

Summary of Title II MMA Regulations

Title II, Subpart A – General Provisions

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Subpart A of the Title II regulations (a) covers definitions, (b) delineates types of MA plans, and (c) implements the MMA provision regarding CMS's imposition of user fees on MA plans. These provisions generated a fair amount of commentary, FR 4594-4600, and a corresponding number of changes between the proposed and final regulations.

Definitions

The most significant changes in the final regulations relate to MA plans who enroll specialized needs individuals. In creating specialized needs plans (SNP), the MMA provided very little detail. CMS was left to grapple with the threshold questions of whether and to what extent SNP would be distinct from other types of MA plans. The final regulations adopt a flexible approach, defining SNPs as plans that either exclusively enroll special needs individuals or enroll "a disproportionate percentage of specialized needs individuals." § 422.2(3). CMS will designate the latter "on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise . . ." and other factors. *Id.* An SNP must also offer Part D benefits. *Id.*

CMS also broadened the definition of "institutionalized" in response to comments. The definition now provides that a special need individual is considered institutionalized if he or she "resides or is expected to continuously reside for 90 days or longer in a long-term care facility which is a skilled nursing facility (SNF) nursing facility (NF); SNF/NF; an intermediate care facility for mentally retarded (ICF/MR); or an inpatient psychiatric facility." § 422.2 (italics indicate changes). The proposed regulations had a narrower and more formalistic definition requiring a 90-day assessment in CMS's Minimum Data Set. FR 4596.

Although CMS specifically solicited comments in the proposed regulations on how to define "chronic and disabling conditions" for the purpose of classifying special needs individuals, it declined to adopt any of the definitions

offered by commentators "[b]ecause this is a new 'untested' type of MA plan" and also because CMS wanted to avoid constraining "plan flexibility." FR 4596. Instead, CMS adopted a "case-by-case" approach in the final regulations. § 422.2(3).

Types of MA Plans

Apart from conforming changes that reflect the final definition of SNPs, the final regulations made only one change of substance from the proposed regulations. New § 422.4(c) has been implemented to set forth the rules for when MA plans must provide Part D coverage:

1. All MA coordinated care plans (HMOs, PPOs, POS) must offer at least one MA-PD in each service area.
2. MA organizations offering MSA plans are not permitted to offer Part D coverage.
3. FSS plans have the option of providing Part D coverage.

User Fees

The MMA authorizes CMS to expend up to \$200,000,000 for beneficiary education and information, but that amount must be offset by any user fees assessed by CMS to MA organization. See FR 4599. The final regulation makes no substantive changes to the proposed regulations. See § 422.4(c); FR 4715.

Title II, Subpart B – Eligibility, Election, and Enrollment

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Introduction

With two exceptions, CMS did not materially change its proposed regulations covering eligibility, election, and enrollment in MA plans.¹ The two exceptions concern enrollments in Special Needs Plans (SNP) and disenrollment.



Eligibility to Elect an MA Plan

Both as proposed and in the final regulation, CMS adopted its pre-existing rules on eligibility. CMS did, however, add a subsection, § 422.50(2)(iii), that permits an individual with ESRD to elect an SNP that has opted to enroll subscribers with ESRD. Additionally, CMS added phrasing in § 422.50(5) that allows CMS to approve alternative election mechanisms. The preamble states that CMS might some day approve a web-based election process. FR 4601.

Eligibility to Elect a Special Needs MA Plan

Much of the commentary CMS received on proposed § 422.52 concerned whether an SNP could limit enrollment to subgroups (*e.g.*, dual eligibles with AIDs) of special needs individuals. FR 4601-602. CMS decided to allow such limitations on a case-by-case basis in order generally to facilitate the coordination of Medicare and Medicaid services, but also to allow certain unique plans to continue their existing focus. It did, however, state that it would issue subsequent guidance on how SNPs who focus on subsets of special needs individuals will be evaluated and approved. FR 4602.

A major change from the proposed regulation is a new “grandfathering” provision for SNP enrollees. New § 422.52(f)(2) now provides, in this regard, that an SNP subscriber cannot be involuntarily disenrolled from the SNP even if the enrollee no longer meets the definition of a special needs individual.

Continuation of Enrollment for MA Local Plans

CMS received no comments on proposed § 422.54. FR 4603. The final regulation is unchanged as a consequence. Local MA plans can designate continuation areas beyond their service areas and subscribers who move into a continuation area can elect to remain enrolled in the same local plan.

FOOTNOTE

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Unless otherwise indicated, MA plans refer to both local and regional MA plans.

Enrollment in an MSA Plan

Proposed § 422.56 implemented the MMA’s authorization to make MSA’s permanent and unlimited as to enrollment and to prohibit individuals eligible for FEHBP or VA benefits from enrolling in an MSA. The final rule adopts the proposed rule without change. FR 4604.

Election Process

Proposed § 422.60 has been adopted without substantive changes. The regulation provides that MA plans can limit enrollments and that the enrollment forums and procedures must be approved by CMS. FR 46011.

