratio of the number of Medicare beneficiaries enrolled to the total number of individuals enrolled in the MA organization.

(e) Direct graduate medical education payments made to MA organizations under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

■ 52. Section 422.402 is revised to read as follows:

§ 422.402 Federal preemption of State law.

The standards established under this part supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to the MA plans that are offered by MA organizations.

■ 53. Amend § 422.404 by revising paragraph (a) to read as follows:

§ 422.404 State premium taxes prohibited.

(a) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivisions or other governmental authorities with respect to any payment CMS makes on behalf of MA enrollees under subpart G of this part, or with respect to any payment made to MA plans by beneficiaries, or payment to MA plans by a third party on a beneficiary's behalf.

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■ 54. A new subpart J is added to read as follows:

Subpart J—Special Rules for MA Regional Plans

Sec.
422.451 Moratorium on new local preferred provider organization plans.
422.455 Special rules for MA Regional plans.
422.458 Risk sharing with regional MA organizations for 2006 and 2007.

Subpart J—Special Rules for MA Regional Plans

§ 422.451 Moratorium on new local preferred provider organization plans.

CMS will not approve the offering of a local preferred provider organization plan during 2006 or 2007 in a service area unless the MA organization seeking to offer the plan was offering a local preferred provider organization plan in the service area before December 31, 2005.

§ 422.455 Special rules for MA Regional Plans.

(a) *Coverage of entire MA region.* The service area for an MA regional plan

will consist of an entire MA region established under paragraph (b) of this section, and an MA region may not be segmented as described in § 422.262(c)(2).

(b) *Establishment of MA regions*—(1) *MA region*. The term ''MA region'' means a region within the 50 States and the District of Columbia as established by CMS under this section.

(2) *Establishment*—(i) *Initial establishment*. By January 1, 2005, CMS will establish and publish the MA regions.

(ii) *Periodic review and revision of service areas*. CMS may periodically review MA regions and may revise the regions if it determines the revision to be appropriate.

(3) *Requirements for MA regions*. CMS will establish, and may revise, MA regions in a manner consistent with the following:

(i) *Number of regions*. There will be no fewer than 10 regions, and no more than 50 regions.

(ii) *Maximizing availability of plans*. The main purpose of the regions is to maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, or geographic location, especially those residing in rural areas.

(4) *Market survey and analysis*. Before establishing MA regions, CMS will conduct a market survey and analysis, including an examination of current insurance markets, to assist CMS in determining how the regions should be established.

(c) *National plan*. An MA regional plan can be offered in more than one MA region (including all regions).

§ 422.458 Risk sharing with regional MA organizations for 2006 and 2007.

(a) *Terminology*. For purposes of this section—

Allowable costs means, with respect to an MA regional plan offered by an organization for a year, the total amount of costs that the organization incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan in the region in the year and in providing rebatable integrated benefits, as defined in this paragraph, reduced by the portion of those costs attributable to administrative expenses incurred in providing these benefits.

Rebatable integrated benefits means those non-drug supplemental benefits that are funded through beneficiary rebates (described at § 422.266(b)(1)) and that CMS determines are additional health benefits not covered under the original Medicare program option and that require expenditures by the plan. For purposes of the calculation of risk corridors, these are the only supplemental benefits that count toward allowable costs.

Target amount means, with respect to an MA regional plan offered by an organization in a year, the total amount of payments made to the organization for enrollees in the plan for the year (which includes payments attributable to benefits under the original Medicare fee-for-service program option as defined in § 422.100(c)(1), the total of the MA monthly basic beneficiary premium collectable for those enrollees for the year, and the total amount of rebatable integrated benefits), reduced by the amount of administrative expenses assumed in the portion of the bid attributable to benefits under original Medicare fee-for-service program option or to rebatable integrated benefits.

(b) *Application of risk corridors for benefits covered under original fee-for-service Medicare*—(1) *General rule*. This section will only apply to MA regional plans offered during 2006 or 2007.

(2) *Notification of allowable costs under the plan*. In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization must notify CMS, before that date in the succeeding year as CMS specifies, of—

(i) Its total amount of costs that the organization

incurred in providing benefits covered under the original Medicare fee-for-service program option for all enrollees under the plan (as described in paragraph (a) of this section).

