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42 CFR Parts 417 and 422

Medicare Program; Establishment of the Medicare Advantage Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417 and 422

[CMS–4069–P]

RIN 0938–AN06

Medicare Program; Establishment of the Medicare Advantage Program

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement 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. See the "Executive Summary'' in the **SUPPLEMENTARY INFORMATION** section for an outline of the key features of the MA program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 4, 2004.

ADDRESSES: In commenting, please refer to file code CMS–4069–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on issues in this document to *http://www.cms.hhs.gov/regulations/ecomments* (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4069–P, P.O. Box 8018, Baltimore, MD 21244–8018.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public website.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Eligibility, Election, and Enrollment—Lynn Orlosky, (410) 786–9064 or Randy Brauer, (410) 786–1618.

Benefits and Beneficiary Protections—Frank Szeflinski, (303) 844–7119.

Quality Improvement Program—Tony Hausner, (410) 786–1093.

Submission of Bids, Premiums, and Plan Approval—Ann Hornsby, (410) 786–1181.

Payments to MA Organizations—Anne Hornsby, (410) 786–1181.

Special Rules for MA Regional Plans—Marty Abeln, (410) 786–1032.

Contracts with MA Organizations—Frank Szeflinski, (303) 844–7119.

Beneficiary Appeals—Chris Gayhead, (410) 786–6429.

General Information—(410) 786–1296.

SUPPLEMENTARY INFORMATION:

Executive Summary: Beginning in 2006, the Medicare Advantage program would:

- Provide for regional plans that would make private plan options available to many more beneficiaries, especially those in rural areas.
- Expand the number of kinds of plans provided for, so that beneficiaries can choose from Health Maintenance Organizations, Preferred Provider Organization plans (the most popular type of employer-sponsored plan), Fee-for-Service plans, and Medical Savings Account plans, if available where the beneficiary lives.
- Enrich the range of benefit choices available to enrollees, including not only improved prescription drug benefits, but also other benefits not covered by traditional Medicare, and the opportunity to share in savings where 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 plans to provide continuing pressure on plans to improve service, improve benefits, invest in preventive care, and hold costs down in ways that attract enrollees. These improvements would be fostered through enhanced and more stable payments to organizations, improvements in program design, introduction of new flexibility for plans, and reductions in impediments to plan participation. At the same time, the traditional Medicare program will be enhanced by addition of a prescription drug benefit, and beneficiaries will retain the ability to remain in or return to this enhanced Medicare if they prefer it to a private health plan.
- 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. As such, Medicare can drive changes in the entire health care system. For example, as providers and health plans implement innovations, such as e-prescribing, that can result in improved quality of care for Medicare beneficiaries, these improvements would be passed on to other public health programs and commercial health care markets. Similarly, competing Medicare health plans will seek efficient ways to provide health care to their beneficiaries, such as through prevention and disease management

strategies to avoid costly care in the future. These efficiencies will spill over into plans' commercial, Medicaid and other markets, driving changes in the overall health care system.

Throughout the preamble we identify options and alternatives. We welcome comments and ideas on our approach and on alternatives to help us design the Medicare Advantage program to operate as effectively, successfully, and efficiently as possible in meeting the needs of Medicare beneficiaries.

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–4069–P and the specific "issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7195.

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I. Background

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

(If you choose to comment on issues in this section, please include the caption "Background—Medicare Prescription Drug, Improvement, and Modernization Act of 2003'' at the beginning of your comments.)

Title II of MMA makes important changes to the current Medicare+Choice (M+C) program—it replaces M+C with a new Medicare Advantage (MA) program under Part C of Medicare. This title provides for additional opportunities for organizations to offer private plans to Medicare beneficiaries beginning in 2006. In an effort to increase beneficiary choice of plans across all regions of the country, including rural areas, Title II of the MMA establishes a MA regional contracting option. As discussed below, MA regional plans would be subject to somewhat different rules than MA local plans. MMA also provided extra incentives, such as a stabilization fund, bonus payments, and risk sharing to encourage organizations to participate as regional plans.

The MMA also increases payments to MA organizations beginning in 2004. The increased payments and other changes under MMA are intended to boost plan participation and thus offer more choice of plans to beneficiaries and improve health and overall health system efficiency. The MMA requires that increased payment amounts be used to increase benefits, reduce beneficiary costs, or enhance beneficiary access to services. As explained below, beginning in 2006, we would require MA organizations to submit "bids'' for covering Medicare services, and if these bid amounts are below a benchmark amount established under the new law, this difference will be shared with enrollees. These provisions will potentially reduce Medicare costs.

One of the principal goals of the MMA is to provide beneficiaries with a choice in how they get their Medicare benefits. Under the MA program, to the extent that all parts of the country have at least one regional plan, all beneficiaries would have a choice in how they get their Medicare benefits, whether through a Medicare Advantage plan or the traditional fee-for-service program. Also, depending on plan offerings in the area in which they reside, beneficiaries would have the choice of a variety of types of local coordinated care plans, such as health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), and preferred provider organization plans (PPOs) including both regional and local PPOs, as well as Medical Savings Account (MSA) plans and private fee-for-service (PFFS) plans. In addition, the MMA permits us to contract with specialized MA plans that create plans for enrollees with special needs, such as institutionalized or Medicaid-eligible individuals, or those with severe or disabling chronic conditions.

The competition among these various types of plan offerings in a region should improve health care quality for beneficiaries. Plans will have to compete not only on price but on quality to attract beneficiaries' enrollment and to keep them enrolled over time. Such competition based on quality should precipitate development and implementation of innovations to prevent chronic diseases and manage the care of diseases for Medicare enrollees and other enrolled populations.

With these new and improved choices, Medicare beneficiaries, like Federal employees and retirees in the Federal Employees Health Benefits (FEHB) Program, would have the opportunity to obtain improved benefits, improved services, and reduced costs. However, those who prefer would be able to remain in traditional Medicare, enhanced by the new Part D drug benefit. All would have the opportunity to switch among plans, or to or from traditional Medicare, during the annual election period (or "open season'') in November and December. Over time, participating plans will be under continued 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 would 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 traditional Parts A and B of Medicare and the new Part D drug benefit and apply these innovative techniques may be able to pass on savings that may result from the care coordination to the enrollee through reduced premiums or additional benefits.

Beginning in 2006, payments for local and regional MA plans would be based on competitive bids rather than administered pricing. MA organizations would submit an annual aggregate bid amount for each MA plan. An aggregate plan bid is based upon their 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). To determine an organization's payment, CMS would compare the non-drug portion of the aggregate bid to the local or regional plan benchmark, which is an average of county rates in the plan's service area. For a plan with a bid below its benchmark, CMS would pay the MA organization the total plan bid (for Parts A, B, and D benefits plus any supplemental bid amount), risk adjusted for the plan risk profile, plus the rebate amount. (The rebate amount is 75 percent of the difference between the plan bid and benchmark, and is used to provide mandatory supplemental benefits. The remaining 25 percent is retained by the Government.) For a plan with a bid equal to or above its benchmark, CMS would pay the MA organization the plan benchmark, risk adjusted.

We would be able to negotiate bid amounts with plans in a manner similar to negotiations conducted by the Office of Personnel Management with Federal Employees Health Benefits (FEHB) plans. In the spirit of the FEHB process, CMS would 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 will be addressed in separate rulemaking, changes made in 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 the actuarial equivalent.

We have identified many areas in which we believe we can prevent or reduce unnecessary burden, duplication, or complexity either in interpreting the new MMA provisions or in modifying existing rules to accommodate Medicare Advantage reforms. In addition to those specifically discussed, we request suggestions for other burden-reducing reforms or innovations we can incorporate in the final regulation that will improve the ability of plans to participate in the program without compromising quality or services.

B. Relevant Legislation

(If you choose to comment on issues in this section, please include the caption "Background—Relevant Legislation'' at the beginning of your comments.)

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, 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 health maintenance organizations (HMOs)) that had been offered under section 1876 of the Act, and new options that were not previously authorized. Three types of M+C plans were authorized under the new Part C, as follows:

- M+C coordinated care plans, including HMO plans (with or without point-of-service options), provider sponsored organization (PSO) plans, and preferred provider organization (PPO) plans.
- 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 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 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.

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 a final rule with comment period published in the **Federal Register** on June 29, 2000 (65 FR 40170). 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 on March 22, 2002 (67 FR 13278).

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.

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.
Section 1859—Definitions; Miscellaneous provisions.

This proposed rule addresses the new MA provisions in Title II of MMA. Subtitle B—Immediate Improvements, contained in Title II, requires immediate payment adjustments for 2004 to MA plans. These payment adjustments were implemented in 2004 and payment adjustments for 2005 will be implemented in 2005. The requirement in 1858(a)(2)(D) to conduct a market survey and analysis before establishing MA regions is occurring concurrent with the publication of this proposed

MA rule. Therefore, the announcement of the MA Regions will not be included in this proposed rule. As noted above, the provisions in Title I of the MMA will be set forth in a separate proposed rule.

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

C. Codification of Regulations

(If you choose to comment on issues in this section, please include the caption "Background—Codification of Regulations'' at the beginning of your comments.)

The proposed regulations set forth here are codified in 42 CFR Part 422—The Medicare Advantage Program. Note that the regulations for managed care organizations that contract with us 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

(If you choose to comment on issues in this section, please include the caption "Background—Organizational Overview of Part 422'' at the beginning of your comments.)

MMA amends the existing provisions of the Medicare statute found in Part C of Title XVIII, sections 1851 through 1859 of the Act, and adds a new section 1858 to the Act. This proposed 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 proposed rule does not set forth unchanged regulations text from the previous part 422. Thus, this proposed 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 those subparts, H, L, and N are not set forth in this proposed 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 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 M—Beneficiary grievances, organization determinations, and appeals.

Subpart O—Intermediate Sanctions

Each of these subparts is discussed below in section II of this preamble.

II. Provisions of the Proposed Rule

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)

(If you choose to comment on issues in this section, please include the caption "Extension of Reasonable Cost Contracts (§ 417.402)'' at the beginning of your comments.)

Authority for cost HMOs/CMPs (cost plans) had been due to expire on December 31, 2004. Section 234 of the MMA modified section 1876(h)(5) of the Act to extend authority for cost plans beyond the previous limit of 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 (as defined in section 1851(a)(2)(A)(i) of the Act) of the same type (that is, either two local or two regional plans) 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. The minimum enrollment requirements of the "competing'' MA plans that would trigger mandatory non-renewal or service area reduction for cost HMOs/CMPs are: (1) At least 5,000 enrollees for the portion of the service area that is within a metropolitan statistical area having more than 250,000 people and counties contiguous to such an area; and/or (2) at least 1,500 enrollees for any other portion of such service area.

We interpret 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. An alternative reading of the statute might permit a cost plan to continue operating in its entire service area until such time as all parts of the cost plan's service area are subject to MA competition meeting applicable thresholds. We believe the approach we have taken is consistent with the stated intent in the Conference Agreement that cost plans be required to operate under the same provisions as other private plans that enter the cost plan's service area. We invite comment on the approach we have taken.

We propose 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.

We incorporate these changes into regulation by removing obsolete text and by revising other portions of § 417.402(b), and by adding a new § 417.402(c).

Subpart A—General Provisions (§ 422.1)

(If you choose to comment on issues in this section, please include the caption "Subpart A—General Provisions'' at the beginning of your comments.)

1. Overview

Subpart A begins with a brief section (§ 422.1) that lists the statutory authority that is implemented in part 422 (sections 1851 through 1859 of the Act).

This proposed rule would amend § 422.1(a) by adding the new section 1858 of the Act, which would be implemented in proposed subpart J. Under § 422.2, we set forth new definitions for terms used in part 422 that we believe need clarification. These definitions provide the generally applied meaning for terms that are used throughout part 422. Where necessary, we have included in specific subparts of part 422 definitions for terms used primarily in those subparts. As discussed below, § 422.4 briefly describes the two new types of coordinated care MA plans provided for under section 1851(a)(2)(A) of the Act. The provisions formerly contained in § 422.6 and § 422.8 relating to application requirements and evaluation and determination procedures have been removed from subpart A and added as § 422.501 and § 422.502 of subpart K. Thus, prospective MA plans may find all applications and contracting information organized in one place. Section 422.6 (formerly § 422.10) describes 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)

In § 422.2, we have included new definitions required under MMA and found under section 1859 of the Act. In addition, § 422.2 provides definitions that are not found in specific subparts of the regulation because they apply broadly to part 422. For example, in § 422.2, we provide the definition of "MA regional plans'' as set forth in section 1859 of the Act because this term is used throughout part 422. However, a definition like "benchmark'' found in section 1853 of the Act, that is specific to § 422.258 *et seq.,* is not described here but in that section. Finally, the statute specifies other new definitions under section 1859 of the Act, such as the definition of "specialized MA plans,'' and they are incorporated into this section.

We remove definitions for "ACR'', "Additional benefits,'' "Adjusted community rate,'' and "M+C'' as these terms will not apply after 2006. We also revise 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. Such 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.

However, optional supplemental benefits retain 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. These services may be grouped or offered individually. Note that 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 have removed "additional benefits'' from the definition of "basic benefits'' since MA plans will no longer offer additional benefits. In addition, we have 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 have 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 are established—Regional MA plans, which are regional PPO plans, and specialized MA plans for special needs individuals. First, we define 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.

Next, we define 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.

In all, CMS will establish between 10 and 50 regions, as described in § 422.455 (subpart J). A regional MA plan's service area is one or more entire MA regions. Thus, we define an "MA regional plan'' as a private health plan that operates as a PPO, but serves an entire CMS-designated region. Like 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. MA regional plans are further described in § 422.4 below, which describes types of contracting options under the MA program.

We define an "MA local plan'' as one that is not an MA regional plan. Also defined under part 422 is the "Prescription Drug Sponsor,'' "Prescription Drug Plan (PDP),'' and a "Medicare Advantage 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.

The other new type of contracting option available is a specialized MA plan for special needs individuals, as provided for under section 231 of the MMA. Section 1851(a)(2)(A) of the Act is amended by adding a new clause (ii) providing for specialized MA plans for special needs beneficiaries. Those specialized MA plans are therefore to be treated as coordinated care plans. In section 1859(b)(6)(A) of the Act, specialized MA plans for special needs beneficiaries are defined to be MA plans that exclusively serve special needs individuals defined in section 1859(b)(6)(B) of the Act, described below.

Currently, MA plans may not selectively limit enrollment to a subgroup, for example, institutionalized individuals (except for areas in which an organization is permitted to limit enrollment to retirees obtaining their employer/union coverage through an MA plan, as permitted through waivers authorized under section 1857(i)(1) of the Act). The establishment of specialized MA plans would allow MA plans to exclusively enroll special needs individuals in MA plans that have targeted clinical programs for these individuals.

We may designate an MA plan as a specialized MA plan, if the plan "disproportionately'' serves special needs beneficiaries. We will establish quantitative criteria to be able to designate MA plans that disproportionately serve special needs beneficiaries as specialized MA plans. For example, one possible criterion might consider the presence of four or more chronic conditions for an enrollee to represent a "complex'' medical condition. Persons with complex medical conditions might be appropriately treated by a specialized MA plan. We may also establish criteria to validate that specialized MA plans have incorporated processes or clinical programs that are designed to address the unique needs of enrolled special needs beneficiaries. We expect to determine these criteria based on diagnosis data or other administrative data that we collect, such as diagnosis data for risk adjustment. In an effort to focus the care management on special needs individuals, a specialized MA plan may limit enrollment to special needs individuals beginning in January 2004 through December 2009, as described under § 422.52.

An issue related to specialized MA plans for special needs individuals is the availability of prescription drugs. Special needs individuals in particular need access to prescription drugs to manage and control their severe or disabling chronic conditions. From a disease management perspective, a non-prescription drug plan would not serve the interest of special needs individuals. Additionally, effective January 1, 2006, specific dual eligible individuals described in section 1935(c)(6)(A)(ii) of the Act are required to receive drug coverage solely through the Medicare Part D program. In other words, effective January 1, 2006, a full-benefit dual eligible who is also a Part D eligible individual will only be able to receive drug coverage through the Medicare Part D program. Eligibility for drugs under Title XIX will no longer be available for these individuals.

Therefore, we propose that effective January 1, 2006, all special needs plans, as defined in section 1859(b)(6)(B) of the Act, will need to provide Part D coverage. Again, for individuals with special needs enrolled in a special needs plan, this would be the only means for them to receive their Part D coverage as they cannot receive it through an MA plan that does not offer prescription drug coverage. We would welcome comments on this proposed requirement. The authority for such a requirement is found in our establishing requirements for special needs individuals under section 1859(b)(6)(B)(iii) of the Act. In addition, we also are interested in receiving comments 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.

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

For the purpose of defining a special needs individual above, "institutionalized'' means to reside 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). We are not at this time proposing a definition of "severe or disabling chronic condition.'' However, we welcome comments on whether we should set standards for the designation of an individual with severe or disabling chronic conditions and what criteria should be used. For example, does the individual need medical management by a specialist (for example, endocrinologist or cardiologist)? Does the individual have complex medical conditions? Does the individual qualify for the plan's disease or case management program? Are there specific benefits or interventions provided to these individuals that are not provided to the general MA population?

We would also welcome comments on whether we should allow specialized MA plans to exclusively enroll certain subgroups of Medicaid or institutionalized beneficiaries. If it were determined to be appropriate to enroll subgroups of either Medicaid or institutionalized beneficiaries, what would the appropriate subgroups be?

We note that MMA allows for the enrollment of End-Stage Renal Disease (ESRD) beneficiaries in specialized MA plans designed for this population. Thus, ESRD beneficiaries for whom an MA plan would receive payment at the ESRD rates would be considered special needs individuals who would benefit from enrollment in a specialized MA plan.

Finally, we would welcome comments on whether there are appropriate quality oversight mechanisms for specialized MA plans that would be appropriate to require to ensure that special needs individuals experience improved quality.

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 the existing plans under the M+C program and to increase the number of areas in which private health care options are available to Medicare beneficiaries. As under the M+C program, entities can contract with us to provide three general categories or types of plans: MA coordinated care plans, MA MSA plans, and MA PFFS plans. However, the establishment of the MA program is designed to afford beneficiaries two additional types of plan choices within the coordinated care plan category—regional PPO coordinated care plans as defined in § 422.2 or specialized MA coordinated care plans, also defined in that section. These new MA coordinated care plan entities must conform to the contracting requirements described in § 422.504 *et seq.*

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 Preferred Provider Organization plans (PPOs) 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 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 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: The PPO (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) 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 health maintenance organization. For PPO-type plans that are offered by MA organizations that are licensed or organized under State law as health maintenance organizations, 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.

Section 722 of the MMA, which amends section 1852(e) of the Act effective January 1, 2006, is consistent with this interpretation insofar as it limits the applicability of the definition of PPOs in section 1852(e)(3)(A)(iv) of the Act (which is the same definition currently appearing in section 1852(e)(2)(D) of the Act) to subparagraph (A) of paragraph 1852(e)(3) of the Act. Effective January 1, 2006, MA organizations that offer MA local plans that are PPOs will only need to provide 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, this exception to the normal rule in section 1852(e)(2) of the Act that data are to be collected from all clinical sources is afforded solely to PPOs that are offered by MA organizations that are not licensed or organized under State law as health maintenance organizations—section 1852(e)(3)(A)(iv)(III) of the Act. To the extent that a local PPO is offered by an MA organization that is licensed or organized under State law as a health maintenance organization, the normal data collection, analysis, and reporting requirements in clause (3)(A)(i) continue to apply. We propose to modify the definition of PPOs in § 422.4 to account for this more limited interpretation of State licensure requirements and to modify headings in § 422.152(b) and (e).

Another change in the type of MA plans authorized is the elimination of previous limits on enrollment in MA MSAs, described at § 422.56. As directed by section 233 of the MMA, MA organizations are authorized to offer medical savings account (MSA) plans as a permanent option. A Medicare MSA plan combines a high-deductible insurance policy and a savings account for health care expenses. The Medicare program pays premiums for the insurance policies and makes a contribution to the beneficiaries' medical savings account (MSA). The beneficiaries use the money in their MSAs to pay for their health care before the high deductible is reached. The sum of the premium and the contribution to the account would equal the payment made by Medicare to any other MA plan for a beneficiary.

By way of background, the Balanced Budget Act of 1997 (BBA) authorized a demonstration project for MSA plans when it created the Medicare+Choice program. MMA changes restrictive rules that governed the MSA demonstration. MMA eliminates 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 such plans. It also exempted MSA plans from certain quality assurance requirements that the BBA applied to "network'' MSA plans. The Congress made these changes in light of the fact that no MSA plans participated in the demonstration. We are particularly interested in comments on whether these changes are sufficient to attract MSA plan sponsors and beneficiary enrollment.

Finally, we delete the descriptions of M+C network MSA plan and M+C non-network MSA plan as different types of plans at § 422.4(a)(2)(B)(ii), since the distinction between network and non-network MSAs for the purpose of quality assurance requirements is no longer applicable.

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

The last section of subpart A contains regulations implementing the user fees provided for in section 1857(e)(2) of the Act. MMA expands 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. In 2006 and beyond, user fees will help to offset the costs of educating over 41 million beneficiaries about the drug benefit through written materials such as a publication describing the drug benefit, internet sites, and other media. For example, CMS will develop a prescription drug price comparison Web site for beneficiary use. We may also provide information to beneficiaries on quality measures, networks, and other dimensions.

Additionally, 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 State health insurance programs (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).

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 (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 (discussed below) of $200,000,000, whichever is less.

Finally, 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 would 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.

The remaining portion of the costs of the beneficiary education campaign is the fee-for-service beneficiaries' portion of the campaign. It represents the portion of costs of fee-for-service informational materials, designed to enable beneficiaries to make informed choices among health plans and Medicare fee-for-service. This amount is funded through CMS' appropriations.

Subpart B—Eligibility, Election and Enrollment

(If you choose to comment on issues in this section, please include the caption "Subpart B—Eligibility, Election and Enrollment'' at the beginning of your comments.)

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

The regulations contained in this subpart are largely the same as those now used in the M+C program. We have made the necessary terminology changes throughout subpart B to reflect the replacement of the M+C program with the MA program. Substantive changes are discussed below.

Under § 422.50 introductory text, we would clarify that, for this subpart, a reference to an "MA plan'' should be read to include both MA local and MA regional plans, unless specifically noted otherwise in the text.

In addition, based on our experience with the M+C program, we believe that it is important to provide additional optional mechanisms for elections that take advantage of modern technology, such as allowing an individual to enroll at a secure Web site or at a health plan's customer service center. Section 1851(c) of the Act allows the Secretary to designate other enrollment mechanisms. These options promote a more efficient and simplified election process for beneficiaries as well as partner organizations. Therefore, we would revise § 422.50(a)(5) to allow other election methods as approved by us.

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

We would include a new § 422.52 to describe the eligibility requirements for enrollment into specialized plans for special needs beneficiaries, which have been authorized under section 231 of MMA. Individuals would be eligible to enroll in these specialized plans if they are institutionalized, entitled to Medicaid ("dual eligible''), or have a severe and disabling condition and meet the requirements specified by CMS. We are considering including in this last category individuals with a disabling condition who are not in an institution but require a similar level of care. We invite comments on this approach. Specialized MA plans would be able to restrict enrollment solely to those individuals who are in one or more classes of special needs individuals.

In general, we believe that the new requirements regarding special needs MA plans primarily are intended to encourage more choices for certain populations by allowing plans that specialize in the treatment of beneficiaries with particular needs by providing and coordinating services for these individuals and to limit plan enrollment to such individuals. This provision could encourage plans to develop new products in the market place by giving them the opportunity to develop expertise in efficiently serving such specialized populations. We also have the authority to waive section 1851(a)(3)(B) of the Act, which precludes beneficiaries with ESRD from enrolling in MA plans. This authority grants us the discretion to permit people with ESRD to enroll in a special needs MA plan. We also are considering whether beneficiaries with ESRD should be considered to meet the requirements for special need status and invite comments on this idea.

We are permitted to apply to special needs plan enrollees 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 provision provides for continued eligibility in certain situations. Specifically, this provision allows a PACE eligible individual to be deemed to continue to be enrolled even if the individual no longer meets the PACE eligibility requirements if, in absence of continued coverage under a PACE program, the individual reasonably would be expected to meet the requirements within the succeeding 6-month period. Similarly, we propose to allow special needs individuals who no longer meet the "special needs'' criteria to remain enrolled in an MA special needs plan if it is reasonable to assume that, absent the continued special needs care available under the plan, they would again meet the eligibility criteria for that MA plan within the succeeding 6-month period.

We note that a special needs plan is described as "an MA plan that exclusively serves special needs individuals.'' We have considered the question of whether this means that the plan is exclusively offered to special needs individuals, and exclusively enrolls special needs individuals, or whether it means that it only provides care to special needs individuals, and has no enrollees who do not meet the definition of a special needs individual. In the latter case, if an existing plan were designated as a special needs plan, existing enrollees who did not meet the definition of a special needs individual would be required to terminate their enrollment.

We do not think that this was intended by the Congress, and therefore have interpreted "exclusively serves'' special needs individuals to mean that the plan is only offered to special needs individuals, and only enrolls such individuals. Existing enrollees of such a plan, however, would be "grandfathered'' and could remain enrolled. Therefore, we are providing in proposed § 422.52(e) that individuals who are enrolled in MA plans that are subsequently designated as "special needs plans'' would be able to continue to be enrolled. Those individuals would be able to remain enrolled or choose to elect other MA plans during appropriate election periods provided to all MA eligible individuals.

We invite comment on the above approach, and on the alternative approach under which only special needs individuals could be enrolled and receive services through the plan, and any non-special needs individual would have to terminate enrollment involuntarily if his or her plan wanted special needs plan status. To ensure that the non-special needs individuals would be able to elect a new plan outside of an enrollment period, we intend to establish a special election period for these individuals. We have historically established SEPs for exceptional circumstances in our manual instructions rather than through regulation. Thus, we would establish such an SEP through that process.

We would distinguish the situation of a "grandfathered'' plan enrollee who enrolled in the plan before it had special needs status from a case in which a new special needs plan was created that was designed to provide services only to people in a special needs category. For example, if a special needs plan was established to exclusively provide services to institutionalized individuals, and had no capacity to provide care to individuals not in a contracting institution, we would not expect the plan to allow an individual to remain enrolled in the plan if he or she no longer required institutional care.

In this case, unlike the grandfathered enrollees of an existing MA plan designated as a special needs plan, we would expect individuals to be informed before initial enrollment that they could only remain enrolled in this plan for so long as they remained institutionalized. If such a notice is given, we believe that a new special needs plan could require disenrollment when a person no longer had special needs status. Such a disenrollment would be pursuant to section 1851(e)(4)(B) of the Act, as the individual would "no longer be eligible'' for that plan "because of a change in * * * circumstances. * * *'' (This would also be the basis for disenrollment of grandfathered

enrollees if we were to adopt the alternative reading of the word "serves,'' under which grandfathered enrollees could not remain enrolled because the plan could only provide services to special needs individuals.)

The statute also provides us with the authority to designate an MA plan to be a special needs plan if it "disproportionately serve[s] special needs individuals.'' Under our current interpretation of the word "serves,'' this would mean a plan that disproportionately enrolls special needs individuals. At a minimum, this would mean it enrolls special needs individuals in a proportion greater than such individuals exist in the area served by the plan. We invite comments on the question of whether this "minimum'' definition would be appropriate, or whether there is another level of special needs enrollees (for example, 50 percent or more) that should be required in order to be considered a special needs plan under this "disproportionately serves'' provision.

We note that under this provision as we are interpreting it, the plan would remain exempt from the requirement to enroll all MA eligible individuals, but would nonetheless enroll some MA individuals who are not special needs individuals. Operationally, this could be accomplished in a number of ways. For example, the plan could impose a cap on the number of non-special needs individuals enrolled at any point in time, or cap the number of special needs individuals served. It also might enroll two special needs enrollees for every one enrollee who does not meet the definition.

Other than the requirement that all MA eligible individuals be permitted to enroll, and—if we choose to waive it'the preclusion on enrolling individuals with ESRD, all other MA provisions would apply to specialized needs plans (for example, payment rules, appeal rights, quality assurance requirements, enrollment procedures).

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

Section 1851(b)(1) of the Act is amended by section 222(l)(3)(A)(i) of the MMA to limit the offering of MA plan continuation areas to MA local plans only. We would revise § 422.54 to specify that this provision would apply only to local MA plans.

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

Section 1851(b)(4)(A) of the Act is amended by section 233 of the MMA to eliminate the cap on the number of individuals that may enroll in MA MSA plans and to make the program permanent by removing the enrollment cut-off date. While unchanged by the MMA, section 1851(b)(2) of the Act states that individuals enrolled in health benefit plans in the Federal Employees Health Benefit Plan, the Veterans Administration, or the Department of Defense may not enroll in an MSA until or unless the Director of OPM adopts policies to ensure that the enrollment will not result in higher government spending under these programs. While the existing exclusion of enrollees of other Federal programs is reflected in current regulations at § 422.56(b), the regulatory language does not provide for such individuals to be eligible following the adoption of new policies by OPM. We understand that the Office of Personnel Management's current policy is to encourage the creation of high deductible plans for Federal employees and retirees, and we will explore with OPM whether such a policy can now or in the future be certified to the Secretary. Therefore, we are revising the regulations to allow for that policy to be implemented in the future, as provided in the statute. We would revise § 422.56 to reflect these changes.

5. Election Process (§ 422.60)

We are proposing conforming changes throughout § 422.60, as in § 422.50(a)(5), to allow us to approve other election mechanisms in addition to paper forms. We are also streamlining § 422.60(e) to allow for notice options for MA plans other than the traditional mailing of a written document.

We are also proposing to clarify the regulation at § 422.60(b) to provide that MA organizations may submit requests to restrict enrollment for capacity reasons at CMS at any time during the year. There are several reasons why MA organizations may need to restrict enrollment for capacity reasons, especially those that are clearly outside of the MA organization's control. For instance, we have allowed capacity limits for certain organizations when a large competitor, in the same service area, has non-renewed its contract. The remaining contractor may not have the capacity to enroll a large percentage of its competitor's enrollees. Another example is a case in which an MA organization loses its contract with a large hospital system or physician group and thus can no longer handle the potential number of enrollees it previously estimated it could.

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

a. Annual Coordinated Election Period

Section 1851(e)(3)(B) of the Act is revised by sections 102(a)(2) and 102(a)(5) of the MMA to permanently establish the annual coordinated election period as November 15 through December 31 of each year. For 2006, the annual coordinated election period is extended through May 15, 2006.

b. Initial Coverage Election Period

Section 1851(e)(1) of the Act is amended to provide that, "if any portion of an individual's initial enrollment period under Part B occurs after the end of the annual, coordinated election period [for 2006, from November 15, 2005 to May 15, 2006], the initial enrollment period under this part shall further extend through the end of the individual's initial enrollment period under Part B.''

We believe that this provision is intended to allow an individual who still has time to decide whether to enroll in Medicare Part B upon becoming eligible for Medicare to be able to enroll in an MA plan upon deciding to enroll in Medicare Part B. In using the words "further extend,'' we believe the Congress made clear that this new sentence was designed to expand upon the beneficiary's opportunity to choose to enroll in an MA plan by extending or lengthening the time the beneficiary has relative to the existing rules.

Accordingly, we are interpreting this sentence to apply only to the extent that its application would result in an extension of an initial enrollment period for an MA compared with the period that would apply if the sentence had not been added. Under the alternative interpretation, in which an MA initial enrollment period would end when the Medicare Part B initial enrollment period ends, individuals who defer Medicare Part B enrollment, such as those who decline enrollment while continuing to work, would be adversely impacted. The initial enrollment period for Medicare Part B is directly associated with an individual's eligibility for Medicare Part B, not with an individual's actual enrollment in Medicare Part B.

To ensure that an individual who is first eligible for MA has the full opportunity to elect an MA plan, we are interpreting the statute 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. The new sentence added to section 1851(e)(1) of the Act

accordingly would only extend an individual's MA initial election period, never reduce or eliminate it.

c. Open Enrollment Periods Through 2005

Section 1851(e)(2)(A) of the Act is amended to extend the open enrollment and disenrollment period through 2005, providing unlimited opportunities for MA eligible beneficiaries to enroll in, disenroll from, and or change enrollment in an MA plan. We would revise § 422.62(a)(3) to reflect this extension.

d. Open Enrollment Periods During 2006

Section 1851(e)(2)(B)(1) of the Act is revised to establish that the open enrollment period in 2006 will be the first 6 months of 2006. In addition, for individuals who first become eligible during 2006, an open enrollment period will be provided as the first 6 months the individual is MA eligible during 2006, but not to extend past December 31, 2006. After December 31st, 2006, all individuals are provided the 3-month open enrollment period from January through March, as provided in the next section.

e. Open Enrollment During 2007

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

A new clause is added to section 1851(e)(2)(C) of the Act that limits a change of election made during an open enrollment period in 2006 and later years to the same type of plan the individual making the election is already enrolled in. Specifically, an individual in an MA plan that does not provide drug coverage may only change 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. An individual enrolled in an MA plan that includes Part D coverage similarly may only enroll in another MA plan with Part D coverage, or change to original Medicare coverage with an election of a Part D plan. (We note that section 1851(e)(2)(C)(iii)(I) of the Act 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 section 1851(e)(2)(C)(iii) of the Act, 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.) Although the MMA and conference agreement are clear, we think that there may be some concern that the policy set forth in section 1851(e)(2)(C)(iii)(II) of the Act, as added by section 102(a)(6)(C) of the MMA, may be somehow inconsistent with the voluntary nature of the Part D program. Specifically, that policy would require a Medicare beneficiary who has changed their mind after initially electing Part D coverage through an MA plan to maintain drug coverage for the entire year, even if they decide during the open enrollment period that they do not want that coverage. (Of course, a Part D enrollee could always forego Part D coverage through a PDP by failing to pay premiums under the plan). We are soliciting comments from interested parties as to whether there is a way to interpret the statute, and whether it would be advisable, on a policy basis, to excuse the requirement that an enrollee who elects their option to disenroll from an MA–PD plan during an open enrollment period, enroll only in another MA plan with prescription drug coverage or enroll in fee-for-service Medicare with Part D coverage.

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

We would revise § 422.66 with conforming changes in keeping with our proposed clarification at § 422.50(a)(5) regarding election mechanisms other than, and in addition to, forms. As proposed in § 422.60(e), we are making similar changes in § 422.66(b) to provide for other notice mechanisms, as well as a more efficient notice process. This includes removing 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 the authority to implement default enrollment rules at 1851(c)(3)(A)(ii) for the MA–PD program, which begins in 2006. If applied, these rules provide that an individual who is in a health benefits plan providing any prescription drug coverage will be deemed to make an election into an MA–PD offered by the same organization during the individual's initial election period surrounding Medicare entitlement. This statutory provision was originally created under The Balanced Budget Act of 1997 (BBA) for the Medicare+Choice (M+C) program. In developing regulations for the BBA, CMS decided *not* to default individuals to M+C plans offered by the same organization in which they were enrolled. Our rationale was that to implement such a process would require CMS to have access to information prior to the individual's initial coverage election period. Since we did not have access to the individual's information on health plans in which they were enrolled, we did not believe it would be feasible to implement a default process at that time.

Rather than implement a default enrollment process for these individuals who are enrolled in a health plan, we require (at section 422.66(d)(1) of our regulations) that an M+C plan offered by an M+C organization must accept any individual who is enrolled in a health plan offered by that M+C organization the month immediately preceding the month in which the individual becomes entitled to Part A and enrolled in Part B, as well as meeting the other M+C eligibility requirements. This requires an affirmative action by the individual; however it does not extend so far as to automatically enroll the individual (that is, "default'') into the M+C plan.

In addition to our previous concerns regarding this provision, we are also concerned that, beginning in 2006, an individual's ability to choose his/her health care coverage will be limited to certain periods. Within these specified periods, an individual is limited to one election (either enrollment or disenrollment). If an individual makes an election of any type (including one by "default''), s/he is prohibited from making another choice until the next annual election period in November. Default enrollment may therefore limit an individual's choice by utilizing the individual's single election. In addition, automatically enrolling an individual assumes that the "default'' plan would

be the plan that the individual would have chosen absent such a default process. This may not be the case. Given the variety of potential options available to these individuals, and the implications of choosing those options (including penalties for late enrollment in Part D), we must carefully consider the consequences of implementing a default enrollment process.

We must also carefully consider the implications a default enrollment process may have on individuals enrolled in employer groups. For example, such a process could conflict with the incentives that the MMA will provide to employers to encourage them to maintain creditable coverage for their employees. Such a provision could negatively impact married individuals enrolled in employer group plans if an individual has just become entitled to Medicare (and is enrolled in plan under default enrollment) while his or her spouse, who is already entitled to Medicare, receives coverage through the employer group in another health plan. On the other hand, we may learn from system processes we are establishing under the new Medicare-approved discount drug plan, such as data sharing with the States and other agencies. We could consider offering MA plans the option to establish a process with its employers to automatically enroll individuals, with an option for individuals to decline before enrollment. We recognize that any strategies to streamline and improve enrollment could lead to an overall reduction in costs. These are all important issues that must be carefully considered.

Since the Secretary has the discretion to not implement the default enrollment provision, we would continue to require affirmative elections by the individual upon becoming entitled to Medicare as provided under § 422.66. This ensures 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, we encourage input from the public on this provision given the new Part D program, including the benefits, as well as the impact of implementing such a provision.

We would implement 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). We would revise § 422.66(e) to add language that incorporates these changes.

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

To coordinate the effective date of elections with the new special annual coordinated election period, section 1851(f)(3) of the Act is amended by establishing that the effective date of elections for the annual coordinated election period do 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 propose to revise § 422.68(b) to provide for this coordination and make the effective date of elections in the annual coordinated election period for 2006 that are made in 2006 (that is, from January 1–May 15, 2006) the first day of the calendar month following the month in which the election is made.

9. Disenrollment by the MA Organization (§ 422.74)

We are clarifying the regulation at § 422.74(d)(1) regarding disenrollment for nonpayment of premium to provide more flexibility to MA plans in developing rules for those individuals who fail to pay their basic and supplementary premiums. Under the current regulations at § 422.74(d)(1), MA plans are required to provide, at minimum, a 90-day grace period before disenrolling individuals for failure to pay the premium. Thus, MA plans must maintain enrollment for individuals who do not pay their premiums for more than 90 days. We propose to provide greater flexibility to MA organizations by replacing the 90-day grace period in § 422.74(d)(1) with the approach taken in § 417.460(c)(1), which governs disenrollment from HMOs with cost contracts under section 1876. Cost HMOs must take certain actions before an individual may be disenrolled for nonpayment of premium, including demonstrating a reasonable effort was taken to collect the monies and providing the individual with written notice. While no specific timeframe dictates the process, certain steps must be taken. Generally, this process takes at least 30 days before a disenrollment is effective, given that disenrollments are effective the first of the month. Similarly, we propose to remove the mandatory timeframe before disenrollment would occur, focusing on the required and important steps that still must be taken. Such steps would continue to include requiring that proper notice be provided to individuals before that action is taken, and the MA organization would have to be able to demonstrate to us that it has made reasonable efforts to collect unpaid premium amounts. The notice would also inform the enrollee of his or her rights under the organization's grievance procedures. These revisions would not, however, preclude organizations from offering a more generous grace period than provided in the regulation, if they so choose.