Election of Coverage Under an MA Plan

CMS implemented several changes to its proposed regulation on election of coverage. CMS noted that the MMA’s “lock-in” provisions appeared contradictory, FR 4604, and appeared to make the election of drug coverage a one-time, permanent choice. CMS concluded, after a further reading of the statute, that Congress intended only to limit elections in or out of Part D coverage during a calendar year. FR 4605. It therefore added § 422.62(a)(4)(iii) to state that enrollees can switch plans and Part D coverage without limitation during each annual coordinated election period (November 15 through December 31). For enrollments beginning in 2007, when enrollees are permitted a single election during the first three months of a year, 422.62(a)(5)(i)(A) was changed to allow enrollees in original Medicare and a PDP to elect an MA-PD; correspondingly, § 422.62(a)(5)(i)(B) was revised to state that enrollees in regular Medicare who are not in a PDP cannot enroll in an MA-PD or PDP. Neither of these limitations apply to election during the annual coordinated election period. § 422.62(a)(5)(iii). CMS indicated in the preamble that it will need to develop a database that will allow plans to verify whether enrollees are making permitted elections. FR 4605.

Coordination of Enrollment and Disenrollment

Most of the commentary regarding proposed § 422.66 concerned the so-called “deemed elections” that will occur effective January 1, 2006, when 2005 enrollees in MA plans will be automatically enrolled in the MA-PD if the MA plan converts to an MA-PD plan for 2006. FR 4606-



4607. The final regulations have been modified to provide that such automatic enrollment will only occur if the 2005 MA plan was already offering prescription drug coverage, § 422.66(e)(3), or the MA plan only offers an MA-PD in 2006. § 422.66(e)(2). In cases where a 2005 MA plan does not offer prescription drug coverage, and the plan offers both an MA only and an MA-PD plan in 2006, the deemed election will be to the 2006 MA only plan. § 422.66(e)(4). These rules only apply, of course, to enrollees who do not make affirmative elections during open enrollment periods.

Effective Dates of Coverage and Change of Coverage

Final § 422.68 did not materially change from the proposed rule; nor did CMS receive any comments. FR 4607.

Disenrollment by the MA Organization

The proposed disenrollment regulations generated a significant amount of commentary. In response to some of those comments, CMS agreed to shorten the grace period for disenrollment for failure to pay premiums in § 422.74(d)(1)(i)(B), from 90 days to 30 days. FR 4608.

CMS also substantially revised its proposed rules on disenrollment for disruptive behavior, but not in a way that makes such disenrollments easier. First, it modified this definition of disruptive behavior to extend only for behavior that “substantially” impairs an MA plan’s ability to arrange for or provide services to this disruptive enrollee or others. § 422.74(d)(2)(i). Further, CMS must review and approve the request to disenroll, § 422.74(d)(2)(iii), and the MA plan must make “reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions . . .” § 422.74(d)(2)(iii). CMS also notes that an individual’s non-compliance with medical advice or treatment cannot be deemed disruptive behavior. § 422.74(d)(2)(i).

In response to comments about whether an enrollee’s failure to make cost-sharing payments could be “disruptive” behavior sufficient to permit disenrollment, CMS states in this preamble that it would deal with such circumstances on a case-by-case basis. FR 4609.

Approval of Marketing Materials and Election Forms

In final § 422.80(a), CMS agreed to codify its “file and use” approach to marketing materials. FR 4609. Under this approach, if CMS does not disapprove marketing materials within 45 days, they can be used. For certain MA organizations deemed by CMS to meet established performance standards, this period is shortened to 5 days. FR 4609.

Title II, Subpart C – Benefits and Beneficiary Protections

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General Requirements

The proposed rule included a provision requiring a physician or other entity that does not have a contract with an MA MSA plan to accept as payment in full the amount they could have collected had the individual been enrolled in the MA MSA plan. The final rule retains this provision. CMS points out that the protection against billed charges that exceed the Medicare participating fee schedule amount for a Medicare-covered services is statutory and has been reflected in regulation since 1998; the MA regulation simply extended the protection to MA MSA plans based on the MMA’s extension of the underlying statutory protection to include enrollees in MA MSA plans. § 422.100(b)(2); FR 4611.

Requirements Relating to Basic Benefits

Uniform Application of Local Medical Review Policies (“LMRPs”)

The proposed rule included a provision permitting an organization offering an MA regional plan to 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 final rule retains the provision, with modifications to clarify that CMS takes the position that a regional plan must elect a *single* FFS contractor group for local coverage determinations or policies that it will apply to *all* members of the regional plan.



The final rule also requires that MA organizations that elect to apply local coverage policies uniformly across a local MA plan's service area (as permitted under the M+C final regulations and continued in the MA final regulations), or across an MA regional plan's service area, to inform enrollees and providers – including through the Internet — of the applicable local coverage policy that applies to the MA plan enrollees. CMS acknowledges that in order to comply with this latter provision, MA organizations electing to apply uniform local coverage policies must create a web site upon which to post links to or copies of the applicable policies. § 422.101(b)(4)-(5); FR 4612-13.

Notice of Status of Beneficiary Out-of-Pocket Limits

The proposed rule included a provision requiring regional plans to track limits on incurred out-of-pocket beneficiary costs related to deductibles and catastrophic limits for original Medicare covered services, and to notify enrollees when the deductible, if any, or a limit had been reached. The final rule retains this provision, but extended the notice provision to require notice to providers as well. CMS notes that to the extent that an enrollee is not aware of his or her deductible and/or cap status, the enrollee *and the provider* should have “reasonable access” to such information at the time of service. § 422.101(d); FR 4614.

Special Rules for Self-Referral and Point of Service (“POS”) Option

The proposed rule included a provision requiring the network provider to document in the enrollee's medical record why an item or service was medically necessary but not available through the plan. The final rule retracts this requirement as overly prescriptive, and does not dictate where the documentation must appear. § 422.105(a); FR 4618.