(ii) Its total amount of costs that the organization incurred in providing rebatable integrated benefits for all enrollees under the plan (as described in paragraph (a) of this section), and, with respect to those benefits, the portion of those costs that is attributable to administrative expenses that is in addition to the administrative expense incurred in provision of benefits under the original Medicare fee-for-service program option.

(c) *Adjustment of payment*—(1) *No adjustment if allowable costs within 3 percent of target amount*. If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there will be no payment adjustment under this section for the plan and year.

(2) *Increase in payment if allowable costs above 103 percent of target amount*—(i) *Costs between 103 and 108 percent of target amount*. If the allowable costs for the plan for the year are greater than 103 percent, but not greater than 108 percent, of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount equal to 50 percent of the difference between those allowable costs and 103 percent of that target amount.

(ii) *Costs above 108 percent of target amount*. If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) of the Act by an amount equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between those allowable costs and 108 percent of that target amount.

(3) *Reduction in payment if allowable costs below 97 percent of target amount*—(i) *Costs between 92 and 97 percent of target amount*. If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and those allowable costs.

(ii) *Costs below 92 percent of target amount*. If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a)of the Act) by an amount (or otherwise recover from the plan an amount) equal to the sum of-

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between 92 percent of that target amount and those allowable costs.

(d) *Disclosure of information*—(1) *General rule*. Each MA organization offering an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section; and

(2) According to existing § 422.502(d)(1)(iii) (section 1857(d)(2)(B) of the Act), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs

provided to CMS under paragraph (b)(2) of this section.

(3) *Restriction on use of information.* Information disclosed or obtained for the purposes of this section may be used by officers, employees, and contractors of DHHS only for the purposes of, and to the extent necessary in, implementing this section.

(e) *Organizational and financial requirements*—(1) *General rule.* Regional MA plans offered by MA organizations must be licensed under State law, or otherwise authorized under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more plans. However, as provided for under this section, MA organizations offering MA regional plans may obtain a temporary waiver of State licensure. In the case of an MA organization that is offering an MA regional plan in an MA region, and is not licensed in each State in which it offers such an MA regional plan, the following rules apply:

(i) The MA organization must be licensed to bear risk in at least one State of the region.

(ii) For the other States in a region in which the organization is not licensed to bear risk, if it demonstrates to CMS that it has filed the necessary application to meet those requirements, CMS may temporarily waive the licensing requirement with respect to each State for a period of time as CMS determines appropriate for the timely processing of the application by the State or States.

(iii) If the State licensing application or applications are denied, CMS may extend the licensing waiver through the end of the plan year or as CMS determines appropriate to provide for a transition.

(2) *Selection of appropriate State.* In the case of an MA organization to which CMS grants a waiver and that is licensed in more than one State in a region, the MA organization will select one of the States, the rules of which shall apply in States where the organization is not licensed for the period of the waiver.

(f) *Regional stabilization fund*—(1) *Establishment.* The MA Regional Plan Stabilization Fund (referred to in this paragraph (f) as the ''Fund'') is available beginning in 2007 for two purposes:

(i) *Plan entry.* To provide incentives to have MA regional plans offered in each MA region under paragraph (f)(4) of this section.

(ii) *Plan retention.* To provide incentives to retain MA regional plans in certain MA regions with below-national-average MA market penetration under paragraph (f)(5) of this section.

(2) *Availability of funding from savings.* Funds made available under section 1853(f) of the Act are transferred into a special account in the Treasury from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) of the Act, ''payments From Trust Funds,'' on a monthly basis.

(3) *Funding limitation*—(i) *General rule.* The total amount expended from the Fund as a result of the application of this section through the end of a calendar year may not exceed the amount available to the Fund as of the first day of that year. For purposes of this section, amounts that are expended under this title insofar as those amounts would not have been expended but for the application of this section will be counted as amounts expended as a result of that application.

(ii) *Application of limitation.* CMS will obligate funds from the Fund for a year only if the Chief Actuary of CMS and the appropriate budget officer certify that there are available in the Fund at the beginning of the year sufficient amounts to cover all of those obligations incurred during the year consistent with paragraph (f)(3)(i) of this section. CMS will take those steps, in connection with computing additional payment amounts under paragraphs (f)(4) and (f)(5) of this section and including limitations on enrollment in MA regional plans receiving those payments or computing lower payment amounts, to ensure that sufficient funds are available to make those payments for the entire year.