Current regulations at § 422.74(d)(2) generally prevent an individual from being disenrolled from an MA plan if his or her behavior is related to "diminished mental capacity.'' While we originally intended this provision to protect the rights of individuals with mental illness, the language requiring that the individual's behavior not be related to diminished mental capacity has proven to be overly broad. The unintended impact of the current regulations has been to prohibit disenrollment of individuals whose violent and threatening behavior put the health and safety of enrollees, staff, and the public at risk. Therefore, we are amending the regulation by revising § 422.74(d)(2) to ensure due process and beneficiary protections, while at the same time protecting the health and safety of that individual as well as others. The changes include redefining disruptive behavior as "disruptive or threatening,'' as well as retaining the "unruly, abusive, or uncooperative'' language. The revised provision would also require that the behavior be by an individual with "decision-making capacity,'' meaning someone with the ability to understand the consequences of his or her behavior. In addition, we are proposing limiting re-enrollment in the MA program he or she has been disenrolled from under this provisions, as well as a provision to provide for expedited disenrollment in cases where there is an immediate threat of health and safety to others.

M+C organizations and providers also have expressed concern regarding nonpayment of cost sharing, including co-payments, for health plan services. The statute specifically permits individuals to be disenrolled for non-payment of premiums, but it does not

provide for disenrollment due to nonpayment of cost-sharing. This has proven increasingly problematic since M+C organizations and providers have no effective mechanism to deal with individuals who repeatedly refuse to meet their cost-sharing responsibilities, potentially resulting in disruptions to the plan's ability to maintain its provider network. Thus, we are considering new regulatory language that would include nonpayment of cost sharing as "noncompliant'' behavior under the disruptive behavior provisions because it limits the health plan's ability to provide services both to the individual and potentially to other enrollees. Although we are not proposing specific regulatory language at this time, we invite comments on adopting an interpretation of nonpayment of cost sharing as "disruptive behavior,'' as well as comments on the elements that we propose to include in language. As part of the regulation, we intend to require the policy be applied consistently, however, we would be clear that an exception would prohibit low-income individuals from being disenrolled under this provision. We would also indicate that the cost-sharing amount must represent a "significant'' cumulative amount and that the MA plan would be expected to have an established threshold that would be approved by CMS. CMS envisions MA organizations would submit such thresholds at the time their annual payment rates are submitted to CMS for approval. In addition, we propose to include that the behavior must be based upon a repeated failure to pay cost sharing. Since the language for disenrollment for nonpayment of cost sharing would fall under the regulations for disruptive behavior, the process for disruptive behavior as provided in regulations and in manual instructions would be applied, including: required approval by CMS before such disenrollment is permitted and beneficiary notice requirements. This would also require plans to offer payment agreements with the beneficiary as part of the requirement under disruptive behavior to make a serious effort to work with the beneficiary. We may include guidance on this matter in a final regulation based upon comments received.

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

We have in place a program that recognizes consistent compliance with marketing guidelines by providing for streamlined approval of marketing materials submitted by organizations that have demonstrated compliance. Called the "File and Use'' program, organizations that have demonstrated to us that they continually meet a specified standard of performance will have certain types of marketing materials (such as advertising materials or other materials that do not describe plan benefits) deemed to be approved by us if they are not disapproved within 5 days of submission to us for prior approval. Thus, under these circumstances, organizations only need to submit material for our approval 5 days befor its distribution.

The advantages of File & Use are that the organization can decrease the time it takes to begin using certain marketing materials and improve planning and budgeting for publication of these materials.

In addition, we are making the time frames under § 422.80(e)(5) consistent with those provided under § 422.80(a)(1). Currently, under § 422.80(a)(1), the review period for marketing materials is at least 45 days, unless using model materials provided by CMS, in which case the review period is decreased to no more than 10 days. However, the standards for M+C marketing under § 422.80(e)(1)(v) refer only to the 45-day period. Hence, we will now add a reference to the 10 day period in this section to be consistent with § 422.80(a)(1).

We are also making clarifying changes under those marketing activities the MA plans may not participate in, such as specifically using the term "targeted marketing'' when discussing discriminatory activities and engaging in any marketing activity that CMS prohibits in its marketing guidance.

Finally, while all entities in which CMS does business with are required to adhere to all Federal laws, with regard to marketing, it is important to refer here to section 1140 of the Act prohibiting the misuse of symbols, emblems, or names in reference to Social Security or Medicare. While we have not reiterated this provision in our proposed rule, we believe that it is important to highlight this reference in the discussion of marketing requirements.

Subpart C—Benefits and Beneficiary Protections

(If you choose to comment on issues in this section, please include the caption "Subpart C—Benefits and Beneficiary Protections'' at the beginning of your comments.)

In the areas of benefits and beneficiary protections, we are proposing regulatory reforms based on our program experience, as well as provisions implementing new requirements in the MMA. We have tried in these proposed rules 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 and, in some extreme cases, have caused Medicare+Choice organizations to nonrenew their contracts or reduce service areas in which they offer Medicare+Choice plans. We have done all this while keeping foremost in our consideration 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 are proposing include: (1) New beneficiary protections in cases in which an MA organization offers an "in-network'' point-of-service (POS) option; (2) revisions to the rules limiting beneficiary cost sharing related to emergency episodes, (3) the elimination of administratively burdensome requirements on MA plans that are duplicative of activities already conducted by us, and (4) the elimination of a number of unnecessary, duplicative, or overly burdensome access to care provisions.

We also are proposing new rules that would apply only to MA regional plans, which are created under the MMA. These rules would afford specific additional protections to Medicare beneficiaries that enroll in those plans. For instance, MA regional plans must provide for catastrophic limits, or stop-loss, on beneficiary out out-of-pocket cost-sharing amounts related to original Medicare benefits received in and out of the MA regional plan's network of providers.

Finally, we propose regulations implementing incentives for MA regional plans to serve all areas. These incentives involve a new payment mechanism for "essential hospitals.'' We also provide for special access to care rights for enrollees in MA regional plans related to out-of-network cost sharing.

1. General Requirements (§ 422.100)

Section 233(c) of the MMA amended section 1852(k)(1) of the Act to include enrollees in MSA plans offered by an MA organization with MA coordinated care plans described in section 1851(a)(2)(A) of the Act as having protection from balance billing by non-contracting providers. A physician or other entity that does not have a contract with an MSA plan is now required to accept as payment in full,

for covered services provided to an MSA plan enrollee, the amount the physician or other entity could have collected had the individual not been enrolled in the MSA plan.

This provision applies to physicians and other entities, but not to providers of services. For purposes of this portion of the preamble discussion, "provider of services'' has the same meaning as "provider of services'' defined in section 1861(u) of the Act. Providers of services are covered by section 1866(a)(1)(O) of the Act related to charges they can impose on a Medicare Advantage plan enrollee when the provider of services does not have a contract with the Medicare Advantage organization sponsoring the plan in which the beneficiary is enrolled.

In cases in which participating physicians do not have an agreement in place governing the amount of payment, and treat beneficiaries enrolled in a coordinated care plan described in section 1851(a)(2)(A) of the Act or an MSA plan, they must accept the amount they would have received under fee-for-service Medicare as payment in full. Generally, the amount they would receive under fee-for-service Medicare is based on the participating physician fee schedule and includes both the amount paid by the Medicare carrier as well as the cost-sharing (generally 20 percent) due from the fee-for-service beneficiary or another source (that is, a Medigap plan).

In cases in which non-participating physicians do not have an agreement in place governing the amount of payment, and treat beneficiaries enrolled in a coordinated care plan described in section 1851(a)(2)(A) of the Act or an MSA plan, they also must accept the amount they would have received under fee-for-service Medicare as payment in full. Additionally, non-participating physicians are permitted to accept assignment on a case-by-case basis. If they do accept assignment on a claim, then the amount a non-participating physician must accept as payment in full is generally the non-participating fee-schedule amount. Non-participating physicians that do not accept assignment on a claim can generally balance bill up to, but no more than, 115 percent of the non-participating physician fee schedule amount. This limit on charges is known as the "limiting charge.''

These fee-for-service billing limits have always applied to charges that providers and other entities could impose when providing covered services to enrollees in MA coordinated care plans where there is no agreement in place governing the payment amount. The MMA adds the same protections for MSA plan enrollees.

MSAs are "high deductible'' MA plans and are defined at section 1859(b)(3) of the Act. Until the deductible is met, the MSA enrollee is generally responsible for payment of all covered services. Once the 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 MSA that assumes responsibility for payment, providers and other entities are required to accept the amount that fee-for-service would have paid as payment in full. We are also proposing to make conforming changes to § 422.214 to account for this new beneficiary protection for MSA enrollees.

To address this MMA requirement and other changes in the MMA and for purposes of administrative simplification and clarification, we propose the following provisions:

- We would delete the parenthetical "(other than an M+C MSA plan)'' from the first sentence of § 422.100(b)(2) and replace it with "(and an MA MSA plan, after the annual deductible in § 422.103(d) has been met).''
- We would modify 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 would remove § 422.100(e), as it is duplicative of § 422.111(b)(2), and we would accordingly redesignate paragraphs (f) through (j) as paragraphs (e) through (i), respectively.
- We would remove the reference to operational policy letters in § 422.100(f), as instructions on benefit policy guidelines and requirements have been incorporated into the Medicare Managed Care Manual and other written instructions.
- We would add "or encourage disenrollment'' to § 422.100(f)(2) after "discourage enrollment,'' as one of the prohibitions on the design of benefit packages.

2. Requirements Relating to Basic Benefits (§ 422.101)

Section 221 of the MMA adds a new section 1858 to the Act. Section 1858(g) of the Act provides 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 fee-for-service beneficiaries in any part of an MA region to apply to its enrollees in all parts of an MA region. Application of these local coverage determinations by an MA regional plan may be appealed under provisions of section 1869(f)(2) of the Act.

We interpret section 1858(g) of the Act to mean that the MA regional plan, if it chooses to exercise this option, must elect a single fee-for-service contractor's local coverage determination that it will apply to all members of an MA regional plan. The MA organization offering an MA regional plan may not select local coverage policies from more than one fee-for-service contractor that it will apply to all members of the plan. We invite comment on this interpretation and our proposed policy related to it.

We propose the following provisions:

- We would add a new § 422.101(b)(4) related to election of a local coverage determination by MA regional plans to provide for new language in section 221 of the MMA.
- We would remove reference to operational policy letters (OPLs) in § 422.101(b)(2), as all OPLs related to general coverage guidelines have been incorporated into the Medicare Managed Care Manual and other written instructions.

The MMA provides for new cost-sharing requirements in the statute at section 1858(b) of the Act related to MA regional plans. There are three specific requirements:

1. MA regional plans, to the extent they apply deductibles, are permitted 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 fee-for-service program (Medicare Part A and Part B benefits).

3. Regional MA plans are required to have an additional catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the original fee-for-service program. This second 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.

We propose to make MA regional plans responsible for tracking these beneficiary out-of-pocket limits and for notifying members when they have been

met. We also propose to require MA regional plans to track and limit incurred rather than paid out-of-pocket expenses.

• We would add § 422.101(d) to account for these new cost-sharing requirements.

The MMA also adds new section 1859(b)(4) to the Act. MA regional plans are required to provide reimbursement for all covered benefits, regardless of whether the benefits are provided within or outside the network of contracted providers.

MA regional plans are preferred provider organizations (PPOs) and are defined at section 1859(b)(4) of the Act. (However, it should be noted that the statute does not preclude HMOs and other entities from offering other MA plan types on a region-wide basis, nor does it preclude other entities from offering MA regional plans as long as these plans meet statutory and regulatory requirements related to MA regional plans including, but not limited to, sections 1859(b)(4), 1851(a)(2)(A), and 1858(b) of the Act.) As PPOs, MA regional plans are permitted to impose differential cost sharing related to non-emergent services received from non-network providers. To the extent differential cost-sharing is part of the benefit package, the MA regional plan would generally be responsible for its portion of payment to a non-network provider and the enrollee would be responsible for the remainder—up to the limits discussed in item 2 and 3 of this part of the preamble.

In applying the actuarially equivalent level of cost sharing with respect to MA bids related to benefits under the original Medicare program option set forth under § 422.308, only the catastrophic limit on out-of-pocket expenses for in-network benefits (item 2 above) is to be taken into account.

We would accommodate these requirements related to MA regional plans by adding a § 422.101(e) to this section.

3. Supplemental Benefits (§ 422.102)

An MA plan may 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 value that would apply to these members if they remained enrolled in the original Medicare program. This reduction in cost sharing can be included as a mandatory supplemental benefit. We propose the following provisions:

• We would add § 422.102(a)(4).

• We would remove the reference to "additional benefits'' in § 422.102(a)(1), as those benefits are no longer applicable to MA plans offered on or after January 1, 2006.

• We would remove 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.

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

We would remove the extraneous word "under'' from the second sentence of paragraph (a).

5. Special Rules for Point of Service Option (§ 422.105)

"Point of Service'' (POS) is an option in some plans that allows enrollees to use providers who are not preferred, on a fee-for-service basis. To clarify an issue that has created confusion for both beneficiaries and MA organizations, we propose to include the following statement as introductory text to § 422.105 of the regulation:

"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, then when those members receive what is a covered item or service from contracted providers 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.''

We believe that indemnifying the Medicare member in such a situation conforms with normal industry practice and also clarifies 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 insists on receiving what would otherwise be covered services from a contracted provider (but for the lack of a referral or pre-authorization), then the contracted provider would be required to inform the member that those services will not be covered under the plan. The provider would also be required 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. We propose the following provisions:

• We would remove the extraneous word "only'' from § 422.105(a)(1) and § 422.105(a)(2), and we would modify § 422.105(a)(1) to account for the fact that beginning January 1, 2006, there will no longer be any additional benefits under the MA program.

• We propose to add § 422.105(a)(4) to clarify that although an MA regional plan may offer a POS–LIKE benefit to members, it still may not deny reimbursement for *any* covered benefit, regardless of whether such benefit is provided within the network of contracted providers.

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. Specifically, section 222(j)(1) of the MMA redesignated existing section 1857(i) of the Act as section 1857(i)(1) of the Act and adds a new sub-heading—"Contracts with MA Organizations.'' Section 222(j)(2) of the MMA created a new section 1857(i)(2) of the Act with a sub-heading of "Employer Sponsored MA Plans.''

Section 222(j)(2) of the MMA allows us to waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered by an employer, a labor organization, 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 labor organizations. Section 222(j) of the MMA further states that the MA plan may restrict enrollment to individuals who are beneficiaries and participants in such a plan.

We propose a new paragraph (d) to account for this new statutory authority, which is effective for plan years beginning on or after January 1, 2006. We would also revise the paragraph heading for existing paragraph (c) to "Waiver or modification of contracts with MA Organizations.'' In addition, we make editorial corrections to the first sentence of paragraph (c)(2) and to remove the second sentence. We remove the second sentence of paragraph (c)(2) because we believe that instructions related to the specific manner in which ACRs or bids are to be filed and specific requirements related to the filings are

better suited to manual instructions and other written instruments.

- We would revise the paragraph (c) heading.
- We would make editorial corrections to paragraph (c)(2).
- We would add a new paragraph (d) to allow for employer sponsored MA plans effective January 1, 2006.

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

Section 232 amended section 1856(b)(3) of the Act to remove all ambiguity related to State authority over the MA program. 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. Therefore, we would amend paragraph (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. Consistent with specific preemption authority now provided by section 1856(b)(3) of the Act, MAs are permitted by section 1852(a)(4) of the Act to *fully* recover from liable third parties according to section 1862(b)(2) of the Act.

We would amend paragraph (f) of § 422.108 to account for enhanced preemption authority provided by section 232 of the MMA.

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 MAs. We have 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 on August 22, 2003, at 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 contract year.

Under this 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 all these average amounts exceeded the threshold under § 422.109(a)(1), 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, as noted in the preamble to the August 22, 2003 final rule, 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 so-called "2 percent minimum update'' counties paid under section 1853(c)(1)(C)) of the Act. In accordance with section 1853(c) of the Act, the CMS Office of the Actuary 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 has 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, the minimum percentage increase rate (the so-called "minimum 2 percent rate'') 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.

Therefore, we are proposing to revise the regulatory change established in the August 22, 2003 final rule, in order to implement this new MMA payment provision that became effective January 1, 2004. Specifically, the changes to § 422.109 and § 422.256, which established a new "NCD adjustment factor'' effective CY 2004, which was to be added to the county rates in counties receiving the "minimum'' 2 percent update, will be eliminated. We propose the following provisions:

- We would remove the final paragraph of § 422.109(a)(2).
- We would amend § 422.109(a)(2) to remove "all'' from the first clause of the first sentence.

The "national standardized annual capitation rate'' described in § 422.254(f) is already an average and does not need to be further "normalized'' by multiplication "by the total number of Medicare beneficiaries for the applicable calendar year.''

- We would remove the portion the first sentence of § 422.109(a)(2) to remove all language after "§ 422.254(f).''
- We would revise § 422.109(c)(3) to read: "Costs for significant cost NCD services or legislative changes in benefits for which our 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.''
- We would remove paragraphs (c)(3)(i) and (c)(3)(ii).

9. Discrimination Against Beneficiaries Prohibited (§ 422.110)

We would make the following correction to this section, to bring it into conformance with § 422.50(a)(3)(ii). We would modify paragraph (b) to say 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 offered by the organization at the time of first entitlement to Medicare, but residing outside the MA plan's service area, to remain enrolled that such an allowance would also need to be applied to individuals with end-stage renal disease.

The new paragraph (b) would read:

(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.

We would remove paragraph (c), as it is duplicative of a requirement appearing in § 422.502(h) of the current MA regulation. In the subpart K section of this preamble related to § 422.502(h) (redesignated as § 422.504(h)), we explain why we are proposing to modify the language currently found there.

10. Disclosure Requirements (§ 422.111)

When the Balanced Budget Act of 1997 introduced the M+C program, the Annual Coordinated Election Period was established as the month of November. In subsequent legislation, the Annual Coordinated Election Period for years after 2001 was changed to November 15 through the end of December. We propose that rather than changing the date in § 422.111(d)(2) to a "date certain,'' we would leave the date flexible—should the Congress again decide to change the date on which the Annual Coordinated Election Period begins. Additionally, this proposed change is consistent with section 1851(d)(2)(A) of the Act, the authority for this regulatory requirement. The intent of section 1851(d)(2)(A) of the Act and § 422.111(d)(2) of the regulation is simply to provide notice to plan members of impending changes to plan benefits, premiums, and copays in the coming year. That notice is to be provided at least 2 weeks before the onset of the Annual Coordinated Election Period as a means of ensuring that plan members will be in the best possible position to make an informed choice on continued enrollment in or disenrollment from that plan.

Section 422.111(d)(2) would be modified to say that plan members need to be notified of January 1 changes at least 15 days before the Annual Coordinated Election Period defined in section 1851(e)(3)(B) of the Act.

Section 422.111(c)(1) states that an MA plan must disclose the information in § 422.111(f) upon request to individuals eligible to elect an MA plan.

We would remove § 422.111(f)(4), as the requirement to provide information on Medigap and Medicare Select as 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 State Health Insurance Assistance Program (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 will continue to require MA plans to publicize the availability of information on Medigap, Medicare Select, and other MA plans through appropriate CMS information channels. This will not only remove unnecessary administrative burden, but it will also ensure that reliable, accurate, and complete information is made available to those seeking it.

Since the introduction of *http://www.medicare.gov* in 1998, we have substantially increased the amount of personalized information available to Medicare beneficiaries, making it one of the government's most comprehensive and customer-oriented sites available to the public. The web site hosts twelve separate database applications to help individuals make their own health care decisions. The most significant ones are: the Medicare Personal Plan Finder (which contains costs, benefits, quality, satisfaction and disenrollment measures), Nursing Home Compare (which contains basic characteristics, staffing information and inspection results), the Prescription Drug and Other Assistance Programs application (which contains the most extensive, nationally complete listing of the Medicare-approved discount drug cards, including price comparisons, as well as other government and private programs designed to help with prescription drug costs), and the Medicare Eligibility Tool (which assists users in determining when they are eligible, how to enroll and what they need to consider when joining Medicare). Other tools providing customized results include: the Participating Physician and Supplier Directories, Home Health and Dialysis Facility Compare, Your Medicare Coverage, Helpful Contacts, Publications, and Frequently Asked Questions. By updating all information on the web site at least once a month, the information provided to Medicare beneficiaries via *http://www.medicare.gov* is the most reliable and consistent information available.

Much of the information available through *http://www.medicare.gov* is also available via the 1–800 MEDICARE helpline. 1–800 MEDICARE is a major information channel for providing the most personalized and reliable information to people with Medicare. As a result of the MMA, we are receiving the largest call volume ever for 1–800 MEDICARE. The beneficiary can call 1–800 MEDICARE to find out the most reliable information on public and private programs that offer discounted or free medication, programs that provide help with other health care costs, and Medicare health plans that include prescription coverage. The caller can always talk to a live person at 1–800 MEDICARE to get the facts they need. When a beneficiary calls 1–800 MEDICARE, we can send them a personalized brochure that allows them to look at discount cards based on their drug needs and their preferences about how to get their medicines, and their enrollment forms. We can also give the beneficiary personalized brochures containing information on their health plan choices, nursing homes and Medicare participating physicians in their area.

1–800 MEDICARE is available 24 hours a day, 7 days a week, to provide the one-on-one service that our Medicare beneficiaries need to make appropriate health care decisions.

We would also remove § 422.111(f)(6), since this is also a Secretarial responsibility under section 1851(d)(2)(A)(ii) of the Act and is also to occur as part of the Secretarial "open season notification.'' We propose the following provisions:

- We would redesignate paragraph (f)(5) as paragraph (f)(4), and we would redesignate paragraphs (f)(7) through (f)(11) as paragraphs (f)(5) through (f)(9).
- We would remove a portion of the existing paragraph (f)(7)(iv) and all of paragraph (f)(7)(v) (the new paragraphs (f)(5)(iv) and (f)(5)(v)) to remove the requirement that MAs and MSAs provide comparative information related to other MA plans. The new paragraph (f)(5)(iv) would read, in full: "In the case of an MA MSA plan, the amount of the annual MSA deposit.'' The new paragraph (f)(5)(v) would be deleted. The existing paragraphs (f)(7)(vi) through (f)(7)(viii) would be redesignated as paragraphs (f)(5)(v) through (f)(5)(vii).
- We would change "contracted is terminating'' to "contract is terminating'' in the second sentence, just before the comma, in § 422.111(e).

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 propose to modify paragraph (b)(3) in this section. We will, however, specifically require MA organizations to provide information on contracted providers in other geographic areas to enrollees who plan to travel (for instance) by adding a new paragraph (f)(10), requiring MA organizations to provide detailed information on contracted providers in other areas upon request.

- We would modify paragraph (b)(3) by inserting "reasonably be expected to''

between "may'' and "obtain'' in the first sub-clause of the first full sentence, so it would read: "The number, mix, and distribution (addresses) of providers from whom enrollees may *reasonably be expected to* obtain services;''

• We would add a new paragraph (f)(10), which would read: "The names, addresses, and phone numbers of providers from whom the enrollee may obtain in-network coverage in other areas.''

Section 1851(d)(3)(F) of the Act, as modified by the MMA, would 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 would add a new paragraph (b)(11) to account for this.

• We would change the existing paragraph (f)(11) (the new paragraph (f)(9)) related to supplemental benefits to read: "*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.''

• In § 422.111(c)(1), we would insert "in'' between "required'' and "paragraph.''

The Internet has proven to be an inexpensive and widely available source of information on health plans. Almost all FEHB insurance plans, most large employer plans, and commercial HMOs maintain websites for the convenience of enrollees. Many MA organizations also currently provide information on the MA plans they offer on websites available through the Internet.

We currently require MA plans to communicate with us via electronic media—§ 422.502(b) (redesignated as § 422.504(b)). Finally, all MA coordinated care plans would be required to offer Part D drug benefits to the enrollees of at least one of their plans and as part of that offering will be required to maintain formulary and other information on an Internet Web site.

Therefore, pursuant to our authority under section 1856(b) of the Act to establish standards by regulation, we are considering imposing a requirement that all MA plans set up an Internet Web site that will 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. We are interested in receiving comments on whether or not such a requirement should become part of the MA regulation.

11. Access to Services (§ 422.112)

There are no new access standards for MA regional plans, and existing MA standards will generally apply. An important provision (discussed below) will likely improve access to hospital services for MA regional plan enrollees. In attempting to create region-wide networks, MA regional plans will be forced to bargain with hospitals, that are, in effect, the only hospital (or the only hospital with a particular service or services) in a broad area. Such a hospital would have what some call "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 attempts to address this situation through a provision that would make limited funds available to supplement payments to such hospitals.

While we reviewed our existing regulatory requirements related to network adequacy and propose to remove some that are either duplicative or, in our view, overly onerous without a resultant payoff in beneficiary protections, we have retained our core requirements. We expect 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. Note that we will continue to require MA organizations to make a list of network providers available to prospective enrollees prior to enrollment. Finally, Medicare beneficiaries can simply choose to remain in the original Medicare fee-for-service program, if they cannot find an MA plan that meets their needs.

We note that the Office of Personnel Management does not mandate specific access standards while it serves nearly 2 million retirees who are located around the country in a manner similar to Medicare beneficiaries. Yet, "An Analysis of the Availability of Medicare+Choice, Commercial HMO, and FEHBP Plans in Rural Areas: Implications for Medicare Reform'' by the Rural Policy Research Institute (*at http://rupri.org/healthpolicy/*) shows that 98 percent of rural counties demonstrate usage of three or more FEHB plans, which is in sharp contrast to the 16 percent of rural counties showing access to even a single M+C coordinated care plan. We expect the Medicare Advantage program to produce a pattern of plan availability more like the FEHB program than to the current M+C program.

In order to encourage MA organizations to offer MA regional plans covering rural areas, we are considering one new requirement related to an exception process for enrollees in an area without a preferred provider for a specific medically-necessary service. We discuss this requirement and the exception process later in this section of the preamble. We welcome comment on this possible change and on any of the other changes we propose to make to our access to care standards.

We propose to make three technical corrections to this section of the regulation. By removing unnecessary administrative burden, and in light of protections afforded by the MMA, which makes certain access requirements redundant, we hope to facilitate participation by MA organizations in the new Medicare program. We would remove or modify three current requirements from § 422.112 of the regulation. None of these requirements are based on statutory authority, and many of them become unnecessary as they are replaced or superseded by requirements in the MMA.

Effective January 1, 2006, the MMA—section 1852(e) of the Act—requires all MA coordinated care plans to focus quality assurance activities on "chronic care improvement programs.'' We note that MA private fee-for-service plans and MSA plans are already exempt from this requirement. We also note in section 1852(e)(3)(A)(iii) of the Act, that to the extent that MA local PPOs have a contracted network, they must also meet the same quality assurance requirements as do all other MA coordinated care plans. To the extent that all coordinated care plans will be required to focus on quality improvement activities on identifying and monitoring enrollees with multiple or severe chronic conditions, and also to measure and improve the health outcomes of those enrollees, it would be redundant and to a degree unnecessarily proscriptive to suggest a specific approach to those quality improvement activities in the context of and as a means of ensuring enrollee access to care. We would delete § 422.112(a)(4)—serious and complex medical conditions.

Written standards are simply one tool MA coordinated care plans can use to ensure adequate access to medically necessary health care items and services.

The three items enumerated in § 422.112(a)(7) are redundant of other parts of the regulation. Section 422.112(a)(7)(i), related to written standards for access to care, is duplicative of § 422.112(a)(1). Sections 422.112(a)(7)(ii) and (a)(7)(iii), related to written standards that allow for medical necessity determinations and patient input into treatment plans, are duplicative of § 422.206—Interference with health care professionals' advice to enrollees prohibited, § 422.202(b) Participation procedures—Consultation, and § 422.152(b)(3)(paragraph new (b)(2)). We would delete paragraph (a)(7)—written standards.

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. While 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. While it may be reasonable to expect coordinated care plans to undertake these coordination, continuity, and integration requirements, it is less clear that MA private fee-for-service 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 private fee-for-service plans. We are therefore considering eliminating most of the requirements in § 422.112(b) for MSAs and private fee-for-service plans. We are also considering eliminating or modifying many of the requirements in § 422.112(b) for local PPOs and regional MA plans. Finally, we are considering the continued appropriateness of these continuity of care standards for all other coordinated care plans. We are seeking comment on this proposal. We would specifically welcome 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.

Special access requirements apply to MA regional plans beginning in 2006 based on section 221(c) of the MMA, which created a new section 1858 of the Act. Specifically, section 1858(h) of the Act creates special access rules for MA regional plans as a means of enabling MA organizations that offer MA regional plans to meet provider access requirements under section 1852 of the Act and thus under § 422.112 of the regulation.

Beginning for benefits offered to MA enrollees of an MA regional plan for contract year 2006, if an MA organization certifies that it was unable to reach an agreement with an "essential hospital'' paid under subsection (d) of section 1886 of the Act, 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 amount that we would make to the MA organization.

An "essential hospital,'' for purposes of this section, means a general acute care hospital as defined in section 1886(d) of the Act that we determine the MA regional plan must have under contract in order to meet our access requirements. The determination of "essential hospital'' status is only conferred after application to us by an MA organization offering an MA regional plan. Additionally, as part of its application to establish the hospital as an "essential hospital,'' the MA regional plan must also certify that it made a good faith effort to contract with the hospital. The MA organization must also 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. Finally, in order to qualify for the additional payment, 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.

The intent of the additional payment to the section 1886(d) "essential hospital'' is to facilitate an MA regional plan's ability to meet network adequacy requirements across large geographic areas—an MA region. Such an "essential hospital'' would become part of the contracted network of providers of the MA regional plan and in-network enrollee cost-sharing rules would apply.

Payments under this new authority, however, are limited to a total of $25 million for 2006, and the prior year's amount updated by the market basket percentage increase under section 1886(b)(3)(B)(iii) of the Act for future years.

We invite comment from the public as to how we can ensure that payments are limited to the amount specified. We also invite comment on how we can best ensure that a "good faith effort'' to contract has actually occurred. For instance, should we require negotiations to occur before the admission of an MA regional plan patient? Or, in the case of an emergency admission, should we permit negotiations between the MA regional plan and the hospital to occur after admission, or perhaps even after discharge?

Additionally, we invite comment on the best way to determine that a hospital's actual costs for services provided to an MA regional plan enrollee actually exceeded the amount that would normally be payable to that hospital under section 1886 of the Act with respect to those services. Total additional payments under this section are limited to $25 million in 2006 and in subsequent years, $25 million increased by the market basket percentage increase as specified in statute. 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 under fee-for-service Medicare had the "essential hospital'' been a critical access hospital. We would like input on how to best minimize the administrative burden associated with implementing this statutory provision, while still ensuring the accuracy and integrity of the process.

We would add a new paragraph (c) to account for the special access requirements related to MA regional plans beginning in 2006 based on "essential hospitals.''

Instead of always requiring comprehensive, contracted provider networks in all cases, we propose to require MA regional plans to offer beneficiaries reasonable access to in-network cost-sharing, even if there are no contracted providers of a specific type available in a geographic location within the service area. This is the exception process mentioned earlier in this section of the preamble. We also propose a new requirement related to this exception process, which is similar

to a United States Office of Personnel Management (OPM) requirement imposed on the FEHB Blue Cross and Blue Shield Basic Option plan to address similar circumstances.

We propose to permit relaxation of comprehensive network adequacy requirements for MA regional plans, but only to the extent that beneficiaries are not put "at risk'' for high cost sharing related to services received from non-network providers. This new tolerance that we propose to afford MA regional plans need not be applied on a plan-wide basis, but rather can be applied in a county or portion of a region where, for example, the MA regional plan is unable to secure contracts with an adequate number of a specific type of provider or providers to satisfy our comprehensive network adequacy requirements.

Such an exception process 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. The MA organization, in such a case, could designate a non-contracted provider from whom (or from which) the enrollee could obtain the service at in-plan cost sharing levels. Or, the MA organization could allow the enrollee to seek the service from any provider and guarantee that in-plan cost sharing limits would apply.

In applying the above principle, we need to consider two forms of beneficiary cost sharing. One is the cost sharing related to a specific item or service—for instance, a hospital coinsurance charge. Another is the "catastrophic limits'' that MA regional plans must apply to benefits under the original Medicare fee-for-service option. MA regional plans are required to provide reimbursement for all covered benefits regardless of whether those benefits are received from network providers—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)—section 1858(b)(2)(B) of the Act and the new § 422.101(d)(2) and (d)(3).

We propose to permit MA regional plans with lower out-of-network cost sharing to have less robust networks of contracted providers. While we propose to permit MA regional plans with more robust networks of contracted providers to impose higher cost sharing charges on individuals going out-of-network. This is because if the plans' networks were robust, we would not expect beneficiary access to be unduly limited by higher cost-sharing requirements when they seek care from out-of-network providers. However, for plans with less robust networks, we propose to limit those plans' ability to impose higher cost-sharing requirements for out-of-network care. We believe 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. For instance, we could require MA regional plans that have less than 20, 50, or 70 percent of hospital beds in the service area (or portion of the service area) under contract to charge lower out-of-network cost sharing to individuals accessing non-network hospitals. In other words, in such a case, we would require the MA regional plan to charge lower coinsurance for out-of-network hospital care as a means of ensuring adequate access to hospital services.

Similarly and related to the "catastrophic limits'' on out-of-pocket expenditures, to the extent that an MA regional plan had a less robust network of contracted providers, we would require a convergence in the cost sharing limits that apply to network and all (network and non-network) services. While for plans with more robust contracted networks, we would allow the "catastrophic limits'' to diverge.

We ask for comment on the measures we should adopt to assess the robustness of contracted provider networks. We also seek comment on the thresholds we should adopt relative to the cost-sharing limits (related to both individual services and the catastrophic limits on out-of-pocket costs that regional MA plans must provide related to in-network and all services) that should apply to services when contracted provider networks are less than robust. For instance, would it be adequate to adopt fee-for-service cost sharing limits for individual services as a means of ensuring adequate access, or should a different standard apply, and why? We specifically ask for comments in this area. Finally, related to out-of-pocket cost-sharing limits for in-network and all services, is there a formula that we should apply that rationally expresses the maximum out-of-pocket cost sharing that we should permit? Is there a means of quantifying how the two out-of-pocket cost-sharing limits should converge, or how much we should allow divergence, based on the robustness of the contracted provider network?

The preceding discussion is from the perspective of an MA regional plan establishing compliance with our access requirements at the time of initial application or on a continuing basis. From a beneficiary perspective, the MA regional plan would always need to provide an accessible and available source of treatment at network cost sharing levels. Our normal access standards would apply. For instance, where community patterns of care call for travel of no more than 30 minutes or 30 miles to access hospital services, then MA regional plans would need to ensure comparable access to a contracted hospital. To the extent that an MA regional plan did not actually have a contracted hospital within 30 minutes or 30 miles, then the MA regional plan would need to designate a non-contracted hospital from which the member could receive care at network cost sharing levels. Such a requirement would be similar to a requirement imposed by OPM related to the Basic Option plan offered to Federal employees and annuitants under the FEHB program where normal OPM access standards are not met.

We provide for this exception to the normal access requirements related to MA regional plans by proposing to add a new paragraph (ii) to § 422.112(a)(1). We invite comment on the access standards we should establish for primary care, specialty, and institutional providers.

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

Policies on enrollee cost-sharing for emergency care are historically a point of contention. Cost-sharing limits for emergency care are important to ensure that there is no disincentive to receive emergency care that is critical to a beneficiary's health.

On the other hand, since the proposed M+C regulation was published in June 1998, when the cost-sharing limit of $50 on out-of-network emergency services was initially established, there have been unforeseen consequences that have tended to increase confusion rather than contribute to the goal of appropriate access. Additionally, the $50 emergency services cost-sharing limit has not increased since 1998, despite changing market conditions. For instance, in recent years, some M+C plans have established inpatient hospital copays of $200 per day and fee-for-service Medicare coverage has a per-hospital stay deductible of $840 in 2004. These hospital copays, combined with the

regulatory definition of "emergency services'' that includes inpatient care "until stabilized,'' requires a review of § 422.113(b)(2)(v).

Section 422.113(b)(2)(v) reads: "[The M+C organization is financially responsible for emergency and urgently needed services—] With a limit on charges to enrollees for emergency services of $50 or what it would charge the enrollee if he or she obtained the services through the M+C organization, whichever is less.''

The regulation states that emergency services continue until the enrollee is stabilized. Hence, a strict (and unintended) reading of the current regulation could require an assessment of the exact time that stabilization occurred in order to determine when the $50 "emergency services'' cost-sharing limit ends and when inpatient "post-stabilization'' cost sharing can begin. A detailed review of the member's medical record is needed to make a stabilization assessment in order to assess cost-sharing liability. This review of the medical record is an administrative burden on plans as well as appeal review entities—our reconsideration contractor and Administrative Law Judges. All are required to spend considerable amounts of time determining when stabilization occurred for purposes of properly assigning enrollee cost sharing. This is contrary to medical practice, which does not generally identify when a patient is stabilized.

We propose to modify the regulation to clarify that the $50 limit for "emergency services'' at § 422.113(b)(2)(v) 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 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). Making this clarification would retain cost-sharing limits for both emergency services and post-stabilization care, while eliminating the unanticipated complexities and administrative burden associated with this section of the regulation.

We believe that final regulations published on September 9, 2003, and effective November 10, 2003 (68 FR 53222), provide support for this change. These regulations establish the rule that requirements related to the Emergency Medical Treatment and Labor Act (EMTALA) *end* at the time a patient is admitted. We recognize that EMTALA rules related to patients who present to hospitals with emergency medical conditions and our rules related to allowable cost sharing in the MA program are not a perfect fit; however we do believe that similar administrative difficulties warrant similar administrative solutions. In addition to the consonance this change would have with our EMTALA rules, we also believe that this clarification will allow the MA program to reflect current commercial practices. Finally, the clarification is consistent with our intent. We propose the following provisions:

We propose to change "emergency services'' to "emergency department services'' in § 422.113(b)(2)(v).

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

Section 211(j) of the MMA allows MA private fee-for-service plans that have a contracted network of providers through which the plan entirely meets access and availability requirements (for a specific category of health care professional or provider) to provide for a higher beneficiary copayment in the case of health care professionals and providers of that category who do not have contracts with the plan. Generally, this would permit a private fee-for-service plan to charge higher co-pays to members who opt out of a private fee-for-service plan's contracted network. This provision does not apply to private fee-for-service 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.

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

Under our authority under section 1856 of the Act to establish MA standards by regulation, we are proposing to extend the provisions in § 422.133 to SNF services provided in cases in which an MA organization elects, under § 422.101(c), to provide Medicare covered SNF care in the absence of a prior qualifying hospital stay. Note that our policy to waive the 3-day hospital stay requirement for MA plans does not require MA plans to cover SNF stays without a 3-day hospitalization. The policy simply allows such SNF stays to be considered Medicare-covered if the MA plan chooses to cover them. In such an instance, we are proposing to require by regulation 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 stay. We propose to deem that a hospital discharge has occurred prior to an admission for SNF services, and provide the MA enrollee full rights to the "home SNF'' benefit. For example, the reference in § 422.133(b)(3) to the SNF "in which the spouse of the enrollee is residing at the time of discharge from the hospital'' would be deemed to refer to the SNF in which the spouse of the enrollee is residing at the time covered extended care services are initiated. We propose to add a new paragraph (b)(4).

Subpart D—Quality Improvement Program

(If you choose to comment on issues in this section, please include the caption "Subpart D—Quality Improvement Program'' at the beginning of your comments.)