Coordination of Benefits with Employer Group Health Plans and Medicaid

The proposed rule included a provision permitting CMS to waive requirements that would hinder the design or offer of, or enrollment in, an MA plan sponsored by an employer or labor organization. The final rule retains this provision, with modifications to clarify that CMS has the

authority to exercise its waiver authority at its own discretion as well as upon written application from an entity seeking to offer, sponsor, or administer such a plan. § 422.106(d); FR 4619-4620.

Disclosure Requirements

The final rule includes a requirement, not reflected in the proposed rule, that MA organizations that have Internet web sites post on their sites their Evidence of Coverage, Summary of Benefits, and information regarding their provider network. CMS notes, however, that this requirement applies only to those organizations that maintain Internet web sites, and that such electronic postings will not relieve plans of their obligation to provide enrollees with written, hard copy materials upon enrollment and annually thereafter. § 422.111(f)(12); FR 4623.

Access to Services

CMS had proposed to delete the requirement that MA organizations establish written standards addressing access to care, on the grounds that they were duplicative of other regulatory provisions. However, a number of commenters objected, and CMS ultimately agreed to restore the requirement, noting the agency's belief that the requirement for written standards would at least prompt plans to affirmatively address and memorialize their plans for providing access to services. § 422.112(a)(7); FR 4624.

Continuation of Care

CMS noted in the proposed rule that it was contemplating eliminating the continuity of care provisions set forth in 42 C.F.R. § 422.112(b)(1)-(6), as potentially inappropriate for an entity primarily engaged in the business of insurance. Based on comments to the proposed rule, CMS retained the provisions in the final rule, but modified them to limit their applicability to only coordinated care plans (and not PFFS plans or MSAs) and, within the context of coordinated care plans, only to the services provided and coordinated by contracted network providers. § 422.112(b); FR 4625.

Access “Exception” for MA Regional Plans

The proposed rule contemplated an exception to otherwise applicable access requirements for MA regional



plans with less robust networks, provided that the plans also imposed lower out-of-network cost sharing. In the preamble to the final rule, CMS notes that it will not prescribe specific levels of cost sharing based on the robustness of the plan's provider network. However, the final rule does require MA organizations sponsoring MA regional plans to designate a non-contracted provider from whom the enrollee may obtain covered services at in-network cost sharing levels if such services are not available from a network provider. Alternatively, the MA organization may permit the enrollee to seek services not available and accessible from a contracted network provider from any qualified provider at in-network cost sharing levels. § 422.112(a); FR 4626.

The proposed rule also permitted an MA organization sponsoring an MA regional plan to seek designation of a hospital as an essential hospital eligible for additional funding if, among other things, the MA organization made a "good faith" effort to contract with the hospital. The final rule clarifies what is meant by a "good faith" effort. Specifically, CMS requires that the plan demonstrate that it offered the hospital a contract providing for the payment of rates in an amount no less than the amount the hospital would have received under Medicare FFS and that there are no competing Medicare participating hospitals in the area to which plan enrollees could reasonably be referred for inpatient services. § 422.112(3)-(4); FR 428-29.

Title II, Subpart D –Quality Improvement Program

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There were no substantial changes to Subpart D from the proposed regulations, despite numerous comments received by CMS. The comments ranged from requests for plans to disseminate educational material, use of Quality Improvement Organization (QIO) technical assistance, and suggestions regarding using specific performance measures, physician advisory committees, inclusion of private fee-for-service plans and Medical Savings Account (MSA) plans in all Quality Improvement (QI) requirements, pay for performance incentives, development of special needs

measures, development of nationally recognized quality measures, and additional guidance on physician encouragement of participation in QI projects.

Quality Improvement Program

By 2006, each MA plan (other than a private fee-for-service or an MSA plan) must have an ongoing quality improvement program that includes a chronic care improvement program and quality improvement projects that "can be expected to have a favorable effect on health outcomes and enrollee satisfaction for each plan offered." Although the rule requires plans to "encourage" its providers to participate in such quality improvement initiatives, no additional guidance on this matter is provided. § 422.152(a); FR 4723.

Data and Reporting Requirements

MA plans must report the status and result of each quality improvement project to CMS as requested. § 422.152(d); FR 4724. Additionally, MA organizations offering a coordinated care plan (except for regional MA plans) including local PPO plans offered by MA organizations that are licensed or organized under State law as HMOs, must collect, analyze, and report performance under the plan to CMS. These plans must also report to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and make informed decisions with respect to the available choices for Medicare coverage. § 422.152(b); FR 4723.

MA regional PPO plans and local PPO plans not licensed or organized under state law as an HMO are required to collect, analyze, and report performance under the plan to CMS. If the organization uses written protocols for utilization review, the organization must have mechanisms to evaluate utilization of services and to inform enrollees and providers of services of the results of the evaluation. § 422.152(e); FR 4723. These MA regional and local PPO plans will need only to collect, analyze, and report data for services furnished by providers that have contracted with the MA organization under those PPO plans. However, a local PPO offered by an MA organization that is licensed or organized under State law as an HMO will be required to meet the normal data collection, analysis, and reporting requirements. FR 4597.



Finally, *all* MA plans are required to (1) maintain a health information system that collects, analyzes, and integrates data necessary to implement its quality improvement program and make such data available to CMS; (2) conduct a formal evaluation, at least annually, of the impact and effectiveness of the quality improvement program; and (3) correct all problems that arise through internal surveillance, complaints or other mechanisms. § 422.152; FR 4724.

Title II, Subpart E – Relationships with Providers

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Subpart E of the final regulation is substantially unchanged from the proposed regulations. CMS maintains most existing requirements regarding provider relationships with MA organizations.