(4) *Plan entry funding*—(i) *General rule.* Funding is available under this paragraph for a year in the following situations:

(A) *National plan.* For a national bonus payment described in paragraph (f)(4)(ii) of this section, when a single MA organization offers an MA regional plan in each MA region in the year, but only if there was not a national plan offered in each region in the previous year. Funding under this paragraph is only available with respect to any individual MA organization for a single year, but may be made available to more than one such organization in the same year.

(B) *MA Regional Plans.* Subject to paragraph (f)(4)(i)(C) of this section, for an increased amount under paragraph (f)(4)(iv) of this section for an MA regional plan offered in an MA region that did not have any MA regional plan offered in the prior year.

(C) *Limitation on MA regional plan funding in case of national plan.* There will be no payment adjustment under paragraph (f)(4)(iii) of this section for a year for which a national bonus payment is made under paragraph (f)(4)(ii) of this section.

(ii) *National bonus payment.* The national bonus payment under this paragraph will—

(A) Be available to an MA organization only if the organization offers MA regional plans in every MA region;

(B) Be available for all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and

(C) Be subject to amounts available under paragraph (f)(3) of this section for a year and be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization.

(iii) *Regional payment adjustment*—(A) *General rule.* The increased amount under this paragraph for an MA regional plan in an MA region for a year must be an amount, determined by CMS, based on the bid submitted for that plan (or plans) and will be available to all MA regional plans offered in that region and year. That amount may be based on the mean, mode, or median or other measure of those bids and may vary from region to region. CMS will not limit the number of plans or bids in a region.

(B) *Multi-year funding.* Subject to amounts available under paragraph (f)(3) of this section, funding will be available for a period determined by CMS.

(C) *Application to all plans in a region.* Funding under this paragraph for an MA region will be made available for all MA regional plans offered in the region.

(D) *Limitation on availability of plan retention funding in next year.* If plans receive plan entry funding in a year, plans in that region are prohibited from receiving plan retention funding in the following year.

(iv) *Application.* Any additional payment under this section provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(5) *Plan retention funding*—(i) *General rule.* Funding is available under this paragraph for a year with respect to MA regional plans offered in an MA region for the increased amount specified in paragraph (f)(5)(ii) of this

section but only if the region meets the requirements of paragraphs (f)(5)(iii)(A), (f)(5)(iii)(B), (f)(5)(iii)(C) and (f)(5)(iii)(E) of this section.

(ii) *Payment increase*. The increased amount under this paragraph for an MA regional plan in an MA region for a year will be an amount, determined by CMS, that does not exceed the greater of—

(A) 3 percent of the benchmark amount applicable in the region; or

(B) The amount as (when added to the benchmark amount applicable to the region) will result in the ratio of-

(*1*) That additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i)of the Act, ''the risk-adjusted benchmark amount'' for the region and year, to the adjusted average per capita cost for the region and year, as estimated by CMS under section 1876(a)(4) of the Act and adjusted as appropriate for the purpose of risk adjustment; being equal to—

(*2*) The weighted average of those benchmark amounts for all the regions and that year, to the average per capita cost for the United States and that year, as estimated by CMS under section 1876(a)(4)of the Act and adjusted as appropriate for the purpose of risk adjustment.

(iii) *Regional requirements*. The requirements of this paragraph for an MA region for a year are as follows:

(A) *Notification of plan exit*. CMS has received notice (as specified by CMS), before a new contract year, that one or more MA regional plans that were offered in the region in the previous year will not be offered in the succeeding year.

(B) *Regional plans available from fewer than two MA organizations in the region*. CMS determines that if the plans referred to in paragraph (f)(5)(iii)(A) of this section are not offered in the year, fewer than two MA organizations will be offering MA regional plans in the region in the year involved.

(C) *Percentage enrollment in MA regional plans below national average*. For the previous year, CMS determines that the average percentage of MA eligible individuals residing in the region who are enrolled in MA regional plans is less than the average percentage of those individuals in the United States enrolled in those plans.

(D) *Application*. Any additional payment under this paragraph provided for an MA regional plan for a year will be treated as if it were an addition to the benchmark amount otherwise applicable to that plan and year, but will not be taken into account in the computation of any benchmark amount for any subsequent year.