1. Overview

The MMA amended section 1852(e) of the Act in a number of significant ways. First the heading of the section was changed from quality assurance to quality improvement. It also deleted the sections of the Act that provided a list of "elements'' that an MA plan's quality assurance program was required to address. These provisions were removed and replaced with several new provisions, including the following:

- Each MA plan (other than an MA private fee-for-service plan or an MSA plan) must have an ongoing quality improvement program.
- Each ongoing quality improvement program must have a chronic care improvement program.
- Each MA plan must provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality, such as HEDIS, CAHPS, and HOS, as discussed below. PPOs however, are only required to collect, analyze, and report data that are furnished by providers that have a contract with the PPO. The MMA also provides for the Secretary to establish separate rules for implementing this requirement with respect to MA regional plans. (See § 422.152(e).)

In response to these amendments, we would change the heading and all references in the section from "quality assurance'' to "quality improvement.'' In addition, we would modify many of the provisions in § 422.152 that address quality assurance and performance improvement programs. We would also delete the provisions of § 422.154 that address external review, and add requirements related to MA–PD benefits to those that can be "deemed'' to be met

based on accreditation under § 422.156(b).

The key provisions of this subpart form the cornerstone for a competition based program in quality of care. We already place information from these systems on the Medicare.gov web site, such as Health Plan Employer Data Information Survey (HEDIS), and Consumer Assessment of Health Plans (CAHPS). We will be exploring additional ways to enhance the use of quality of care systems as part of a competition based program.

2. Quality Improvement Program (§ 422.152)

To reflect the congressional intent to refocus the section on quality improvement, rather than quality assurance, we would change the heading of § 422.152 from "quality assessment and performance improvement program'' to "quality improvement program.'' The revised section 1852(e)(1) of the Act excludes MA private fee-for-service (PFFS) and MSA plans from the requirement to have an ongoing quality improvement program. This exclusion is, in part, because enrollees of MA PFFS and MSA are not restricted to seeking care from a network of providers. In addition, some believe MA PFFS and MSA plans lack the ability to influence the behavior of providers and enrollees. We would modify § 422.152(a) to reflect that each plan (except MA private-fee-for-service and MSA plans) offered by a MA organization must have an ongoing quality improvement program. As required under section 1852(e)(2) of the Act, we would require MA plans to have a chronic care program in place as part of their quality improvement program. As discussed below, we are proposing that this program be required to meet requirements set forth in § 422.152(c).

Under our authority in section 1856(b)(1) of the Act to establish standards by regulation, we are proposing to require that the quality improvement program required under section 1852(e)(1) of the Act include quality improvement projects that could be expected to have a favorable effect on health outcomes and enrollee satisfaction, and that meet regulatory requirements set forth in proposed § 422.152(d).

We believe that the broad requirements in proposed § 422.152(d) will not present an undue burden for MA organizations, which have years of experience in carrying out performance improvement projects under the current version of § 422.152(d), which, as discussed below, is more prescriptive than the revised version we are proposing in this rule.

In light of the substantially revised quality requirements under this proposed rule, we believe that it is reasonable to expect all MA plans, including regional and local PPOs, to meet the quality improvement project requirements in proposed § 422.152(d). MSAs are excluded from this requirement altogether. We would also require an organization offering an MA plan to encourage its providers to participate in CMS and HHS quality improvement initiatives. Also, MA organizations are encouraged to seek technical assistance from the State quality improvement organization in designing and implementing quality improvement initiatives. By encouraging this participation, MA organizations are facilitating quality improvement in a variety of health care settings.

Our previous quality improvement efforts for M+C coordinated care plans focused on requiring improvement in specific clinical topics and included specific performance measures to be improved. Thus, while we propose to retain regulatory requirements for quality improvement programs, we would revise the requirements in the current § 422.152(b) to enhance plans' ability to target quality improvement efforts to their enrollees' needs by deleting, modifying, and renumbering most of the requirements in this paragraph. Similar to the existing requirements, this paragraph would provide quality requirements for MA coordinated care plans, but would no longer refer to MSA plans. We would also address certain local PPO and all regional MA plan quality requirements in another paragraph—§ 422.152(e) of this section. We are interested in comments on whether or not we should require plans to use comparable measures across plans and making QI program size/scope proportionate to plan size.

The requirements in the existing § 422.152(b)(1) and § 422.152(b)(2) would be retained, as we believe these standards are integral to any plan's quality improvement program, and are consistent with the requirements of private accrediting organizations. Section § 422.152(b)(1), for example, would require that in processing a request for initial or continued authorization of services, MA plans would need to follow written policies and procedures that reflect current standards of medical practice. Section 422.152(b)(2) would require MA plans to have mechanisms in place to detect both under utilization and over utilization of services.

We are directed in section 1852(e)(3)(B)(i) of the Act to require the collection of only the types of data that we collected as of November 1, 2003. We address this requirement in § 422.152(b)(3). We interpret section 1852(e)(3)(B)(i) of the Act to mean that we can continue to require MA coordinated care plans to collect, analyze, and report their performance by using the measurement systems that are currently required, such as HEDIS, Health Outcomes of Seniors (HOS), and CAHPS, as appropriate for the type of plan. We believe that, consistent with private sector practices, we would be allowed to add, delete, or modify measures within these systems. Changes to these measurement systems are generally reviewed and approved by a committee with representatives from managed care plans, beneficiary advocacy groups, private and public health care purchasers.

We are interested in comments on the following options. There are two basic ways to go (1) use the same metrics across all plan types which allows consumers to compare all plans (both groups of plans (for a specific plan type), or specific plans (across or within plan types)) for a larger set of metrics, or (2) tailor the metrics to specific plan types, which limits the dimensions upon which consumers would be able to compare plans.

If, in the future, we believe that a new measurement system should be used to assess MA plans' performance, we are required under section 1852(e)(3)(B)(ii) of the Act to submit a report to Congress that is prepared in consultation with MA organizations and private accrediting organizations. Thus, we have proposed to remove the provisions in § 422.152(c) that address measuring and reporting performance. We also would remove all the requirements relating to minimum performance levels and requirements that address clinical and non-clinical areas.

We will continue to look for cost-effective ways to measure quality for MA plans and will use a variety of procedures to get input from the public, MA organizations, private accrediting organizations, and seek Congressional review.

Proposed § 422.152(b)(3)(ii) would require MA plans to make available to us the 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).

Section 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 health maintenance organization to follow the same quality improvement requirements as other MA coordinated care plans. Quality improvement requirements for local PPOs that meet the definition of a local PPO that is specified in § 422.152(e)(1) (local PPOs that are not offered by organizations that are licensed or organized under State law as HMOs) are addressed in that paragraph.

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

We would replace the provisions in § 422.152(c) with requirements for MA plans' chronic care improvement programs. As directed by MMA, we would require MA plans to develop criteria for participating in 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. The criteria must also provide mechanisms for monitoring MA enrollees that are participating in the chronic care improvement program. We invite comments on these requirements to help us provide additional guidance to MA plans on additional criteria and mechanisms that might be useful to help them identify and monitor MA enrollees that are participating in their chronic care improvement program. For example, are there data or approaches used to identify special needs individuals with severe or disabling chronic conditions who might benefit from enrollment in specialized MA plans that could also be used in the identification of MA enrollees who would benefit from participating in a chronic care improvement program because of their severe chronic conditions?

4. Quality Improvement Projects (§ 422.152(d))

As noted above, we have proposed to delete many of the prescriptive requirements for quality improvement projects that appear in the current § 422.152(d). While MMA has resulted in the deletion of a number of the more prescriptive requirements of quality improvement programs, it still retained the basic requirements of such projects. The MMA retained the requirements of the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality, for example, HEDIS, HOS, and CAHPS. Furthermore, it added the chronic care improvement program. As mentioned, these aspects of the program provide the cornerstone for a competition based program in quality of care. We already place information from these systems on the Medicare.gov Web site. We will be exploring additional ways to enhance the use of quality of care systems as part of a competition based program. We propose deleting the list of clinical and non-clinical topic areas because it is our intention that MA plans select the topic area for a quality improvement project based on the needs of their enrolled population. It is our intention, however, that MA plans would select topic areas that are relevant to a Medicare population.

We would delete the requirement of including the entire relevant population in the measurement because it has been proven that sampling is an approved method for assessing the performance of providing care and services to a population. Since MA plans conduct quality improvement projects for both the Medicare program and private accreditation organizations, we feel that it is appropriate for them to conduct projects that include both Medicare and non-Medicare enrollees. Thus, they would be allowed to conduct a study of persons with Coronary Artery Disease that includes enrollees that are both over and under 65. However, the sample of enrollees that are studied must be appropriately representative of Medicare beneficiaries. Since the MA plans would be selecting their own topics, it is not necessary for us to ensure that the entire spectrum of clinical and non-clinical areas are addressed by an MA plan. Similarly, we propose deleting the requirement that addresses national and statewide projects because MA plans would be selecting their quality improvement project topics by assessing the needs of their population. Thus, we would delete the following requirements:

- The lists of required clinical and non-clinical areas (§ 422.152(d)(4), § 422.152(d)(5)).
- The requirement that an entire relevant population must be included in the measurement set (§ 422.152(d)(2)).
- The provision authorizing us to ensure that the entire spectrum of clinical and non-clinical areas are addressed by establishing the number and distribution of projects (§ 422.152(d)(3)).
- The requirement for participation in national or site-wide projects (§ 422.152(d)(6)(ii))).

In § 422.152(d)(1), we would require that quality improvement projects be initiatives that include the entire organization and focus on clinical and non-clinical areas. The projects would need to follow the regular quality improvement process (measure, intervene, and then remeasure to determine if the intervention resulted in improvement). We have retained the provisions that quality improvement projects must measure performance, and the interventions must be system-wide and include the establishment or alteration of practice guidelines. In addition, the projects must focus on improving performance and involve systemic and periodic follow-up on the effect of the interventions.

To ensure that the measures (or quality indicators) used in quality improvement projects are reliable and relevant for improving the health care and services furnished to MA enrollees, we would require in § 422.152(d)(2) 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, in § 422.152(d)(3), we would require that the data used in an MA plan's quality improvement projects be valid and reliable and based on systemic ongoing collection and analysis of information. We would also require in § 422.152(d)(4) that the interventions achieve measurable and sustained improvement. We would not define what constitutes measurable and sustained improvement in the regulation, but we mean some movement in the quality indicator in an upward or downward direction as appropriate.

Finally, in § 422.152(d)(5), we would retain the requirement that MA plans report the status and results of their projects when requested by us. At this time, we believe that because of the various changes just described, the reporting and review burden would be much less than the current process used in the M+C program. We are considering using a model similar to the one used by private accrediting organizations, where quality projects would be submitted before an onsite monitoring review. For plans selecting MA deeming, their quality improvement projects would be collected and evaluated by the accrediting organization that would be conducting the deeming review.

5. Requirements for MA Regional Plans and MA Local Plans That Are PPOs as Defined in § 422.152(e)

As noted above, section 1852(e)(3)(A)(ii) of the Act provides 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 for MA regional plans. Section 1852(e)(3)(A)(ii) of the Act further provides that these requirements for MA regional plans could not exceed the requirements established for MA local plans that are PPO plans as defined in section 1852(e)(3)(A)(iv) of the Act—local PPO plans that are offered by an organization that is not licensed or organized under State law as an HMO. We propose to apply these same principles in applying general quality requirements, beyond those relating to the collection, analysis, and reporting of data. Thus, as noted above, and as provided in the current regulations, we propose a separate set of requirements for these specific PPOs, which we would also apply to regional MA plans.

In § 422.152(e)(1), we would provide a definition for the term "local PPO plan'' as used in this section. The other requirements in this paragraph are the requirements that apply to PPOs under current regulations. We are aware that some organizations that offered PPO plans felt that some of the performance measures required of PPO plans in the M+C program were difficult to collect in a PPO environment. To address this concern, we will assess all the performance measurement and reporting requirements and make the necessary adjustments. We anticipate that PPOs will not be required to collect data such as medical records, because they have difficulty in obtaining such records. We will work with outside experts, the public, MA organizations, and private accrediting organizations on developing HEDIS measures appropriate to PPOs and welcome comments on these issues. We anticipate that in early 2005 that we will finalize the reporting requirements for PPOs.

In § 422.152(f), we retain the provisions that address health information systems, quality improvement program review, and remedial action. MA organizations would 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 quality improvement program. The organization would also be required to ensure that the information it receives from providers of services is reliable and complete. In addition, for each plan, there would have to 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, an MA organization would be required to correct all problems that come to its attention through internal surveillance, complaints, or other mechanisms.

MMA removed the provision that each MA organization's quality assurance program include a separate focus on racial and ethnic minorities. Thus, we would remove the current § 422.152(f)(4) addressing this issue. It should be noted that CMS specified that the 2003 national projects for M+C plans be Clinical Health Care Disparities or Culturally and Linguistically Appropriate Services. Thus, this requirement has already been initiated by the plans.

MMA removed the requirement that for each plan it operated the MA organization would have an agreement with an external quality review and improvement organization. Thus, we would remove the corresponding regulatory requirements in § 422.154.

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 have added this provision to the list of deemable requirements in § 422.156(b).

Subpart E—Relationships With Providers (§ 422.210)

(If you choose to comment on issues in this section, please include the caption "Subpart E—Relationships with Providers'' at the beginning of your comments.)

MMA has not changed most existing MA program requirements concerning MA organization relationships with providers. Since these aspects of the program have worked well, we generally have proposed to keep the existing provisions of subpart E as they are. The only exceptions, which are discussed below, are modifications to the physician incentive plan requirements to reflect changes made by MMA to section 1852(j)(4) of the Act.

Section 222(h) of MMA revised section 1852(j) of the Act to eliminate requirements that were set forth in section 1852(j)(4)(A)(ii)(II) and (iii) of the Act and to require only that an MA organization "provide assurances satisfactory to the Secretary'' that it meets certain stop loss protection requirements that were in what was section 1852(j)(4)(A)(ii)(I) of the Act, and that remain in the revised version of section 1852(j)(4) of the Act. Section 1852(j)(4)(A)(ii)(II) of the Act had required that, where a physician incentive plan places physicians at substantial financial risk, MA 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.'' This requirement was deleted. We have proposed to delete this requirement in § 422.208(h). We are redesignating existing paragraph § 422.208(i) as § 422.208(h).

We note that the surveys that were previously required under this section were covered for the most part by our administration of the CAHPS survey, which will be continued.

Section 1852(j)(4)(A)(iii) of the Act contained a requirement that descriptive information be provided to the Secretary to permit the Secretary to determine compliance with the requirements in section 1852(j) of the Act. This requirement was also deleted by section 222(h) of MMA. We note that in a final rule published on August 22, 2003, at 68 FR 50840 through 50859, we had deleted a regulatory provision that had previously implemented this reporting requirement by requiring routine reporting of data to us. This final rule proposed that the information only be made available to us upon request. Given the MMA amendment providing that the MA organization will now only be providing "assurances,'' the need to gather data to make an independent determination no longer exists. Moreover, the Congress repealed the statutory basis for requiring that the information be provided. We therefore propose to revise § 422.210 to eliminate the requirement that information on physician incentive plans be disclosed to us.

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

(If you choose to comment on issues in this section, please include the caption "Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval'' at the beginning of your comments.)

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 MMA makes to pricing and payment rules for MA organizations, we propose to replace these subparts with new subparts F and G. In doing so, we will reverse the order of provisions to reflect the chronology of events in the new MA

bidding system more accurately. In this proposed rule, provisions addressing bid submissions and CMS review of bids come first in subpart F, and a description of the methodology and process for CMS' payment to MA organizations follows in subpart G.

The proposed rules in the new subpart F set forth the annual bid submission process for organizations intending to offer MA local and regional plans in the upcoming year. In particular, they address the basis for bids, what must be included in the bid, and other information MA organizations must submit by law for each plan, such as the actuarial bases for the bid. The proposed rules set forth general rules that apply to all MA organizations, and special rules for certain types of plans. They contain authority to review the submitted bids and the standards for reviewing those bids, including the actuarial analyses that are mandated by the MMA, and describe the negotiation process between MA organizations and us.

After provisions addressing submission, review, and approval of bids, the proposed regulations address "bid-to-benchmark'' comparisons, including how local and regional benchmark amounts are determined and how beneficiary premiums and savings are calculated. The rules also set forth how beneficiary savings are used for beneficiary rebates and Government savings, and distinguish between calculations for regional MA plans and local MA plans. The proposed rules also describe the various premium payment options available to beneficiaries, and require that beneficiary premiums and cost-sharing be uniform within a service area (or service area segment). Finally, the new subpart F describes the options for distributing the beneficiary portion of the rebate.

We propose to replace the previous MA provisions from the old subpart G (now subpart F) almost in their entirety, with the exception of the following proposed provisions, which largely retain existing language:

§ 422.262(d), *monetary inducement prohibited,* which precludes an MA organization from providing cash or other monetary rebates as an inducement for enrollment or for any other reason or purpose.

§ 422.262(e), *timing of payments,* which gives beneficiaries the right to make premium payments on a monthly basis, and protects them from a termination of coverage for failure to make these payments except as provided in § 422.74(b). The only change to this provision is the addition of the prescription drug premium to the list of beneficiary premiums.

§ 422.270, *incorrect collection of premiums and cost sharing,* which addresses cases in which an MA organization collects more than the amount of beneficiary premium allowed. Under this provision, the organization is required to refund these over-collections through an adjustment to current and future premiums. This language is identical to the current MA regulation now in subpart G at § 422.309.

1. Basis and Scope (§ 422.250)

Proposed § 422.250 sets forth the basis and scope of the revised subpart F, noting that it is based largely on section 1854 of the Act, but includes provisions from sections 1853 and 1858 of the Act. Section 422.250 notes that subpart F addresses 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)

There are several general terms defined in parts of section 1853 and section 1854 of the Act that apply to both bidding rules (subpart F) and payment calculations (subpart G), so we define these terms in the regulatory text for this part. The proposed definitions throughout both subparts F and G are intended to reflect the statutory definitions they implement in a simplified manner. We will identify clearly those cases in which we propose independently to define a term that is not defined in the statute. In this preamble, we provide an overview of rate terms used in both subparts F and G.

Mandatory and optional supplemental benefits are defined at § 422.102. In subparts F and G 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 these types of supplemental benefits.

The MMA introduces regional MA plans, thus revising section 1853(d) of the Act to define two types of payment areas. For MA regional plans, the payment area is an MA region, and for MA local plans, the payment area is a county (called an "MA local area'').

Under the rate setting method for the previous M+C program, the general rule was that an annual capitation rate was the rate for a county, and an MA payment area was a county. Under the MMA, the "annual MA capitation rate'' continues to be 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 ESRD enrollees, to State-level rates). Note, however, that section 1858 of the Act does require us to calculate a regional per capita rate, described in proposed § 422.262(b)(3) as the "statutory region-specific non-drug amount.'' We chose to not define this term separately in proposed § 422.252, however, because it is an intermediate product that we would use to arrive at the administrative pricing component of the region-specific benchmark amount (discussed below).

Proposed § 422.252 also includes a definition of "MA–PD plan,'' which means an MA local or regional plan that offers prescription drug coverage under Part D. We would note that MSA plans are not allowed to offer Part D prescription drug coverage, and private fee-for-service plans may but do not have to offer Part D coverage.

The following terms are also defined in proposed § 422.252:

"Unadjusted MA statutory non-drug monthly bid amount'' is defined as the plan's estimate of its monthly required revenue for Part A and Part B original Medicare 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; an amount for coverage of basic prescription drug benefits under Part D (if applicable), and an amount for provision of supplemental benefits, if any.

In the preambles to subparts F and G, the term "basic A/B bid'' is used to refer to the unadjusted MA statutory non-drug monthly bid amount. The term "bid'' refers to the aggregate monthly bid amount unless otherwise indicated.

"Plan basic cost sharing'' means cost sharing that would be charged by a plan for benefits under the original Medicare fee-for-service 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 by 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 (based on a weighted average of capitation rates in the region) and the plan bid component (based on a weighted average of plan bids in the region).

"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 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).

3. Submission of Bids (§ 422.254)

General rule. Section 1854 of the Act was amended by the MMA to replace the adjusted community rate (ACR) proposal system currently in effect under the MA program with a bid submission process. No later than the first Monday of June each year, beginning for contract year 2006, MA organizations must submit bids for each plan that they intend to offer in the following year. 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), discussed below.

Section 1853(a)(1)(H) of the Act, as proposed in § 422.254(a)(2), gives us the authority to determine if ESRD MA enrollees should be included in the MMA bidding process. We propose that ESRD enrollees be fully incorporated into the plan's aggregate bid for contract year 2007 and succeeding years. However, for contract year 2006, we are concerned that MA organizations would have to submit bids in June 2005, and at that time they would have very little experience with the impact on their payments of the new ESRD risk adjustment model, which is effective January 1, 2005. Therefore, we propose three options for handling the costs of ESRD enrollees in the June 2005 bid submission. We invite comment on these approaches.

One option for contract year 2006 only is that MA organizations would not include costs for ESRD enrollees in their basic A/B bids and supplemental bids. We would pay MA organizations for ESRD enrollees using the MMA rate setting methodology, as discussed at proposed § 422.304(c)(1)(i). A second option for 2006 only is that MA organizations would not include costs for ESRD enrollees in their basic A/B bids, but would include costs for ESRD enrollees in the supplemental portion of the bid in order to determine the appropriate price of supplemental benefits other than Part B premium reductions. The third option would be that MA organizations fully incorporate ESRD enrollees in the pricing of both basic and supplemental benefits for contract year 2006 and succeeding years. That is, we would not delay full incorporation until 2007.

Under all three options, ESRD enrollees would be included in plan estimates of the amount it would cost to provide qualified prescription drug coverage under Part D for 2006.

Regardless of whether a plan's ESRD enrollees were excluded from the basic A/B bid or from both basic and supplemental bids for 2006, they would still be subject to the same premium and cost sharing as other plan enrollees under the uniformity of premiums provision in proposed § 422.262(c). Accordingly, for any plan offering a Part B premium reduction to MA plan enrollees, we would adjust our payments for ESRD enrollees to reflect that part of the plan benefit package is payment of all or a portion of the enrollee's Part B premium. For further discussion of payments to MA organizations for ESRD enrollees, see the subpart G preamble discussion of § 422.304(c)(1)(i).

Bid requirements. Proposed § 422.254(a) and (b) would implement section 1854(a)(1)(A) and section 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.

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 for the risk adjustment factors (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; (2) the amount to provide basic prescription drug coverage; and/or (3) the amount to provide supplemental coverage, if any.

We state in proposed § 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 state in proposed § 422.254(b)(3) that the bid submission would contain all estimated required revenue, including administrative costs and return on investment (profit, retained earnings). We state 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.

When estimating required revenue, a plan would include adjustments for the effect that providing any non-Medicare benefit has on utilization. This method of pricing supplemental coverage would apply to both mandatory and optional supplemental benefits.

To the extent that the provision of reductions in Part A, Part B, and/or Part D cost sharing results in higher utilization of these benefits, the additional expenditures attributable to the change in cost sharing structure are categorized as mandatory supplemental benefits. That is, 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.

The basic A/B bid should assume a utilization pattern consistent with Medicare cost-sharing. The portion of the aggregate bid related to the provision of basic prescription drug coverage should assume a utilization pattern consistent with defined standard cost sharing. Since the basic A/B bid is used to determine rebates and the portion of the bid related to Part D basic benefits is used to determine the monthly prescription drug beneficiary premium, these amounts cannot reflect the utilization effect of cost-sharing reductions provided through supplemental benefits.

Plans would make an actuarial projection for their populations concerning the expected utilization of each supplemental benefit (both mandatory and optional supplemental benefits) and the appropriate pricing of such benefits. We would verify the reasonableness of these projections as part of the bid review process (in the same way that we would verify the reasonableness of plans' projections of enrollment numbers and enrollment mix for an optional supplemental product). 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 payments not subject to rebates while under-pricing supplemental benefits to make the offering attractive to enrollees. To prevent this kind of strategy, the accurate pricing of Part A, Part B, and Part D benefits and supplemental benefits have equal importance in the bidding process.

We propose to exercise our authority under section 1856(b) of the Act (allowing CMS to establish MA standards by regulation) 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 such a rule, MA organizations would still be permitted to offer non-Medicare benefits such as dental and optical services as optional supplemental benefits. We are concerned about the effects of allowing a benefit that affects the level of cost-sharing and utilization of benefits to be offered at the enrollee's option. Allowing MA organizations to offer cost sharing-reductions and enhancements to Part A and Part B Medicare benefits as optional supplemental benefits arguably would be inconsistent with a multi-component bid, where one component is a bid amount for all of the supplemental benefits a plan intends to offer, both mandatory and optional. Costs for part of the supplemental bid amount would be carried by all enrollees, while costs for part would be carried by those who choose the benefit. Also, optional supplemental benefits do not exist under Part D. We are exploring the issue of whether allowing MA–PD plans to include drug coverage in an optional supplemental benefit would require a request for a waiver under section 1860D–21(c)(1) of the Act.

If we were to implement this restriction on optional supplemental benefits, MA organizations would still be able to provide choice by offering multiple plans within the same service area that have different mandatory supplemental benefits. We invite comments on this issue.

The MMA does not alter the percentage of the amount paid to MA organizations in 2006 that is adjusted by the CMS–HCC risk adjustment model. As previously provided, 75 percent of the payment will be subject to risk adjustment, and the remaining 25 percent will be based on the demographic model. Since the statute requires us to combine different approaches to adjusting capitation rates in 2006, we believe this raises the issue of whether MA organizations should be required to submit one or two different bids for each plan in order for each portion of the payment to be based on an appropriately standardized bid.

We propose that since we must make blended payments in 2006 for MA organizations, that MA organizations submit a blended bid for 2006, with one portion being based on a beneficiary with a nationally average risk profile (that is, the "1.0 beneficiary") and the second one being based on a beneficiary with a nationally average demographic profile. We invite comment on this approach or others that may be feasible. Note that some demonstrations have an alternative transition schedule to 100 percent risk adjusted payments, so these organizations would have to submit a blended bid for 2006 and 2007.

Proposed § 422.254(b)(4) would implement section 1854(a)(6) of the Act and would address an issue arising from section 1852(a)(1)(B) of the Act, which warrant a full discussion. Section 1854(a)(6) of the Act requires organizations to submit, for each MA plan, a bid consisting of three components, along with a statement of the actuarial basis for each of those components: (1) The original Medicare fee-for-service benefit package; (2) basic prescription drug coverage; and (3) any coverage beyond the first two components (supplemental health care benefits).

In the case of the first component, the health plan's basic A/B bid is the statement of the expected revenue the bidder requires to provide the Medicare-covered benefit package. This component of the aggregate bid may not include services not covered by Medicare. A simple example of what must be included as supplemental coverage rather than basic Medicare coverage would be routine physician services provided outside of the United States. The physician services would have to be included in the bid component referred to as "the provision of supplemental health care benefits" (section 1854(a)(6)(A)(ii)(III) of the Act), not in the component for the "provision of benefits under the original Medicare fee-for-service program" (section 1854(a)(6)(A)(ii)(I) of the Act). Medicare does not cover these services, but an MA plan may cover them as supplemental services.

A more complicated example would be that the "original Medicare" component of the bid may not include any inpatient hospital days that a health plan covers where such services would not be covered under original Medicare solely because an individual has exhausted the Medicare lifetime reserve days. To the extent that the care is "bundled" as part of a benefit package that a particular MA plan offers to Medicare enrollees, in order to use the plan cost and utilization data as the basis of its bid, the health plan must disaggregate the hospital benefit to determine costs (revenue needs) attributable to covered versus non-covered care. As part of the bid review process, we would ensure that only Medicare-covered services are included in a plan bid. (Note that under the prior M+C program we required "unlimited hospital days" to be shown on the Adjusted Community Rate Proposal as an additional benefit.)

Requiring that the "original Medicare" bid component only include covered care enables a fair comparison to determine the extent to which a plan can save money (or will cost more) in relation to a benchmark that consists primarily of Medicare fee-for-service expenditures for covered services in a given area. With a correct bid for this component, rebate dollars can be correctly calculated. If a health plan includes non-covered care in the basic A/B bid and this bid amount is below the benchmark, dollars that should have been returned to beneficiaries as rebate dollars will not be available to finance rebates (and dollars that should have been returned to the Government will not be available). Instead, the health plan will use those funds received from the Government to finance benefits that should have been classified as mandatory supplemental (non-covered) benefits. Those non-covered benefits included in the basic A/B bid would be financed at 100 percent of their cost to the plan, rather than having only 75 percent of the rebate dollars available to finance the benefit as a mandatory supplemental benefit (for example). Another health plan in the exact same situation that had correctly classified the services as non-covered services and had priced them as a mandatory supplemental benefit will appear more expensive to prospective enrollees

because 25 percent of the cost of the benefit becomes a "cost'' to the beneficiary.

Actuarial equivalence of cost sharing. In connection with the "original Medicare'' component of the bid, section 1852(a)(1)(B) of the Act states that "the term 'benefits under the original Medicare fee-for-service program option' means those items and services (other than hospice care) for which benefits are available under Medicare Parts A and B to individuals entitled to benefits under Medicare Part A and enrolled under Medicare 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*''. The provision regarding cost sharing is necessary because it reflects a feature of the structure of the Medicare program which provides that a certain share of the cost of covered care is to be borne by beneficiaries (or third parties paying on behalf of beneficiaries). Those costs, in original Medicare fee-for-service, are not financed by Government funds, and the costs would not be financed by Government funds in the bidding system (unless rebate dollars are available).

We have examined a number of ways to incorporate this Part A/B cost sharing provision in the bidding process, and in particular how to determine whether a bid incorporates cost sharing that would be considered actuarially equivalent to the cost sharing of original fee-for-service Medicare. As a starting point, we discuss the concept of actuarially equivalent cost-sharing by describing a hypothetical plan with the original Medicare cost-sharing rules. We then discuss three methods of implementing the MMA provision for determining what level of plan cost sharing is actuarially equivalent to original Medicare: (1) The current method that defines original Medicare cost sharing as a national average per capita uniform dollar amount, and a possible variation on this approach, the localized uniform dollar amount; (2) the plan-specific approach; and (3) the proportional approach (including national, regional, or local proportions).

One way in which a health plan could have a basic A/B bid for Medicare services that conforms to the provision in section 1852(a)(1)(B) of the Act is to design a plan that covers only Medicare-covered services and uses the same cost-sharing rules as Medicare (the hospital deductible, 20 percent coinsurance for outpatient services, etc.). For such a plan, there is no issue of actuarial equivalence since the plan has "cost sharing as required under Parts A and B'' of Medicare, as specified in 1852(a)(1)(B) of the Act. For this hypothetical plan, the actual dollar amount of the basic A/B bid may be quite different from the local Medicare fee-for-service expenditures, and from the dollar amount of cost sharing beneficiaries face in fee-for-service Medicare—for a number of possible reasons.

Among the possible reasons for variation are that local fee-for-service cost sharing amounts reflect a mix of types of supplemental coverage that Medicare beneficiaries may have. It is well known that beneficiaries with generous supplemental coverage (Medigap, Medicaid, some employment-based coverage) who do not directly face the expense of cost sharing have higher Medicare expenditures, and consequently higher cost sharing (though paid for by a third party). Individuals with only Medicare coverage have much lower expenditures and lower cost sharing. Expenditures of enrollees in the hypothetical plan with Medicare cost sharing may be closer to the level of expenditures for beneficiaries with no supplemental coverage. The private plan may also have lower expenditures overall because it has secured discounts below the Medicare rates from its network of providers, and the plan is likely to have utilization controls that reduce certain types of care or which shift care to a different setting or type of provider. This hypothetical plan's basic A/B bid for the coverage of Medicare services, and the associated cost sharing, would reflect the unique features of the private plan, and when expressed as a dollar amount there would most likely not be a match between the plan cost sharing amount and the amount in fee-for-service Medicare for the service area in which the plan is operating.

In reality, it is unlikely that there would be any plan meeting the requirement in section 1852(a)(1)(B) of the Act by imposing exactly the cost-sharing structure that Medicare uses. Hence, the law permits the use of an actuarial equivalence approach to determine the appropriate cost-sharing component of a basic A/B bid that would actuarially equal the "cost sharing as required under Parts A and B.'' Three methods of implementing the actuarial equivalence standard are discussed below: the uniform amount, plan-specific amount, and proportional methods.

Uniform Amount Method. The new section 1852(a)(1)(B) of the Act is similar to a provision in the law that continues to apply to MA plans through 2005, dealing with the determination of "excess amounts'' used to fund extra benefits. When Medicare payments 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). Section 1854(f)(1)(B) of the Act provides that:

For purposes of this paragraph, the excess amount, for an organization for a plan, is the amount (if any) by which—

(i) The average of the capitation payments made to the organization under section 1853 for the plan at the beginning of contract year, exceeds

(ii) The actuarial value of the required benefits described in section 1852(a)(1)(A) under the plan for individuals under this part, as determined based upon an adjusted community rate described in paragraph (3) *(as reduced for the actuarial value of the coinsurance, copayments, and deductibles under parts A and B).* [Emphasis added.]

The way in which this provision is currently implemented is through the determination of a uniform national dollar amount representing 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). All plans are required to use this national average amount as the "the actuarial value of the coinsurance, copayments, and deductibles under parts A and B,'' to comply with section 1854(f)(1)(B) of the Act. There are a number of drawbacks with this uniform dollar approach, including the sources of variation in cost sharing noted above (as well as regional variation in cost sharing). In the context of a bidding system, this national uniform dollar approach does not adequately recognize differences among private health plans and differences between private plans and fee-for-service Medicare.

The uniform amount approach could create distortions in the MA plan bids and have a negative impact on plans and on beneficiaries. In a situation in which the national dollar value of Medicare cost sharing (currently $113.07 per month for CY 2004) exceeds the appropriate amount for a particular health plan because the plan is very efficient and its expenditures are low in relation to those of Medicare, the plan bid would be depressed because of the assumption that $113 per month in revenue is collectible from enrollees. This would result in a greater difference between the plan bid and the benchmark, with 75 percent of that difference required to be rebated to

beneficiaries. Some or all of that rebate money can be used to fund the cost sharing that beneficiaries would face, which in this case the Government has deemed to be $113. This plan would be forced to fund a portion of the plan's own cost of providing the Medicare benefit with beneficiary dollars that otherwise would have been available for extra benefits.

For example, a plan could determine that its total revenue needed for providing the Medicare benefit is $500 per person per month—including $80 received as enrollee cost sharing revenue. Assume that the plan is operating in a county in which the benchmark is $600 (exactly equal to local fee-for-service expenditures, and with cost sharing in the area at exactly the $113 national level). Rather than state that its estimated required revenue for the Medicare package, after cost sharing, is $420 ($500 less $80), the plan is obligated to state its bid as $387 ($500 less $113). This affords the plan 75 percent of $213 (or $160) for rebates. In order to "make itself whole'' the plan needs $33 to fully fund its Medicare benefits, yet it will receive only $25. This $33 amount would be identified under the uniform amount approach as a reduction in enrollee cost sharing (in relation to the $113 level), and a net amount of $127 will remain for other rebate financing. If the plan reduces cost sharing to 0, $47 is left for other benefits (because $80 is the actual cost sharing liability for enrollees that needs to be "bought down''). Had the plan been allowed to correctly state its bid for its particular circumstances, the plan would have had 75 percent of $180 (or $135) for rebate purposes. If the plan reduces cost sharing to 0, a net of $55 is left for other benefits (or $8 per person per month more than under the uniform amount approach). (Distortions also occur when less efficient plans are required to understate their cost sharing level.)

We believe the current uniform amount method creates distortion under the MA bidding system both in the bids and levels of savings returned to the enrollee and to the Government, and limits the flexibility of MA plans to provide competitive benefits and to pass on cost savings to beneficiaries.

A more feasible version of the current national approach would be to use a localized uniform amount. Under this method, we would publish localized (for example, county-level or MSA-level) cost-sharing values to be used for purposes of actuarial equivalence. The values would be based on actual per-beneficiary FFS cost sharing, projected to the contract year and standardized to a 1.0 risk score.

In addition to the localized uniform dollar amount approach, there are two other methods we are considering: the plan-specific amount and the proportional approach. The plan-specific method for determining the PMPM amount of beneficiary cost sharing is based on the MA organization's pricing and utilization estimates. The organization would also use these estimates to generate its basic A/B bid. In contrast, the proportional method is based on fee-for-service pricing and utilization experience, either national, regional, or local proportions.

Plan-Specific Amount Method. A second approach eliminates the distortions caused by the uniform amount approach by allowing an MA organization to use actuarial assumptions and projections to determine the level of cost sharing that beneficiaries would face if the plan imposed the Medicare cost sharing structure or an actuarially equivalent structure. That is, whether an MA organization intends to offer a basic package or, through the use of mandatory supplemental benefits, intends to offer a plan with reduced cost-sharing, the organization would determine the basic A/B bid as if it were offering a plan that consists of Medicare-only benefits offered 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 so as 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. Thus, under a plan specific approach, the cost-sharing estimate and the basic A/B bid would be the result of the same estimating process enabling the organization to factor in any discounts it receives from providers, any utilization controls that influence services received, and any other plan-specific factors that should be considered in determining a fair and accurate bid.

To the extent that a plan does intend to use mandatory supplemental benefits, the question arises as to the relationship between the estimate of cost-sharing and plan revenue requirements for the assumed basic A/B package to the estimate of cost-sharing and revenue requirements under the integrated package that the plan intends to offer. Assume, for example, that the bidding organization, through the use of mandatory supplemental benefits intends to have no cost sharing at all in its plan and will rely on provider discounts and good utilization management to offer an efficient Medicare product. Because the basic A/B bid involves significant levels of cost sharing, utilization and hence plan revenue needs would increase from the estimate of plan revenue needed for basic A/B coverage to that for the planned integrated package (that is, basic A/B plus mandatory supplemental benefits). As previously discussed, this additional utilization resulting from reduced cost sharing would be included in the costs of mandatory supplemental coverage as part of the bid component for supplemental benefits. (Note that under the provisions of section 1854(a)(6)(A) of the Act, bids are for an "enrollee with a national average risk profile.'' The actuarial determination of cost sharing would also be for an enrollee with a national average risk profile.)

This method of determining the Medicare cost sharing amount is more complicated than the uniform amount method. However, we would not expect the calculation to be burdensome to MA organizations, since they would have to develop plan-specific estimates of cost sharing in order to price cost-sharing reductions provided as mandatory supplemental benefits. These kinds of actuarial estimates are necessary in connection with the design of any type of plan benefit package an MA organization offers or considers offering. While the Medicare cost sharing structure is complicated and varies by type of service provided, we would note that current MA plans have equally varied cost sharing applied to different services in the plans offered to Medicare enrollees. The plan-specific approach is also consistent with our position that additional utilization arising from reduced cost sharing must be priced as part of the mandatory supplemental component of the plan bid.

Proportional Method. Another method of determining a Medicare level of cost sharing is to use a proportional approach. 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.

Using a fixed national proportion is a variation on the uniform national dollar method, but it recognizes variation in expenditures at the health plan level. However, even within fee-for-service Medicare, there is significant variation by area in the cost-sharing proportion, ranging from 13 percent in Maryland to 20 percent in Nebraska in 1999 (compared to the national average of 16.8 percent). To address the issue of geographic variation in cost sharing, which also became a concern in the Medicare+Choice program, we are considering the development of regional or local cost-sharing proportions.