Assurances on Physician Incentive Plans

Unlike pre-MMA requirements, each MA organization will now have to provide assurances to CMS that they are in compliance with physician incentive plan (PIP) requirements of § 422.208. § 422.210; FR 4724.

A physician incentive plan means any compensation arrangement to pay a physician or physician group that may directly or indirectly have the effect of reducing or limiting the services provided to any plan enrollee. § 422.208(a); FR 4724.

The final rule at § 422.208, like the proposed rule, includes a slight change from the pre-MMA requirements. Prior to the MMA, if a PIP placed physicians or physician groups at substantial financial risk, MA organizations were required to conduct periodic surveys of current and former enrollees to determine enrollees' access to services and the quality of those services *and* have either aggregate or per-patient stop-loss protection. The MMA removed this "periodic survey" requirement. Instead, MA organizations are only required to assure that all physicians and physician groups at substantial financial risk have stop-loss protection. § 422.208; FR 4724.

Special Rules for Services Furnished by Non-Contract Providers

Under § 422.214(b), any non-contract provider (*i.e.*, any provider that does not have a contract that establishes payment amounts for services furnished to beneficiaries enrolled in an MA coordinated care plan, an MSA plan or an MA PFFS) will be paid at fee-for-service Medicare rates. This does not apply to a Section 1861(u) "provider of services" which include hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, and hospice programs. Section 1861(u) providers, in instances where they are also non-contract providers as defined above, will be paid at fee-for-service Medicare rates less any payments under 42 CFR § 412.105(g) (indirect medical education payments to hospitals for managed care enrollees) and § 413.86(d) (payment for direct medical education costs). § 422.214(b); FR 4724-25.

Title II, Subpart F – Submission of Bids, Premiums, and Related Information and Plan Approval

Shauna Alonge

Key MA Terminology

CMS adopted in final its proposed definitions of key terms related to the submission and evaluation of bids, including:

- Annual MA capitation rate
- MA monthly basic beneficiary premium, MSA premium, prescription drug beneficiary premium, and supplemental beneficiary premium
- MA-PD plan
- Monthly aggregate bid amount



- Unadjusted MA area-specific and region-specific non-drug monthly benchmark amounts
- Unadjusted MA statutory non-drug monthly bid amount

§ 422.252; FR 4725.

CMS issued a clarifying amendment to the final regulation making it clear that “MA local area” means a payment area consisting of a county or equivalent area specified by CMS. *Id.*

Mid-year Plan Entry and Benefit Enhancement

Under the new MMA bid submission process, CMS has retained the requirement that MA organizations must submit bids for each MA plan they intend to offer by the first Monday in June of the year before the contract year, beginning with contract year 2006. § 422.254(a); FR 4725. In keeping with its goal to promote the integrity of the competitive bidding process, with limited exceptions, CMS will not permit either (1) mid-year plan entry (defined as either a new plan or a new service area) or (2) mid-year benefit enhancement.

CMS relaxed its proposed rule to permit the following exceptions:

New Mid-Year Plan Entry:

- A local MA plan whose Part D bid is not included in the national average bid, if the plan will be offered in counties where there are no other PDPs or MA-PD plans.
- A local MA plan that does not offer Part D benefits, if the plan is offered in an area with no other MA competitors.
- PACE plans.
- Employer/union group health plans, except those offering enrollment to the general public will face stricter entry requirements.

FR 4639-40.

Mid-Year Benefit Enhancements (MYBEs)

CMS is against permitting plans to make what could be considered *de facto* adjustments to their approved bids which could incentivize them to overbid or underbid. In the final rule, CMS adopted the following exceptions to the ban on mid-year benefit changes contained in the proposed rule, so long as the changes are to non-drug benefits.

Restricted MYBEs:

- The change can be effective no earlier than July 1 of the contract year and no later than September 1;
- Change requests must be submitted to CMS prior to July 31 of the contract year; and
- Twenty-five percent of the value of the change will be retained by the federal government.

FR 4640.

Submissions would have to include documentation for any enhancement of benefits, including data on where the revenue requirements were overstated in the initial bid submission. The annual CMS Call Letters will include information on the types of mid-year non-drug enhancements that CMS will consider.

Unrestricted MYBEs:

- PACE plans (non-drug benefits)
- Employer/union groups, except those offering enrollment to the general public will face stricter enhancement requirements. Mid-year enhancements are permissible, however, for that part of the benefit package available only to employees or union members, as CMS does not consider such benefits to come within the MA plan.

FR 4640.



End Stage Renal Disease Costs: Inclusion Delayed Until 2007

CMS has decided in its final rule not to require the inclusion of costs for ESRD enrollees in plan bids until contract year 2007. CMS believes that by using the cost metric it has under development, plans will be able to offer ESRD enrollees the same premium and cost sharing as other plan members, as mandated by Congress. The cost metric will be explained in the 2006 and 2007 Call Letters. § 422.254(a)(2); FR 4725.

Bid Requirements

MA plans are required to submit an aggregate monthly bid amount for each proposed MA plan that is a standardized bid reflecting a nationally average risk profile for the factors set forth in § 422.308(c). This amount is the sum of several estimates, including the organization's estimate of the revenue required for the following categories of coverage for an eligible beneficiary with a national average risk profile: the "basic A/B bid;" the amount for basic prescription drug coverage; and/or the amount to provide supplemental coverage. Bid submissions are also required to include all estimated required revenue for administrative costs and return on investment. § 422.254; FR 4725. Each bid must offer a uniform benefit package for the service area or area segment for local plans. *Id.* at § (b)(2). CMS will conduct a determination of reasonableness for each element of plan estimated costs. §§ 422.254(b)(3), (256)(a), (b). The formulas for calculation of various benchmarks are contained in §422.258; FR 4727. The regulations recognize that certain benchmarks for regional plans cannot be calculated until after bid submission, such as the rebate, cost sharing, and premium amounts. § 422.258; FR 4727.