(E) *2–consecutive-year limitation*. In no case will plan retention funding be available under this paragraph in an MA region for more than 2 consecutive years.

Subpart K-Application Procedures and Contracts for Medicare Advantage Organizations

■ 55. Amend § 422.500 by-

A. Revising the section heading.

B. Designating the undesignated introductory text as paragraph (b) and adding the heading ''Definitions.≥

C. Adding new paragraph (a).

■ The revisions and addition read as follows:

§ 422.500 Scope and definitions.

(a) *Scope*. This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

(b) *Definitions*. For purposes of this subpart, the following definitions apply:

* * * * *

§ 422.501, § 422.502, and § 422.504 [Redesignated]

■ 56. Redesignate § 422.501, § 422.502, and § 422.504 as § 422.503, § 422.504, and § 422.505, respectively.

■ 57. Add new § 422.501 to read as follows:

§ 422.501 Application requirements.

(a) *Scope*. This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan.

(b) *Completion of an application*. (1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application, in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract; or

(ii) For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, the requirements described in this part.

(c) *Responsibility for making determinations*. (1) CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plans meet the requirements of this part.

(2) A CMS determination that an entity is qualified to act as an MA organization is distinct from the bid negotiation that occurs under subpart F of this part and such negotiation is not subject to the appeals provisions included in subpart N of this part.

(d) *Resubmittal of application*. An application that has been denied by CMS may not be resubmitted for 4 months after the date of the notice from CMS denying the application.

(e) *Disclosure of application information under the Freedom of Information Act*. An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), must label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5. Any final decisions as to whether material is privileged is the final decision of the Secretary.

■ 58. Add new § 422.502 to read as follows:

§ 422.502 Evaluation and determination procedures.

(a) *Basis for evaluation and determination*. (1) CMS evaluates an application for an MA contract on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits, public hearings, and any other appropriate procedures.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets the applicable requirements of § 422.501.

(b) *Use of information from a prior contracting period*. If an MA organization has failed to comply with the terms of a previous contract with CMS under title XVIII of the Act, or has failed to complete a corrective action plan during the term of the contract, CMS may deny an application based on the applicant's failure to comply with that prior contract with CMS even if the

contract applicant meets all of the current requirements.

(c) *Notice of determination*. Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract under this part of its determination and the basis for the determination. The determination is one of the following:

(1) *Approval of application*. If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as an MA organization.

(2) *Intent to deny*. (i)If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization and/or has not provided enough information to evaluate the application, CMS gives the contract applicant notice of intent to deny the application for an MA contract and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the intent to deny notice, the contract applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(3) *Denial of application*. If CMS denies the application, it gives written notice to the contract applicant indicating —

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act;

(ii) The reasons why the applicant is not qualified; and

(iii) The applicant's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(d) *Oversight of continuing compliance*. (1) CMS oversees an MA organization's continued compliance with the requirements for an MA organization.

(2) If an MA organization no longer meets those requirements, CMS terminates the contract in accordance with § 422.510.

§ 422.503 [Amended]

■ 59. Amend newly redesignated § 422.503 by-

A. Redesignating paragraphs (b)(1) through (b)(5) as paragraphs (b)(2) through (b)(6) respectively.

B. Adding new paragraph (b)(1).

C. Revising newly redesignated paragraph (b)(4)(ii).

D. Revising newly redesignated paragraph (b)(4)(vi)(F).

E. Adding new paragraphs (b)(4)(vi)(G)(*1*), and (*2*).

F. Adding new paragraph (b)(4)(vi)(H).

G. Revising newly redesignated paragraph (b)(6) introductory text.

H. Revising newly redesignated paragraph (b)(6)(i).

■ The revisions read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(1) Complete an application as described in § 422.501.

* * * * *

(4) * * *

(ii) To operate a quality improvement program and have an agreement for external quality review as required under this part.

* * * * *

(vi) * * *

(F) Procedures for internal monitoring and auditing.

(G) * * *

(*1*) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(*2*) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(H) For MA-PDPs, A comprehensive fraud and abuse plan to detect and prevent fraud, waste, and abuse as specified at § 423.504(b)(4)(vi)(H) of this chapter.