Using a proportional approach, plan pricing assumptions are built into the total value of the benefit package. However, any utilization effect within the plan of a Medicare-like cost-sharing structure is not factored in. Another factor that is not recognized in a straight national or local proportional method is that the mix of services within a health plan, and the costs associated with each category of services, may be different from the mix in fee-for-service Medicare. For example, plans may tend to favor post-acute care over acute care, which, if fee-for-service Medicare were to do the same, would alter the total cost sharing and the distribution of the cost sharing in relation to the types of services from which cost-sharing revenue is derived.

To refine the proportional method, and to attempt to be more consistent with the letter of the law ("cost sharing for * * * services as required under A and B''), we could develop service-specific proportions of cost sharing applied to the different categories of expenditures health plans would have (for example, a proportion would be stated for inpatient hospital care, a proportion for physician services, etc.). In order to further refine this approach, we would also incorporate assumptions about how health plans generally use services. We would then announce the (local area) service-by-service proportions plans would use to determine their actuarial equivalent of Medicare cost sharing. Such a local, adjusted proportional approach would be relatively easy for plans to implement, but it would involve an additional burden on us to develop varying percentages by area and by service category. Assumptions made about the distribution of services provided by private plans may not be consistent with the experience and practices of individual plans.

We invite comment on each of the alternatives we are considering to replace the national uniform amount method: localized uniform dollar amounts; plan-specific amounts; and proportions (national, regional, or local). We would have liked to provide a comparison of the effects on plan bids of these three methods for determining a level of beneficiary cost sharing that is actuarially equivalent to original Medicare. This is not possible at this time, however, because we have not fully developed these options. To specify impacts we would need to know exactly what data elements we would collect and what formulas we would use. We invite comment on the details of these alternatives methods and how best to implement them.

PACE organizations and the MMA bidding methodology. We believe, based on conference report language, that the Congress intended 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 PACE organizations intending to offer Part D drug coverage to PACE enrollees. We expect that PACE plans would be required to submit bids to provide Part D drug benefits under Title I of the MMA, addressed in a separate rulemaking.

Information required. Sections 422.254(c) and (d) implement section 1854(a)(6)(A) of the Act by setting out the information MA organizations must submit for coordinated care plans (including regional MA plans and specialized MA plans) and private fee-for-service plans. Proposed § 422.254(e) specifies information that must be submitted for MSA plans.

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, and any capacity limits, the actuarial bases for determining the bid amounts and proportions, and information on the plan's cost sharing, including the actuarial values of deductibles, coinsurance, and co-payments. Additional information required on drug coverage is specified at section 1860D–11(b) of the Act.

Under proposed § 422.254, 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 options specified by the statute for a mandatory supplemental benefit: (1) Provision of supplemental health benefits, including additional health care benefits, reduction of cost sharing for original Medicare benefits and/or Part D benefits; and/or (2) reduction of the Part B, Part D, and/or mandatory supplemental benefit premium(s). For further discussion of requirements for rebates, see § 422.266.

Since MA regional plans may serve multiple regions, and each region is a separate service area, we will develop procedures to allow MA organizations to file consolidated bid information for multi-region MA plans (including national plans), in order to encourage the offering of regional plans, in accordance with section 1854(a)(1)(C) of the Act.

In addition to the information cited above, in 2006 and/or 2007, MA organizations offering regional plans must submit as a part of the bid package sufficient information for us to calculate risk corridor amounts. This information includes projected allowable costs (see discussion of subpart J) and the portion of the allowable costs attributable to administrative expenses incurred in providing these benefits. In addition, the plan must provide the total projected costs for providing rebatable integrated benefits as well as the portion of rebatable integrated benefits that are attributable to administrative expenses.

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 have not yet determined the format for initial bid submission, and we will provide future guidance on these requirements.

Special rules for MSA plans. Section 422.254(e)(2) implements section 1854(a)(3) and section 1854(b)(2)(D) of the Act by indicating that bids are not required for MA MSA plans. However, for MSA plans MA organizations must submit 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 deductible, and the beneficiary supplemental premium, if any. MSAs are prohibited from offering Part D coverage (although MSA enrollees may choose to enroll in a prescription drug plan).

A supplemental benefit for an MSA plan cannot cover the MSA deductible. Health insurance policies for benefits described in section 1882(u)(2)(B) of the Act must not be treated as covering such a deductible.

Our goal is to maximize the diversity of plans available in the MA program, and to this end we welcome any comments that would help us improve our payment methodology for MSA plans.

4. Negotiation and Approval of Bids (§ 422.256)

Authority to review and negotiate bids. The provisions in proposed § 422.256 implement section 1854(a)(6)(B) of the Act, which provides 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 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 two programs. For example, the OPM authority applies to negotiating the level of plan benefits, while Medicare benefits under Parts A and B 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, 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. Further, 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.

As provided under § 422.256(a)(2) and in accordance with section 1854(a)(6)(B)(iii) of the Act, we may not 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 such 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 private fee-for-service plans or any amounts submitted by MSA plans.

Standards of bid review. Section 422.256(b) implements section 1854(a)(6)(B)(ii) and (iii) and section 1854(e)(4) of the Act, which together establish 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 in section 1302(8) of the Public Health Service Act. We interpret this reference to mean that the Congress intends for a plan bid to reflect the plan's estimated required revenue in providing coverage, 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) implements section 1854(e)(4) of the Act by providing for a limitation on applicable cost-sharing for coordinated care and private fee-for-service 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 are interpreting "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. Essentially, the requirement in section 1852 of the Act (discussed in connection with proposed § 422.254(b)(4)) 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 bids. Section 1854 of the Act places a cap on *actual* enrollee cost-sharing liability for Medicare Parts A and B benefits in relation to average cost sharing in fee-for-service Medicare in the service area as estimated by us. This means that if a plan's *aggregate* bid includes a mandatory supplemental benefit, the plan can have an actuarial value of cost sharing that is less than that under original Medicare because the plan rebate has been applied to a buy down plan cost sharing.

There has been some confusion about whether an MA plan can substitute a premium for some portion of the cost sharing under original Medicare. Section 1854(b)(2)(A)(i) of the Act (which would be implemented at proposed § 422.262(a)(1)) mandates 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.

Under the previous M+C program, we allowed M+C organizations to reduce beneficiary basic premium amounts as a part of the ACRP process, that is, they were allowed to take a negative adjustment on their additional revenues. Under the MMA, this type of adjustment is no longer permitted for the basic bid for benefits under the original Medicare

program. 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.

Negotiation process. Section 422.256(a) implements section 1854(a)(6)(B)(i) of the Act, which provides us the authority to negotiate with MA organizations. As mentioned above, 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.

At this time, we have not completed development of the bidding and approval process. We expect to revise the current Adjusted Community Rate Proposal tool (both the Plan Benefit Package and the ACR spreadsheet) to align with MMA provisions for bid submission. We expect that the process of bid negotiation between 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.

In addition, MA organizations may need to adjust the allocation of rebate dollars in a plan bid (see discussion below), so would also need to resubmit the bid.

Rules for adjustment of rebate dollar allocation. As required by section 1860D–13(a)(4) of the Act, CMS must publish a national average monthly bid amount for Part D based on an average of plan bid amounts. This means MA organizations must submit their plan bids (including the estimated drug premium amount) before knowing the national average monthly bid amount for basic coverage. Since section 1854(b)(2)(A) of the Act requires that organizations with basic A/B bids below benchmarks charge a zero basic beneficiary premium, in their initial bid submission MA organizations will allocate rebate dollars to mandatory supplemental benefit packages (to ensure that all beneficiaries receive the full value of their rebate amount, which may include the provision of a Part D premium reduction. For example, a plan may have an estimated Part D monthly premium of $35, and offer a mandatory supplemental package that applies $35 of its rebate to "buy down'' the Part D premium to zero.

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 $1.00 Part D premium and return to the zero premium in the initial bid submission.

For this reason, we anticipate that some MA organizations will make minor technical adjustments to the benefit structures of their non-prescription drug bids. The adjustments would consist of reallocation of beneficiary rebate dollars in the mandatory supplemental benefit among the different categories allowed by law: Additional benefits, reductions in Part A/B cost sharing, reduction to the mandatory supplemental premium, and reductions in Part B and Part D beneficiary premiums. Modifications to Part D cost sharing could not be made, however, given the implications that such modifications would have on projected reinsurance dollars which then impacts the pricing of the bid for basic Part D benefits. Changes to the basic Part D portion of the bid would have implications for the national average monthly bid amount and, hence, the basic beneficiary premium that we would have just previously calculated for the year.

Note that the bid cannot be changed unless mutually agreed upon by CMS and the MA organization representatives as a result of our review and negotiation process. An example of an appropriate change would be if an MA organization elects to allocate rebate dollars to reduce its estimated Part D premium to zero in its initial June bid submission, and the outcome of the national average premium calculation is that the plan has an excessive allocation of rebate dollars so that the Part D premium has become a negative amount, such as –$3.25, this plan would have to reallocate $3.25 to other mandatory supplemental benefits to ensure enrollees receive the full amount of the rebate. Conversely, if another MA organization also elects to allocate rebate dollars to have a zero Part D premium, and the comparison with the national average drug premium results in an insufficient allocation of rebate dollars so that the Part D premium has become $1.42, this plan would have the option of reallocating the $1.42 of beneficiary rebate dollars to return to a zero premium, as submitted in the original June bid. (Bid amounts must be submitted no later than the first Monday of June each year, beginning for contract year 2006).

We also recognize 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 cost sharing (that is, increase or decrease reductions in the initial June bid submission), other than for Part D benefits, and certain premiums to arrive at the supplemental, Part B, and Part D premiums originally submitted.

We propose the following rules for the negotiation process concerning reallocation of rebate dollars due to excessive or insufficient allocation.

(1) Local 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.

(2) Local MA plans with underestimated allocations to Part D premium reduction have the option of reallocating beneficiary rebate dollars to 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 to not adjust the new premium or reallocate the appropriate amount to achieve the initial premium submitted.

(3) Regional MA plans may reallocate beneficiary rebate dollars to achieve the supplemental, Part B, and Part D premiums in their initial bid submission.

(4) Local MA plans not offering Part D benefits (these would only be private fee-for-service 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.

We believe that it is appropriate for MA organizations to only make technical adjustments or modifications during the negotiation process initiated by CMS in order to create a bidding process with integrity, to ensure that bids are meaningful, and to avoid the endless cycle of CMS benchmark calculation-plan benefit adjustment-CMS benchmark calculation. We invite comments on this issue.

5. Calculation of Benchmarks (§ 422.258)

Proposed § 422.258 would implement the new section 1853(j) of the Act (added by the MMA) by providing a description of how benchmarks for local MA plans are calculated. We will calculate benchmarks for each county, that is, MA local area. For a service area that is entirely within an MA local area, 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. The monthly capitation rate for each local area is multiplied by the plan's projection of the proportion of its enrollees that will reside in each local area. These enrollment projections would be based on information submitted by the local plans for bidding purposes, as mandated under section 1854(a)(6)(A)(iii) of the Act. These products would be summed to yield the local area benchmark amount for that MA plan.

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 as the most recent month for which data is available.

Proposed § 422.258(b) and (c) would implement section 1858(f) of the Act by providing a description of how regional MA plan benchmarks are calculated. We would calculate benchmarks for the MA regional area. The benchmark amount for regional plans would be a blend of two components, the MA area-specific benchmark amounts and the plan bid amounts. The purpose of the blend would be to be more responsive to market conditions in the region by allowing plan bids to influence the final benchmark amount. This blending would allow a more accurate reflection of the actual revenue needs of the plans to be included in the bidding process.

Proposed § 422.258(b)(1) would implement section 1858(f)(2) of the Act by describing the two components of the MA regional benchmark, the statutory component and the plan bid component.

The statutory component would be based on the local area capitation rates. For each local area, the capitation rate would be multiplied by the ratio of the number of MA eligibles (based on the reference month), residing in the area to the number of MA eligibles (based on the same reference month) residing in the region. These products would be summed across all local areas in the region to yield the statutory component.

The plan-bid component would be based on the bids of all MA plans in the region. For each plan offered in a region, we 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)) and then sum these products across all plans offered in the region. We then multiply this by 1 minus the statutory market share to determine the plan-bid component of the regional benchmark.

The weighted average of plan bids for a region would be determined based on the number of regional plans offered in the region in a given year and the number of regional plans offered in the reference month. Section 1858(f)(5) of the Act, which we would implement in proposed § 422.258(c)(4) and (c)(5), addresses how to account for varying numbers of plans and different size plans in a region when determining the regional benchmark amount. If two or more regional plans were offered in the region in the reference month, the plan-bid component would be based on the weighted average of the plan bids, unadjusted for risk adjustment. Each plan's bid would be multiplied by the ratio of the number of MA eligibles in the reference month enrolled in the plan to the number of MA eligibles in the reference month enrolled in all the plans in the region. These products would be summed across all plans in the region to yield the plan-bid component.

If only a single regional plan is offered in the region in a year, the plan-bid component would be this plan's bid. If there were no regional plans offered in the reference month, but two or more new regional plans are offered in the region in a year, we may give equal weight to each plan's bid in determining the plan-bid amount. Alternatively, we may weight the bids based on each plan's estimate of its projected enrollment, with the reasonableness of the projections subject to our approval.

The MA regional benchmark would be the weighted average of the statutory component and the plan-bid component. The statutory component would 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 divided by the total number of MA eligibles in the nation. The plan-bid component would be multiplied by the non-statutory market share, which is the number of MA eligibles in the nation who were enrolled in an MA plan during the reference month divided by the total number of MA eligibles in the nation. These components would be added to yield the MA regional benchmark.

6. Beneficiary Premiums (§ 422.262)

Proposed § 422.262(a) would implement section 1854(b)(2)(A) of the Act, and would describe the new methodology for calculating the MA monthly basic beneficiary premium. This premium will now be determined by comparing the unadjusted plan bids to unadjusted benchmark amounts.

(1) For an MA plan with an unadjusted statutory non-drug bid amount (basic A/B bid) that is less than the appropriate unadjusted non-drug benchmark amount, the basic beneficiary premium is zero.

(2) For an MA plan with an unadjusted statutory non-drug bid amount (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 (if any) the bid amount exceeds the benchmark amount. All approved premiums must be charged—that is, plans are not allowed to waive 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, proposed § 422.262(b) states that 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. In the case of an MSA plan, there are no basic beneficiary premiums since we instead make a deposit to the enrollee's MSA. MSA plans are high deductible insurance policies, not managed care plans. This means the only beneficiary premium for an MSA plan would be a supplemental premium.

Uniformity of premiums and cost-sharing. The MMA continues current MA regulations now in subpart G at § 422.304(b) regarding uniformity of beneficiary premiums and cost sharing within MA plans.

MA organizations offering local MA plans within segments of service areas must submit separate bids for those segments that will have different premiums and cost sharing. Section 1858(a)(1) of the Act mandates that regional MA plans must provide uniform premiums and cost sharing within a region, specifying that section 1854(h) of the Act (allowing segmented service areas) does not apply to regional MA plans.

Section 1854(d)(1) of the Act would be implemented in proposed § 422.262(e), describing the rules on the timing of payments by MA enrollees of their beneficiary premiums.

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 benefits in the same manner that Part B premium reductions are handled; (2) setting up an electronic funds transfer; or (3) through other appropriate means we may identify. The Congress provided for other beneficiary payment options including payment by an employer. Under employment-based retiree coverage, payment could be made on behalf of an employee, a former employee, or a dependent. All premium payments deducted from Social Security benefits would be credited to the appropriate Trust Fund as we specify, and will be paid to the appropriate MA organization. We would consult with the Commissioner of Social Security and the Secretary of the Treasury to determine which Trust Funds are the appropriate ones to credit. The MA organization must not impose a charge for individuals electing to pay their premiums through a deduction from their Social Security payments.

We would transmit the appropriate information (for example, name, social security number, consolidated monthly beneficiary premium owed by each beneficiary for each month in the year), and other information to the Commissioner of Social Security (SSA) as agreed to with SSA. We would consult with the Commissioner of Social Security about what information is appropriate to transmit. We would update this information, as necessary, during the year. We invite comments on the additional appropriate beneficiary payment options that we could institute as well as uses for and development of electronic funds transfer mechanisms to help beneficiaries pay their premiums.

7. Calculation of Savings (§ 422.264)

Under section 1854(b)(3)(A)(iii) of the Act, in calculating the monthly savings as a step in determining beneficiary rebate amounts for MA local plans beginning in 2006, the Congress gave the Secretary the flexibility to determine whether the risk adjustment factors to be applied to the local benchmarks and bids are determined on a State-wide basis, a plan-specific basis, or some other basis.

The advantage of applying a State-wide risk adjuster to benchmarks and basic A/B bids is that it ensures savings (and rebates) are uniform for beneficiaries in local plans in the same State. That is, plans with equal basic A/B bids (below the benchmark) within a State would have equal savings and rebates. This means that beneficiaries in equally efficient plans would not be either rewarded or penalized because they chose a plan with less healthy enrollees or a plan with healthier than average enrollees.

However, equally efficient plans with less healthy populations (as compared to the State-wide average) would be disadvantaged by a State-wide risk adjuster because it would be more costly for those plans to provide supplemental benefits with the same value as provided by healthier plans. The use of rebate dollars to reduce premiums (which is a dollar-for-dollar reduction in any kind of plan) is different than the use of rebate dollars to finance extra benefits, which cost more for a plan with less healthy enrollees. The cost difference for plans with a less healthy enrollee population is based on the assumption that enrollees in plans with a higher than average risk profile would use more services than enrollees in plans with lower risk profiles.

An additional practical complication of applying a State-wide risk adjustment factor might arise in situations where plans serve health care markets that cross State lines, since enrollees in the same plan who live in different States would be subject to different risk adjustment factors.

Section 1854(b)(3)(A)(iii) also provides the option of applying a plan-specific risk adjuster to the calculation of savings. This approach would address the above problem, in that among plans with equal basic A/B bids (below the benchmark), plans with less healthy enrollee populations would receive more rebate dollars and thus would be able to offer mandatory supplemental benefits that have close to the same value as plans with healthier enrollee populations. However, this would mean that plans operating at similar levels of efficiency, but with different risk profiles, would not have uniform beneficiary savings and rebates.

We are reviewing options for this adjustment and request comments on these two approaches.

In the case of States or other areas in which no local plans have been offered in the previous year, we may use average risk adjustment factors applied to comparable States or applied on a national basis.

Under section 1854(b)(3)(B) of the Act, we would apply an average risk adjustment factor (State-wide or some other applicable risk adjustment factor) to determine the risk-adjusted basic A/B bid and benchmark amounts for each local plan offered.

Section 1854(b)(3)(C) of the Act addresses how to determine the amount of savings for each local MA plan, if any, by calculating the amount by which the risk-adjusted benchmark amount exceeds the risk-adjusted bid amount. This provision would be implemented in proposed § 422.264(d).

Under section 1854(b)(4)(A)(iii) of the Act, for regional MA plans, the Congress provided us the flexibility to determine the basis for the risk-adjustment factors to be applied to regional benchmarks and bids. These could include average risk factors calculated on a regional or other geographic area or on a plan-specific basis.

Under section 1854(4)(B) of the Act, we would apply an average risk-adjustment factor (region-wide or some other applicable risk-adjustment factor) to determine the risk-adjusted bid and regional benchmark amounts for each regional plan offered.

Section 1854(b)(4)(C) of the Act addresses how to determine the amount of savings for each regional plan, if any, by calculating the amount by which the risk-adjusted benchmark amount exceeds the risk-adjusted bid amount.

The foregoing provisions would be implemented in § 422.264(d) and (e).

8. Beneficiary Rebates (§ 422.266)

Beneficiary rebate rule. 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) would provide, as set forth in section 1854(b)(1)(C)(ii) of the Act, that the beneficiary rebate could be provided in the following forms: 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, 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 credited toward the prescription drug premium or Part B premium.

Proposed 422.266(b)(1) provides 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 would 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 would 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 would 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.

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 bidding process, we believe that it is no longer appropriate to allow MA organizations to enter the program with a new plan or to offer mid-year enhancements to an existing plan. Allowing an MA organization to offer a new plan after the June bidding cycle would not comply with section 1854(a)(1)(A) of the Act, which requires MA organizations to submit a bid for any plan it intends to offer in its service area (or segment of service area for local plans). Any mid-year benefit enhancements would be *de facto* adjustments to benefit packages for which bids were submitted earlier in the year based on their organization estimated revenue requirements. In essence, allowing mid-year benefit enhancements by an organization for a plan for which it submitted a bid in the previous June could render the bid meaningless.

9. Incorrect Collection of Premiums and Cost-Sharing for All Years (§ 422.270)

This section, 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. The MA organization is required to refund the over-collections, and if the amounts incorrectly collected were premiums or included premiums, the MA organization may refund the enrollees through an adjustment to future premiums for all MA plan enrollees or a combination of a premium adjustment and a lump sum payment. An MA organization that collects amounts in excess of those permitted is subject to intermediate sanctions and civil money penalties under subpart O.

Subpart G—Payments to Medicare Advantage Organizations

(If you choose to comment on issues in this section, please include the caption "Subpart G—Payments to Medicare Advantage Organizations'' at the beginning of your comments.)

As discussed above in connection with subpart F, we have proposed to revise subparts F and G in their entirety, and to reverse the order of the subjects addressed in these subparts. The current subpart F deals with payment rules while the current subpart G contains provisions relating to MA organizations' submission of benefit information and premium rules. Proposed subpart F addressed the provisions for MA organizations to submit bids for contract years after 2005, as well as provisions governing beneficiary premiums. In proposed subpart G, we would implement new MMA provisions governing payments to MA organizations.

The proposed regulations address how MA organizations continue to be paid on a monthly basis, but now based on the new methodology of plan bids established by the MMA. The proposed rules specifically provide that the specific amount of the payment for MA organizations (except MSA plans) depends upon the plan bid-to-benchmark comparison. The rules provide for an exception that payments for ESRD enrollees may be made outside of the MMA bidding methodology, but will be based on the new MMA capitation rates.

Further, the proposed text sets forth the calculations for the annual capitation rates established by the MMA and details the adjustments that will be made to capitation rates, benchmarks, bids, and MA organization payments. The regulations in this subpart describe the risk adjustment methodology and data requirements that must be met in order to properly adjust payment and benchmark amounts for the health status of enrollees, and then include the new date for publication of annual capitation rates, regional benchmarks, and payment methodology changes. Finally, they set forth a variety of special rules, including payments for enrollees electing hospice, and rates for payments to Federally qualified health centers (FQHCs).

1. Basis and Scope (§ 422.300)

Proposed § 422.300 sets 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 indicates that the regulations in this subpart set forth the requirements 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. Since we are only able to share risk with regional MA organizations, see subpart J, § 422.458 for a description of risk corridors to be used by regional MA organizations in 2006 and 2007 only.

2. Monthly Payments (§ 422.304)

Under the current MA program, as set forth at section 1853(a)(1)(A)(i) of the Act, an MA organization is paid a fixed statutorily determined administrative amount each month, regardless of its actual revenue needs of providing services to the Medicare population enrolled in its plan(s). The MMA replaces this methodology beginning in 2006. We provide in proposed § 422.304(a) that, with the exception of payments to MSA plans and payments for ESRD enrollees in all other plans (discussed below), we would make advance monthly payments to an MA organization for each enrollee for coverage of original fee-for-service benefits in the plan payment area for a month, using the new bidding methodology described here and in the proposed subpart G regulations text.

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) describes 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. The other 25 percent of savings remains in the Trust Funds (except for regional MA amounts used for the regional plan stabilization fund). We pay plans that have beneficiary rebates the amount of their aggregate bid (adjusted both for risk using the appropriate enrollee risk factor determined under our risk adjustment model and for intra-area payments variations) and the amount of the rebate (less any reduction in the Part B premium.

If the risk-adjusted plan basic A/B bid is equal to or greater than 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. This amount is adjusted for risk using the appropriate enrollee risk factor, for intra-area payment variations, and for the effects of risk adjustment on the enrollee basic premium. We apply a further adjustment to all plan payment amounts for variations among local payment rates

Under section 1853(a)(1)(D) of the Act, which would be 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 methodology we applied before the enactment of the MMA, specifically to establish special rates that are actuarially equivalent to rates in effect before the enactment of the MMA. We believe the MMA provided us with flexibility for determining ESRD payments because the cost and utilization patterns for ESRD beneficiaries are distinct from aged and disabled beneficiaries. We propose to continue paying MA organizations for their ESRD MA enrollees based on the State ESRD capitation rates. We would use the State ESRD rates calculated under the MMA rate setting methodology set forth in proposed § 422.306. We would continue to risk adjust the State payment rates, as provided at § 422.308(c). We also would continue to reduce payments for ESRD enrollees for the ESRD network fee, as provided in § 422.208(c)(4), as set forth at section 1881(b)(7) of the Act.

However, the mandate to pay using pre-MMA payment rates raises a payment issue regarding ESRD enrollees. Under the previous M+C program, an M+C plan could offer as an additional benefit the reduction of some or all of the standard Part B premium. CMS reduced the monthly payment to the M+C organization, and 80 percent of this reduction was applied to reduce the enrollees' Part B premiums. Twenty percent of this payment reduction was savings to the M+C program. This 80–20 split, which was in effect before the MMA, applied to all M+C plan enrollees, including those with ESRD. It is analogous to the MMA requirement that 25 percent of the difference between basic A/B bid and benchmark be returned to the government as savings.

Therefore, one option is for CMS to pay the risk-adjusted State rate per enrollee, which would be analogous to paying the benchmark to all plans, even those with basic A/B bids below the benchmark. Since the concept of splitting a payment reduction into government savings and plan benefit existed prior to the MMA, 75 percent of any reduction in CMS's payments for a plan would be applied to the Part B premium for plan enrollees.

Another option would be to consider the use of the State capitation rates in calculation of plan benchmarks as sufficient implementation of section 1853(a)(1)(H) of the Act. Accordingly, ESRD enrollees would be fully incorporated into the bid process, and payments for all enrollees would be either the risk adjusted aggregate bid plus rebate and other relevant adjustments discussed below or the risk adjusted benchmark. (Both bid and benchmark amounts would reflect the plan's relative weights of ESRD enrollees costs versus aged/disabled enrollee costs.) See the discussion in the Subpart F preamble on when to incorporate ESRD enrollees into the bid amount. We invite comments on these and other feasible payment approaches.

Special rules for payments to MSA plans. Section 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 payment provisions is that MSA plans become local MA plans, and we would make payments to MA organizations for MSA enrollees based on the non-drug benchmark amount (instead of county rates), 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 set forth at § 422.308(c).

Our goal is to maximize the diversity of plans available in the MA program, and to this end we welcome any comments that would help us improve our payment methodology for MSA plans.

RFB plans. Section 422.304(c)(3) on special rules for religious and fraternal benefit (RFB) society plan enrollees is unchanged from the current MA regulation, now in subpart F at § 422.250(a)(2)(iii), allowing us to make payment adjustment reflecting the actuarial characteristics and utilization patterns of enrollees.

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.

Section 422.304(e) implements 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. (Note that the terminology used in the statute to refer to statistical areas is inconsistent with new definitions and designations of metropolitan areas published by the Office of Management and Budget in June of 2003. The terms "consolidated metropolitan statistical area'' and "primary MSA'' are no longer used. There are now metropolitan statistical areas and metropolitan divisions of such areas, a change which is reflected in the text of the proposed rule.)

3. Annual MA Capitation Rates (§ 422.306)

For years before 2004, payments to MA organizations were based on the highest of three amounts: (1) 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, (2) a "floor amount,'' based on an amount specified in statute, subject to an update factor, and (3) 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), and the 100 percent of fee-for-service (FFS) costs rate introduced by the MMA. For the next phase, the MMA specified that beginning with 2005, annual capitation rates will be minimum increase rates except for years when we rebase the FFS rate; in rebasing years, the rate is the higher of the minimum 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. As noted above, the minimum percentage increase rate is modified to be the greater of 102 percent of the prior year's rate or the prior year's rate increased by the national per capita MA growth percentage.

The MMA also provides that no less than every 3 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 no less than once every 3 years. The statute gives us the authority to determine how often to "rebase'' the rate book within this 3-year window. We intend to announce our intention annually in the 45-Day Advance Notice regarding whether we will rebase the rate book for the upcoming year.

4. Adjustments to Capitation Rates, Benchmarks, Bids, and Payments (§ 422.308)

The annual capitation rates described above will be adjusted under provisions set forth in proposed § 422.308.

Language in proposed § 422.308(a) remains the same as that currently in subpart F of the current regulations governing MA 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 provide 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 (less or more healthy), we would 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 and succeeding years, 100 percent of payment will be risk-adjusted. 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, the transition blends are one year behind that for MA organizations. Therefore, PACE organizations will receive 100 percent risk adjusted payments in 2008 and succeeding years.

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 factors. 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. A plan-level working aged adjustment is applied to the risk-adjusted portion of the payment. 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.

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 local and regional MA plans to account for variations in "local payment rates'' within each 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.

This adjustment relating to risk adjustment recognizes that costs in some portions of a plan's service area could be higher than those in lower-cost areas covered by the plan. Plans serving both low-cost and high-cost areas will have bids and benchmarks reflecting costs averaged across these areas, since these are weighted by a plan's projected enrollment. Those plans whose actual enrollment reflects a greater proportion of residents in higher-cost areas than was projected for enrollment when calculating the plan bid may see payments coming in below cost projections.

Although the statutory language referring to adjustments for intra-area variations is similar for regional plans (section 1853(a)(1)(F)(i) of the Act) and local plans (section 1853(a)(1)(F)(ii) of the Act), we are interpreting the phrase "variation in local payment rates'' to mean that there could be different reasons for the variation in payment rates in regional versus local plans. For example, regional MA plans could have significant variation in their payment areas because they are required to cover at least one State, thereby being compelled to include urban and rural areas in one region. These areas could have significantly different provider practice and beneficiary utilization patterns, wage indices, and other factors that affect the cost of providing services to plan enrollees.

Therefore, we may apply different methodologies to regional and local plan payments to adjust for rate variations within a plan's service area. Also, we are assuming the statutory language would allow approaches other than adjusting back to county capitation rates.

We are reviewing options for this adjustment other than making adjustments based on county rates. One option would be to apply an index based on local fee-for-service rates compared to the national fee-for-service average. Another possibility is an index that reflects input price differences, such as some indicator of local wage rates to a national average. We may apply separate adjustments to regional and local plans.

In deciding how to proceed, we will review Medpac's upcoming study on MA payments, required by the MMA, which will include an analysis of the bases for variation in costs among different areas, including differences in input prices, utilization, and practice patterns. We also invite public comments on the best approach to this adjustment.

Adjustment relating to risk 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. Without this adjustment, a plan with a higher-than-average risk score would receive a total payment (beneficiary premium plus Government contribution) that was less than the plan's bid, which represents the plan's estimated revenue requirements (in addition to member cost sharing). Conversely, a plan with a lower-than-average risk score would receive a total payment that exceeded its bid.

Proposed § 422.308(e)(1) specifies 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) specifies 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 is an unintended omission for local plans, since section 1853(a)(1)(F) of the Act mandates this adjustment for both regional and local plans serving more than one county.

This adjustment must be applied after risk adjusting the payment for the individual MA enrollee's health status and after taking into account adjustments for intra-area variation in local payment rates under § 422.304(d).

Adjustment of payment to reflect the number of enrollees. Proposed § 422.308(f) would implement section 1853(a)(2)(A) of the Act, which is unchanged by MMA. We therefore are proposing 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. In the final rule titled "Modifications to Managed Care Rules,'' published August 22, 2003 at 68 FR 50840, we amended the MA regulations to refine the definition of "significant'' cost and interpret appropriate adjustment of payments to include a new "NCD adjustment factor'' effective for CY 2004 that was to be added to the county rates in those counties receiving a 2 percent minimum update rate.

Since all capitation rates under the MMA now automatically build in the annual national MA growth percentage, there is no longer a need to implement the NCD adjustment factor. Therefore, we are proposing to reverse the regulatory change established by the August 22, 2003 final rule, to eliminate this adjustment factor. Proposed § 422.308(g) reflects this change. See the preamble discussion for § 422.109 for additional information on this issue.

Section 1858(c) of the Act provides for temporary risk corridors for adjusting payments to regional plans, and proposed § 422.308(h) specifies 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 (see the discussion of regional plan risk corridors in proposed § 422.458 below).

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 would 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 reflects changes we made in the methodology for risk adjusting MA payments, under which we moved from the collection of extensive encounter data to collecting targeted risk-adjustment data. The risk-adjustment data that are referenced in this section are data that are used in the application of the current risk-adjustment model. Originally enacted in the BBA, section 1853(a)(3)(B) of the Act provides us with the authority to collect traditional Medicare data in a standard format, but allows MA organizations to submit data in alternative formats. This data collection authority is retained in the MMA. In addition, under this same authority, we believe that we may also collect data regarding other enrollee characteristics such as functional limitations if the data are used in the risk adjustment model.

The language in § 422.310 is similar to that used in subpart F of the current MA regulations at § 422.257. The following summarizes the highlights of those provisions. Under our data collection authority, § 422.310 specifies that each MA organization must submit to us all data necessary (as stipulated under this section) to characterize the context and purpose of each service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner. The BBA gave us the authority to collect data regarding inpatient hospital services and other services as we deemed necessary. The BIPA affirmed the collection of ambulatory data. Under section 1853(a)(1)(C) of the Act, beginning for payments in calendar year 2006, we will use these data to determine the risk adjustment factors to be applied to the basic A/B bid and the benchmark amounts upon which the payments and monthly savings for an organization are based. We may also use the data for other purposes, such as quality improvement studies and program integrity functions.

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 fee-for-service 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 a data, a sample of medical records, for conducting validation studies of the risk adjustment data CMS receives. MA organizations will still be required to submit a sample of medical records in a manner specified by CMS to support the validation studies. We do not use medical records data for any other purpose.

The risk adjustment data must be submitted according to the timeframes specified by CMS. 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.

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 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 the beginning of each annual, coordinated election period 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 was similarly changed by MMA to no later than 45 days before the first Monday in April.

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.

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 bid) and the monthly benchmark amount. 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 in enrollees' MSAs in a given service area, since the uniform premium amount will be subtracted from the uniform benchmark amount for every enrollee in the plan service area.

While monthly premiums are uniform within a plan, 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. As noted above, we invite comments on improved methods for making payments to MSA plans.

8. Special Payment Rule for Federally Qualified Health Centers (§ 422.316)

MMA added a new 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 to pay and agree to 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.

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 are reflected in proposed § 422.318, which otherwise retains existing language from subpart F applicable only to subsection (d) hospitals.

10. Special Rules for Hospice Care (§ 422.320)

Proposed § 422.320 revises 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. Previously, no payment was made to an MA organization on behalf of a Medicare enrollee who had elected hospice care under § 418.24 except for the portion of the payment applicable to the additional benefits. Now the MA organization will be paid the portion of the payment attributable to the beneficiary rebate 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 plan 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 plans do provide a service similar to hospice known as "end-of-life-care."

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 at § 422.268. Section 422.322(a)(2) has been 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) (which are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund).

12. Payments to MA Organizations for Graduate Medical Education Costs (§ 422.324)

These provisions are identical to the current MA provisions in subpart F at § 422.270, and require 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.

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

(If you choose to comment on issues in this section, please include the caption "Subpart I—Organization Compliance with State Law and Preemption by Federal Law" at the beginning of your comments.)

The MMA amended section 1856(b)(3) of the Act relating to Federal preemption of State law. Before this amendment, section 1856(b)(3) of the Act provided for two types of preemption, general and specific. Section 1856(b)(3)(A) of the Act provided that State laws that were inconsistent with M+C rules were preempted. Section 1856(b)(3)(B) of the Act provided that, even if a State law did not conflict with an M+C standard, it was preempted if it addressed one of four specified areas (benefit requirements, including cost-sharing rules; requirements relating to the inclusion or treatment of providers; requirements concerning coverage determinations and related appeals and grievance processes; and requirements relating to marketing materials and summaries and schedules of benefits concerning M+C plans).

Thus, the presumption was that a State law was *not* preempted if it did not conflict with an M+C requirement, and did not fall into one of the four specified categories. MMA reversed this presumption, providing that State laws are presumed to be preempted unless they fall into two specified categories. Specifically, section 1856(b)(3) of the Act now states that "the standards established under this section shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency)." The reason for such broad preemption authority is that the Congress intended that the MA program, as a Federal program, operate under Federal rules. There has been some confusion in recent court cases with respect to the preemption of State laws. Therefore, this broad preemption would apply prospectively, that is, it would not affect previous and ongoing litigation related to preemption of State laws. Furthermore, we believe the Congress broadened this authority to facilitate the operation of regional PPOs, which may have service areas that cross State lines.

We note that the Conference Report makes it clear that the Congress intended to broaden the scope of preemption through this change. Thus, we 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.

If a State requirement could be considered to relate to State licensing simply because the State could revoke a health plan's license for a failure to meet the requirement, this would mean that States could impose virtually any requirement they wished to impose without the requirement being preempted. This would extend even to State laws that were specifically preempted under the pre-MMA version of section 1856(b)(3) of the Act, such as benefit requirements, rules regarding the inclusion and treatment of providers, and rules regarding coverage decisions and related grievances and appeals. Because we believe that it is clear that the Congress intended to broaden the scope of Federal preemption, not to narrow it, we also believe that the exception for laws relating to State licensing must be limited to requirements for becoming State licensed (such as filing articles of incorporation with the appropriate State agency, or satisfying State governance requirements), and not extended to rules that apply to State licensed health plans.

Upon review of this regulation, we do not believe that the language in existing paragraph (c) of § 422.402 is necessary. Section 422.402(c) currently states that nothing in this section may be construed to affect or modify "any other law or regulation that imposes or preempts a specific State authority." We do not believe that this paragraph has any real effect, since the real issue would be whether the preemption in section 1856(b)(3) of the Act is controlling on the matter. This analysis would be unaffected by language in a regulation implementing section 1856(b)(3) of the Act. We therefore are proposing to remove the current § 422.402(c).

We therefore propose to revise § 422.402 to clearly state that the MA standards supersede State law and regulation with the exception of licensing laws and laws relating to plan solvency. Accordingly, with the exceptions of State licensing laws or State laws related to plan solvency, State laws do not apply to MA plans offered by MA organizations.

MMA also amended section 1854(g) of the Act, which prohibits States from imposing taxes on premiums paid to MA Organizations by us. Section 232 of

the MMA amended section 1854(g) of the Act to provide that States are also 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. We have incorporated this clarification at § 422.404(a).

Subpart J—Special Rules for MA Regional Plans

(If you choose to comment on issues in this section, please include the caption "Subpart J—Special Rules for MA Regional Plans'' at the beginning of your comments.)

We are proposing a new Subpart J which would implement the provisions in the new section 1858 of the Act. Section 1858 of the Act sets forth the special rules that apply to new regional MA plans. We note that the regional MA plans would have many similarities with local MA plans. For example, both regional and local MA plans would be subject to the same process of bidding against a "benchmark'' amount. In the case of regional plans, however, the benchmark amount would be region-wide, based on a weighted average of the benchmark amounts for the payment areas in the region in question, and (unlike local plans) including plan bids as a determinant of the benchmark. This methodology is set forth in sections 1853 and 1854 of the Act, and would be implemented in subparts F and G of part 422, as discussed in the discussions of those two subparts above.

The Congress has also provided for a number of unique financial and administrative incentives designed to support the introduction of regional PPO plans. These incentives would assist plans as they enter this new line of business and learn the market dynamics of serving beneficiaries across larger geographic areas. We have placed many of the special regional PPO requirements and incentives in subpart J.