Bid Review

The regulations set forth CMS's authority to conduct negotiations with MA plans on such issues as appropriate assumptions (*e.g.*, pricing, utilization, or enrollment), rebates, and supplemental benefits. § 422.256(a). The regulations also make clear that CMS may not accept bid levels that it determines are not reasonable. § 422.256(b). The preamble to the final regulation also indicates that certain other issues, such as withdrawal of bids and correction of errors in bids, are still under consideration

and will be the subject of future agency guidance. FR 4651.

Supplemental Benefits

In response to public comments, CMS has decided not to require that the non-drug portion of the supplemental bid be adjusted to include expenditures associated with induced demand for Medicare-covered benefits resulting from offering cost sharing reductions. Therefore, for the time being, plans will not be required to make such assumptions in their estimates of revenue requirements for Part A and B benefits. § 422.254(b)(4); FR 4726.

Payment Rates: Defining the Actuarial Equivalent Amount of Cost Sharing

In its proposed rule, CMS offered three alternative approaches to determining an actuarially equivalent amount of cost sharing for the basic A/B bid. In the final rule, CMS has withdrawn both the "localized uniform dollar amount" and the "plan-specific" approaches, in favor of the "proportional approach." CMS expects to issue additional details on this approach in its Advance Notice of Methodological Changes for MA Payment Rates due to be released on February 18, 2005. §§ 422.254(b)(4), (c); FR 4726.

Beneficiary Rebates

Under the MMA, an MA plan with savings, *i.e.*, the basic A/B bid is less than the benchmark, must provide to the enrollee a monthly rebate equal to 75% of the savings amount for the plan year. The remaining 25% would be retained by the Medicare Trust Fund. § 422.266(a); FR 4728-9. Permissible uses for rebate dollars set forth in the proposed regulation were adopted in final by CMS, and the agency also clarified in its final regulation that rebate dollars may be used to reduce the premium for either the non-drug or drug portions of the supplemental benefit. § 422.266(b); FR 4728. If the rebate amount would exceed any enrollee premium obligations, the plan would have to provide supplemental benefits. Actual cash payments to enrollees are prohibited.



Title II, Subpart G –Payment for MA Organizations

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There were no substantial changes to Subpart G from the proposed regulations with the exception of the geographic intra-service area rate (ISAR) adjustment.

The MMA introduced major changes in the payment rules for private Medicare plans. These changes are discussed in detail in the preamble text for subparts F and G of these regulations. This subpart sets forth the rules for making payments to MA organizations offering local and regional MA plans, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), and other payment rules. Section 422.458 in subpart J covers rules on risk sharing payments to MA regional organizations. § 422.300; FR 4729.

Advance Monthly Payments for MA Organizations (except MSA plans)

Beginning in 2006, CMS will pay MA organizations (except MSA plans) based on the relationship between each plan's bid for Medicare medical benefits and a "benchmark" amount in an MA payment area (as defined).

- For a plan with a risk-adjusted bid *below* the risk-adjusted benchmark, CMS pays the risk-adjusted bid amount plus 75% of the difference between the bid and the benchmark in the form of a "rebate". Plans receiving rebates from CMS must use the rebates to provide extra non-drug, mandatory supplemental benefits to beneficiaries and/or to reduce beneficiary cost sharing or premium payments.
- For a plan with a risk-adjusted bid *at* the risk-adjusted benchmark, CMS pays the risk-adjusted benchmark amount.
- For a plan with a risk-adjusted bid *above* the risk-adjusted benchmark, CMS pays the

risk-adjusted benchmark amount, and the beneficiary pays a basic beneficiary premium equal to the difference between the bid and benchmark amounts.

§ 422.304(a); FR 4729.

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. § 422.304(b); FR 4729, 4655. 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. § 422.308(f); FR 4731.

Risk Adjustment

The MA payments will be adjusted for: (1) geographic "intra-service area rate (ISAR) adjustment"; (2) "government premium adjustment;" and (3) risk-adjustments for age, gender, disability status, institutional status, and other factors CMS determines to be appropriate, including health status, in order to ensure actuarial equivalence. §§ 422.304(a)(1)(i) and 422.308; FR 4729-4731.

CMS notes in the preamble that the geographic ISAR adjustment would take into account the difference between the distribution of enrollment across counties in the plan's service area assumed in the plan's bid and the actual geographic mix of enrollment at the time payment is made. FR 4659. The proposed rule mentioned four methods that could be used for this adjustment to a plan's service area. The final rule preamble specifies that MA plan rates will be used as the method for calculating the ISAR adjustment for local and regional plans. *Id.* However, on a case-by-case basis, MA regional plans (but not local plans) may provide justification for using plan-specific information as the ISAR adjustment. *Id.* Additional detail about the ISAR adjustment will be provided in the Advance Notice of Methodological Changes for 2006 Medicare Advantage Payment Rates, which CMS has released at <http://www.cms.hhs.gov/healthplans/rates/2006/45day-cover.asp>. *Id.*



Further, § 422.304(e)(4) provides that geographic adjustments must be “budget neutral,” which means that geographic areas that receive higher rates must be offset, dollar-for-dollar, by reductions in other geographic areas. FR 4730.