* * * * *

(6) The MA organization's contract must not have been non-renewed under § 422.506 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified CMS of the intention to non-renew the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing MA payments in the payment area or areas at issue; or

* * * * *

■ 60. Amend newly redesignated § 422.504 by-

A. Revising paragraph (e)(4) introductory text.

B. Revising paragraph (e)(4)(ii)

C. Revising paragraph (e)(4)(iii).

D. Removing paragraph (f)(2)(vii).

E. Redesignating paragraph (f)(2)(viii) as paragraph (f)(2)(vii).

F. Revising paragraph (h).

G. Revising paragraph (i)(3)(ii).

■ The revisions read as follows:

§ 422.504 Contract provisions.

* * * * *

(e) * * *

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless-

* * * * *

(ii) There has been a termination, dispute, or allegation of fraud or similar fault by the MA organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, fraud, or similar fault; or

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the MA organization at any time.

* * * * *

(h) *Requirements of other laws and regulations*. The MA organization agrees to comply with-

(1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. 3729 et. seq.), and the anti-kickback statute (section 1128B(b)) of the Act); and

(2) HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164.

(i) * * *

(3) * * *

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with the requirements set forth at paragraph (i)(4)of this section.

* * * * *

■ 61. Amend newly redesignated § 422.505 by adding paragraph (d).

§ 422.505 Effective date and term of contract.

* * * * *

(d) *Renewal of contract contingent on reaching agreement on the bid*. Although an MA organization may be determined qualified to renew its contract under this section, if the organization and CMS cannot reach agreement on the bid under subpart F of this part, no renewal will take place, and the failure to reach an agreement is not subject to the appeals provisions in subpart N of this part.

■ 62. Amend § 422.506 by-

A. Revising paragraph (a)(2)(i).

B. Revising paragraph (a)(2)(ii).

C. Revising paragraph (a)(3) introductory text.

■ The revisions read as follows:

§ 422.506 Nonrenewal of contract.

(a) * * *

(2) * * *

(i) CMS in writing, by the first Monday in June of the year in which the contract would end;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative MA plans, Medigap options, and original Medicare and must receive CMS approval prior to issuance.

* * * * *

(3) CMS may accept a nonrenewal notice submitted after the first Monday in June if-

* * * * *

■ 63. Amend § 422.510 by revising paragraph (a)(4) to read as follows:

§ 422.510 Termination of Contract by CMS.

(a) * * *

(4) There is credible evidence that the PDP sponsor committed or participated in false, fraudulent, or abusive activities affecting the Medicare program, including submission of false or fraudulent data.

* * * * *

■ 64. Amend § 422.520 by-

A. Revising the section heading.

B. Revising paragraph (a)(3).

C. Redesignating paragraph (b) introductory text as paragraph (b)(1).

D. Adding new paragraph (b)(2).

E. Adding new paragraph (d).

■ The revisions and additions read as follows:

§ 422.520 Prompt payment by MA organization.

(a) * * *

(3) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request.

(b) * * *

(2) The MA organization is obligated to pay contracted providers under the terms of the contract between the MA organization and the provider.

* * * * *

(d) A CMS decision to not conduct a hearing under paragraph (c) of this section does not disturb any potential remedy under State law for 1866(a)(1)(O) of the Act.

■ 65. Add new § 422.527 at the end of subpart K to read as follows:

§ 422.527 Agreements with Federally qualified health centers.

The contract between the MA organization and CMS must specify that—

(a) The MA organization must pay a Federally qualified health center (FQHC) a similar amount to what it pays other providers for similar services.

(b) Under such a contract, the FQHC must accept this payment as payment in full, except for allowable cost sharing which it may collect.

(c) Financial incentives, such as risk pool payments or bonuses, and financial withholdings are not considered in determining the payments made by CMS under § 422.316(a).

Subpart L-Effect of Change of Ownership or Leasing of Facilities During Term of Contract

■ 66. Amend § 422.550 by revising paragraph (a)(2) to read as follows:

§ 422.550 General provisions.

(a) * * *

(2) *Asset transfer*. Transfer of title and property to another party constitutes change of ownership.