However, there are certain provisions relevant to regional MA plans that are not located in subpart J that we also note below to assist the reader in identifying the unique features of MA regional plans, which are required to be structured as preferred provider organizations (PPOs).

To encourage the formation of regional plans, a two-year moratorium is established on new local preferred provider plans from January 1, 2006 until December 31, 2007. PPOs that exist prior to this date (including demonstration PPOs) can continue and expand enrollment in their existing service area (*See* § 422.451). Regional MA PPO plans also would have certain mandatory features to encourage beneficiary enrollment. For example, MA regional plans, to the extent they use deductibles, would have a single deductible for all original Medicare fee-for-service benefits (Part A and Part B) received through providers in the plan's provider network ("preferred providers'').

In addition, beneficiaries in regional plans would have an annual catastrophic cap on their out-of-pocket spending for both in-network and out-of-network costs of Part A and B benefits. (*See* section 1858(b) of the Act which is implemented in § 422.112 of subpart C of this proposed rule.) Note that both the single deductible and the annual cap on out-of-pocket spending would be part of a cost sharing structure in which the aggregate actuarial value of the cost sharing across the enrolled population of the plan is equivalent to the aggregate level of Medicare FFS cost sharing. That is, on average enrollees in MA regional plans are paying the same level of cost sharing as they would if the plan's cost sharing structure were the same as Medicare's, but individual enrollees with higher than average health care costs may be paying less in actual cost sharing than they would under Medicare's cost sharing structure because of the catastrophic cap.

A network adequacy fund would also be implemented that would assist regional plans in forming adequate networks, particularly in rural areas. This fund would provide enhanced payments for certain essential hospitals that accept enrollees in regional PPOs. (*See* section 1858(h) of the Act, which is implemented in § 422.112 of subpart C of this proposed rule.)

As discussed in more detail below, the new subpart J would contain regulations that address: (1) The provision in section 1858(a) of the Act for the establishment of MA regions, including the principal factors we must balance in selecting these regions; (2) the availability of a temporary waiver of the State licensure requirement; (3) the MA regional plan risk corridors; and (4) the availability of a stabilization fund for MA regional PPO plans.

1. Establishment of the MA regions (§ 422.455)

In this proposed section we would implement section 1858(a) of the Act, which requires us to establish the regions that would constitute the service areas for the regional MA plans. Under the statutory requirements of section 1858(a) of the Act, MA regional plans would be required to serve an entire region. We would announce the MA regions by January 1, 2005. The regional plan would become operational on January 1, 2006. The statute also specifies 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. The statute also requires that we establish between 10 and 50 regions within the 50 States and the District of Columbia. To assist us in developing the MA regions, we must conduct a market survey and analysis, including an examination of current insurance markets. We may periodically review MA regions and, based on the review, revise the regions. An MA regional plan may be offered in more than one region, including all regions.

In the MMA Conference Agreement, the Congress has also provided some general suggestions for us in establishing the MA regions. To the extent possible, the conferees suggest that each region include at least one State, that the regions not divide States across regions, and include multi-State Metropolitan Statistical Areas in a single region.

At this point, we would propose also to consider the following factors in selecting the MA regions:

- The number of eligible Medicare beneficiaries residing in each region.
- The regional payment rates would be reasonably similar.
- To the extent possible each region would contain a balance between rural and urban areas.
- Consideration would also be given to the inclusion of health care market areas within regions.
- To the extent possible, PPO regions should be the same as drug regions.

Due to the requirement to conduct a market analysis, we are not proposing specific regions at this time. We are interested in receiving comments regarding how we can best address the considerations discussed above in selecting the regions in order to meet our goal of maximizing beneficiary access to MA regional PPO plans. We are also interested in comments related to other factors we should consider in defining regions. Our objective is to obtain broad public comment on the supporting information and analysis that will be used by us to inform our selection of the regions. We held a public meeting in Chicago, Illinois on July 21, 2004 to discuss options for PPO and PDP regions. The meeting materials containing preliminary regional PPO and PDP options may be found at *http://www.cms.hhs.gov/medicarereform/mmaregions.*

2. Risk Sharing (§ 422.458)

Section 1858(c) of the Act provides that Medicare 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 1858(c) of the Act defines which plan costs ("allowable costs'') and plan revenues ("target amount'') we may consider to determine risk-sharing payments to regional MA plans. Under section 1858(c)(1)(D) of the Act, a subset of supplemental benefits called "rebatable integrated benefits'' must be included on both the cost and revenue sides of risk corridor calculations. Proposed § 422.258(a) defines rebatable integrated benefits 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. We discuss in more detail below what supplemental benefits may be considered rebatable integrated benefits.

Proposed § 422.258(a) would implement section 1858(c)(1)(C) of the Act by defining allowable costs for an MA regional plan as the total amount of costs incurred in a year in providing benefits covered under the original Medicare fee-for-service program option for all enrollees 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.

Proposed § 422.258(a) would implement section 1858(c)(2)(D) of the Act by defining the target amount for an MA regional plan as the total amount of payments made to the organization for enrollees in the plan for the year (which means payments attributable to the bid for 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, plus 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 and rebatable integrated benefits.

Proposed § 422.258(b)(2) implements 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 are the only supplemental benefits that can be included in a plan's allowable costs. We would have discretion to evaluate whether certain rebatable benefits should be included in allowable costs for risk corridor calculations. (Note that rebatable integrated benefits must be offered as mandatory supplemental benefits because, as discussed in subpart F, rebate dollars cannot be used to fund optional supplemental benefits.)

Rebatable integrated benefits. Premium reductions funded by rebates (that is, reductions in the Part B, Part D, and/or supplemental premiums) would not be considered rebatable integrated benefits because premium reductions do not involve expenditures by the plan; they represent foregone revenue. However, any rebate-funded additional health benefits not covered by original Medicare would be considered rebatable integrated benefits.

We invite comment on the issue of whether reductions in cost sharing funded by rebate dollars should be considered rebatable integrated benefits. One approach is to consider cost sharing reductions as an expense to the plan and thus not foregone revenue, that is, if the enrollee pays a smaller share of provider costs, the plan pays a larger share. The second approach is to define a supplemental benefit as a rebatable integrated benefit only if it would not have an impact on the utilization of basic benefits. This approach is parallel with the Part D prescription drug benefit, where CMS does not share risk beyond the basic benefit. Under this second approach, then, we would not share risk on non-Medicare benefits with utilization effects on Parts A, B, and D benefits. That is, cost sharing reductions would not be rebatable integrated benefits.

If we take the first approach, an issue arises. For mandatory supplemental benefits that are non-Medicare benefits and require expenditures by the plan yet are only partly funded by rebate dollars, we would consider whether and how to include only the rebate-funded portion of the costs and revenues in the risk corridor calculation, as a rebatable integrated benefit. We invite comment on this issue, including any concerns about the burden of identifying the relevant portions of costs and payments.

If we take the second approach, a different issue arises. Since the pricing of supplemental benefits includes the utilization effect of cost-sharing reductions on benefits under the original Medicare fee-for-service program, the target amount would not reflect these costs. However, unless an adjustment is made, allowable costs would include the utilization effect of the supplemental benefits. Therefore, we would require that allowable costs be reduced by an estimate of the utilization effect of supplemental benefits. We would assume that any such adjustment would be consistent with the assumptions used in originally pricing the supplemental benefits.

We invite comment on approaches for determining what supplemental benefits are considered to be rebatable integrated benefits.

Payment Adjustments

Proposed § 422.358(c) would implement section 1858(c)(2) of the Act relating to payment adjustments. There would 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.

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 would 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 would 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.

Conversely, 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 would reduce the total monthly payment to the plan by 50 percent of the difference 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 would 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.

Disclosure of Information

Proposed § 422.358(d) would implement section 1858(c)(3) of the Act relating to disclosure of information. Each contracting MA plan must provide the information that we deem necessary to carry out this section. While 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.

3. State Licensing Waiver

Proposed § 422.458(e) would implement section 1858(d), of the Act setting forth organizational and financial requirements, 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.

MA organizations ordinarily must be State licensed to bear risk in each State within a region. However, 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. We would waive the State licensing requirement to allow sufficient time for the processing of the application by the State or States where an application is pending.

This waiver can only be granted if the organization demonstrates to us that it has filed the necessary application to meet the other State's requirements. If an organization is granted a waiver, the organization would select the licensing rules of one State in the region and apply those rules to the States in which the organization did not have State licensure until the organization is licensed in all the States. In the event that the waivered MA organization's State licensure application is denied, we would extend the waiver until the end of the year or a shorter period as we determine is appropriate to provide for a transition for the enrollees in the plan or plans offered by the organization.

4. Stabilization Fund

Proposed § 422.438(f) would implement the provisions in section 1858(e) of the Act providing for the creation of a Regional Stabilization Fund. During the past several years, a number of organizations have withdrawn from the Medicare+Choice program due to changing market conditions and an inflexible statutory payment formula. Plans' costs were rising at a faster rate than Medicare payment rates. We had no discretion under the law to respond quickly to these market changes, resulting in plan withdrawals that have affected millions of beneficiaries.

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 and plan retention in MA regions with below average MA penetration. Initially, $10 billion would be available for expenditures from the Fund beginning on January 1, 2007, and these start-up funds would only be available until December 31, 2013.

Funds would be drawn from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in a proportion that reflects the relative weight that the benefits under Parts A and B represent of the actuarial value of the total benefit. Additional funds would be available in an amount equal to 12.5 percent of average per capita monthly savings from regional plans that bid below the benchmark. The additional funds would be deposited on a monthly basis into a special account in the Treasury. 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 would report to the Congress on the underlying market conditions in the regions. These reports would give the Congress time to respond to the market conditions through changes to the regions or the underlying payment system.

The funds would be available in advance of appropriations to MA regional plans in accordance with specified funding limitations. The total amount projected to be expended from the Fund in any year may not exceed the amount available in the Fund as of the first day of that year. If the use of the stabilization fund results in increased expenditures under Title XVIII, the increased expenditures would be counted as expenditures from the Fund. We would only obligate funds if the Chief Actuary of CMS, 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 would 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 would first be made from amounts made available from the initial funding.

5. Plan Entry Funding

Plan entry incentives are available for either a one-year national bonus payment or multi-year adjustments in regional payments; however, in no case can there be a regional payment adjustment if there is a national bonus for that year. In order to encourage the offering of plans in all regions, the national bonus payment would be available to an MA organization that elects to offer a regional plan in each MA region in a year, but only if a national plan is not offered in the previous year.

Funding is only available for a single year, but more than one organization can receive the incentive in the same year. The national bonus payment would: (1) Be available to an organization only if it offers plans in every MA region; (2) be available to all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and (3) be 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.

We would determine the adjusted payment amount based solely on plans' bids in the region, and the adjusted payment amount would be available to all plans offered in the region. The amount can be based on the mean, mode, median or other measure of the bids and may vary from region to region, but the payment amount would not be determined through a method that limits the number of plans or bids in the region. We expect that such an adjustment would represent a fixed percentage of the relevant measure of plan bids in the region. Such a payment adjustment would be treated as a change to the benchmark amount in that region for purposes of calculating individual plan payments and beneficiary rebates.

6. Regional Payment Adjustment

Subject to funding limitations, we would determine the period of time that funds are available for regional payment changes to encourage plan entry. If funding would be provided for a second consecutive year under this provision, we would submit a report to the Congress describing the underlying market dynamics in the region and recommending changes to the payment

methodology. Multi-year funding may be made available to all MA plans offered in a region. If this multi-year increased amount is made available to MA plans in a region, funding would not be available for plan retention in the region in the following year. Regional payment adjustments would not be taken into account when computing the underlying benchmark for the subsequent year.

7. 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. Incentives for plan retention could take the form of an increased payment to plans in regions that meet specific requirements. The requirements are: (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; (4) funds have not already been awarded for 2 consecutive years.

Any additional payment amount would be treated as if it were an addition to the benchmark amount otherwise applicable, but would not be taken into account in the computation of the benchmark for any subsequent year.

If plans receive funding under this part for a second year, we would submit a report to the Congress that describes the underlying market dynamics in the region and includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans.

The incentive for plan retention payment would 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.

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

(If you choose to comment on issues in this section, please include the caption "Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations'' at the beginning of your comments.)

Proposed changes to the existing MA provisions concerning applications and contracts are discussed below. We realize, however, that the programmatic changes contained in this proposed rule may require additional changes to existing MA contracting provisions that could reduce the administrative burden and increase the effectiveness of these provisions. We are studying this issue, requesting comments and will implement the appropriate changes in the final rule.

We are proposing that the application requirements and evaluation and determination procedures from subpart A (§ 422.6 and § 422.8) be incorporated into subpart K. As a result, the subpart K title would be changed to "Application Procedures and Contracts for Medicare Advantage Organizations.'' The application requirements from subpart A would be added as § 422.501 and the evaluation and determination procedures would be included as § 422.502, with mostly nomenclature changes. The one exception is a change to the compliance program requirements at § 422.502(b)(3)(iv)(G). We believe that mandatory reporting of potential fraud by government contractors is critical, especially in light of the corporate fraud scandals that occurred over the past several years. It is also in keeping with the Sarbanes-Oxley Act of 2002, under which the Securities and Exchange Commission adopted new regulations designed to make corporate compliance and disclosure requirements stronger and more effective. In short, we believe that the self-reporting requirements included in this rule are keeping with the change in the legal, regulatory, and business climates since the compliance program requirements were first implemented. We propose adding the following text to § 422.502(b)(3)(iv)(G): If the MA organization discovers from any source evidence of misconduct related to payment or delivery of health benefits under the contract, it must conduct a timely, reasonable inquiry into that misconduct. If, after reasonable inquiry, the MA organization has determined that the misconduct may violate criminal, civil, or administrative law, the MA organization must report the existence of the misconduct to the appropriate Government authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. If the potential violation relates to Federal criminal law, the civil False Claims Act, Federal Anti-Kickback provisions, the civil monetary penalties authorities (primarily under section 1128A and 1857 of the Social Security Act), or related statutes enforced by the HHS Office of Inspector General, the report must be made to that Office. The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees, etc.) in response to the potential violation referenced above.

The existing § 422.501 would be redesignated as § 422.503, the existing § 422.502 would be redesignated as § 422.504, and the existing § 422.504 would be redesignated as § 422.505.

We also propose to add a new paragraph (1) To what would now be § 422.503(b), clarifying that the completion of an application as described in § 422.501 is a condition necessary to contract as an MA organization. The current paragraphs (1) through (5) would be re-designated as paragraphs (2) through (6).

We propose technical corrections to what would now be § 422.503(b)(4)(ii) and § 422.503(b)(4)(vi)(F). In § 422.503(b)(4)(ii), we replaced the word "plan'' with the word "implement.'' In § 422.503(b)(4)(vi)(F), we replaced the word "provisions'' with the word "procedures.'' We also propose technical corrections to newly redesignated § 422.503(b)(6) and § 422.503(b)(6)(i). The current language states "The M+C organization's contract must not have been terminated by CMS under § 422.510 within the past 2 years unless * * *.'' Section 1857(c)(4) of the Act, however, which is implemented in this provision, applies to plans that elect to non-renew their contracts, not plans terminated by us. We accordingly propose to revise the newly redesignated § 422.503(b)(6) introductory text to read "The MA organization's contract must not have been non-renewed under § 422.506 within the past 2 years unless * * *.'' Although newly redesignated § 422.503(b)(6)(i) already refers to the MA organization initiating the end of the contract, it uses the term "terminated'' and we propose to change it to "non-renew,'' which is the term used in the regulations. We would revise § 422.503(b)(6)(i) accordingly.

We are proposing several technical corrections to § 422.504 (formerly § 422.502). The first corrections would be to proposed § 422.504(e)(4). We

propose to clarify that paragraph (e)(4) introductory text provides that "HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the end of the final contract period * * *" The previous language was not clear that this provision applied after CMS and the MA organization severs their relationship. In paragraph (e)(4)(ii) we propose to add "allegation of" to clarify our use of the word fraud. In paragraph (e)(4)(iii) we propose to add "or similar fault" after the word "fraud." We propose to remove § 422.504(f)(2)(vii) since MSAs are no longer demonstrations. Section 422.504(f)(2)(viii) would be redesignated as § 422.504(f)(2)(vii). We propose to revise § 422.504(i)(3)(ii) by removing § 422.504(i)(3)(ii)(A) "The M+C organization oversees and is accountable to CMS for any functions or responsibilities that are described in these standards." It is not necessary for this provision to be included in contracts between MA organizations and providers. The MA organization is already held accountable for adhering to and otherwise fully complying with all terms and conditions of its contract with us through what would now be § 422.504(i)(1), "MA organization relationship with related entities, contractors, and subcontractors." In addition, there is no statutory requirement that this provision appear in contracts between MA organizations and downstream providers.

Based on the bidding process and establishment of benchmarks, we propose to no longer allow an MA organization's contract to be effective at any time other than the first of the contract year.

We are proposing to move the notification date for nonrenewal of contracts in § 422.506(a)(2)(i) and § 422.506(a)(3) to the first Monday in June to match the bid submission date. We are also proposing to move the notification date for nonrenewal of contracts in § 422.506(a)(2)(i) and § 422.506(a)(3) to the first Monday in June to match the bid submission date. We are also proposing a clarifying change to § 422.506(a)(2)(ii) by adding "prior to issuance" after the existing "CMS approval."

We are proposing to revise § 422.510(a)(4) by adding the phrase "There is credible evidence" in front of the existing language about an MA organization that committed or participated in fraudulent or abusive activities. We have also added the word "false" in front of "fraudulent."

We are proposing technical and clarifying changes to § 422.520, "Prompt payment by MA organization." The phrase "from non-contracted providers" would be added to § 422.520(a)(3) to clarify that this provision was intended to refer only to claims from non-contracted providers (versus contracted providers). Claims by contracted providers are addressed in § 422.520(b). We also propose to add a new § 422.520(b)(2), providing that the MA organization is obligated to pay contracted providers according to the terms of the contract between the MA organization and the provider. Finally, we are proposing that a new paragraph (d) be added clarifying that a CMS decision not to conduct a hearing under paragraph (c) of § 422.520 does not disturb any potential remedy under State law for the non-contracted provider, or affect the provider's rights to pursue payment as provided under section 1866(a)(1)(O) of the Act. Section 1866(a)(1)(o) of the Act establishes that Medicare participating providers who do not have a contract establishing payment amounts agree to accept, as payment in full for covered services provided to MA beneficiaries, an amount equal to the amount the provider would have collected under fee-for-service Medicare if the beneficiary was not enrolled in an MA plan.

Finally, we are proposing a new § 422.527, addressing payments to Federally Qualified Health Centers (FQHC). MMA added a new section 1857(e)(3)(A) of the Act, which applies only to 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. Under such a contract, the FQHC must accept this payment as payment in full, except for cost sharing allowed by the contract, and the supplemental Federal payment now provided for in section 1833(a)(3)(B) of the Act, which was added by MMA. We believe that the statute did not intend to require MA organizations to contract with FQHCs. The intent of the statute was to establish payment terms between MA organizations and FQHCs. If an MA organization chooses to contract with an FQHC, the payment terms would be as described in § 422.527.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

(If you choose to comment on issues in this section, please include the caption "Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract" at the beginning of your comments.)

We are studying the modification of existing change of ownership provisions in order to reduce the administrative burden of these requirements and to increase the effectiveness of these provisions. We request comments regarding how these provisions can be modified to accomplish these objectives. In particular, we seek comments regarding: the situations which constitute a change of ownership, how these provisions should be applied to large companies with multiple business units, the notification requirements related to a change of ownership, the novation agreement provisions, and the provision related to the leasing of facilities.

Subpart M—Grievances, Organization Determinations, and Appeals

(If you choose to comment on issues in this section, please include the caption "Subpart M—Grievances, Organization Determinations, and Appeals" at the beginning of your comments.)

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, this proposed rule generally proposes to maintain the existing regulatory requirements in subpart M of part 422, which implement these statutory requirements. However, in addition to making the minor changes needed to conform these subpart regulations to MMA terminology and other provisions, we also have undertaken a review of the existing MA grievance and appeal requirements to identify needed refinements. Also, as discussed at the end of this section of the preamble, we are proposing 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.

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. As discussed in detail below, 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 (a decision that is unfavorable to the MA enrollee, in whole or in part) 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 each type of plan—including coordinated care plans such as HMOs and PPOs, non-network MSA plans, and PFFS plans.

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)

MMA amended section 1852(g)(5) of the Act to incorporate the provisions of section 1869(b)(1)(E)(iii) of the Act, which 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).'' Although other provisions in section 1869 of the Act do not apply to MA appeals, the existing MA regulations incorporate regulations implementing section 1869 of the Act in implementing the appeals provisions in section 1852(g) of the Act. Specifically, the existing MA regulations incorporate 42 CFR part 405, subparts G and H, and 20 CFR part 404, subparts J and R. Since we will be implementing revisions to section 1869 of the Act in a separate rulemaking creating a new subpart I of part 405, we propose to revise the cross-references for MA appeals at § 422.560(a)(3), § 422.561, and § 422.562 accordingly. We note that when revisions are made to the section 1869 regulations implementing the MMA changes in the way the amount in controversy is determined, these revised provisions will apply to MA appeals.

As noted above, section 1852(g) of the Act requires an MA organization to establish procedures for hearing and resolving disputes between the organization and its Medicare enrollees concerning organization determinations.

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. Section 422.566(b) lists actions that are organization determinations, and we are proposing to explicitly specify in that section that a reduction of services constitutes an organization determination that an enrollee may appeal. We fully recognize that reductions of care are a natural outcome of medical services, particularly when an enrollee is progressing along an expected care continuum. When this issue was raised in past rulemaking vehicles, commenters stated that routine notifications in reduction of care situations would confuse enrollees, perhaps causing them to believe that something was wrong in common situations where the discontinuation of services was fully planned and appropriate. We agreed to consider this issue in future rulemaking. The approach proposed here basically clarifies existing policy, under which reductions in service were always appealable issues. Notice requirements would apply whenever an enrollee disputes the reduction. Under those circumstances, MA organizations would consider the disputed discontinuation of service a new request for an organization determination under § 422.566. 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.

Standard timeframes and notice requirements for organization determinations (§ 422.568)

The only substantive change we are proposing in § 422.568 is the elimination of the practitioner's notice requirement currently set forth in § 422.568(c). This section requires 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. This provision has proven problematic to implement and impossible to monitor. Instead of requiring practitioners to provide notices to enrollees at each patient encounter, we would propose instead to require MA organizations to provide specific information in the plan's Evidence of Coverage about enrollees' rights when they are denied services in physician office settings.

We are also proposing to modify § 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. This is a right that already was established under the grievance provision at § 422.564(d)(2); thus, we are merely making a conforming change.

Timeframe and notice requirements for expedited organization determinations.

Section 422.572(c) now requires that if an MA organization first notifies an enrollee of its expedited determination orally, it must mail written confirmation to the enrollee within 3 calendar days of the oral notification. The regulations concerning determinations made within standard timeframes do not require a written follow-up for favorable determinations. We propose in this regulation to revise this provision to eliminate the requirement that oral notice 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.

4. Requests for Reconsiderations (§ 422.582)

The only substantive change we are proposing regarding standard reconsiderations pertains to the manner in which a party to an organization determination would request an appeal. Proposed § 422.582(a)(1) would allow a party to request a standard reconsideration orally or in writing. We have received several requests to modify our policy on the basis that the appeals process would be more convenient and accessible for enrollees, and enable MA organizations to provide better customer service.

Currently, § 422.584(e) specifies that when an MA organization grants a request for an expedited reconsideration, it must give notice in accordance with § 422.590(d). Proposed § 422.584(e) would require 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 above for expedited organization determinations under § 422.570(d)(2)(ii), proposed § 422.590(a) and § 422.590(d)(2) would require an MA organization to 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 reconsideration. This is a right that already was established under the grievance provision at § 422.564(d)(2); thus, we are merely making a conforming change.

5. Administrative Law Judge (ALJ) Hearings, Appeals to the Medicare Appeals Council, and Judicial Review (§ 422.600 through § 422.612)

If the independent reviewer's reconsidered determination is not fully favorable to the enrollee, any of the parties listed in § 422.574 have a right to request a hearing before an ALJ, assuming that the required minimum amount in controversy is met. (Note that the MA organization does not have a right to request a hearing before the ALJ.) If the ALJ hearing does not result in a favorable determination, any party (including the MA organization) may request that the Appeals Council review the ALJ decision. Following the administrative review process, any party (including the MA organization) is entitled to judicial review of the final determination if the amount remaining in controversy meets the required threshold. As mentioned above generally, the MMA made revisions to provisions in section 1869 of the Act that address the amount in controversy required for ALJ and judicial review. Specifically, these changes provide for an inflation adjustment to these amounts, based on changes to the Consumer Price Index. MMA also amended section 1852(g)(5) of the Act to provide that these revised provisions of section 1869 also apply for purposes of MA appeals. These changes will be set forth in an upcoming final rule in new subpart I of part 405. We propose to revise § 422.600 to cross-reference these revised regulations, and make revisions to § 422.612 to reflect the fact that the amount in controversy is now subject to change.

The regulatory provisions at 42 CFR part 405, subparts G and H, and 20 CFR part 404, subpart J, concerning reopenings of appeals and Departmental Appeals Board review also historically have been cross-referenced in the managed care and M+C appeals regulations. Like other provisions of section 1869 of the Act that will be implemented in an upcoming final rule in a new subpart I of part 405, we propose to modify the cross-references for MA appeals at § 422.608 and § 422.616(a).

6. Noncoverage of Inpatient Hospital Care—Notice and QIO Review (§ 422.620 and § 422.622)

Under § 422.620(a), when an MA organization has authorized coverage of the inpatient admission of an enrollee, either directly or by delegation (or the admission constitutes emergency or urgently needed care), the MA organization (or hospital that has been delegated the authority to make the discharge decision) must provide a written notice of noncoverage when the beneficiary disagrees with the discharge decision, or the MA organization (or the hospital that has been delegated the authority to make the discharge decision) is not discharging the individual but no longer intends to continue coverage of the inpatient stay.

Section 422.620(b) now specifies that an MA organization (or, by delegation, the hospital) must obtain the concurrence of the physician responsible for the enrollee's in-patient care before issuing a notice of noncoverage to an enrollee. However, since publication of our April 4, 2003 final rule that eliminated routine discharge notices in hospitals, an enrollee's right to receive a notice of noncoverage is linked to physician concurrence only 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. Under § 422.620(a), an MA organization must issue a notice of noncoverage when an enrollee disagrees with an MA organization's decision to discharge the enrollee or discontinue coverage of the inpatient stay. Under § 422.620(b) of that final rule, we inadvertently failed to include a corresponding change that physician concurrence is necessary for discharging the enrollee rather than for issuing the notice. Therefore, we propose to revise the regulations to clarify that an MA organization's obligation to provide a notice of noncoverage when an enrollee objects to being discharged is not contingent upon physician concurrence.

We also are proposing 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 is consistent with § 422.620(a)(1)(ii), which requires the MA organization to provide a notice to the enrollee when it is not discharging the enrollee, but no longer intends to continue coverage of the in-patient stay.

7. Advance Beneficiary Notices in the MA Program

As Medicare choices have expanded, the relationships among providers, enrollees, and managed care organizations have evolved and become more complicated, often allowing for greater flexibility and choice in making decisions about care. Open access managed care arrangements, where enrollees seek services outside their provider network, or vary their provider choices through tiered cost-sharing arrangements, challenge the constraints of more traditional "gatekeeper oriented'' coordinated care models. Increasingly, MA organizations, providers, and enrollees have asked for clarification of Medicare appeal rules when disputes arise about care provided outside the traditional coordinated care model. We recognize that this is a complex issue, touching upon many other regulations that come into play during an appeal process. Those regulations might include, but are not limited to, prompt pay provisions, claims procedures, and post-stabilization requirements. Frequently, an appeal dispute involves whether the enrollee understood that the services in question might not be authorized by the MA plan or covered by Medicare.

In other cases, enrollees may wish to access services from a particular network provider, regardless of whether the plan would cover the care, leaving

the provider in an uncertain situation should the plan eventually deny approval for the care.

Nevertheless, to address these types of issues, we are soliciting comments on whether to permit or require network and non-network providers to furnish a type of advance beneficiary notice (ABN) for use when managed care enrollees access non-Medicare covered services.

We are also requesting public comments about whether managed care providers should be permitted or required to furnish an ABN-like document to alert MA enrollees to their possible liability for out of network services that would otherwise be payable by the MA plan if proper referral was obtained. Alternatively, we could require unaffiliated non-network providers to seek organization determinations from the enrollee's MA organization before providing Medicare covered services. Note that this would not include Medicare excluded services, but would include services that would be otherwise offered through the enrollee's managed care plan.

We believe that ABN-like notices could serve a role in these situations, by clarifying potential liability issues. On the other hand, we are cognizant of the possible burden and potential confusion associated with such notices. Therefore, rather than propose to require any ABNs or other related notices at this time, we believe it is preferable to first assess whether commenters believe such an approach is warranted. Thus, we welcome comments on these issues, as well as alternative recommendations.

8. Appeal Procedures for Cost HMO/CMPs and HCPPs

As discussed in detail above, the MMA specifies that, with respect to appeal and grievance procedures, the same statutory provisions that currently apply to the MA program will continue to apply to MA organizations in the future. These provisions, which have been in effect since 1998, were in turn largely based on the grievance and appeal requirements that had applied to managed care organizations that contract with us under section 1876 of the Act (as well as to health care prepayment plans that are paid under section 1833(a)(1)(A) of the Act). For example, the requirements under section 1852(g)(3) of the Act, concerning expedited organization determinations and reconsiderations essentially incorporated the expedited procedures that were issued in our April 30, 1997 final rule with comment (62 FR 23368). (That final rule established expedited processes for organization and reconsidered determinations, and clarified that the definition of an organization determination included discontinuations of service.)

However, because the BBA provided for the temporary continuation of these so-called "cost plans,'' we chose not to eliminate or revise the part 417 appeals regulations that applied to these plans. Instead, we opted to leave these regulations, found in subpart Q of part 417, in place until the availability of cost-based contractors expired in 2002, as provided by the BBA. Since that time though, the BBRA subsequently extended the sunset of the cost plans through 2004, and the policy of parallel regulations has been the source of continuing confusion during the past 6 years, particularly in the complicated and evolving world of appeal policy.

The regulations implementing the BBA provisions creating the M+C program, which were set forth in 1998 under new part 422, would now apply, as amended, to MA organizations under this proposed rule. Under the MMA, however, the conferees provided in section 234 for a potentially indefinite extension of reasonable cost contracts, thus eliminating any certainty regarding the previously scheduled sunset of these contractors. (Cost HMO and CMPs will be allowed to operate until 2008, and could operate indefinitely after that date if there are not two MA plans of the same type, that is, two local or two regional non-PFFS plans operating in the cost contract's service area.) Therefore, we believe it is appropriate to revisit the issue of whether these nonrisk plans should be required to comply with the part 422 grievance and appeal requirements.

Note that on October 25, 2002, we solicited comments on whether HCPPs and the remaining cost HMOs/CMPs should follow the MA appeals and grievance procedures under subpart M of part 422. This proposal took into account that the MA appeals processes provide enhanced enrollee protections, such as shorter timeframes for appeals decision making and streamlined notice procedures. We received comments both supporting and opposing applying the part 422 regulations to cost HMO/CMP organizations. Since that time, based both on the comments we received and further study of the issue, we have concluded that it would be appropriate for organizations offering cost plans to follow the same procedures that would apply to MA organizations, as set forth in subpart M of this proposed rule. Again, this decision is also informed by the MMA's reliance on the existing statute's appeals procedures as the basis for the MA program, as well as the indefinite extended existence of these plans.

Therefore, we are proposing 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 have taken into account that a key difference between cost plans and M+C 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 skilled nursing facilities (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 (subpart I, 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 organizational determination under a cost plan, as defined in § 417.606, enrollees would appeal through the cost plan's appeal process. The plan 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 enrollee cost sharing associated with the services. As discussed above, this process would follow the same rules that apply to other MA organizations, as set forth in subpart M of part 422.

Although the appeals procedures set forth in part 417 and part 422 are largely similar, it is important to note that there have been some recent changes to the part 422 regulations that would apply to cost plans for the first time under this proposal. These changes primarily involve § 422.620, § 422.624, and § 422.626 of subpart M and were set forth in the April 4, 2003 final rule, "Improvements to the Medicare+Choice Appeals and Grievance Procedures,'' also known as the Grijalva regulation. (See 68 FR 16652.) The changes set forth in that final rule established new notice and fast-track appeal procedures for enrollees when an MA organization decides to terminate coverage of its provider services. We are expecting to publish a final rule establishing parallel notice and appeal provisions for original Medicare beneficiaries.

The effect of this proposed rule would be to ensure that all Medicare beneficiaries enjoy the same notice and appeal rights in cases of terminations of Medicare services furnished by hospitals, SNFs, home health agencies, and comprehensive outpatient rehabilitation facilities. Absent these proposed changes, the new notice and fast-track review procedures would apply for all MA enrollees, and for all original Medicare beneficiaries, but would not apply to members of cost plans. This scenario would be confusing and unfair not only for beneficiaries, but also for the providers who are responsible for distributing the service termination notices. Thus, we believe that establishing a level playing field for all Medicare beneficiaries and providers is the only appropriate policy.

9. Federal Preemption of Grievances and Appeals

Under preemption provisions in the BBA that applied to the M+C program, State laws or standards that were stricter than Federal M+C standards generally were not preempted unless they conflicted with, or otherwise precluded compliance with, Federal M+C requirements. However, as noted above in the discussion of subpart I, the BBA also provided for specific preemption of State standards in three specified areas: benefit requirements (rules regarding cost-sharing and rules regarding marketing materials describing benefits were later added to this category), rules regarding the inclusion or treatment of providers (for example, "any willing provider laws''), and rules regarding coverage, along with related appeals and grievance mechanisms. In the M+C regulations, we interpreted the last category to preempt only appeals and grievance mechanisms that addressed the issue of whether services were covered. Thus, general "grievance'' mechanisms addressing issues other than coverage were only preempted to the extent they were inconsistent with, and prevented compliance with, M+C requirements.

As noted in our discussion of subpart I above, 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 do not believe that the new preemption standard would have any effect on coverage appeals provisions. Because our regulations provide for doing so, we would continue to defer to State law on the issue of authorized representatives of enrollees in the appeals process. We do not believe that the Congress intended for the Secretary to regulate matters such as this that he is not equipped to address (for example, spousal rights, powers of attorney, or legal guardianship). Often, authorized representative matters are non-Federal issues.

We are concerned, however, that with State grievance requirements now preempted, we may need to reexamine our Federal grievance requirements. Since 1997, we have engaged in a significant rulemaking activity concerning the extent to which the Secretary should regulate health plans' grievance procedures. (Issues not related to whether services are covered, or how much an enrollee has to pay for services.) We solicited comments on this issue in the M+C interim final rule on June 26, 1998 (63 FR 35030), as well as the M+C final rule on June 29, 2000 (65 FR 40169). The preamble to the interim final rule alerted the public that we would establish a grievance procedure through proposed rulemaking, and sought comments on ways to make it meaningful. Until publication of that proposed rule, M+C organizations by default were subject only to the general Federal requirement that M+C organizations have grievance mechanisms in place, and any State requirements that applied to complaints unrelated to coverage determinations.

On January 24, 2001, we developed a proposed rule that recommended establishing more specific grievance provisions (66 FR 7593). In the proposed rule, we proposed that M+C organizations would notify enrollees of their decisions as expeditiously as the case required, but no later than 30 calendar days after receiving a complaint. In conjunction with the time frame, we also proposed that the M+C organization be permitted to extend the time frame by up to 14 calendar days if the enrollee requested the extension, or if the organization justified a need for additional information and the delay was in the interest of the enrollee. We also proposed that grievances made orally would be responded to orally or in writing, unless the enrollee specifically requested a written response. If grievances were made in writing, then the response would need to be in writing. In addition, we proposed that M+C organizations would be required to describe the enrollee's right to seek a review by a Quality Improvement Organization (QIO) if the grievance involved a quality of care issue. For any complaint involving the QIO, the organization would be required to cooperate with the QIO in resolving the complaint. We further proposed a 72-hour expedited grievance process for complaints about certain procedural matters in the appeals process. The proposed grievance procedures concluded with the requirement that organizations would have a system to track and maintain records on all grievances.

Taking into account the various comments that we received, we published a final rule on April 4, 2003 that only required an expedited grievance process for complaints involving appeals, and recordkeeping (68 FR 16652). We agreed with several commenters that the regulations did not need to be too prescriptive because "many States have processes to address complaints that involve issues other than coverage, and State grievance procedures, unlike appeal procedures, are not specifically preempted by Federal rules'' (68 FR 16652 and 16661). We further reasoned that we should "allow M+C organizations the flexibility needed to maintain current procedures that comply with State requirements.'' *See id.*

In light of section 232(a) of the MMA, which provides that the standards established under the MA program supersede State law or regulation with respect to MA plans, we once again solicit comments on whether we should adopt the above provisions proposed in January 2001 that did not make it into the April 2003 final rule. Such provisions would include the method for filing and the notification and time frames associated with grievances. We also solicit comments on whether we should impose, as a Federal MA requirement, that MA organizations meet State grievance requirements. Such a requirement would have the effect of restoring the status quo before the enactment of the MMA.

We also have considered how the changes made by section 232(a) of the MMA apply, if at all, to State tort or contract law that could affect MA organizations. Our previous position under the M+C program was that State tort or contract remedies may be available to enrollees whose coverage determination disputes go through the Medicare appeals process. We continue to believe that generally applicable State tort, contract, or consumer protection law would not be preempted under section 232(a). First, we believe that section 232(a) was intended to preempt State standards governing health plans, not generally applicable State laws, such as labor laws, employment law, tax laws, etc. that incidentally could have

applicability to MA organizations. We believe that contract laws and tort laws fall in this category, as they do not apply to the organization based on its status as a health plan, but instead apply generally. Even specific types of tort laws, such as malpractice law, apply generally to all medical practitioners, not to health plans specifically.

We also note that tort law, and often contract law, generally are developed based on case law precedents established by courts, rather than statutes enacted by legislators or regulations promulgated by State officials. We believe that the Congress intended to preempt only the latter type of State standards.

Under principles of Federalism, and Executive Order 13132 on Federalism, which generally requires us to construe preemption narrowly, we believe that an enrollee should still have State remedies available in cases in which the legal issue before the court is independent of an issue related to the organization's status as a health plan or MA organization.

10. Employer Sponsored Benefits and Appeals

When an employer, by contracting with an MA plan, provides health care 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 would fall under the requirements of part 422 of our proposed regulations, with respect to Part C benefits.

In drafting these rules, we consulted with the Department of Labor (DOL), employer groups, and the health plan industry in trying to eliminate unnecessary Federal regulation of claims and appeals issues that impact matters within the jurisdiction of both DOL and DHHS. Based on our experience, we have reason to believe that some Medicare eligible individuals may receive integrated health care benefits, that is, Part C benefits through an MA plan and supplemental benefits through an ERISA-covered plan. For example, an employer-sponsored plan may pay the cost-sharing amount for a covered item or treatment offered by an MA plan. Clearly, if the enrollee had a dispute about Part C coverage, he or she could file an appeal with the MA plan. If the enrollee's dispute involved only the amount of cost sharing paid by the employer-sponsored plan, he or she would file an appeal in accordance with the procedures of the ERISA covered plan. In some cases, however, the dispute might involve independent coverage decisions under both Part C and the ERISA plan, possibly necessitating parallel appeal procedures on the same case. In this regard, we are soliciting comments on whether, and to what extent, the application of parallel procedures in this context might be a problem for plans, employers, and/or eligible individuals. We also are soliciting suggestions for addressing problems, if any, resulting from the application of parallel procedures.