With regard to “the government premium adjustment,” the final rule requires CMS to adjust payments to plans with bids above their benchmarks to ensure that plans are not advantaged or disadvantaged by the method of paying based on bid-to benchmark comparisons. § 422.308(e); FR 4731, 4660. For example, under the bidding method, the beneficiary premium is the difference between the unadjusted bid and benchmark. However, 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 equal its revenue needs since the basic premium is not risk adjusted. *Id.* Therefore, the impact that the risk adjustment would have had on the basic premium will be incorporated into CMS payment to the organization through the government premium adjustment. *Id.* This will insure that the sum of CMS’ monthly payment made and the plan’s monthly beneficiary premium equals the unadjusted MA statutory non-drug bid amount, adjusted for risk and for intra-area or intra-regional payment variation. § 422.308(e); FR 4731.

Data Reporting

Each MA organization must submit to CMS certain 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 specified by CMS. As determined by CMS, this 12-month period may include a 6-month data lag. § 422.310; FR 4731.

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. *Id.*

CMS allows a reconciliation process to account for late data submissions and will continue to accept risk adjustment data submitted after the March deadline until

December 31 of the payment year. After the payment year is completed, CMS recalculates the risk factors for affected individuals to determine if adjustments to payments are necessary. Risk adjustment data received after the annual December 31 late data submission deadline will not be accepted for the purposes of reconciliation. The final rule modifies § 422.310(e) to indicate that there may be penalties for submission of false data. § 422.310; FR 4731-4732.

Capitation Rate Methodologies

For 2005, capitation rates were changed as discussed below. In 2006, MA organizations will be paid based on the relationship between each plan’s bid for Medicare medical benefits and a benchmark amount (as discussed above) based on the same capitation rate formula that applies in 2005.

- Beginning in 2005, annual capitation rates will be “minimum percentage increase rates” (the larger of 102% of the previous year’s rate, or the prior year’s rate increased by the Medicare growth percentage) *except for years when CMS rebases the FFS rate.*
- In rebasing years, the payment rate is the higher of the minimum percentage increase rate or the average per capita cost rate which is the FFS rate, risk adjusted, excluding direct medical education and including a VA/DOD adjustment (which has been zero to date due to a lack of reliable data). The MMA requires CMS to rebase the FFS rates no less than every 3 years.

§§ 422.306, 422.308; FR 4730, 4656-4657, 4690.

Although commenters supported annual rebasing in order to adequately pay MA organizations in areas where FFS costs are increasing at a faster rate than the national average, CMS chose not to make this change in the final rule; the final rule, however, gives CMS the option of evaluating on an annual basis whether it is necessary to rebase and requires CMS to do so at least every 3 years. CMS will adjust the minimum percentage increase rate and the adjusted average per capita cost rate 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. *Id.* If CMS determines that the cost of furnishing a national coverage determination (NCD) service or legislative change in benefits is significant, 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 of an NCD service or legislative change in benefits on a fee-for-service basis. *Id.*

Timing

Not later than the first Monday in April each year, CMS will announce for each MA payment area for the following calendar year:

- The annual MA capitation rate.
- The risk and other factors to be used in adjusting those rates for payments for months in that year.
- an explanation of assumptions used and a description of the risk and other factors.

No later than 45 days before making this announcement, CMS will notify MA organizations of changes it proposes to make in the factors and the methodology it used in the previous determination of capitation rates. MA organizations will have 15 days to comment on the proposed changes.

Before the beginning of each annual, coordinated election period, CMS will announce 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. § 422.312; FR 4732.

MSA Plan Requirements and Payments

In the case of an MA MSA plan, CMS pays the unadjusted MA area-specific non-drug monthly benchmark amount for the service area, subject to risk adjustment less 1/12 of the annual lump sum amount (if any) CMS deposits to the enrollee's MA MSA. § 422.304(c)(2); 4730,

4656. The risk adjustment adjusts the payment amounts 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. § 422.304(c)(2); 422.308(c); 422.314; FR 4730.

In response to a comment indicating that the proposed rules on MA MSAs allowed for payment to an MA MSA plan that is risk-adjusted but a deposit to the enrollee's MSA that is not, the final rule altered the way the deposit payment in the MA MSA is calculated. Under the final rule, the monthly MA MSA premium is compared with 1/12 of the *annual capitation rate* as opposed to the benchmark which was used in the proposed rule. § 422.314(c)(1)(i); 4732, 4662. This does not appear to have fully satisfied the commenter's concern, however. CMS also indicated that this issue will be addressed in the Advance Notice of Methodological Changes for MA Payment Rates. *Id.*

Special Rules

This subpart also provides rules for the following special rates:

- for enrollees determined to have end-stage renal disease (ESRD) (§ 422.304(c)(1); FR 4729-4730, 4655) (CMS will establish special rates that are actuarially equivalent to rates in effect before the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 for contract year 2007; for contract year 2006, ESRD costs will be excluded from plan bids and the 2005 payment method will be used. FR 4656);
- payments to Federally Qualified Health Centers (§ 422.316; FR 4732); for coverage that begins or ends during an inpatient hospital stay (§ 422.318, FR 4732);
- payments for hospice care (§ 422.320, FR 4732-4733). No payment is made to an MA organization on behalf of a Medicare



enrollee who has elected hospice care except for the portion of the payment attributable to the beneficiary rebate for the MA plan, plus the amount of the monthly prescription drug beneficiary premium. During the time the hospice election is in effect, the monthly capitation payment to the MA organization will also be reduced; and

- payments to MA organizations for graduate medical education costs (§ 422.324, FR 4733) (with regard to costs MA organizations incur in dealings with non-hospital provider settings under certain conditions).