* * * * *

Subpart M—Grievances, Organization Determinations and Appeals

■ 67. Amend § 422.560 by-

A. Adding paragraph (a)(3).

B. Adding paragraph (c).

■ The additions read as follows:

§ 422.560 Basis and scope.

(a) * * *

(3) Section 1869 of the Act specifies the amount in controversy needed to pursue a hearing and judicial review and authorizes representatives to act on behalf of individuals that seek appeals. These provisions are incorporated for MA appeals by section 1852(g)(5) of the Act and part 405 of this chapter.

* * * * *

(c) *Relation to ERISA requirements*. Consistent with section 1857(i)(2) of the Act, provisions of this subpart may, to the extent applicable under regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

■ 68. Amend § 422.561 by-

A. Removing the definition of ''authorized representative''.

B. Revising the definition of ''Enrollee''.

C. Adding the definition of ''Representative''.

■ The revisions and addition read as follows:

§ 422.561 Definitions.

* * * * *

Enrollee means an MA eligible individual who has elected an MA plan offered by an MA organization.

* * * * *

Representative means an individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in the appeal. Unless otherwise stated in this subpart, the representative will have all of the rights and responsibilities of an enrollee or party in obtaining an organization determination or in dealing with any of the levels of the appeals process, subject to the applicable rules described in part 405 of this chapter.

■ 68a. Amend § 422.562 by—

A. Revising paragraph (b)(4)(iv).

B. Revising paragraph (b)(4)(vi).

C. Revising paragraph (c)(1)(ii).

D. Revising paragraph (d).

■ The revisions read as follows:

§ 422.562 General provisions.

* * * * *

(b) * * *

(4) * * *

(iv) The right to an ALJ hearing if the amount in controversy is met, as provided in § 422.600.

* * * * *

(vi) The right to judicial review of the hearing decision if the amount in controversy is met, as provided in § 422.612.

(c) * * *

(1) * * *

(ii) The QIO review decision is subject only to the appeal procedures set forth in part 478 of this chapter.

* * * * *

(d) *When other regulations apply*. Unless this subpart provides otherwise, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act), apply under this subpart to the extent they are appropriate.

■ 69. Amend § 422.564 by—

A. Redesignating paragraphs (d) and (e) as paragraphs (f) and (g).

B. Adding a new paragraph (d).

C. Adding a new paragraph (e).

■ The additions read as follows:

§ 422.564 Grievance procedures.

* * * * *

(d) *Method for filing a grievance*. (1) An enrollee may file a grievance with the MA organization either orally or in writing.

(2) An enrollee must file a grievance no later than 60 days after the event or incident that precipitates the grievance.

(e) *Grievance disposition and notification*. (1) The MA organization must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days

after the date the organization receives the oral or written grievance.

(2) The MA organization may extend the 30-day timeframe by up to 14 days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the MA organization extends the deadline, it must immediately notify the enrollee in writing of the reasons for the delay.

(3) The MA organization must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

(i) All grievances submitted in writing must be responded to in writing.

(ii) Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.

(iii) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the MA organization must cooperate with the QIO in resolving the complaint.

* * * * *

■ 70. Amend § 422.566 by revising paragraph (b)(4) to read as follows:

§ 422.566 Organization determinations.

* * * * *

(b) * * *

(4) Discontinuation or reduction of a service if the enrollee believes that continuation of the services is medically necessary.

* * * * *

■ 71. Amend § 422.568 by-

A. Revising paragraph (a).

B. Revising paragraph (c).

■ The revisions read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

(a) *Timeframe for requests for service.* When a party has made a request for a service, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension.

* * * * *

(c) *Written notice for MA organization denials.* If an MA organization decides to deny service or payment in whole or in part, or if an enrollee disagrees with an MA organization's decision to discontinue or reduce the level of care for an ongoing course of treatment, the organization must give the enrollee written notice of the determination.

* * * * *

■ 72. Amend § 422.570 by revising paragraph (d)(2)(ii) to read as follows:

§ 422.570 Expediting certain organization determinations.

* * * * *

(d) * * *

(2) * * *

(ii) Informs the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision not to expedite; and

* * * * *

■ 73. Amend § 422.572 by —

A. Revising paragraph (b).

B. Revising paragraph (c).

■ The revisions read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(b) *Extensions.* The MA organization may extend the 72–hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(c) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of an adverse expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification.