Subpart O—Intermediate Sanctions

(If you choose to comment on issues in this section, please include the caption "Subpart O—Intermediate Sanctions'' at the beginning of your comments.)

We are proposing a technical correction to § 422.752(a)(8). "Entity'' was inadvertently left out of the regulation text. We are proposing that paragraph (a)(8) introductory text would read "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 individual or entity) for the provision of any of the following.''

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-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.

Section 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 422.506 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 422.568 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, subpart I of this chapter for a description of the procedures to follow in requesting judicial review.

Section 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 another CMS approved election method and gives 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).

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.

(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) The beneficiary has a right to submit any information or explanation that he or she may wish to submit to the MA organization.

(d)(3)(iii) 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.

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 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 or the SSA.

Section 422.620 How Enrollees of MA Organizations Must Be Notified of Noncovered Inpatient Hospital Care

(c) 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.

Section 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 to allow the plan to file designated marketing materials with CMS 5 days before their distribution.

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

(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 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 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

(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.

The burden associated with this requirement is the time and effort necessary for the plan to submit the required bid materials to CMS. 350 MA

organizations offering 400 plans 100 hours per plan bid 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 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.

The burden associated with this requirement is the time and effort necessary for a plan to 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–P], *Christopher_Martin@omb.eop.gov.* Fax (202) 395–6974.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

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 proposed rule with an effect on the economy of $100 million or more in any one year. While we do not believe that this proposed rule will have independent effects of this magnitude, the Medicare Advantage program taken as a whole will have effects that far exceed this threshold. Since this rule, once issued in final form, 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, combined with an Initial Regulatory Flexibility Analysis ((IRFA), 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 proposed 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 IRFA, and some effects of the legislation (for example, on Medigap plans) are analyzed in more detail in that preamble.

The Prescription Drug, Improvement, and Modernization Act of 2003 (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 preferred provider organization (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 $24.8 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 proposed rule is to implement the statutory provisions of Title II of the MMA, which deal with the Medicare Advantage program. Insofar as the proposed 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 our proposed 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—particularly the section dealing with alternatives considered—discuss these types of issues in greater detail. The proposed rule also introduces changes to Medicare private health plan requirements which, 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.)

1. Objectives of the Proposed Rule

The primary goal of the MMA is to expand the health plan choices available to Medicare beneficiaries. There is also the expectation that private 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.

Regional Plans. The introduction of regional plans, and the payment policies that apply to such plans, attempt to address both the payment issues affecting plan participation and the structural issues that have prevented greater access to plans. There were two

primary motivating factors in the decision to use a regional PPO approach as one of the means of achieving the MMA goals of increased plan participation and increased beneficiary enrollment in private plans. One factor is that the regional approach requires plans to serve extensive geographic areas specified by CMS. This is a departure from the practice of allowing private plans to pick and choose the counties in which to offer Medicare plans, which will continue to be the policy for local MA plans. The regional service area approach seeks to ensure that areas not heretofore served by private plans in Medicare—particularly, rural counties—will have private, coordinated care plan options available (*see* the MMA conference report discussion of section 201 at pp. 90–91).

The PPO Model. The other motivating factor in choosing the regional approach relates to the choice of the PPO model as the structure for regional plans. The choice of this model is partly a consequence of the decision to require coverage of large geographic areas. Other types of health plans, such as plans that rely exclusively on networks of employed or contracted providers (for example, the more traditional health maintenance organization models) have had difficulty forming viable networks in rural areas. The cost of the infrastructure required in the operation of such a model has also acted as a barrier to serving areas in which enrollment levels would be too low to warrant the necessary level of investment. Another factor in choosing the PPO model reflects consumer preference as seen in the commercial sector, where the PPO model is the model of choice in the employment-based health care market. PPOs are preferred over HMOs by consumers because of their less restrictive provider access, and PPOs are preferred over indemnity FFS plans because they do employ managed care techniques and differential cost sharing to control costs, and there is quality assurance.

Promoting Competition. One of the purposes of the MMA is to promote plan competition, which in turn is expected to lead to greater efficiency among plans and more benefits for enrollees. Certain features of the MMA that promote plan participation are of limited duration in the expectation that plan entry will occur: for example, though plan payments increased effective March of 2004, the provision by which the Government receives 25 percent of the savings that plans can achieve does not take effect until 2006. Similarly, many of the incentives provided to regional plans (such as risk sharing, and the entry and retention bonuses) are time-limited. In highly competitive markets where multiple plans are available to beneficiaries, there is strong evidence that competition among plans leads to improved benefits for enrollees and promotes greater plan efficiency. In an analysis of Medicare health plan benefit premiums and offerings, Pizer and Frakt found that "the effects of competition are comparable in importance to the effects of payment rates. The finding that more intense competition increases benefits and reduces premiums, although predictable from a theoretical standpoint, empirically confirms that it is possible for the Medicare Program to increase benefits without increasing spending or shifting additional costs to beneficiaries. Conversely, reduced competition would have the reverse effect. We acknowledge that competition and spending are related by the fact that lower payments can be expected to induce plan exit, thereby undermining competition. Nevertheless, this research shows that the Federal Government has a strong institutional interest in safeguarding and promoting interplan competition in the M+C Program, independent of its policy on payment rates.'' (Steven D. Pizer, and Austin B. Frakt, "Payment Policy and Competition in the Medicare+Choice Program,'' Health Care Financing Review, fall 2002, volume 24, number 1.)

General Impact. In general, the law and regulations will have a positive impact on beneficiaries. Transfer payments from the Federal Government will go towards the provision of additional 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 benefits. This will help improve the availability of health plan choices for beneficiaries. 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 fee-for-service 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 proposed regulations. For local plans, the MMA increased Medicare Advantage payment rates beginning in 2004, by using county fee-for-service 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. Note that CMS is currently implementing health status risk adjustment in a "budget-neutral'' manner and will continue to do so in 2005. The difference in payment between the total health status-adjusted payment rates and the rates adjusted only by demographic factors continues to be paid to the health plan "sector,'' 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 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 fee-for-service 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 private fee-for-service plans). In addition, the comparison is made to local values of cost-sharing in fee-for-service Medicare rather than to the current use of national values.

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 Medicare Advantage plans, regional plans must cover an entire region. Regions will be designated by CMS after a market analysis (as discussed later and in the preamble text for subpart J). To facilitate the ability of regional plans to operate in multiple States, plans can meet Federal solvency and licensure requirements for a period of time pending an organization's meeting such requirements for each State (*see* the preamble text for subpart J). In the first two years of formation of regional plans, there is a moratorium imposed on the formation or expansion of local plans that operate as PPOs.

Regional plans have various 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 will be used to encourage plan entry (including a bonus for plans operating in the entire Nation) or to prevent plans from discontinuing contracts;
- Inclusion of plan bids in determining benchmark amounts (as opposed to the benchmarks for local plans, which are comprised only of the local MA payment rates); and
- Access to additional funding payable to "essential'' hospitals (as described in the subpart G preamble text).

Other structural changes affecting Medicare health plans include provisions for plans that can exclusively serve special needs individuals, special treatment of enrollees with end-stage renal disease (paid outside of the bidding system—*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 (subpart J).

In the following section we list those areas in which CMS will exercise discretion through this rulemaking, either because the law entails a choice of options or because we have elected to exercise regulatory discretion.

3. Regulation Required in the Law

Designation of Regions. The most important feature of the MA program that the statute leaves to the discretion of CMS is to determine the boundaries for the regions in which regional MA plans will operate. Following a market analysis, CMS will designate between 10 and 50 regions, using certain guidelines stated in the MMA (as discussed in the preamble text for subpart J). Some of the issues relating to the configuration of regions are discussed later in the section on alternatives considered. The impact of the configuration of regions cannot be fully evaluated until the regions are designated. The estimates contained in this analysis (shown in Table 2, for example) are for illustrative purposes and are based on the assumption that there would be 15 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 are discussed in the alternatives considered section below.

4. CMS 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 (where the uniform, plan-specific, and proportional amount methods of determining actuarial equivalence are discussed).

Treatment of Induced Demand as a Supplemental Cost. To the extent that CMS decides to use the "plan-specific'' approach to determining cost sharing that is actuarially equivalent to that of traditional Medicare, an additional issue arises. If a plan proposes, through a supplemental benefit, to lower cost sharing included in the base package (the portion of the bid which is used to determine whether rebates or a basic premium apply), we propose that the additional expenditures arising from the induced demand caused by the cost sharing reduction be included in the cost of the supplemental benefits rather than in the cost of the base package.

That is, because cost sharing reduces utilization of services, and plan bids for the basic package are determined using the cost sharing structure of fee-for-service Medicare, if cost sharing is reduced below Medicare levels, the result is higher utilization of services, and higher expenditures. We believe these expenditures should not be included as part of the bid for the basic Medicare package. The additional expenditures would not have arisen if the cost sharing were at Medicare levels or at an actuarially equivalent level. In other words, the additional expenditures do not comprise a part of the bid for the basic benefit package as it is defined in the statute. We propose that the portion of utilization expenditures that result from the reduced cost sharing would be "paid for'' entirely as a supplemental benefit. This requirement, consistent with a parallel requirement for Part D drug coverage, assures that the determination of whether rebates or a premium is applicable is based on an "apples-to-apples'' comparison of a specific set of benefits reflecting a specific cost sharing structure.

Prohibiting Use of Rebate Dollars for the Purchase of Optional Supplemental Benefits. As stated in the preamble text for subpart F, a bidding system in which there is the possibility of rebate funds that must be spread over the entire enrolled population of a plan is difficult to implement if the rebates can be used to finance optional supplemental benefits that enrollees may decline. Because each enrollee should receive the same level of rebate value as any other enrollee of the same plan, enrollees would have to be offered a menu of options to fashion a combination of rebate possibilities to arrive at the dollar amount of rebate that the enrollee is entitled to. (This issue is discussed more fully in the preamble and the "alternatives considered'' section of this impact analysis.)

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. CMS is requesting comment on the ways in which such adjustments can be made. (This issue is also discussed in the "alternatives considered'' section.)

5. Provisions of the Proposed Rules Not Based on Specific MMA Changes

As discussed throughout the preamble, 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 private plans will increase over the next several years. We expect the absolute level of private plan enrollment to increase because of the greater availability of plans, and we expect the rate of enrollment in private plans ("penetration'') to increase because plans will be able to offer plan designs that will meet the needs of Medicare beneficiaries, 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 made by 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.

The uncertainty inherent in attempting to make projections of what might transpire in the health care marketplace is illustrated by the projections that were made for earlier legislation that brought about a major reform of Medicare health plan contracting, the Balanced Budget Act of 1997 (BBA). The BBA sought to expand the availability of private plans throughout the United States (particularly to rural areas), with the expectation that the generous benefit packages that Medicare plans had been offering would continue to be offered and would be available to more beneficiaries. It was also assumed that the new types of plans introduced in the BBA—such as provider-sponsored health plans—would proliferate. For example, in the impact analysis for the regulations implementing the Medicare+Choice program enacted in the BBA (**Federal Register**, vol. 63, no. 123, June 26, 1998), it was noted the Congressional Budget Office had projected that by 2002 there would be 125 provider-sponsored organizations enrolling one million Medicare beneficiaries, and that in particular "a significant portion of the enrollment [would] be in rural areas.'' The actual outcome was that only a handful of PSOs were formed, and, with regard to projections of increased enrollment because of the BBA, what actually occurred was a decline in enrollment due in part to payment changes made by the BBA and also due to changes in the

overall health care marketplace that affected Medicare health plans.

Recent Plan Participation and Enrollment Trends. As of June 2004 about 11 percent of beneficiaries are enrollees of Medicare risk-bearing private plans. This figure compares to a historical high of about 16 percent "penetration'' (percent enrolled) achieved in 1999. The reduced penetration is partly a function of reduced access to plans. As of January 2004, about 61 percent of Medicare beneficiaries had access to a private coordinated care plan (and 75 percent had access to a private plan if private fee-for-service plans are included among the types of available plans). In 1998 (the year in which the highest access level was attained), 74 percent of beneficiaries had access to at least one Medicare+Choice plan (there were no private fee-for-service plans in 1998).

Although the national access figure is 61 percent in 2004, 75 percent of Medicare beneficiaries residing in metropolitan counties have access to at least one MA coordinated care plan, but only 14 percent of the residents of non-metropolitan counties—where about 23 percent of all Medicare beneficiaries reside—have access to a coordinated care plan. In terms of plan participation, at the end of 1998, there were 346 Medicare risk contracts, a number that has declined to 145 coordinated care plan contracts as of March 2004 (though some of the decline is attributable to consolidations within a State). Because in 1999 seventy-two percent of beneficiaries resided in a county in which there was at least one M+C coordinated care plan, the penetration rate in areas in which plans were available was an effective rate of 22 percent (with the "effective'' penetration being the penetration only among those beneficiaries residing in areas in which there were operating plans). As of 2004, the effective penetration rate is 17 percent, with 4.6 million enrollees and a 61 percent level of availability of plans. This decline in "effective penetration'' is partly the result of a decline in generosity of plan benefit offerings as statutorily set payments did not keep pace with plan costs. For example, while in 1999, 61 percent of the Medicare population (85 percent of those with access) lived in a county in which there was a Medicare+Choice plan with no plan premium, by 2003 the figure declined to 29 percent of beneficiaries living in a county with a zero premium plan (50 percent of those with access). (On the decline in benefits and rise in cost sharing in private plans, see, for example, Marsha Gold and Lori Achman, "Average Out-of-Pocket Health Care Costs for Medicare+Choice Enrollees Increase 10 Percent in 2003,'' Commonwealth Fund Issue Brief number 667, August 2003, available at *http://www.cmwf.org,* as well earlier studies of a similar nature cited therein).

Issues in Predicting Beneficiary Behavior. At the individual beneficiary level, there are a number of reasons why Medicare beneficiaries choose to enroll in private plans. Generally MA plans have significantly lower cost sharing compared to traditional fee-for-service Medicare, and private plans have been able to offer additional benefits not covered by Medicare (in particular, outpatient drugs). Hence, private plans have proven to be very attractive to certain lower-income and minority individuals (*see,* for example, Maggie Murgolo, "Comparison of Medicare Risk HMO and FFS Enrollees,'' Health Care Financing Review, fall 2002, volume 24, number 1; and Kenneth E. Thorpe and Adam Atherly, "Medicare+Choice: Current Role And Near-Term Prospects,'' Health Affairs web exclusive, July 17, 2002). The cost of Medigap policies in a particular area also appear to influence Medicare+Choice enrollment (Catherine G. McLaughlin, Michael Chernew, Erin Fries Taylor, "Medigap Premiums and Medicare HMO Enrollment,'' Health Services Research, December, 2002). The relationship between beneficiary income levels and the tendency to enroll in MA plans is shown in Figure 1, which illustrates how lower-income individuals are more likely to enroll in MA plans. (The lowest income groups include beneficiaries eligible for Medicaid, who face certain difficulties in enrolling in MA plans (*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), and who would not have the same incentives to join MA plans as beneficiaries with no Medicaid coverage.) Thus, to the extent that the MMA increases beneficiary choices by making MA plans available in geographic areas where there are currently no plans, we would expect to see lower-income beneficiaries in such areas elect to enroll in plans that would offer benefit packages that reduce their out-of-pocket expenses substantially and provide them with extra benefits that they would otherwise not receive or would have to pay for out-of-pocket. On average, prior to the MA reforms, beneficiaries enrolled in M+C plans had yearly out-of-pocket medical expenses in 2003 that were $667 lower than expenses for beneficiaries in fee-for-service Medicare (with no coverage supplementing Medicare, such as subsidized retiree coverage or Medigap coverage). (*See* Gold and Achman, previously cited, figure 5, page 6). The MA reforms are expected to increase the opportunities for lower cost-sharing and improved benefits for such beneficiaries. Beneficiaries in poorer health, in particular, would find MA plans to be an attractive option: in May 2004, such beneficiaries enrolled in MA plans had annual out-of-pocket costs that were estimated to be $1900 less than beneficiaries in poor health covered by fee-for-service Medicare with no supplemental coverage (based on unpublished CMS data on out-of-pocket costs).

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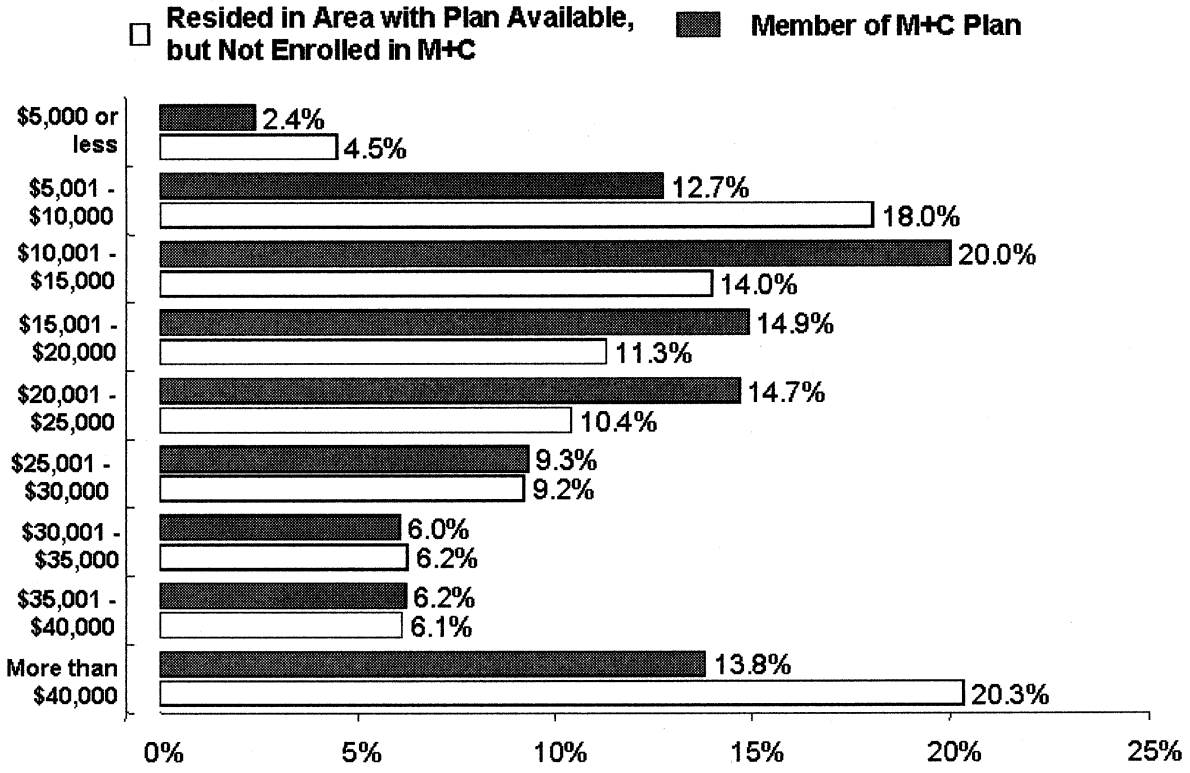
Figure 1: Enrollment Patterns of Medicare Beneficiaries by Yearly Income, Medicare+Choice Enrollment and Traditional Fee-for-Service (In Areas Where M+C Plans Are Available)



Source: Unpublished CMS Medicare Current Beneficiary Survey Data, 2002.

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One population group that has disproportionately lower rates of enrollment in Medicare private plans are disabled Medicare beneficiaries. Table 1 illustrates that while the disabled, a growing segment of the Medicare population, comprised 14 percent of the Medicare population in areas with Medicare+Choice plans in 2002, only seven percent of M+C plan enrollees were disabled (based on Medicare Current Beneficiary Survey Data for 2002). However, the M+C private fee-for-service plan option attracts a higher proportion of the disabled, with 17 percent of private fee-for-service (PFFS) plan enrollees being under 65 as of March 2004. This relatively high rate of enrollment of the disabled in PFFS likely reflects a demand for supplemental coverage in the face of less availability of Medigap coverage for Medicare beneficiaries under age 65. According to a September 2002 study, only 14 percent of disabled Medicare beneficiaries reside in States in which there is Medigap open enrollment for the disabled (Becky Briesacher, Bruce Stuart, Jalpa Doshi, and Sachin Kamal-Bahl, Medicare's Disabled Beneficiaries: The Forgotten Population In The Debate Over Drug Benefits, Commonwealth Fund and Henry J. Kaiser Family Foundation, publication #573, September 2002). The enrollment level of the disabled in PFFS plans would also appear to indicate that the disabled are willing to enroll in private plans when there are not restrictions on the providers they can use, even without the inducement of extra benefits or reduced premiums (which are generally not a feature of private fee-for-service plans). If a preference for broader networks is the reason for the willingness to enroll in PFFS plans, then the regional PPOs that the MMA seeks to promote may be an attractive option for disabled Medicare beneficiaries in that enrollees will have out-of-plan coverage and, in addition, are likely to have extra benefits available. The MMA authority for specialized plans for special needs individuals may also facilitate the enrollment of a higher proportion of the disabled in private plans. (On the disabled and their experience with access to care in Medicare HMOs, see Marsha Gold, Lyle Nelson, Randall Brown, Anne Ciemnecki, Anna Aizer, and Elizabeth Docteur "Disabled Medicare Beneficiaries In HMOs,'' Health Affairs, September/October 1997, particularly pages 155–157).

With regard to minorities and their enrollment in private plans, in 2002 Hispanics were more likely to choose Medicare+Choice enrollment (as compared to non-Hispanic African-Americans and non-Hispanic whites, as illustrated in Table 1). Any changes to the program that would increase the rate of private plan enrollment among the disabled would be likely also to result in higher minority enrollment levels in MA plans. This is because minorities make up a far greater percent of the disabled as compared to their distribution among the aged, as shown in Table 1. Thus, the overall high M+C enrollment rates in 2002 for Hispanics reflects the very high enrollment rates among aged Hispanics. The situation is reversed for the disabled: among Medicare beneficiaries under 65 (entitled to Medicare because of

disability), for the three different racial or ethnic groups (white, black, Hispanic), Hispanics were the least likely to be enrollees of M+C coordinated care plans. Similarly, for blacks, while over one in five aged black enrollees was enrolled in an M+C plan, fewer than one in ten disabled African-American beneficiaries were enrollees of M+C plans.

TABLE 1.—COMPOSITION OF MEDICARE ENROLLMENT BY AGE, RACE AND ETHNICITY IN AREAS WITH MEDICARE+CHOICE PLANS, YEAR 2002

	Composition within total population in areas with plans	Percent of group enrolled in M+C ("penetration")	Composition within FFS in area	Composition in M+C
Aged/Disabled Distribution:				
Aged (Age 65 or Over)	86.4%	21.3%	84.9%	92.9%
Entitled to Medicare Because of Disability (Under Age 65)	13.6%	10.5%	15.1%	7.1%
Racial/Ethnic Distribution:				
Black Non-Hispanic	10.5%	18.9%	10.7%	10.0%
Hispanic	10.3%	23.8%	9.8%	12.3%
White Non-Hispanic	79.2%	19.5%	79.6%	77.7%
	Composition within total aged population in areas with plans	Percent of racial/ethnic group in area enrolled in M+C	Composition of aged within FFS in area	Composition of aged within M+C
Aged by Race/Ethnicity:				
Black Non-Hispanic Aged	9.0%	22.1%	8.9%	9.3%
Hispanic Aged	9.4%	27.7%	8.7%	12.2%
White Non-Hispanic Aged	81.6%	20.5%	82.4%	78.4%
	Composition within total disabled population in areas with plans	Percent of racial/ethnic group in area enrolled in M+C	Composition of aged within FFX in area	Composition of aged within M+C
Disabled by Race/Ethnicity:				
Black Non-Hispanic Disabled	20.3%	9.6%	20.5%	18.7%
Hispanic Disabled	15.7%	8.8%	16.0%	13.1%
White Non-Hispanic Disabled	64.0%	11.2%	63.5%	68.2%

Source: Unpublished CMS Data from the Medicare Current Beneficiary Survey, 2002. Note: Excludes racial/ethnic category "other."

Another factor that influences beneficiary decisions to enroll in M+C is the use of M+C plans as the means of providing retiree health benefits. A substantial number of enrollees (about 18 percent of enrollment) are enrolled as retirees or dependents of retirees of firms that offer retiree coverage through M+C plans. These types of enrollees receive more generous benefits than individual Medicare enrollees of such plans (*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).

A current feature of private Medicare plans that makes them attractive to beneficiaries is the coverage of outpatient drugs. Private drug-only plans will be available to beneficiaries in traditional fee-for-service Medicare as of 2006. There is no direct evidence that we can rely on to assume that beneficiaries will be less likely to enroll in MA plans if drug coverage is available in traditional fee-for-service Medicare (other than pointing out that 18 percent of current enrollees in non-employer-sponsored MA plans are enrolled in plans with no drug coverage, and therefore there is a segment of the population that chooses MA coverage even without drug coverage.) However, for a variety of reasons, we believe the availability of drugs under Part D will only have a marginal impact on private MA plan enrollment. We believe that beneficiaries will view the private MA plans' benefit package integrating drugs and other services as attractive; MA plans will be able to offer drug benefits for a lower premium than PDP plans at a lower cost; and they will continue to be able to offer other extra benefits, including additional drug coverage. Such extra benefits were important in attracting enrollees to private plans in the period of greatest enrollment growth. Another advantageous feature that will continue to be unique to private MA plans is that, unlike PDP plans, they will have the ability to reduce Part B and Part D premiums through the rebates available from Medicare for plans with bids below the applicable benchmark. (Although there are only preliminary results from the experience of Medicare+Choice plans that have offered Part B premium rebates, plans and beneficiaries have had mixed experiences with this relatively new option (*see* "Sub-Zero Premium'' (BIPA 606) M+C Plan Evaluation, final report submitted by Bearing Point to CMS, September 30, 2003, contract number 500–95–0057, task order 6, available at *http://www.cms.hhs.gov/researchers/demos/subzeroevaluation.asp*). However, we believe that in combination with other advantages of MA enrollment, and as beneficiaries and plans become more familiar with the premium rebate option, premium reductions will be a significant inducement for beneficiaries to enroll in MA plans. There is also the issue of whether the number of plan withdrawals in recent years and the publicity surrounding the withdrawals may deter beneficiaries from enrolling in MA plans. Again, we believe that the generous benefit packages and financial advantages of MA membership will outweigh such considerations.)

Issues in Predicting Plan Behavior. With respect to plan behavior, whether plans have been available in a particular community (and whether Medicare beneficiaries have chosen to enroll in such plans) is often a function of local market factors. Brown and Gold found that "the capitation rate strongly influences whether and how quickly Medicare managed care develops and grows in an area, but other factors often outweigh the significance of the payment level'' (Randy Brown and Marsha Gold, "What Drives Medicare Managed Care's Growth?'' Health Affairs (Nov/Dec 1999). Among other factors that they cite as influencing increased Medicare private plan enrollment were factors such as the regulatory environment, whether or not employers and unions are offering supplemental coverage other than through Medicare health plans, and perhaps most importantly whether beneficiaries have greater familiarity with managed care in areas where plans have had a long-standing presence and acceptance in the commercial marketplace and among providers—as in the case of Portland, Oregon, which had, and continues to have, among the highest rates of Medicare private plan penetration even though the benefits available in Oregon have usually been less generous than in other areas with lower penetration levels.

In the case of Oregon, where penetration is near the 50 percent level in urban counties, one factor is that Medicare private plan enrollment includes a much higher percentage of employer-sponsored enrollees (about one-third) than the national average (18 percent) (based on unpublished 2002 CMS data). By way of contrast, in another high-penetration area—Miami-Dade County, Florida—employer-sponsored enrollment is under 5 percent, but the extremely generous benefit packages have attracted about 50 percent of the county's Medicare beneficiaries, who have been able to obtain such benefits as unlimited generic and brand drug coverage, and currently can obtain a full rebate of their Part B premium.

The Medicare regional plans present a market opportunity for insurers to participate in Medicare at less risk, with potentially higher payment levels than local plans in certain areas. With the financial incentives for PPO formation in the MMA, we believe that health plans will view the Medicare regional plan option as a good market opportunity to cover an insured population whose numbers will rise over the coming years, and we believe that many organizations that are already licensed as health insurers in multiple States (and in many cases, licensed in all States) will participate as both local and regional plans.

A major goal in introducing regional plans is to extend health plan access to rural areas through regional MA organizations that will cover relatively large geographic areas (at least the size of a State). There is an extensive literature on the subject of the limited participation of Medicare health plans in rural areas even after the BBA raised payments significantly in rural areas. For example, in testimony to the Congress, the chairman of the Medicare Payment Advisory Commission summed up the reasons for limited availability of Medicare HMOs in rural areas and suggested what remedy there might be: "Even though the floor under payments has been increased substantially (to $475 monthly), coordinated care Medicare+Choice plans offering generous benefit packages at little or no cost have not entered rural areas. We see three reasons for this. First, coordinated care plans rely on provider networks, which are difficult to establish in rural areas. This difficulty arises because rural providers who face little competition have no incentive to accept reduced payments and because there are fewer so-called intermediate entities, such as independent practice associations, willing to accept financial risk. Second, the small populations in many rural areas provide too small an enrollment base over which to spread fixed costs. Third, because relatively few rural areas consume large amounts of health care, there is less scope to achieve efficiency gains * * * What should policymakers do? The efficiency gains and provider discounts that Medicare HMOs in urban areas use to fund additional benefits are unlikely to be achievable in rural areas. Although other alternatives to the current system should be explored—such as risk sharing through partial capitation or split capitation—rural beneficiaries are unlikely to see more generous benefits without an explicit or implicit subsidy.'' ("Report to the Congress: Medicare in Rural America,'' Statement of Glenn M. Hackbarth, J.D., chairman, Medicare Payment Advisory Commission, before the Subcommittee on Health Committee on Ways and Means, U.S. House of Representatives, June 12, 2001.)

As previously noted, the use of the PPO model for regional plans, which are to cover wide areas, is intended to address the structural issues that have prevented Medicare plans from operating in rural areas. The payment issues are addressed through the incentives for the formation and continued participation of regional plans. However, the historical reluctance of Medicare plans to participate in rural areas is also a matter of uncertainty in projecting the extent of plan participation. The designation of regions would also be a factor affecting which rural areas may have plans participating.

There is one further area of uncertainty, and that is related to the issue of medical savings account (MSA) plans. 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.

Projections Provided in the Impact Analysis. The methodology used to project the impact of the law and regulations is partially explained in the section on effects on beneficiaries. The projections are based on the assumption, for illustrative purposes, that there would be 15 regions with at least three regional plans in each region. However, we do not know at this time how many regions will be designated, and there is no limit on the number of regional plans. With regard to the number of MA local plans, the projections of enrollment did not involve assumptions about any specific number of local plans. Instead a certain level of enrollment was assumed for local plans based on the benefits they are expected to offer; and it was assumed that there would be sufficient capacity among local plans to enroll all beneficiaries that are expected to join regional 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 proposed 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 proposed rule does not contain any "mandate'' as such, 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 proposed 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 at page 35012 for further discussion on the history of general Federal preemption of State law prior to the Balanced Budget Act of 1997.

The Balanced Budget Act of 1997 established for the Medicare+Choice program at section 1856(b)(3) 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 the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (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 Medicare Advantage plans by eliminating the general and specific preemption distinctions from section 1856 and broadened 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). § 422.402 of 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. 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 Balanced Budget Act of 1997's preemption law. (*See* pages 35012–35014 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. We will discuss the results of this consultation when this rule is published as a final rule.

We also request public comment on the effect of the preemption provisions included in this proposed rule.

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 and hearing aids, as well as additional drug coverage), reduction in out-of-pocket expenditures for covered services (either as reduced cost sharing, on average, compared to fee-for-service Medicare, or reduced premium expenditures 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 A and B coverage valued at $1.4 billion. For 2005, the expected dollar value of benefits for beneficiaries will include approximately $256 million in remaining contributions to plan stabilization funds that plans must use by the end of 2005. (Effective for years after 2005, the MMA eliminated the "stabilization fund'' option that was used by some plans to deposit Medicare payments for use in a later contract year to finance the cost of additional benefits or premium reductions. These funds will have to be used in the 2005 contract year. There is also a potential spillover effect of increased provision of benefits that competing plans in the same area would have to offer to remain competitive with plans using the stabilization fund dollars.) The estimate of benefits for beneficiaries is shown in Table 2.

The data in Table 2 (and in Table 4) 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 area; (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 previously noted, we assume that there will be at least three regional plans in each region (in our illustrative case that assumes that there are 15 regions), 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 significantly more revenue available than regional PPO plans for the provision of extra benefits and reduced out-of-pocket expenditures. However, we would also expect that in many areas, there will only be regional plans available, and no local MA coordinated care plans. 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 fee-for-service Medicare). The projections of Tables 2 and 4 show the distribution of dollars among 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 using more funds to provide extra benefits, reduced cost sharing, and lower premiums. Some plans may offer very few extra benefits but would still be attractive to enrollees, as noted elsewhere, and would be viewed by beneficiaries as more advantageous than FFS Medicare with Medigap coverage, for example.

The dollar figures shown in Tables 2 and 4 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 fee-for-service Medicare.

TABLE 2.—PROJECTED BENEFITS TO MA ENROLLEES RESULTING FROM TITLE II PROVISIONS OF THE MMA, YEARS 2004 TO 2009, IN MILLIONS (AMOUNTS ABOVE AMOUNTS IN ABSENCE OF MMA TITLE II PROVISIONS); PROJECTED TOTAL PLAN ENROLLMENT, 2004 TO 2009, IN MILLIONS

	Year 2004	Year 2005	Year 2006	Year 2007	Year 2008	Year 2009	Total, Years 2004–2009
Enrollment Projection, Local Plans	4.662	5.088	6.449	6.547	6.685	6.825	.....
Enrollment Projection, Regional Plans	.....	.....	3.064	4.665	5.534	6.815	.....
Total Value of Transfer Payments Used for Extra Benefits and/or Premium and Cost Sharing Reductions, Local Plans	134	201	220	177	148	121	1001
Total Value of Transfer Payments Used for Extra Benefits and/or Premium and Cost Sharing Reductions, Regional Plans	.....	.....	48	118	117	117	400
Total Value of Transfer Payments Used for Extra Benefits and/or Premium and Cost Sharing Reductions, Both Types of Plans	134	201	268	295	265	238	1,401

Because of the MMA payment increases effective March 2004, beneficiaries enrolled in private plans have already seen reduced expenditures and increased benefits.

The March payment increases varied by geographic area. For example, because of the MMA provision that made fee-for-service payment rates one of the "prongs'' of payment, New Jersey counties had an average 24.3 percent payment rate increase on an enrollment-weighted basis (all counties in New Jersey had 86 or more enrollees and have MA plans available). As a result, in New Jersey, the average monthly M+C coordinated care plan premium across all counties declined from $56 to $15. In all 21 of New Jersey's counties coordinated care plans have added a drug benefit. Previously, a drug benefit was available from an M+C coordinated care plan in only one county for 2004 before the MMA changes (though the two PPO demonstration projects operating in New Jersey did offer drug coverage). As of December 2003, only seven percent of New Jersey Medicare beneficiaries were enrolled in M+C plans or PPO demonstration plans. In July 1999, sixteen percent of New Jersey beneficiaries were enrolled in M+C plans. We would expect enrollment in New Jersey to rise because of the availability of better benefits. (In addition, a Medicare contracting plan in New Jersey recently announced that it would expand its Medicare service to include eight more counties.)

There are notable geographic differences in the benefit offerings of MA plans. In addition to the access differences between rural and urban counties that have already been discussed, the generosity of benefits has been lower in rural areas than urban areas. In 1999, for example, while the enrollment weighted premium for all enrollees of M+C plans was $5 per month, for the three percent of enrollees residing in rural counties and enrolled in M+C plans, the enrollment-weighted premium was $14 per month. In 1999, when 84 percent of the universe of M+C enrollees had drug coverage in a basic plan (zero premium or mandatory premium), 57 percent of rural enrollees had this level of drug coverage. For the March 2004 benefit offerings, this difference between rural and urban areas persists. Zero premium plans are available to 68 percent of urban beneficiaries in counties where there are plans, but only 30 percent of the beneficiaries who live in a non-MSA county in which there is an operating MA coordinated care plan or demonstration PPO have access to a zero premium plan. In rural areas, 72 percent of those with access to a plan can obtain drug coverage through a private plan, while in urban counties with plans available, 95 percent of beneficiaries have access to a drug coverage plan.

This difference between urban and rural areas may persist among MA local plans, which can vary benefits by county. With MA regional plans, there is a requirement that benefits must be uniform throughout the entire region. Hence, regional plans cannot offer different benefits in rural and urban counties, which will eliminate the disparity between such counties in the regional plan arena. However, there may be differences between regions in the generosity of benefits regional MA plans offer, and the degree of disparity would depend in part on the make-up of the regions, which CMS will determine at a later date.

Table 3 illustrates the variation that exists in current coordinated care plan offerings across States. The table lists the types of MA benefit packages available in the counties of each State in which plans are available (coordinated care plans and PPO demonstration plans). The counties are categorized by the most generous benefit package being offered by at least one plan in each county. The table indicates whether the State has any counties in which there are (a) zero premium plans with drug coverage included in the zero premium plan, (b) plans with zero premium but no drug coverage, (c) plans that include drug coverage in a benefit offering for which there is a premium, and (d) counties in which plans charge a premium but no drug coverage plan is offered. This kind of benefit variation at the State level will not occur with regional plans because of the uniform benefit requirement, as noted above, and because Medicare will now include a drug benefit.