Title II, Subpart I – Organization Compliance with State Law and Preemption by Federal Law

Kenneth M. Bruntel

The final regulation is unchanged from proposed § 422.402 (Federal preemption of State law) and § 422.404 (State premium taxes prohibited). A number of comments expressed concerns that the exception to Federal preemption in the MMA for state licensure and solvency requirements could allow states indirectly to regulate MA plans. CMS responded that both the MA and its regulations were sufficiently clear and straightforward to preclude states from regulating MA plans. FR 4663-4. In response to comments about direct and indirect premium taxes, CMS reiterated its view that the MMA and its regulations were unambiguous.

Title II, Subpart J – Special Rules for MA Regional Plans

Linda M. Lavache

Two-Year Moratorium on Expansion of Local PPO Plans

The final rule is substantially unchanged from the proposed rule. An MA organization is precluded from offering a new PPO plan in a service area unless the organization offered a PPO plan in that area in 2005. CMS considers a PPO plan to have been offered in 2005 only if the MA organization had enrolled beneficiaries in the plan before January 1, 2006. § 422.451; FR 4733. An MA plan could, if it were already offering one MA PPO plan in a service area, offer additional plans with different benefit designs in the same service area.

Establishment of MA Regions

The final rule is unchanged from the proposed rule and reiterates the MMA requirement that CMS establish no fewer than ten and no more than fifty regions. The preamble notes that CMS was not permitted to include Puerto Rico or U.S. territories in an MA region. FR 4667-68. In determining how many MA regions to create, CMS evaluated comments in favor of and against single-state MA regions and multi-state MA regions. CMS also conducted a market analysis, examining payment rates, population size per region, current existence of commercial plans, and other factors. CMS ultimately established thirty-four PDP regions and twenty-six MA regions. This created some single-state regions but, inevitably, several multi-state regions were established. The regions were announced on December 6, 2004 and can be found at <http://www.cms.gov/medicarereform/mmaregional>. § 422.455; FR 4715-16.

Risk Sharing

The rules on MA regional plan risk corridors set forth in the proposed regulation are essentially unchanged in the final rule. In the proposed rule, CMS noted that it has discretion to determine whether reductions in cost sharing for Part A and Part B benefits should be considered rebatable integrated benefits (RIBs). The final rule codifies this position. Cost sharing reductions for Part A and Part



B benefits will be considered plan expenditures under § 422.458(b)(2)(ii). Moreover, such reductions will be considered RIBs, as long as the reductions are supported by plan rebate dollars and not by the beneficiary supplemental premium. § 422.458(b); FR 4668-69. RIBs are the only supplemental benefits that are considered allowable costs for the purpose of computing risk sharing payments. FR 4668. Reductions in Part D cost sharing and Part B or Part D premium reductions cannot be considered RIBs. FR 4669.

The final rule regarding state licensing requirements is also substantially unchanged from the proposed rule. An MA plan must be licensed under state law as a risk-bearing entity. With respect to MA regional plans, MA organizations can obtain a temporary waiver of the state licensing requirements if they meet the conditions set forth in the MMA: (1) they are licensed as risk bearing in at least one state in a region, (2) they have applied for licensure in the other states, and (3) if a license were denied, the waiver is limited to the end of a plan year or as deemed necessary to provide for a transition. § 422.458(e); FR 4669. A technical change to § 422.458(e)(2) was made in response to a comment and the regulation now provides that, for the purpose of CMS's temporary waiver, CMS will apply the licensure rules in the state in which a regional plan is licensed to the other states in which license applications are pending.

The proposed regulation on the regional plan stabilization fund remains unchanged in final § 422.258(f). CMS received no comments in the proposed rule with regard to plan entry funding, regional payment adjustments, and plan retention funding. FR 4671. Several comments complained about the fact that the stabilization funds discriminated against local MA plans. CMS responded that the MMA intended to provide an additional incentive for offering MA regional plans. *Id.*

Title II, Subpart K – Application Procedures and Contracts for Medicare Advantage Organizations

Lloyd M. Weinerman

Record Retention Requirements

The proposed rule contained a 6-year period for which records needed to be retained. The final rule substantially increased the time period to ten years from the end of the final contract period or the completion of a Government audit, whichever is later. This increase from a six-year to a ten-year period was made in order to conform to the statute of limitations for discovery of violations under the False Claims Act. § 422.504(e)(4); FR 4737.

Compliance with Laws and Regulations

The proposed rule required an MA organization to comply with “all other applicable laws and rules” but did not define what those laws and rules might be. The final rule clarifies that the laws and regulations CMS has in mind are those that are designed to prevent fraud, waste, and abuse. Examples of such laws are Federal criminal law, the False Claims Act, and the federal healthcare Anti-kickback Act. § 422.504(h)(1); FR 4737.

Self-Reporting

The proposed rule contained an explicit requirement that an MA organization must self-report to CMS any suspected violations of law, regulation, or other wrongdoing. The final rule eliminates this explicit reporting requirement. However, the final rule makes it clear that CMS expects an MA organization that is offering a PDP to comply with the requirements in the final PDP regulations concerning the need to have a comprehensive fraud and abuse plan where one of the critical features is a requirement for reporting violations to the appropriate authorities in the event there is suspected fraud or misconduct. § 422.503(b)(vi)(H); FR 4737; § 423.504(b)(4)(vi)(H); FR 4555.