* * * * *

■ 74. Amend § 422.582 by-

A. Revising paragraph (a).

B. Revising paragraph (b).

C. Revising paragraph (c)(2) introductory text.

■ The revisions read as follows:

§ 422.582 Request for a standard reconsideration.

(a) *Method and place for filing a request.* A party to an organization determination must ask for a reconsideration of the determination by making a written request to the MA organization that made the organization determination. The MA organization may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a party must file a request for reconsideration within 60 calendar days from the date of the notice of the organization determination.

(c) * * *

(2) *How to request an extension of timeframe.* If the 60-day period in which to file a request for reconsideration has expired, a party to the organization determination may file a request for reconsideration with the MA organization. The request for reconsideration and to extend the timeframe must—

* * * * *

■ 75. Amend § 422.584 by revising paragraph (e) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(e) *Action following acceptance of a request.* If an MA organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590.

* * * * *

■ 76. Amend § 422.590 by —

A. Revising paragraph (a)(1).

B. Revising paragraph (d)(2).

■ The revisions read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Request for services.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard

reconsideration. The MA organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. For extensions, the MA organization must issue and effectuate its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

* * * * *

(d) * * *

(2) *Extensions*. The MA organization may extend the 72–hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an MA organization's decision to deny). When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires but no later than upon expiration of the extension.

* * * * *

■ 77. Amend § 422.600 by-

A. Revising paragraph (a).

B. Revising paragraph (b).

■ The revisions read as follows:

§ 422.600 Right to a hearing.

(a) If the amount remaining in controversy after reconsideration meets the threshold requirement established annually by the Secretary, any party to the reconsideration (except the MA organization) who is dissatisfied with the reconsidered determination has a right to a hearing before an ALJ.

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with part 405 of this chapter.

* * * * *

■ 78. Amend § 422.602 by—

A. Revising paragraph (a).

B. Revising paragraph (b).

C. Revising paragraph (d).

■ The revisions read as follows:

§ 422.602 Request for an ALJ hearing.

(a) *How and where to file a request*. A party must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request*. Except when an ALJ extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 days of the date of the notice of a reconsidered determination. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020.

* * * * *

(d) *Insufficient amount in controversy*. (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 422.600, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 422.600, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

■ 79. Revise § 422.608 to read as follows:

§ 422.608 Medicare Appeals Council (MAC) review.

Any party to the hearing, including the MA organization, who is dissatisfied with the ALJ hearing decision, may request that the MAC review the ALJ's decision or dismissal. The regulations under part 405 of this chapter regarding MAC review apply to matters addressed by this subpart to the extent that they are appropriate.

■ 80. Amend § 422.612 by—

A. Revising paragraph (a)(2).

B. Revising paragraph (b).

C. Revising paragraph (c).

■ The revisions read as follows:

§ 422.612 Judicial review.

(a) * * *

(2) The amount in controversy meets the threshold requirement established annually by the Secretary.

(b) *Review of MAC decision*. Any party, including the MA organization, may request judicial review (upon notifying the other parties) of the MAC decision if it is the final decision of CMS and the amount in controversy meets the threshold established in paragraph (a)(2) of this section.

(c) *How to request judicial review*. In order to request judicial review, a party must file a civil action in a district court of the United States in accordance with section 205(g) of the Act. See part 405 of this chapter for a description of the procedures to follow in requesting judicial review.

■ 81. Amend § 422.616 by revising paragraph (a) to read as follows:

§ 422.616 Reopening and revising determinations and decisions.

(a) An organization or reconsidered determination made by an MA organization, a reconsidered determination made by the independent entity described in § 422.592, or the decision of an ALJ or the MAC that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, under the rules in part 405 of this chapter.

* * * * *

■ 82. Amend § 422.620 by—

A. Revising the section heading.

B. Revising paragraph (b).

C. Revising paragraph (c).

■ The revisions read as follows:

§ 422.620 How enrollees of MA organizations must be notified of noncovered inpatient hospital care.

* * * * *

(b) *Physician concurrence required*. Before discharging an individual or changing the level of care in an inpatient hospital setting, the MA organization must obtain the concurrence of the physician who is responsible for the enrollee's inpatient care.