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Table 3: Distribution of Counties in States by Highest Level of MA Benefit Packages Available in County, March 2004

State	0 Premium Access With Drugs Included	0 Premium Access But No Drugs	Premium Charged, Drug Coverage Available	Premium Charged And No Drug Coverage	State	0 Premium Access And Drugs	0 Premium Access But No Drugs	Premium Charged, Drug Coverage Available	Premium Charged And No Drug Coverage
ALABAMA	X				MONTANA	No M+C CCP Plans or PPO Demo Plans			
ALASKA	No M+C CCP Plans or PPO Demo Plans				NEBRASKA	X			
ARIZONA	X				NEVADA	X			
ARKANSAS	No M+C CCP Plans or PPO Demo Plans				NEW HAMPSHIRE			X	
CALIFORNIA	X		X		NEW JERSEY	X			
COLORADO			X		NEW MEXICO	X			
CONNECTICUT	X	X	X		NEW YORK	X	X	X	
DELAWARE	No M+C CCP Plans or PPO Demo Plans				N. CAROLINA	X		X	
DIST. OF COL.	No M+C CCP Plans or PPO Demo Plans				N. DAKOTA	No M+C CCP Plans or PPO Demo Plans			
FLORIDA	X		X		OHIO	X	X	X	X
GEORGIA				X	OKLAHOMA	X		X	
HAWAII				X	OREGON			X	X
IDAHO				X	PENNSYLVANIA		X	X	X
ILLINOIS	X		X	X	PUERTO RICO	X			
INDIANA	No M+C CCP Plans or PPO Demo Plans				RHODE ISLAND	X			
IOWA	X				S. CAROLINA	No M+C CCP Plans or PPO Demo Plans			
KANSAS		X	X		S. DAKOTA	No M+C CCP Plans or PPO Demo Plans			
KENTUCKY		X	X		TENNESSEE	X		X	X
LOUISIANA	X				TEXAS	X			
MAINE	No M+C CCP Plans or PPO Demo Plans				UTAH	No M+C CCP Plans or PPO Demo Plans			
MARYLAND	X				VERMONT	No M+C CCP Plans or PPO Demo Plans			
MASSACHUSETTS			X		VIRGINIA			X	
MICHIGAN			X	X	WASHINGTON			X	
MINNESOTA			X	X	W. VIRGINIA			X	
MISSISSIPPI	No M+C CCP Plans or PPO Demo Plans				WISCONSIN	X			X
MISSOURI	X	X	X		WYOMING	No M+C CCP Plans or PPO Demo Plans			

High penetration in MA plans may affect the Medigap market. To the extent that Medicare beneficiaries will be leaving Medigap plans to join MA plans,

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or will join MA plans on becoming eligible for Medicare rather than choosing fee-for-service Medicare with Medigap coverage, there is a potential effect on the cost of Medigap premiums in some markets. If fewer new enrollees enroll in Medigap plans, and if MA continues to enroll disproportionately younger beneficiaries, premiums will rise as Medigap subscribers age and use more services. As premiums rise, the premium rate may cause some subscribers to discontinue Medigap coverage (in favor of MA enrollment, or fee-for-service coverage without a supplement), causing a further increase in Medigap premiums as only the subscribers with the greatest perceived health care expenditures maintain their Medigap coverage. If MA plans continue to attract younger or healthier beneficiaries, and relatively older or sicker beneficiaries remain in fee-for-service Medicare, there is a further potential Medigap effect leading to rising premiums. The Medigap effects can potentially have a greater impact on rural areas in a State (where Medigap is a more common form of supplemental coverage than in non-rural areas). Because most Medigap plans are rated on a statewide basis, if the movement away from Medigap to MA plans is the result of the ability of urban local plans to offer extremely generous benefits that regional plans are unable to match, the market changes in the urban area(s) could cause Medigap premium rates to rise for all the State's beneficiaries, even for those beneficiaries that may not have the range of choices available to urban areas. With regard to any Medigap effect, however, it should be noted that the most recent trends in the data from the Medicare Current Beneficiary Survey for 2001 show a significant rise in the number of beneficiaries with Medigap coverage, possibly due to the decline in the availability of employer-sponsored retiree coverage.

F. Effect on Health Plans and Insurers

Health plans will see significant benefits as a result of the MMA through the transfer payments from the Federal Government to participating plans. Plan payments will increase significantly, allowing plan revenues and profits to rise as enrollment increases with the offering of better benefits. 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 for an interim transition period, 2006 to 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 $23.4 billion. Of this amount, plan administrative costs (which include profits and retained earnings) are expected to total $1.2 billion (over and above amounts that otherwise would have been paid). The remaining amounts will finance the provision of health care benefits (together with other revenue the plan has, such as member premiums). 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 4. (The basis for these projections is discussed in the section on effects on beneficiaries, in the discussion of Table 2.)

TABLE 4.—PROJECTED BENEFITS TO MA PLANS RESULTING FROM TITLE II PROVISIONS OF THE MMA, YEARS 2004 TO 2009, IN MILLIONS (AMOUNTS ABOVE AMOUNTS IN ABSENCE OF MMA TITLE II PROVISIONS); PROJECTED TOTAL PLAN ENROLLMENT, 2004 TO 2009, IN MILLIONS

	Year 2004	Year 2005	Year 2006	Year 2007	Year 2008	Year 2009	Total, years 2004–2009
Enrollment Projection, Local Plans	4.662	5.088	6.449	6.547	6.685	6.825	.....
Enrollment Projection, Regional Plans	.....	.....	3.064	4.665	5.534	6.815	.....
Total Value of Transfer Payments Used for the Provision of Medicare A and B Benefits, Local Plans	1,430	2,155	2,356	1,894	1,590	1,299	10,724
Total Value of Transfer Payments Used for the Provision of Medicare A and B Benefits, Regional Plans	.....	.....	1,225	2,990	2,978	2,966	10,159
Total Value of Transfer Payments—Plan Administrative Costs (Including Profit), Local Plans	174	262	286	230	193	158	1,303
Total Value of Transfer Payments—Plan Administrative Costs (Including Profit) Regional Plans	.....	.....	142	345	344	343	1,174
Total Value of Transfer Payments to Plans, Both Types of Plans	1,604	2,417	4,009	5,459	5,105	4,766	23,360

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. The possible consequences of these differences in service area configurations are discussed further in the section on alternatives considered.

Although we have emphasized the additional benefits that we expect plans to be able to offer, by having eliminated the adjusted community rate process and its requirement that permissible plan profit levels must be the same as for a plan's commercial product, and having eliminated the limit on premiums related to cost sharing for Medicare-covered benefits, plans can potentially increase their profit levels, as their competitive situation permits.

Plans with bids exceeding the benchmark can also be assured of having adequate revenue to operate as Medicare plans. These provisions may 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, 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 proposed rule also has several administrative changes that will reduce plan burden, including the file-and-use approach to marketing material review, 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 regulation CMS–4041–F on August 22, 2003 and effective September 22, 2003. In the regulatory impact statement of that rule (pages 50,853 and 50,854 of the **Federal Register**) we said: "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. 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 only advantage gained and the only 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 Use and File 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. We note that CMS initiated this burden reduction. To the extent that MA organizations did not bring the burden associated with these disclosure requirements to our attention as part of the regulatory reform initiative, they probably also have not actually been called upon to so disclose through actual requests for such information. Therefore, the level of administrative burden mitigation is likely negligible.

As stated in the preamble, we request suggestions for other burden-reducing reforms or innovations that will improve the ability of plans to participate in the program without compromising quality or services. We are particularly interested in comments on whether, within the statutory construct, there are structural or administrative requirements in the MA program that would act either as a barrier to plan entry into the MA market or would adversely impact plan participation, and consequently, beneficiary choice.

Other Effects. Although most Medicare health plans and organizations that can participate as MA plans stand to benefit from the MA provisions, as previously noted Medigap insurers may face price pressures and see declining enrollment if MA enrollment increases to the level that CMS projects, and if fewer individuals in fee-for-service Medicare buy Medigap, though there is the mitigating factor previously discussed regarding the trend of an increase in the number of Medicare beneficiaries with Medigap policies. 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 private fee-for-service 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 fee-for-service Medicare costs). Private fee-for-service plans generally have not competed directly against coordinated care plans. Private fee-for-service plans offer less generous benefit packages than MA coordinated care plans, but they do offer some level of supplemental coverage for individuals (including, in the case of two organization, drug coverage), 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 would have a competitive advantage over Medicare private fee-for-service plans that had usually targeted areas in which there were no MA local plans. MA regional plans can 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 private fee-for-service plans; regional plans must operate as a PPO model. All but one of the current private fee-for-service plans is sponsored by an organization that is part of a firm that has local MA plan contracts—though the one exception is the largest PFFS plan.)

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), 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. As also noted previously, 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.

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), 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 a August 22, 2003, **Federal Register** notice on p. 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 for CMS 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 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 proposed rule at § 422.106(d). We do not know to what extent employers or labor organizations may be interested in pursuing waivers under this new authority. For an employer or union to contract in this manner may require that the employer or union obtain State licensure as a risk-bearing entity and meet any licensure and solvency standards imposed by the State for health plans. To the extent that such licensure would be required, there may, however, be a few entities that already offer health insurance for their own employees or offer insurance on the market that may be interested.

However, we do 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 Hileman *et al.*, previously cited). 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. This particular market segment is attractive to MA plans for a number of reasons, including the ease of marketing to a large group, their status as previously insured individuals, and the ability to offer seamless continuation of coverage between active worker status as a plan enrollee 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.

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 directly to beneficiaries. For the period 2004 through 2009, the total amount of such transferred funds is projected to be $23.4 billion above what would otherwise have been incurred in the absence of the Title II provisions of the law. The total expenditure figure assumes that $5.2 billion of the stabilization fund dollars for regional MA plans are used in the period 2004 through 2009. The preceding figure assumes a private plan penetration rate, for illustrative purposes, of 33 percent by 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.

The section on alternatives considered examines the impact on expenditures in choosing between statewide and plan-specific risk adjustment to determine rebate amounts. Another issue that has an effect on expenditures is the payment adjustment relating to risk adjustment for bids that exceed the benchmark. Proposed § 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 ensure that the total revenue a plan receives for its actual enrollees matches 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, and through 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, 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 healthier on average than Medicare beneficiaries in traditional fee-for-service. 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.

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. There is also an impact on beneficiaries, who will have higher premiums in plans with bids over the benchmark with healthier-than-average enrollees, and lower premiums in such plans with sicker-than-average enrollees, as compared to a system in which the plan premium is risk adjusted.

J. Administrative Costs

The administrative cost estimates for MA plans included in the section on effects on health plans and insurers are based on the administrative costs currently incurred by Medicare Advantage plans. The administrative cost figures shown in Table 4—at 10 percent of revenue—include 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 (weighted by enrollment).

K. Analysis of Effects on Small Entities

The Regulatory Flexibility Act (RFA) requires us to determine whether a proposed rule will have a "significant economic impact on a substantial number of small entities.'' If so, the RFA requires that an Initial Regulatory Flexibility Analysis (IRFA) 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 these proposed rules. (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 IRFA. We welcome comments on this approach and on whether we have missed some important category of effect or impact.

We do not believe that these proposed rules will create a significant economic impact on a substantial number of small entities.

However, we have prepared a voluntary IRFA. Under longstanding HHS policy we prepare an IRFA if significant impacts of a proposed rule on small entities are positive rather than negative. We also prepare an IRFA 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 an IRFA 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 our proposed rules 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, a $2,000 per enrollee cost. 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 these proposed rules 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 IRFA for the Medicare Advantage provisions of Title II of the MMA. We note that there is a related IRFA in the companion proposed 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) 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 competitors 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 M+C 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 M+C organizations with revenues below the SBA threshold. (Note that the number of M+C 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 smallfirms 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 creation of the Medicare Advantage program 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 proposed rule.

Despite these conclusions, it is possible that there is some potentially burdensome effect on insurance firms we have failed to anticipate. We request comments on whether any provisions of these rules may inadvertently create problems or burdens for any "small'' firms in the health insurance industry with annual revenues below $6 million.

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 M+C market, and most are potential entrants or

reentrants as local Medicare Advantage plans. According to the InterStudy data, about one third of HMOs currently participating in M+C are non-profit. Some HMOs, profit or non-profit, may be potential entrants in the new regional MA markets. This may depend, in part, on how we later define regional boundaries. It will certainly 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 Medicare Advantage, there are two distinct (though overlapping) markets: local and regional. All existing M+C 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. As discussed previously in this analysis, only about one fifth of U.S. counties, though over 60 percent of the eligible population, have an M+C HMO 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 proposed rules. These rules will have beneficial effects on local plans, by reducing some administrative burdens, but the changes we propose, singly and collectively, do not rise to the level of "significant economic impact'' on local HMOs.

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 2009.

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 proposed 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. As discussed elsewhere in this Preamble, we cannot yet predict how many regions there will be, or how their boundaries will be drawn. That decision is not a subject of these proposed rules, but will be announced administratively at a later time.

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. Elsewhere in this Preamble we ask for comments on some aspects of defining networks and network adequacy, but the alternatives under consideration would all allow normally operated PPOs reasonably feasible methods of building their networks.

We know of one group of potential regional competitors who may be affected by regional boundary decisions. 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. While no decision we make on regional boundaries are not likely to adversely affect current plan operations or revenues, if these plans were not able to compete effectively in multi-State regions they might forego an important business opportunity. We request comments on whether these or any other types of plans face potential disadvantage and, if so, what steps could be taken by us to reduce such problems. However, we note that there are many ways by which health plans can compete on a regional or national basis, and that the Blue Cross plans themselves have a history of national cooperation in the FEHB program. Therefore, we are interested in suggestions not only for steps we might take, but that plans might take, to ameliorate any problems created by the regional structure. Additionally, 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. In other words, it is not clear whether, and, if so, the extent to which, regional boundary decisions potentially constrain plan participation in Medicare Advantage in any important way, and we request comments on this. We will also provide additional opportunities at a later time to comment on possible regional boundaries, as discussed previously in this Preamble.

Another potential problem facing regional plans is the requirement, in the statute, that they apply for licensure in each State in which they operate. Since the statute preempts State standards for benefits, coverage, and provider networks, leaving effectively only

solvency standards as State-imposed requirements, we anticipate no important problems for plans. However, we request comments on any problem that the statute may create. In this regard, we note that at present some insurance carriers operate in multiple States, either directly or through subsidiaries, under the far more burdensome legal requirement of meeting every standard in each of those States.

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, *etc.* 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. However, if there are any statutory or regulatory requirements that impose unnecessary burdens on smaller firms otherwise able to compete effectively, we request comments and suggestions on these.

In summary, the Medicare Advantage 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. We do have discretion on regional boundaries. If we later decide to design regions that make it harder for some non-profit entities to compete regionally, this will reflect a decision that the objectives of beneficiary access and choice take precedence. However, it is not clear that there is any real conflict, because an organization seemingly disadvantaged as a regional plan may be advantaged as a local plan. In fact, the local plan model provides significant flexibility in terms of letting plans define their own market and service areas, without having to meet the network adequacy and other requirements of the MA regional market area.

Throughout this preamble we have identified regulatory alternatives that may lessen burden on entities of any size. We are particularly interested in comments on those that may differentially affect smaller insurance firms, and on identification of ways to alleviate unnecessary burden, consistent with the underlying purposes of the Medicare Advantage program.

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 an agreement on payment levels. As described in more detail under the Subpart C preamble section, if we find the hospital's participation "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 to occur in 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 are positive. 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). However, despite the large number involved (about one in seven hospitals participate), these 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.

We are not aware of any consequential burden on hospitals in our regulatory proposals for this program, but welcome comments.

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 proposing to amend the existing rules in several places to remove requirements that would be inappropriate if applied to MSAs. Nothing we propose adds burden; we welcome comments on any remaining barriers to the sponsorship of MSA plans.

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 plan; the statute gives them the flexibility to sponsor plans directly. The statute and the proposed regulation provide for waivers of any Medicare Advantage requirement that would unduly impede employer or union-sponsored plans. We request comments on any potential barriers affecting employers of any size that we should address more directly.

7. Other Requirements in the Regulatory Flexibility Act

The RFA lists five general requirements for an IRFA 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 proposed 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 not, however, addressed the various categories of burden reducing alternatives listed in the RFA as appropriate in IRFAs. These alternatives, such as an exemption from coverage of the rule for small entities, establishment of less onerous requirements for small entities, or use of performance rather than design standards, simply do not apply to a situation in which a program beneficial to entities both large and small is being created, and in which the regulations do not create economically "significant'' burdens. Furthermore, the consumer choice-driven Medicare Advantage program is overwhelmingly a "performance'' system rewarding plans that operate at lower costs, provide better service, or provide better benefits as evaluated by enrollees and potential enrollees. CMS operates in a stewardship role, not as the promulgator of detailed design standards (except in a few areas, such as procedural protections for enrollees). However, throughout this Preamble we identify issues and options for attention by affected entities, including a number of proposed changes that would lessen the burden of the existing M+C rule. We welcome comments on these and suggestions for additional steps we can take, consistent with the underlying statute, to minimize any unnecessary burdens on current or potential Medicare Advantage plans or other affected entities.

L. Alternatives Considered

In this section we discuss a decision that CMS has made that prohibits plans from applying rebate dollars to optional supplemental packages. The remaining issues discussed in this section address the major areas in which CMS is seeking comment to determine which option to choose among the options offered in the preamble. As part of the impact analysis, we are providing supplemental information that will help readers of this proposed rule understand some of the issues that need to be considered in evaluating the options, or in suggesting alternatives that CMS should consider as options.

1. Designation of Regions

A number of considerations need to be balanced in designating the regions for the regional Medicare Advantage plans. The statute and the conference report for the MMA provide some guidance about what the Congress considers important factors in delineating regions, as has been discussed in the preamble. The designation of regions will be made after the market study required by the MMA. The law provides for a minimum of ten, and a maximum of 50, regions. There are provisions in the law that favor the development of multi-State regions (for example, the use of Federal licensure and solvency standards pending State licensure), or that favor the development of a national plan (the bonus for a national plan). As noted previously, one of the primary reasons for using the regional plan approach is to provide access to health plans for areas in which "local'' plans are less likely to be offered.

The major goal is to maximize access to a choice of private health plans in as many areas as possible. Therefore, an important question is what type of regional configuration, or method of configuring regions, has the greatest likelihood of extending private plan options to areas with no plans or to underserved areas. In terms of public comment, perhaps the greatest benefit for CMS would be to hear from plans and potential plans regarding the factors they would consider important in promoting plan participation. Similarly, other interested parties (beneficiaries, beneficiary advocates, providers), would also have opinions on how the regions should be delineated. We recognize that there are a number of factors that would affect any decision on the designation of regions, including State licensure issues for insurers and size and capital requirements for plans, as well as other potential barriers to initial or subsequent market entry; issues relating to the ability to form provider networks over a wide area; the nature of existing health care market areas for commercial and Medicare plans; the number of competitors that operate in an area or are likely to operate in an area; and the goal of initiating and sustaining competition.

One obvious question is whether the regions should be comprised of the largest possible number (the 50 States, or a close approximation), or a configuration consisting of much larger geographic areas. Designating a relatively small number of large regions may be viewed as providing an undue advantage to larger companies (for example, the several insurance companies already licensed in virtually every State). A larger number of regions may promote the use of local or regional firms that may be better able to form networks because of their current operations in a given State, while an insurer that is new to the market may have more difficulty in network formation. On the other hand, to the extent that participation as a regional plan can involve a relatively high level of risk as a business venture, larger companies may be more willing, and better able, to take such risk. Economies of scale may only be possible if the regions are relatively large and are designed in such a way that a relatively high level of enrollment can be expected. A regional configuration that emphasizes large regions and results in a smaller number of large plans may permit participating plans to have greater leverage in securing provider contracts as compared to a situation in which there are many competitors in an area. Another factor that we are uncertain about is whether it is feasible to assume that, if there are multi-State regions, individual insurance companies would be willing to form consortiums with insurers from other States in order to cover a wider area.

One possibility for the designation of regions is to have the 50 regions consist essentially of the 50 States. Such a configuration may not be the best way to ensure that the designation of regions contributes to the overall goal of maximizing the availability of health plan choices. New Jersey, for example, currently has plans available in every county in the State, including at least one MA coordinated care plan and one demonstration PPO plan in each county. There are nine counties in which only one organization is offering plans, but in all 21 New Jersey counties, there is a zero premium plan available with drug coverage. Making New Jersey a region, if a regional plan were to participate, would bring more competition to the State. However, including New Jersey as one State within a multi-State region might allow Medicare to capitalize on the presumed ability of the highly competitive New Jersey plans to extend their reach beyond New Jersey, and, as discussed previously, help to achieve

the objective of expanding access to private plan choices.

Using Florida as a different kind of example, if Florida by itself were designated as a region, and Florida had only regional plans, all beneficiaries in each Florida county would have the same kinds of benefit offerings. Looking at the current offerings of Florida MA plans as shown in Table 3, there is a range of benefit offerings in the State from county to county, but in all counties in which there are MA plans, drug coverage is available. Some Florida residents must pay a premium to obtain the drug coverage. With a regional plan, there would be a uniform benefit across the State, and the 19 percent of the population (560,000 beneficiaries) that currently does not have access to a private plan could enroll in a plan.

The preamble discusses the kinds of State characteristics that we are looking to balance in the formation of regions. The statute emphasizes extending plans to rural areas. As shown in Table 5, the States with the smallest Medicare populations tend to have the highest proportion of rural beneficiaries as a percent of their Medicare population and also are more likely to be contiguous with each other. Could such States stand alone as individual regions? Would there be a sufficient market to support regional plans in each of these States, or do such small populations require multi-State regions? If it is assumed that multi-State regions must be comprised of States that are contiguous, is there a possible configuration of these smaller States that would create a region in which participation as a regional plan is a viable option for a health insurer? (Note that these States generally are among those with the lowest per capita expenditures. Although this might indicate that there may not be much opportunity for health plans to achieve savings in health care utilization or discounts from providers, it is also true these States are generally the areas in which the fee-for-service component of the benchmarks will be based on floor payments rather than Medicare fee-for-service payments, thereby resulting in potentially higher plan payments and possible higher rebates for enrollees.)

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Table 5: Characteristics of the States with the Lowest Medicare Populations, 1999

State	Contiguous with another State on this list?	Part of an MSA with another State on this list?	Among the 15 States with the highest proportion of rural beneficiaries?	Part of an MSA with one of 15 most populous States?	Medicare private plan penetration, 1999	Per capita FFS expenditures, 1999	Rank in per capita FFS expenditures (1 is lowest per capita)	Rank in private plan penetration (1 is highest penetration)	Percent of Medicare Population That Is Rural, 1999	Resident Medicare beneficiaries: urban, 1999	Resident Medicare beneficiaries: rural, 1999	Resident Medicare beneficiaries: total, 1999
South Dakota	x		x		0.2%	$4,116	7	51	73%	31,980	85,800	117,780
North Dakota	x		x		0.8%	$4,035	4	49	67%	34,080	67,740	101,820
Maine	x				0.6%	$4,434	16	48	47%	114,520	99,860	214,380
Alaska	no contiguous States		x		0.5%	$5,611	38	47	61%	15,780	24,500	40,280
Vermont	x		x		2.0%	$4,353	14	45	74%	22,780	65,260	88,040
Wyoming	x		x		2.9%	$4,342	13	44	68%	20,080	43,580	63,660
Montana	x		x		2.2%	$3,896	2	43	68%	43,600	91,880	135,480
Utah	x	x (Idaho)			3.6%	$3,974	3	42	28%	146,400	57,720	204,120
Delaware				Philadelphia-Camden-Wilmington	3.7%	$5,200	34	37	28%	80,840	30,980	111,820
Idaho	x	x (Utah)	x		9.2%	$4,038	5	26	67%	54,620	108,780	163,400
New Hampshire	x			Boston-Cambridge-Quincy	10%	$4,312	12	25	34%	108,220	56,800	165,020
New Mexico					19%	$4,310	11	13	46%	123,100	106,680	229,780
Hawaii	no contiguous States				38%	$3,648	1	7	28%	118,620	45,000	163,620
Nevada	x				35%	$5,147	32	6	14%	200,620	34,020	234,640
Rhode Island				Providence-New Bedford-Fall River	30%	$5,876	40	5	0%	168,380	-	168,380
								Total for Above States	**42%**	1,283,620	918,600	2,202,220

Source: CMS analysis of penetration reports and MSA designation files (available at http://www.cms.hhs.gov/healthplans/reportfilesdata/), and expenditure information from the Statistical Supplement of the Health Care Financing Review.

At the other end of the scale are the most populous States, shown in Table 6. Potentially, each of these States could be designated a region (notwithstanding

the preceding discussion of the case of New Jersey). Although the rural issue is generally thought of in the context of States such as the Mountain States that are sparsely populated, if access were extended throughout each of these 15 primarily urban States, access will have been extended to 50 percent of all rural Medicare beneficiaries (defining "rural'' as Medicare beneficiaries who reside in counties that are not within an MSA). This would triple the percent of rural beneficiaries with access to coordinated care plans (which stands at about 15 percent currently).

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Table 6: Characteristics of the States with the Highest Medicare Population, 1999

State	Contiguous with a State from list of least populous States?	Medicare private plan penetration, 1999	Per capita FFS expenditures, 1999	Rank in per capita FFS expenditures (1 is lowest)	Rank in private plan penetra-tion (1 is highest)	Percent of Medicare Population that Is Rural, 1999	Resident Medicare beneficiaries: urban, 1999	Resident Medicare beneficiaries: rural, 1999	Resident Medicare beneficiaries: total, 1999
California	x (Nevada)	41%	$ 6,148	45	1	5%	3,672,520	188,560	3,861,080
Florida		28%	$ 6,072	44	8	8%	2,573,640	219,600	2,793,240
Pennsylvania		28%	$ 5,902	42	9	16%	1,740,140	341,860	2,082,000
Massachusetts	x (Rhode Island)	25%	$ 6,361	46	11	2%	937,020	15,260	952,280
New York	x (Vermont)	19%	$ 6,424	48	15	9%	2,436,860	236,940	2,673,800
Ohio		18%	$ 5,124	31	16	19%	1,367,600	329,320	1,696,920
Texas	x (New Mexico)	17%	$ 6,014	43	17	23%	1,712,360	513,760	2,226,120
New Jersey		17%	$ 6,552	49	18	0%	1,200,700	0	1,200,700
Missouri		15%	$ 5,029	28	19	37%	534,060	318,080	852,140
Illinois		12%	$ 5,419	37	22	21%	1,279,840	341,680	1,621,520
Georgia		6%	$ 5,164	33	30	39%	550,680	358,940	909,620
Virginia		6%	$ 4,591	18	32	32%	597,540	280,380	877,920
Michigan		5%	$ 5,613	39	35	21%	1,088,740	296,240	1,384,980
Tennessee		5%	$ 5,087	29	36	37%	510,180	304,580	814,760
North Carolina		4%	$ 4,776	24	39	39%	675,480	436,480	1,111,960
Indiana		4%	$ 4,649	21	40	31%	579,740	258,520	838,260
					Total for Above States	**17%**	21,457,100	4,440,200	25,897,300

Source: CMS analysis of penetration reports and MSA designation files (available at http://www.cms.hhs.gov/healthplans/reportfilesdata/), and expenditure information from the Statistical Supplement of the Health Care Financing Review.

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The conference report for the MMA contains two suggestions relating to the designation of regions that are difficult to reconcile: "The Secretary could not divide states so that portions of the state were in different regions'' and "[t]o the extent possible, the Secretary would include multi-state metropolitan statistical areas (MSAs) in a single region, except that he or she could divide an MSA where necessary to establish a region of such size and geography to maximize the participation of PPOs.'' There are 44 multi-State MSAs, with 37 States having at least one multi-State MSA. Looking at the location of these MSAs across the country, it would be necessary in many cases to divide MSAs between regions or to create very large regions. To divide MSAs, CMS would look to the analysis of health care markets and how they are configured, but we would also invite comment on other factors that we should consider when it appears necessary to divide an MSA so that a part, or parts of, the MSA fall within different regional boundaries.

As discussed in the preamble, we will be conducting a market survey and providing additional opportunity for public input during the course of that work. We welcome comments in response to this proposed rule regarding the many considerations related to the designation of the regions for the MA program as well as for the PDPs and the potential for establishing the same or at least similar regional configurations.

2. Statewide or Region-Wide Versus Plan-Specific Risk Adjustment To Determine Savings

The issue of statewide or region-wide versus plan-specific risk adjustment is discussed in the section dealing with "Calculation of Savings'' (§ 422.264) in the text and preamble of the proposed rule. The statute and the proposed rule state that, for local plans, CMS may use either a statewide average risk adjuster, a risk adjuster for a geographic area different from a State (for example, a metropolitan statistical area), or a plan-specific risk adjuster, to determine the average per capita savings that exist when there are bids below the benchmark. Similarly, for regional plans, CMS may use a region-wide adjuster, an adjuster for a different geographic area, or a plan-specific risk adjuster in determining average per capita savings.

There are two reasons for applying risk adjustment to determine savings (which in turn determine the dollar value of available enrollee rebates). One is that if the savings computation were not subject to risk adjustment, plan enrollees overall would receive higher rebates than are appropriate because current enrollees in Medicare Advantage plans are on the whole healthier than beneficiaries with fee-for-service Medicare coverage (and, in the future if the situation is reversed, or if in a given area enrollees of health plans are sicker than those in fee-for-service Medicare, rebates would be lower than they should be). In other words, risk adjustment ensures that plans are paid appropriately for their enrolled population. The other reason for applying risk adjustment to the savings computation is that a comparison of the ability of health plans to achieve savings should be based on a comparison that takes into account the relative health status of each plan's enrollees in evaluating whether one plan is more "efficient'' than another. To do otherwise would make two plans that are equally efficient look as though one plan (a plan with healthier enrollees) was more efficient than another plan (a plan with sicker enrollees) merely because on a per capita basis the enrollees of the latter plan are more costly than enrollees of the plan with healthier enrollees. If each of the plans is equally efficient, a risk adjustment system would reveal each plan's per capita costs to be the same (assuming beneficiary characteristics other than health status are equal between the two plans). If, under a standard of relative efficiency, two plans are equally efficient, in principle their cost to an enrollee should be the same. If one plan is more efficient than another, beneficiaries would be rewarded for choosing the more efficient plan.

The process called for in the statute for determining a statewide risk adjustment to compute savings for local plans is to compare a risk-adjusted benchmark against risk-adjusted bids. The benchmark, and all plan bids, would be adjusted by the average risk factor for enrollees in all local MA plans in a given State (an enrollment-weighted average that is projected and announced at the time CMS publishes MA rates for a forthcoming year). That is, there is an "apples-to-apples'' comparison of bids to the benchmark, and an "apples-to-apples'' comparison to other plans. The two numbers that are being adjusted, the benchmark and a plan bid, are numbers for an "average'' beneficiary—a beneficiary with demographic and health status characteristics that represent an average across the entire Medicare population in the United States. That is, the benchmark and plan bids that are being adjusted, for purposes of determining the appropriate level of savings, are risk-neutral. (The plan bid that represents a bid for an average, or "1.0'' beneficiary, is referred to in the statute as the "unadjusted MA statutory non-drug monthly bid amount.'')

In terms of the total dollars that will be available as rebate dollars, there is no difference, among equally efficient plans, between a statewide approach versus any other geographic area approach, or a plan-specific approach, to determining an appropriately risk-adjusted savings. In terms of how one plan compares to another in "efficiency,'' a statewide risk adjustment system for rebates treats all equally efficient plans the same with respect to the dollar amount of rebates that are available for enrollees, regardless of the health status of the enrollees. Under a statewide system of determining savings, the adjustment is applied at an area-wide level when the savings computation is subject to risk adjustment. That is, the benchmark, and all bids for the State, are adjusted by the average risk factor across all plans. If, for example, the enrollment-weighted average risk factor across all plans is 1.1 (110 percent of the risk factor for an average beneficiary), both the benchmark and all plan bids are adjusted by this factor to determine the dollar difference between the benchmark and each bid. In essence, this removes relative differences in risk among plans as a factor in determining how one plan's bid compares to another. The only difference that remains among plans is any difference in bids that reflects the relative efficiency of one plan versus another. If all plans are equally efficient—that is, if, for example, all plans are able to provide the Medicare benefit at 80 percent of the benchmark level—all plans will have the same rebate dollar amount available per enrollee (representing 20 percent of the statewide or region-wide benchmark, adjusted by the statewide or region-wide average risk factor). A plan-specific approach would incorporate into the savings computation a risk adjustment factor that can vary from plan to plan, yielding different dollar savings per person at the plan level but resulting in the same total dollar rebates when all plans are equally efficient because the statewide or region-wide method uses a weighted average risk factor across all plans. Assuming that all rebate dollars are used by all plans to reduce the Part B premium, and assuming the risk-adjusted average per capita savings had been computed as $25 per person per month, if an individual joins Plan X, with sicker

beneficiaries, the person receives a $25 reduction in his or her Part B premium, which is the same amount he or she would receive on joining Plan Y, with healthier beneficiaries. This $25 rebate would represent the same value to each beneficiary enrolled in either of the two plans because all beneficiaries across the Nation are faced with the same cost of paying the Part B premium, regardless of their health status or the State or county in which they live. However, if rebate dollars are used for other purposes, the value of the rebate in terms of its "buying power,'' would vary from plan to plan based on the risk profile of the individual plan. Any plan feature that is more expensive if there is higher utilization—for example, the buy-out of cost sharing, or reductions in premiums for supplemental benefits offered by a plan—would have a different value in a plan with a healthier enrollment mix as compared to a plan with sicker enrollees. That is, it costs a plan more to "buy down'' cost sharing for a sicker population than for a healthier population. Enrollees will see that difference as a difference in their out-of-pocket costs, which will be higher in a "sicker'' plan. (For example, if plans have as their starting point an intent to have a $200 copayment for each hospital inpatient admission, and a plan wishes to reduce the copayment to $100 per admission by paying the provider an additional $100 per admission, the total revenue needed to finance this copayment reduction would be higher for a plan with higher rates of hospital admissions than a plan with lower admission rates. If plans have the same level of rebate dollars per capita, the "healthier'' plan can afford enrollees a greater reduction in the hospital copayment (to $50, for example) because the average number of people to whom the copayment applies is lower than in a "sicker'' plan.)

The relatively higher cost of obtaining benefits through a "sicker'' plan can be mitigated by having a plan-specific risk adjustment for the determination of savings. Plans with less healthy enrollees would have rebate amounts higher than other plans that are equally efficient but have healthier enrollees. In terms of what the benefits look like from an enrollee's point of view, a plan-specific adjustment can help achieve parity between "sicker'' and "healthier'' plans. However, as just discussed, a plan-specific approach, if used for a dollar reduction in the Part B premium that makes the "sicker'' plan appear cheaper than the "healthier'' plan defeats the purpose of a rebate, the value of which should only be based on relative efficiency. (As previously discussed, it should also be noted that plan features other than the premium are likely to show a "sicker'' plan as a higher cost plan in terms of cost sharing that enrollees must pay or in terms of the level of extra benefits the plan is able to offer in comparison to a "healthier'' plan. Because of this, the plan-specific approach may be the more desirable approach if the goal is to achieve some type of parity between equally efficient plans.)

As a possible basis for preferring the statewide approach, there is the argument that it is a normal insurance principle that one would expect enrollees of an insurance plan with a relatively sicker covered group to have to pay more than enrollees in a plan with a relatively healthier covered group. As for the plan-specific approach, it is also true that the differences in risk status among plans may even out over time if a plan-specific adjustment is used. More enrollees will be drawn to the less expensive plan (the plan with the higher rebate, which may be less expensive for healthier enrollees, if, for example, extra benefits are the same as in other plans but cost sharing is higher). If beneficiaries make such enrollment choices, the risk profile of the "sicker'' plan will change towards being closer to an average risk profile. Similarly, if a plan that has an apparent advantage in rebates because of selection (enrolling healthier enrollees) rather than because of efficiency, the plan's relative inefficiency will be revealed in subsequent years to the extent that sicker beneficiaries choose to enroll in a plan offering better benefits or lower cost-sharing and premiums.

The preceding discussion deals with plans that are equally efficient and the effects of plan-specific versus statewide risk adjustment in determining rebates. Additional issues arise if there is variation in efficiency among plans and variation in plan risk "profiles'' (the makeup of the plan enrollment by health status). Using a statewide risk adjuster to determine rebates will result in higher program payments if efficient plans have relatively healthier enrollees. Using a plan-specific risk adjustment system will result in higher program payments if efficient plans have relatively sicker enrollees. In general, the lowest program expenditures will occur when the plans with the greatest savings are subject to the lowest possible risk adjustment of those savings—whether it is the plan-specific approach or a statewide or other regional approach. The different effects are illustrated in the hypothetical examples shown in Tables 7, 8, and 9. Tables 10 and 11 show a feature of the law that also affects the outcome, which is that plans in which there are no savings are also taken into consideration in determining the risk adjustment when a statewide or other region-wide method is used.

Table 7 shows that when plans are equally efficient (that is, the savings for a 1.0 beneficiary is the same among plans), either risk adjustment method results in the same level of program payments, regardless of the relative risk profiles of each plan's enrollees. Table 8 shows that if the more efficient of the two plans (in this case, a far more efficient plan) has sicker enrollees, the plan-specific method yields higher rebates and greater program spending. Table 9 shows the situation in which the only difference, compared to the Table 8 scenario, is a reversal of the plan risk scores, with the more efficient plan having healthier enrollees. In such a case, the statewide approach yields higher rebates for plan enrollees and higher program spending. Tables 8 and 9 illustrate that even though it is only the hypothetical Plan ABC that is efficient and has any appreciable savings, how these savings are translated into rebates is very much dependent on the characteristics of competing plans when the statewide or region-wide risk adjustment method is used. Similarly, Tables 10 and 11 illustrate the same circumstances with regard to the effect of plans with no savings. 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.