(c) *Notice to the enrollee*. When applicable, the written notice of non-coverage must be issued no later than the day before hospital coverage ends. The written notice must include the following elements:

(1) The reason why inpatient hospital care is no longer needed or covered;

(2) The effective date and time of the enrollee's liability for continued inpatient care;

(3) The enrollee's appeal rights;

(4) If applicable, the new lower level of care being covered in the hospital setting; and

(5) Any additional information specified by CMS.

■ 83. Amend § 422.622 by revising paragraph (b)(1)(i) to read as follows:

§ 422.622 Requesting immediate QIO review of noncoverage of inpatient hospital care.

* * * * *

(b) * * *

(1) * * *

(i) To the QIO that has an agreement with the hospital under part 475, subpart C of this chapter;

* * * * *

Subpart N-Medicare Contract Determinations and Appeals

■ 84. Amend § 422.648 by adding paragraph (c) to read as follows:

§ 422.648 Reconsideration: Applicability.

* * * * *

(c) Notice of any redetermination favorable to the MA organization applicant, including those resulting from a hearing or Administrator review conducted under this subpart, must be issued by July 15 for the contract in question to be effective on January 1 of the following year.

Subpart O-Intermediate Sanctions

■ 85. Amend § 422.752 by—

A. Revising paragraph (a) introductory text.

B. Revising paragraph (a)(8) introductory text.

C. Revising paragraph (b)

■ The revisions read as follows:

§ 422.752 Basis for imposing sanctions.

(a) *All intermediate sanctions*. For the violations listed in this paragraph (a), we may impose one, or more, of the sanctions specified in § 422.750(a)(2), (a)(3), or (a)(4) on any MA organization that has a contract in effect. The MA organization may also be subject to other applicable remedies available under law.

* * * * *

(8) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 1128 or 1128A of the Act (or with an entity that employs or contracts with such an excluded individual or entity) for the provision of any of the following:

* * * * *

(b) *Suspension of enrollment and marketing*. If CMS makes a determination under § 422.510(a), CMS may impose the intermediate sanctions in § 422.750(a)(2) and (a)(4).

■ 86. Amend § 422.756 by-

A. Revising paragraph (f)(2).

B. Revising paragraph (f)(3).

■ The revisions read as follows:

§ 422.756 Procedures for imposing sanctions.

* * * * *

(f) * * *

(2) In the case of a violation described in paragraph (a) of § 422.752, or a determination under paragraph (b) of § 422.752 based upon a violation under § 422.510(a)(4) (involving fraudulent or abusive activities), in accordance with the provisions of part 1003 of this chapter, the OIG may impose civil money penalties on the MA organization in accordance with part 1003 of this chapter in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

(3) In the case of a determination under § 422.752(b) other than a determination based upon a violation under § 422.510(a)(4), CMS may impose civil money penalties on the MA organization in the amounts specified in § 422.758 in addition to, or in place of, the sanctions that CMS may impose under paragraph (c) of this section.

■ 87. Amend § 422.758 by-

A. Revising the introductory text.

B. Revising paragraph (c).

■ The revisions read as follows:

§ 422.758 Maximum amount of civil money penalties imposed by CMS.

If CMS makes a determination under § 422.510(a), as described in § 422.752(b) excepting those determinations under § 422.510(a)(4), CMS may impose civil money penalties in addition to, or in place of, the sanctions that CMS may impose under § 422.756(c) in the following amounts:

* * * * *

(c) If CMS makes a determination that a MA organization has terminated its contract other than in a manner described under § 422.512 and that the MA organization has therefore failed to substantially carry out the terms of the contract—$250 per Medicare enrollee from the terminated MA plan or plans at the time the MA organization terminated its contract, or $100, 000, whichever is greater.

Nomenclature Changes

■ 88. In part 422, remove ''Departmental Appeals Board'' wherever it appears and add in its place ''Medicare Appeals Council''.

■ 89. In part 422, remove ''DAB'' wherever it appears and add in its place ''MAC''.

■ 90. In part 422, remove ''Medicare+Choice'' wherever it appears and add in its place ''Medicare Advantage''.

■ 91. In part 422, remove ''M+C'' wherever it appears and add in its place ''MA''.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare Supplementary Medical Insurance Program)

Dated: January 10, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 14, 2005.

Tommy G. Thompson,

Secretary of Health and Human Services.

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