TABLE 7.—SAVINGS AND REBATES FOR EQUALLY EFFICIENT PLANS

	Plan ABC	Plan XYZ	Totals
Benchmark	$700	$700	.....
Bid (for "1.0,'' average risk individual)—Both plans equally efficient	$600	$600	.....
Enrollees	1000	1000	2,000

TABLE 7.—SAVINGS AND REBATES FOR EQUALLY EFFICIENT PLANS—Continued

	Plan ABC	Plan XYZ	Totals
Risk At Plan Level in Relation to 1.0—ABC Plan has sicker enrollees	1.4	0.8	.....
Enrollment-Weighted Statewide Average Risk Computation	0.70	0.40	1.10
Savings With Statewide Method: Adjust Bid and Benchmark by Statewide Average Risk Factor			
Adjust Benchmark	$770	$770	.....
Adjust Bid	$660	$660	.....
Per Capita Savings with Statewide Method	$110	$110	.....
Total Savings	$110,000	$110,000	$220,000
Savings With Plan-Specific Method: Adjust Bid and Benchmark by Plan-Specific Risk Factor			
Adjust Benchmark	$980	$560	.....
Adjust Bid	$840	$480	.....
Per Capita Savings with Plan-Specific Method	$140	$80	.....
Total Savings	$140,000	$80,000	$220,000
Computation of Total Medicare Payment to Plans and on Behalf of Enrollees			
Statewide—			
Plan's Risk-Adjusted Bid × Enrollment	$840,000	$480,000	$1,320,000
Statewide Rebate × Enrollment × .75	$82,500	$82,500	$165,000
Total Payment to Plans	$922,500	$562,500	$1,485,000
Per Enrollee Rebate	$82.50	$82.50	.....
Plan-Specific—			
Plan's Risk-Adjusted Bid × Enrollment	$840,000	$480,000	$1,320,000
Plan-Specific Rebate × Enrollment × .75	$105,000	$60,000	$165,000
Total Payment to Plans	$945,000	$540,000	$1,485,000
Per Enrollee Rebate	$105	$60	.....
Net Effect: Each Method Results in the Same Level of Program Payments			

TABLE 8.—SAVINGS AND REBATES WHEN EFFICIENT PLAN HAS SICKER ENROLLEES

	Plan ABC	Plan XYZ	Totals
Benchmark	$700	$700	
Bid (for "1.0," average risk individual)—ABC Plan far more efficient	$600	$699	
Enrollees	1000	1000	2,000
Risk At Plan Level in Relation to 1.0—ABC Plan has sicker enrollees	1.4	0.8	
Enrollment-Weighted Statewide Average Risk Computation	0.70	0.40	1.10
Savings With Statewide Method: Adjust Bid and Benchmark by Statewide Average Risk Factor			
Adjust Benchmark	$770	$770	
Adjust Bid	$660	$769.99	
Per Capita Savings with Statewide Method	$110	$0.01	
Total $$ of Savings	$ 110,000	$11	$110,011
Savings With Plan-Specific Method: Adjust Bid and Benchmark by Plan-Specific Risk Factor			
Adjust Benchmark	$980	$560	
Adjust Bid	$840	$559.99	
Savings with Plan-Specific Method	$140	$0.01	
Total Savings	$140,000	$8	$140,008
Computation of Total Medicare Payment to Plans and on Behalf of Enrollees			
Statewide—			
Plan's Risk-Adjusted Bid × Enrollment	$840,000	$559,992	$1,399,992
Statewide Rebate × Enrollment × .75	$82,500	$8.25	$82,508.25
Total Payment to Plans	$922,500	$560,000.25	$1,482,500
Per Enrollee Rebate:	$82.50	$0.01	
Plan-Specific—			
Plan's Risk-Adjusted Bid × Enrollment	$ 840,000	$559,992	$1,399,992

TABLE 8.—SAVINGS AND REBATES WHEN EFFICIENT PLAN HAS SICKER ENROLLEES—Continued

	Plan ABC	Plan XYZ	Totals
Plan-Specific Rebate × Enrollment × .75	$105,000	$6	$105,006
Total Payment to Plans	$945,000	$559,998	$1,504,998
Per Enrollee Rebate:	$105	$0.01	
Net Effect: Plan-Specific Method Yields Higher Program Payments Totaling: $22,498			

TABLE 9.—SAVINGS AND REBATES WHEN EFFICIENT PLAN HAS HEALTHIER ENROLLEES

	Plan ABC	Plan XYZ	Totals
Benchmark	$700	$700	
Bid (for "1.0," average risk individual)—ABC Plan far more efficient	$600	$699	
Enrollees	1000	1000	2,000
Risk At Plan Level in Relation to 1.0—XYZ Plan has sicker enrollees	.8	1.4	
Enrollment-Weighted Statewide Average Risk Computation	0.40	0.70	1.10
Savings With Statewide Method: Adjust Bid and Benchmark by Statewide Average Risk Factor			
Adjust Benchmark	$770	$770	
Adjust Bid	$660	$769.99	
Per Capita Savings with Statewide Method	$110	$0.01	
Total $$ of Savings	$110,000	$11	$110,011
Savings With Plan-Specific Method: Adjust Bid And Benchmark by Plan-Specific Risk Factor			
Adjust Benchmark	$560	$980	
Adjust Bid	$480	$979.99	
Savings with Plan-Specific Method	$80	$0.01	
Total Savings	$80,000	$14	$80,014
Computation of Total Medicare Payment to Plans and on Behalf of Enrollees			
Statewide			
Plan's Risk-Adjusted Bid × Enrollment	$480,000	$979,986	$1,459,986
Statewide Rebate × Enrollment × .75	$82,500	$8.25	$82,508.25
Total Payment to Plans	$562,500	$979,994.25	$1,542,494
Per Enrollee Rebate	$82.50	$0.01	
Plan-Specific			
Plan's Risk-Adjusted Bid × Enrollment	$480,000	$979,986	$1,459,986
Plan-Specific Rebate × Enrollment × .75	$60,000	$10.50	$60,010.50
Total Payment to Plans	$540,000	$979,996.50	$1,519,997
Per Enrollee Rebate	$60	$0.01	
Net Effect: Statewide Method Yields Higher Program Payments Totaling: $22,498			

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Table 10: The Effect of Plans Bidding Above Benchmark; Efficient Plans Have Healthier Enrollees

	Plan ABC	Plan XYZ	Plan Over1	Plan Over2
Benchmark	$700	$700	$700	$700
Bid (For 1.0)—Plans with Savings Equally Efficient	$600	$600	$750	$780
Enrollees (Total Enrollment 4,000)	1000	1000	1000	1000
Risk At Plan Level—Plans with Savings Have Healthier Enrollees	0.9	0.9	2	2
Enrollment-Weighted Statewide Average Risk Computation (Sum of All for Each Plan = 1.45)	0.225	0.225	0.50	0.50
Savings Using Statewide: Adjust Bid & Benchmark By Statewide Average Risk Factor				
Adjust Benchmark	$ 1,015	$ 1,015		
Adjust Bid	$870	$870		
Per Capita Savings With Statewide Method	$145	$145		
Savings Using Plan-Specific: Adjust Bid & Benchmark By Plan-Specific Risk				
Adjust Benchmark	$630	$630		
Adjust Bid	$540	$540		
Per Capita Savings With Plan-Specific Method	$90	$90		
Computation of Total Medicare Payment to Plans And on Behalf of Enrollees: Statewide			**TOTALS**	
Plan Risk-Adjusted Bid x Enrollment	$ 540,000	$ 540,000	$1,080,000	
Statewide Rebate x Enrollment x .75	$ 108,750	$108,750	$217,500	
TOTAL PAYMENT TO PLANS	$ 648,750	$648,750	$1,297,500	
Per Enrollee Rebate:	**$108.75**	**$108.75**		

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Computation of Total Medicare Payment to Plans And on Behalf of Enrollees: Plan-Specific			
Plan Risk-Adjusted Bid x Enrollment	$ 540,000	$ 540,000	$1,080,000
Plan-Specific Rebate x Enrollment x .75	$ 67,500	$ 67,500	$135,000
TOTAL PAYMENT TO PLANS	$ 607,500	$ 607,500	$1,215,000
Per Enrollee Rebate:	$ 67.50	$ 67.50	
NET EFFECT: Statewide Method Yields Higher Program Payments Totaling $ 82,500			

Table 11: The Effect of Plans Bidding Above Benchmark; Efficient Plans Have Sicker Enrollees

	Plan ABC	Plan XYZ	Plan Over1	Plan Over2
Benchmark	**$700**	**$700**	**$700**	**$700**
Bid (For 1.0)—Plans with Savings Equally Efficient	**$600**	**$600**	**$750**	**$780**
Enrollees (Total Enrollment 4,000)	**1000**	**1000**	**1000**	**1000**
Risk At Plan Level—Plans with Savings Have Healthier Enrollees	**1.4**	**1.2**	**0.8**	**0.7**
Enrollment-Weighted Statewide Average Risk Computation (Sum of All for Each Plan = 1.025)	**0.35**	**0.30**	**0.20**	**0.175**
Savings Using Statewide: Adjust Bid & Benchmark By Statewide Average Risk Factor				
Adjust Benchmark	$717.50	$ 717.50		
Adjust Bid	$615	$ 615		
Per Capita Savings With Statewide Method	$102.50	$ 102.50		
Savings Using Plan-Specific: Adjust Bid & Benchmark By Plan-Specific Risk				
Adjust Benchmark	$980	$840		
Adjust Bid	$840	$720		
Per Capita Savings With Plan-Specific Method	$140	$ 120		
Computation of Total Medicare Payment to Plans And on Behalf of Enrollees: Statewide			**TOTALS**	
Plan Risk-Adjusted Bid x Enrollment	$840,000	$720,000	$ 1,560,000.00	
Statewide Rebate x Enrollment x .75	$76,875	$76,875	$ 153,750.00	
TOTAL PAYMENT TO PLANS	$916,875	$796,875	$ 1,713,750	
Per Enrollee Rebate:	$76.87	$76.87		

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Computation of Total Medicare Payment to Plans And on Behalf of Enrollees: Plan-Specific			
Plan Risk-Adjusted Bid x Enrollment	$840,000	$720,000	$ 1,560,000.00
Plan-Specific Rebate x Enrollment x .75	$105,000	$90,000	$ 195,000.00
TOTAL PAYMENT TO PLANS	$945,000	$ 810,000	$1,755,000
Per Enrollee Rebate:	$ 105	$ 90	
NET EFFECT: Plan-Specific Method Yields Higher Program Payments Totaling $ 41,250			

There is another issue, which is that competing directly against each other. within a State, local plans may not be That is, in a large State, health plans in

one section of the State may not be competing against health plans in another section of the State, or the State could be served by individual plans in individual counties (to use an extreme example), each of which operates in non-overlapping service areas where there is only one plan option available to beneficiaries. In the latter case of single non-competing plans, using a statewide risk adjuster would seem to be unfair to plans and enrollees. In such a situation, it would seem that the fairest approach is to employ a plan-specific risk adjuster. Similarly, if there are discrete market areas smaller than a State in which health plans compete, then—as implied in the statutory language—the appropriate course might be to use a Metropolitan Statistical Area as the geographic area in which a multi-plan risk adjustment system will be used to determine the rebate computation (if CMS decides against the general application of the plan-specific option). In that way, savings that health plans in a particular MSA can achieve would be used for enrollees in that MSA rather than being applicable to a wider geographic area.

The statewide approach to determining rebates differs from the current method of determining savings, which is essentially done on a plan-specific basis (and therefore using the statewide method may result in a different competitive dynamic among plans). The current system for computing extra benefits that enrollees may be entitled to—which will continue through 2005—uses the "adjusted community rate proposal'' process. Under this process for determining whether there is excess revenue, there are actual and implicit adjustments at the plan-specific level to account for the risk profile of a plan's enrollees. The excess revenue determination (that is, the savings computation) is based on a comparison of a plan's stated "average payment rate'' from CMS (a projection of what CMS will pay the plan—which is a risk-adjusted payment) compared to the plan's "adjusted community rate'' (a Medicare term) for its projected Medicare enrollment. This "community rate'' is implicitly adjusted for the risk status of projected Medicare enrollees because the "adjusted'' aspect of the Medicare "adjusted community rate'' is the adjustment that a plan makes to reflect the relatively higher utilization of Medicare enrollees as compared to other enrollees to whom a community rate applies. That is, under a strict community rating system, each group seeking to buy health care coverage from a community-rated plan will receive the same quoted community rate as any other group that is buying coverage (for the same benefit package) from the health plan, regardless of the expected costs and health status of the particular group seeking coverage. For Medicare, plans are allowed to adjust the rate to reflect the utilization and higher expenditures associated with Medicare enrollees. The adjustment is made on the basis of the plan's own history with respect to the relative costs of its Medicare enrollees. Hence, there is an implicit risk adjustment of the "community rate'' as it would apply to this segment of a health plan's enrollment. The amount that, under the current system, a Medicare plan must return to beneficiaries as extra benefits when there is excess revenue is the difference between the "adjusted community rate''—implicitly adjusted for risk, as just described—and Medicare's average payment rate, which is explicitly risk adjusted, using CMS risk adjustment factors, at the plan level. The analogue of the current practice would be the plan-specific approach to determining the calculation of savings (rather than what is essentially a type of pooling of savings across multiple plans if the statewide method were to be used).

As noted in the preamble, we welcome comments on the issues related to statewide versus plan-specific (or other geographic area) risk adjustment for the purpose of determining the distribution of rebates among plan enrollees.

3. Prohibiting Use of Rebate Dollars for the Purchase of Optional Supplemental Benefits

The MMA retains a provision from pre-existing law that allows health plans to have optional supplemental benefits that Medicare enrollees can choose to purchase for an additional premium (section 1852(a)(3)(B)). Such optional supplemental packages are financed entirely by enrollee premiums (as is also currently true of mandatory supplemental packages that all beneficiaries are required to purchase from an MA plan, if the mandatory supplement is approved by CMS). Once the bidding system begins in 2006, the concept of an optional supplemental offering seems inconsistent with the new design of the MA program in two ways: with regard to the question of whether an optional supplemental package can have its price reduced by a rebate (which, as explained below, appears not be administratively feasible); and also with regard to the question of how to deal with an optional supplemental package that, because of its features, would have an effect on a plan's bid for coverage of Part A and B services (for example, an optional supplement that buys down cost sharing for A and B services). As noted in the preamble we are prohibiting plans from applying rebate dollars to optional supplemental premiums, and we are asking for comment on the issue of whether optional supplemental plans may include benefits that affect the utilization of A and B services. (The latter issue is discussed in the preamble.)

Under the current adjusted community rate process (the process by which plans submit premium and benefit proposals to CMS for approval), what in 2006 will become rebate dollars are termed "excess revenue.'' Excess revenue amounts have to be "returned'' to beneficiaries in the form of extra benefits, reduced cost sharing, or reduced premiums for basic or mandatory supplemental benefits—that is, a benefit spread over the entire enrolled population. Excess revenue cannot be used to reduce an optional supplemental premium that beneficiaries can decline to pay. Although the statute governing the use of savings beginning in 2006 states that each enrollee is entitled to a rebate of 75 percent of savings (1854(b)(1)(C)), which can be applied as a credit "toward an MA monthly supplemental beneficiary premium (if any),'' the statute is silent on the question of whether in 2006 rebates may be applied to optional supplemental packages. One could infer that such a use of rebate dollars is permitted because there is no specific statutory prohibition.

As explained in the preamble, we do not believe that applying a rebate to an optional supplemental benefit is consistent with the requirement that each beneficiary enrolled in a plan is entitled to the same dollar value of the rebate ("the MA plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings'' (1854(b)(1)(C)). (There could be an administratively cumbersome way of permitting the use of rebate dollars to optional supplemental premiums. Because enrollees can decline an optional package, enrollees would have to have an alternative option, or a menu of options to choose from, to fully allocate the individual rebate. For example, if the rebate amount was $50 per month, and an optional supplement was offered at $25, enrollees choosing the supplement would have to dispose of $25 (for example, by a reduction in the Part B premium), and those who decline would have to dispose of $50 (for example, by a $50 reduction in the

Part B premium). We believe, however, that this would present overly burdensome administrative problems for health plans as well as for CMS and the Social Security Administration if there were variable Part B premium rates at the sub-plan level. Rather than relying on the plan identifier to determine the appropriate premium reduction amount, each person's record would have to carry the premium reduction information.)

4. Intra-Area Geographic Adjustment to Payments

In addition to the discussion in the preamble of the adjustment for intra-area variation, which the statute says "shall'' be applied to bids and benchmarks, we would note that the statute and the conference report refer only to adjustments to reflect "variations in MA local payment rates,'' for both local and regional plans. A literal interpretation of the language would entail using only the MA payment rates as the basis for making adjustments to bids and benchmarks. Clearly, although for local plans it may be appropriate to use a benchmark adjustment based on variation in local MA payment rates, for a regional plan such an adjustment to the benchmark is problematic because the benchmarks for regional plans include plan bids as a component of the benchmark. Hence, we believe a strictly literal interpretation is not consistent with the Medicare Advantage bidding and payment process.

The initial bid for a multi-county local plan or for a regional plan assumes a certain mix of enrollees from different parts of the geographic area. The plan presents a single average bid that covers its revenue needs for the population that it assumes will enroll in the plan. If the plan's enrollment mix is from a different geographic area with substantially different costs, the plan's initial bid will either be higher or lower than its actual revenue needs. The plan's costs may not bear a direct relation to Medicare payment rates in a county—particularly if the county rate is historically a "floor'' rate (and even when the county rate is based on Medicare fee-for-service rates the payment rate may not represent plan costs, as is clear from the present pattern of extra benefits available to enrollees in MA plans).

The preamble mentions possible ways to ensure that there is an appropriate intra-area adjustment, and seeks public comment on the different options. The suggested approaches seek to establish a relative relationship among the counties in the areas in question, though each is an imprecise measure for purposes of adjusting the bid. For example, in the same way that local Medicare fee-for-service expenditures may not reflect plan revenue needs in a given county, using the relationship between a county's Medicare fee-for-service expenditures and national expenditures, as the preamble suggests, may also not accurately reflect the variation that health plans see in their costs. Using only input prices, as is also suggested, of course ignores utilization differences (practice patterns, beneficiary preferences, the mix of services) that may appropriately be a component of the costs that plans face in a given county.

Another option that we had considered is to have plans themselves provide CMS with the plan's statement of the relationship among counties (or broader geographic area) with regard to the relative revenue needs for each area. CMS would then use the plan's statement of relative costs to make intra-area adjustments. This approach may also be somewhat imprecise in that a plan's revenue needs in a given county may vary with the size of enrollment (for example, a large enrollment base in a county may enable a plan to secure more favorable contracting arrangements from providers, thereby lowering plan costs).

M. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf)*, in Table 12 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. All expenditures are classified as transfers to either beneficiaries or health plans. 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.

TABLE 12.—ACCOUNTING STATEMENT: CLASSIFICATION OF EXPENDITURES, 2004 THROUGH 2009

[Dollars in millions, discounted to 2001 present value]

Transfers	
Three Percent Annual Discount Rate.	
Annualized Monetized Transfers: "On Budget".	19,083.
From Whom To Whom?.	Federal Government To Private Plans.
Annualized Monetized Transfers: "On Budget".	1,659.
From Whom To Whom?.	Federal Government To Medicare Beneficiaries.
Seven Percent Annual Discount Rate.	
Annualized Monetized Transfers: "On Budget".	15,232.
From Whom To Whom?.	Federal Government To Private Plans
Annualized Monetized Transfers: "On Budget".	1,325.
From Whom To Whom?.	Federal Government To Medicare Beneficiaries.

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 proposes to amend 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 contracts are accepted by CMS. CMS will, however, accept and approve applications to modify cost 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 contract. Section 1876 cost 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 service area reduction and contract non-renewal.* CMS will non-renew all or a portion of an HMO's or CMP's service area using procedures in § 417.492(b) 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 year meeting one of 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 year meeting one of 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 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. 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

6. 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).

7. Revise the heading of Part 422 to read as set forth above.

Subpart A—General Provisions

8. 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.

* * * * *

9. 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."

D. Nomenclature change: In the definitions of "M+C eligible individual," "M+C organization," "M+C plan," and "M+C plan enrollee," every occurrence of "M+C" is removed and "MA" is added in its 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 in a long-term care facility for 90 days or longer, as determined by the presence of a 90-day assessment in the Minimum Data Set (MDS).

* * * * *

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 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) means approved prescription drug coverage that is offered under a policy, contract, or plan that has been approved as meeting the requirements specified in part 423 of this chapter and that is offered by a MA organization that has a contract with CMS that meets the contract requirements under part 423 of this chapter and does not include a fallback plan unless specifically identified as a prescription drug plan.

Prescription drug plan (PDP) sponsor means a nongovernmental entity that is certified under part 423 of this chapter as meeting the requirements and standards of that part for that sponsor.

* * * * *

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. 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.

(ii) The extent to which the proposed services area mirrors service areas of existing commercial health care plans or MA plans offered by the organization.

(iii) For MA coordinated care plans and network MA MSA 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.

(iv) For non-network MA MSA plans, CMS may approve single county non-network MA MSA plans even if the MA organization's commercial plans have multiple county service areas.

(2) 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 for Medicaid under title XIX, or has severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA based on criteria established by CMS.

Specialized MA Plans means any type of MA coordinated care plan that exclusively enrolls special needs individuals.

10. 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).

The revisions and additions read as follows:

§ 422.4 Types of MA plans.

(a) *General rule.* * * *

(1) *A coordinated care plan.* * * *

(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, RFBs, and other network plans (except network MSA and PFFS plans).

(iv) A specialized MA plan includes any type of coordinated care plan that exclusively enrolls special needs individuals as defined in § 422.2.

(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.

* * * * *

§ 422.6 [Removed]

11. Remove § 422.6.

§ 422.8 [Removed]

12. Remove § 422.8.

§ 422.10 [Redesignated and Amended]

13. 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) *Collection of fees.* * * *

(2) *Amount to be collected.* * * *

(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' 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' estimate of Medicare Part D prescription drug expenditures for those 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' 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

14. Amend § 422.50 by—

A. Revising the section heading.

B. Adding an introductory text.

C. 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 § 422.4 unless specifically noted otherwise.

(a) * * *

(5) Completes and signs an election form or another CMS approved election method and gives information required for enrollment; and

* * * * *

15. Add § 422.52 to read as follows:

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

(a) *General rule*. To elect an MA plan for special needs individuals, an individual must meet eligibility requirements specified in this section.

(b) *Basic eligibility requirements*. To be eligible to elect a special needs MA plan, an individual must meet the eligibility requirements for that plan, as well as MA as described in § 422.50. Further, the individual must—

(1) Be institutionalized in a Medicare or Medicaid certified institution as defined by CMS; or

(2) Be entitled to medical assistance under a State plan under title XIX of the Act; or

(3) Meet other eligibility requirements established by CMS to identify individuals who would benefit from enrollment in such a specialized MA plan.

(c) CMS may waive § 422.50(a)(2) that excludes persons with ESRD.

(d) *Deeming continued eligibility*. If a special needs MA plan determines that the enrollee no longer meets the eligibility criteria, but it is reasonable to expect that, in the absence of continued coverage under the MA plan, the individual would meet the special needs criteria of the plan within a certain period of time, as specified by CMS, the enrollee may be deemed to continue to be eligible for the MA plan.

(e) *Exceptions*. As specified in § 422.4, CMS may designate certain MA plans that disproportionately serve special needs beneficiaries as "specialized'' MA plans for special needs individuals. If CMS provides the designation:

(1) Individuals already enrolled in an MA plan that CMS subsequently designates as a special needs MA plan may continue to be enrolled in the plan.

(2) The MA plan may restrict future enrollment to only certain specialized needs individuals, as established under § 422.4.

16. 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).

* * * * *

17. 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.

* * * * *

18. 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 have been 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.

§ 422.62 [Amended]

19. 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.

(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. 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 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.

(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 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 or annual election period described in paragraphs (a)(1) and (a)(2) of this section.

* * * * *

20. 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).

* * * * *

(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, the organization does not offer, or the individual does not elect, the option of continuing enrollment, as provided under § 422.54(b)(3)(ii).

(2) 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.

(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) If an individual is enrolled with an MA organization that in 2005 offers more than one MA plan that includes drug coverage; the MA plan in which the individual is enrolled as of December 31, 2005 includes drug coverage; and that MA plan becomes an MA–PD plan on January 1, 2006, the individual will be deemed to have elected to enroll in that MA–PD plan.

(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.

21. Amend § 422.68 by revising paragraph (b) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(b) *Annual election periods.* For an election or change of election made during an annual election period as described in § 422.62(a)(2), coverage is effective as of the first day of the following calendar year except that for the special annual 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.

* * * * *

22. Amend § 422.74 by—

A. Revising the section heading.

B. Revising paragraph (b)(1)(ii).

C. Revising paragraph (c)(1).

D. Revising paragraph (d)(1).

E. Revising paragraph (d)(2).

The revisions read as follows:

§ 422.74 Disenrollment by the Medicare Advantage Organization.

* * * * *

(b) * * *

(1) * * *

(ii) The individual has engaged in disruptive or threatening behaviors specified at paragraph (d)(2) of this section.

* * * * *

(c) * * *

(1) Be provided to the individual before submission of the disenrollment transaction 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.

(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 or threatening behavior*—(i) *Basis for disenrollment.* An MA organization may disenroll an individual from the MA plan if the individual's behavior is disruptive, unruly, abusive, uncooperative, or threatening. Disruptive behavior may not be based upon the use of medical services or noncompliance with medical advice. An individual who engages in disruptive or threatening behavior refers to an individual who exhibits any of the following:

(A) An individual whose behavior jeopardizes his or her health or safety, or the safety of others;

(B) An individual whose behavior impairs the MA's ability to furnish services to either the individual or other individuals enrolled in the plan; or

(C) An individual with decision-making capacity who refuses to comply with the terms of the enrollment agreement.

(ii) *Effort to resolve the problem.* The MA organization must make a serious effort to resolve the problems presented by the individual, including the use (or attempted use) of the MA organization's grievance procedures. The beneficiary has a right to submit any information or explanation that he or she may wish to submit to the MA organization.

(iii) *Documentation.* 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.

(iv) *CMS review of the proposed disenrollment.* CMS will decide after reviewing the documentation submitted by the MA organization and any information submitted by the beneficiary (which the MA organization must forward to CMS) whether the MA organization has met the criteria for disenrollment for disruptive or threatening behavior. CMS will make the decision within 20 working days after receipt of the documentation and will notify the MA organization within 5 working days after making its decision.

(v) *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.

(vi) *Reenrollment in the MA organization.* Once an individual is disenrolled from the MA organization for disruptive behavior, the MA organization has the option to decline future enrollment by the individual for a period of time specified by CMS.

(vii) *Expedited process.* In the event that an individual's disruptive or threatening behavior is so extreme as to have caused harm to others or prevented the MA plan from providing services, CMS may consider allowing an expedited disenrollment process.

* * * * *

23. Amend § 422.80 by—

A. Revising paragraph (a)(2).

B. Adding paragraph (a)(3).

C. Revising paragraph (e)(1)(ii).

D. Revising paragraph (e)(1)(iii).

E. Revising paragraph (e)(1)(iv).

F. Revising paragraph (e)(1)(v).

G. Adding paragraph (e)(1)(ix).

The revisions and additions read as follows:

§ 422.80 Approval of marketing materials and election forms.

(a) * * *

(1) * * *

(2) CMS does not disapprove the distribution of new material or form; or

(3) If the MA plan is deemed by CMS to meet certain performance requirements established by CMS, the MA plan may distribute designated marketing materials 5 days following their submission to CMS.

* * * * *

(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]

24. 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 the heading of newly redesignated paragraph (f).

J. Revising newly redesignated paragraph (f) introductory text.

K. 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 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, expect 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

* * * * *

25. Amend § 422.101 by—

A. Revising paragraph (b)(2).

B. Adding paragraph (b)(4).

C. Adding paragraph (d).

D. 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

* * * * *

(4) Instead of applying rules in paragraph (b)(3) of this section, an organization offering an MA regional plan may elect to have any local coverage determination that applies in any part of an MA region apply to all parts of that same MA region. The election is at the discretion of the MA regional plan and is not subject to CMS pre-approval.

* * * * *

(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 permitted 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) *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) *Additional catastrophic limit.* MA regional plans are required to provide an additional 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 second 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 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 § 422.308, 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.

26. 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)(B) of the Act as a mandatory supplemental benefit.

* * * * *

27. 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.

* * * * *

28. Amend 422.105 by revising paragraph (a) to read as follows:

§ 422.105 Special rules for point of service option.

(a) 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, then when those members receive what is a covered item or service from contracted providers 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. 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 § 422.312;

(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 is permitted to offer a POS–LIKE benefit as described in paragraphs (a)(2) or (a)(3) of this section as a supplemental benefit. An MA regional plan 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 responsibility to provide reimbursement for all covered benefits, regardless of whether those benefits are provided within the network of contracted providers.

* * * * *

29. 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 MA organization in developing its bid.

(d) *Employer sponsored MA plans for plan years beginning on or after January 1, 2006.* (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.

(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.

30. 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.

30. 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.

* * * * *

32. 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]

33. Amend § 422.111 by—

A. Revising paragraph (b)(3).

B. Revising paragraph (c)(1).

C. Revising paragraph (d)(2).

D. Revising paragraph (e).

E. Removing paragraph (f)(4).

C. Removing paragraph (f)(6).

D. Redesignating paragraph (f)(5) as paragraph (f)(4).

E. Redesignating paragraph (f)(7) as paragraph (f)(5).

F. Redesignating paragraph (f)(8) as paragraph (f)(6).

G. Redesignating paragraph (f)(9) as paragraph (f)(7).

H. Redesignating paragraph (f)(10) as paragraph (f)(8).

I. Redesignating paragraph (f)(11) as paragraph (f)(9).

J. Revising newly redesignated paragraph (f)(5)(iv).

K. Removing newly redesignated paragraph (f)(5)(v).

L. Redesignating paragraph (f)(5)(vi) as paragraph (f)(5)(v).

M. Redesignating paragraph (f)(5)(vii) as paragraph (f)(5)(vi).

N. Redesignating paragraph (f)(5)(viii) as paragraph (f)(5)(vii).

O. Revising newly redesignated paragraph (f)(9).

P. Adding new paragraph (f)(10).

The revisions and addition read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(b) * * *

(3) *Access.* The number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected 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.

* * * * *

(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 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 providers from whom the enrollee may obtain in-network coverage in other areas.

§ 422.112 [Amended]

34. Amend § 422.112 by—

A. Revising paragraph (a)(1).

B. Removing paragraph (a)(4).

C. Removing paragraph (a)(7).

D. Redesignating paragraph (a)(5) as paragraph (a)(4).

E. Redesignating paragraph (a)(6) as paragraph (a)(5).

F. Redesignating paragraphs (a)(8) as paragraph (a)(6).

G. Redesignating paragraph (a)(9) as paragraph (a)(7).

H. Redesignating paragraph (a)(10) as paragraph (a)(8).

I. Removing paragraph (b)(4)(i).

J. Redesignating paragraph (b)(4)(ii) as paragraph (b)(4)(i).

K. Redesignating paragraph (b)(4)(iii) as paragraph (b)(4)(ii).

L. Adding paragraph (c).

The revisions and addition read as follows:

§ 422.112 Access to services.

(a) Rules for coordinated care plans.

* * *

(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.

* * * * *

(c) *Essential hospital.* An MA regional plan may seek, upon application to CMS, to designate a 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 as defined in section 1886(d) 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.

(4) 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 enrollees.

(5) If CMS determines the requirements in paragraphs (c)(1) through (c)(4) of this section have been met, it will make payment to the essential hospital in accordance with section 1858(h)(2) of the Act, as limited by the amounts specified in section 1858(h)(3) of the Act.

35. 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 admission.

* * * * *

36. 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) 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.

37. 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

38. In subpart D, remove "quality assurance'' wherever it appears and add in its place "quality improvement.''

39. 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 § 422.152(e)) 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 outcome 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 participating in 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]

40. Remove § 422.154.

41. Amend § 422.156 by adding paragraph (b)(7) to read as follows:

§ 422.156 Compliance deemed on the basis of accreditation.

* * * * *

(b) * * *

(7) Part D prescription drug benefit programs that are offered by MA programs.

* * * * *

Subpart E—Relationships With Providers

§ 422.208 [Amended]

42. 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.

* * * * *

45. 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.

46. 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.)

43. Subpart F is removed.

44. New subpart F is added 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. Payments to MA local plans are based on the payment amount for each MA local area in the local plan's service area.

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 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 fee-for-service 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) 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.

(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.

(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. Plan assumptions about revenue requirements must include adjustments for the effect that providing reductions in Part C and/or Part D cost sharing has on utilization.

(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 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.

(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 and the proportions under paragraph (c)(3) 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.

(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; and

(3) The amount of the plan deductible;

(4) The amount of the beneficiary supplemental premium, if any.

(f) For plans with Part B only enrollees, MA organizations must submit separate bids for their Part A and Part B enrolled members and their Part B only members.

§ 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 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 should reflect the plan's estimated revenue requirements for providing the benefit package, as the term revenue requirements is used in 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.

(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 (b)(3) of this section; and the plan bid component (based on a weighted average of plan bids in the region as described in paragraph (b)(5) 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 amounts.* CMS calculates the monthly regional non-drug benchmark amounts 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 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, any MA regional plan is being offered, and more than one MA plan is being offered: CMS will determine each plan's share of enrollment based on one of two possible approaches. CMS may base this 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 on each plan's estimate of projected enrollment. 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. 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 under § 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 (b)(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 (b)(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 § 422.256 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)(1).

(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, 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) 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; or

(4) According to additional CMS guidelines.

(5) 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.

§ 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) 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), (c)(2), or (c)(3) of this section determined for the purpose of calculating savings amounts for MA local plans.

(1) *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.

(2) 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.

(3) For the purpose of calculating savings for MA local plans CMS has the authority to apply risk adjustment factors determined on a basis other than States, including a plan-specific basis.

(d) *Computation of savings for MA regional plans.* The average per capita monthly savings for an MA local 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), (e)(2), or (e)(3) of this section determined for the purpose of calculating savings amounts for MA regional plans.

(1) *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.

(2) 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.

(3) For the purpose of calculating savings for MA regional plans, CMS has the authority to apply risk adjustment factors determined on a basis other than MA regions, including a plan-specific 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 toward supplemental health care benefits for enrollees as described in § 422.102, which may include the reduction of cost sharing and additional health care benefits that are not benefits under original Medicare. MA organizations may also credit some part, or all, of the rebate, toward an MA monthly supplemental beneficiary premium (if any). 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 that offer a prescription drug benefit 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).

§ 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.

47. Subpart G is removed.

48. New subpart G is added 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.
422.312 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 (described at § 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 (described at § 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 less 1/12 of the annual lump sum amount (if any) CMS deposits to the enrollee's MA MSA, determined in accordance with § 422.314(c), risk adjustment as set forth at § 422.308(c).

(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(b)(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 to MA regional plans, CMS will adjust the payment amounts specified at § 422.304(a)(1) and (a)(2) to take into account variations in local payments rates among the different MA local areas included in the region.

(2) *Intra-service area variations.* For payments to MA local plans with service areas covering more than one MA local area (county), CMS will adjust the payment amounts 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 and beneficiary premiums.* 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.

(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. (For example, the interim risk adjustment factors for CY 2004 were based on data for services furnished during the period July 1, 2002 through June 30, 2003, and the final risk adjustment factors for CY 2004 were based on data for services furnished during the period January 1, 2003 through December 31, 2003.)

(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. (For example, the deadline for submission of data for the period July 1, 2002 through June 30, 2003 was September 5, 2003, and the deadline for the period January 1, 2003 through December 31, 2003 was March 5, 2004.)

(2) CMS allows a reconciliation process to account for late data submissions. CMS continues to accept risk adjustment data submitted after the September and March deadlines until June 30 and December 31 of the payment year, respectively. (For example, until June 30, 2004 for data from the period July 1, 2002 through June 30, 2003; and, until December 31, 2004 for data from the period January 1, 2003 through December 31, 2003.) 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 the 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 IRS Code, to act as a trustee of individual retirement accounts;

(3) Agree to comply with the MA MSA provisions of section 138 of the IRS 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 benchmark amount for the area determined under § 422.306.

(ii) If the monthly MA MSA premium is less than 1/12 of the annual capitation rate, 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; 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 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

49. 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.

50. 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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51. A new subpart J is added to read as follows:

Subpart J—Special Rules for MA Plans

Sec.
422.451 Moratorium on new local preferred provider organization plans.
422.455 Special rules for MA plans.
422.458 Risk sharing with regional MA organizations for 2006 and 2007.

Subpart J—Special Rules for MA 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 plan was offered before December 31, 2005.

§ 422.455 Special rules for MA 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) 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 benefits that require expenditures by the plan. For purposes of the calculation of risk corridors, these are the only supplemental benefits that count towards 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 and 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.* In the case of an MA organization that is offering an MA regional plan in an MA region, 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 and CMS will apply its licensing rules 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 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, 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) *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 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)(ii)(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—Contracts With Medicare Advantage Organizations

§ 422.501, § 422.502, and § 422.504 [Redesignated]

52. Redesignate § 422.501, § 422.502, and § 422.504 as § 422.503, § 422.504, and § 422.505 respectively.

53. 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.* CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plans meet the requirements 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 exceptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), should label the material "privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5.

54. 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) If the application is incomplete, CMS notifies the contract applicant and allows 30 days from the date of the notice for the contract applicant to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the contract 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 from a contract applicant based on the contract 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 may be approval, intent to deny, or denial.

(d) *Approval of application.* If CMS approves the application, it gives written notice to the contract applicant, indicating that it meets the requirements for an MA contract.

(e) *Intent to deny.* (1) If CMS finds that the contract applicant does not appear to be able to meet the requirements for an MA organization within 60 days, 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.

(2) Within 60 days from the date of the intent to deny notice, the contract applicant may respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and may revise its application to remedy any defects CMS identified.

(f) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(1) That the contract applicant does not meet the contract requirements under Part C of title XVIII of the Act;

(2) The reasons why the contract applicant does not meet the contract requirements; and

(3) The contract applicant's right to request reconsideration in accordance with the procedures specified in subpart N of this part.

(g) *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]

55. 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*), (*2*), and (*3*).

F. Revising newly redesignated paragraph (b)(6) introductory text.

G. 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) Personnel and systems sufficient for the M+C organization to organize, implement, control, and evaluate financial and marketing activities, the furnishing of services, the quality assurance program, and the administrative and management aspects of the organization.

* * * * *

(vi) * * *

(F) Procedures for internal monitoring and auditing.

(G) * * *

(*1*) If the MA organization discovers from any source evidence of misconduct related to payment or delivery of health benefits under the contract, it must conduct a timely, reasonable inquiry into that misconduct.

(*2*) If, after reasonable inquiry, the MA organization has determined that the misconduct may violate criminal, civil or administrative law, the sponsor must report the existence of the misconduct to the appropriate Government authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. If the potential violation relates to Federal criminal law, the civil False Claims Act, Federal Anti-Kickback provisions, the civil monetary penalties authorities (primarily under section 1128A and 1857 of the Social Security Act), or related statutes enforced by the HHS Office of Inspector General, the report must be made to that Office.

(*3*) The PDP sponsor must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees, etc.) in response to the potential violation referenced above.

* * * * *

(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

* * * * *

§ 422.504 [Amended]

56. 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 (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 6 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.

* * * * *

(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.

* * * * *

57. 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—

* * * * *

58. 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.

* * * * *

§ 422.520 [Amended]

59. 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.

60. 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 contain the following provisions:

(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.

Subpart M—Grievances, Organization Determinations and Appeals

61. Amend § 422.560 by adding paragraph (a)(3) to 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.

* * * * *

62. Amend § 422.561 by revising the definition of "Authorized representative'' to read as follows:

§ 422.561 Definitions.

* * * * *

Authorized representative means an individual authorized by an enrollee, or under State law, to act on his or her behalf in obtaining an organization determination or in dealing with any of the levels of the appeal process, subject to the rules described in part 405, subpart I of this chapter, unless otherwise stated in this subpart.

* * * * *

63. 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, subpart I 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.

64. 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.

* * * * *

§ 422.568 [Amended]

65. Amend § 422.568 by—

A. Revising paragraph (a).

B. Removing paragraph (c).

C. Redesignating paragraph (d) as paragraph (c).

D. Redesignating paragraph (e) as paragraph (d).

E. Redesignating paragraph (f) as paragraph (e).

F. Revising newly redesignated 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.

* * * * *

66. 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

* * * * *

67. Amend § 422.572 by revising paragraph (c) to read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

* * * * *

(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.

* * * * *

§ 422.582 [Amended]

68. Amend § 422.582 by—

A. Revising paragraph (a).

B. Revising paragraph (b).

C. Revising paragraph (c)(2).

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 an oral or written request to—

(1) The MA organization that made the organization determination; or

(2) An SSA office.

(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. If the SSA receives a request, it forwards the request to the MA organization for its reconsideration. The timeframe within which the organization must conduct its review begins when it receives the request.

(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 or the SSA. If the SSA receives a request, it forwards the request to the MA organization for its reconsideration. The request for reconsideration and to extend the timeframe must—

(i) Be in writing; and

(ii) State why the request for reconsideration was not filed on time.

* * * * *

69. 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.

* * * * *

70. Amend § 422.590 by revising paragraph (d)(2) to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

* * * * *

(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.

* * * * *

71. 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, subpart I of this chapter.

* * * * *

72. Amend § 422.602 by revising paragraph (d) to read as follows:

§ 422.602 Request for an ALJ hearing.

* * * * *

(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.

73. 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, subpart I of this chapter regarding MAC review apply to matters addressed by this subpart.

74. 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) *Review of ALJ's decision.* * * *

(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, subpart I of this chapter for a description of the procedures to follow in requesting judicial review.

75. 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, subpart I of this chapter.

* * * * *

76. 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.* 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.

77. 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 O—Intermediate Sanctions

78. Amend § 422.752 by revising paragraph (a)(8) introductory text to read as follows:

§ 422.752 Basis for imposing sanctions.

(a) * * *

(8) Employs or contracts with an individual or entity who is excluded from participation in Medicare under section 11128 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:

* * * * *

Nomenclature Changes

79. In part 422, remove "Departmental Appeals Board'' wherever it appears and add in its place "Medicare Appeals Council''.

80. In part 422, remove "DAB'' wherever it appears and add in its place "MAC''.

81. In part 422, remove "Medicare+Choice'' wherever it appears and add in its place "Medicare Advantage''.

82. 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: May 26, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 28, 2004.

Tommy G. Thompson,

Secretary.

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