Incomplete Contract Application

The proposed rule provided for a sixty-day period after a notice of intent to deny had been issued for an MA organization to submit missing information from its application. The final rule streamlines the application process and provides that missing information must be submitted within ten days after the organization receives an intent to deny notice. § 422.502(c)(2)(ii); FR 4737.

Title II, Subpart L – Effect of Change of Ownership or Leasing of Facilities During the Term of Contract

Kenneth M. Bruntel

Final § 422.550(a)(2) is unchanged from the proposed regulation. It provides that an MA organization can effect a change of ownership by transferring assets. Under the existing regulations at 42 CFR § 422.550, prior notice to CMS and the approval of a novation agreement is required to transfer an MA plan contract.

Title II, Subpart M – Grievances, Coverage Determinations, and Appeals

Jody Goodman

Introduction

In general, the existing regulatory requirements regarding MA grievances and appeals have been left intact. Minor changes were made to conform the subpart regulations to MMA terminology and to make other refinements. Changes were made to part 417 regulations, which apply only to section 1876 cost contractors and 1833 health care pre-payment plans (HCPPs) to establish

uniform grievance and appeals procedures for all Medicare managed care plans.

Background

MA organizations must establish grievance and appeal procedures that satisfy certain requirements of the statute. These requirements are generally the same for all plan types, except that separate rules apply for drug benefits under MA-PD plans. FR 4676.

General Provisions, Grievances, and Organizational Determinations

Some changes have been made to bring the rules into line with sections 1852 and 1869 of the Act. For example, adjustments have been made with respect to inflation adjustments for the “amount in controversy” required to pursue a hearing and judicial review. In addition, the General Provisions subsection states:

The existing MA regulations incorporate 42 CFR part 405, subparts G and H, and 20 CFR part 404, subparts J and R. Note that in an interim final rule we expect to publish shortly, we intend to create a new subpart I of part 405 to implement significant revisions to section 1869 of the Act. To accommodate these changes, we proposed minor changes to the cross-references for MA appeals at § 422.560 (a)(3), § 422.561, and § 422.562 accordingly.

FR 4676.

CMS has eliminated the requirement that oral notice of an expedited determination be followed up with written confirmation in cases of fully favorable determinations. Notice is required only if the determination is fully or partly adverse to the enrollee, and might engender an appeal. § 422.572(c); FR 4676.



The practitioner's notice requirement of § 422.568(c) has been eliminated. This provision required practitioners to provide general notices to enrollees at each patient encounter of the enrollee's right to receive, upon request, detailed written notice from the MA organization regarding any decision to deny services to an enrollee. Instead, the plan's evidence of coverage (EOC) will contain information on an enrollee's right to receive a detailed explanation if the enrollee believes he or she has been denied care to which he or she is entitled. § 422.568(c); FR 4676-77.

CMS has clarified existing policy by specifying that a reduction of services constitutes an organization determination that an enrollee may appeal. "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." § 422.566(b); FR 4677.

Requests for Reconsiderations

Proposed § 422.582(a)(1) and (a)(2) allowed a party to request a standard reconsideration either orally or in writing. Proposed § 422.590(a) and (d)(2) required an MA organization to inform an enrollee of the right to file an expedited grievance if the enrollee disagreed with the MA organization's decision not to expedite a request for an expedited reconsideration. Because this was a right already provided under the grievance provision at 422.564(d) (now recodified as 422.564(f)), a conforming change was needed. CMS had specified at 422.564(d) (now(f)), that an MA organization must notify the enrollee within 24 hours of receiving a grievance about the organization's refusal to expedite a review. This provision was retained, and conforming changes were made at 422.570(d)(2)(ii) and 422.572(b).

Regarding oral requests for review, CMS agreed with commenters that oral appeals requests may be problematic, and it therefore will not require MA organizations to accept oral requests. Section 422.582(a) has been revised to reflect that an MA organization may adopt a policy for accepting oral requests for reconsiderations. CMS "expect[s] that MA organizations would accept oral requests in instances where there is a clear and compelling reason to

do so . . . [such as] in the case of an illiterate or incapacitated enrollee. . . ." § 422.582(a); FR 4678.

Administrative Law Judge (ALJ) Hearings, Appeals to the Medicare Appeals Council, Judicial Review, and Provisions Affected by Part 405

Because the MMA requires that the ALJ hearing function now conducted by the Social Security Administration be transferred by October 2005 to HHS, references to HHS in sections 422.582 and 422.602 have been eliminated. FR 4678.

Noncoverage of Inpatient Hospital Care

CMS has clarified under § 422.620(b) that a physician must concur before discharging an individual from inpatient care or changing the level of care within an inpatient setting. The MA organization is required to issue a notice of non-coverage if the enrollee objects to the discharge or change in level of care. "If an enrollee disagrees with being discharged from the hospital, then the enrollee is entitled to a notice explaining his or her appeal rights under the law." § 422.620; FR 4678-79.

There was some commentary and dispute concerning "whether to permit or require network and non-network providers to furnish enrollees advance beneficiary notices (ABNs) when they access non-Medicare covered services, or when they face potential liability for out of network services that would be otherwise payable by the MA plan if proper referral were obtained." This issue is unresolved. CMS "will continue to study" the issue and "will pursue additional notice and comment rulemaking before implementing any standard use of ABNs under the MA program." FR 4679.

Appeal Procedures for Cost Plans and HCCPs

CMS has implemented its proposal that the cost plan appeals process follow the same rules that apply to MA organizations. In the interest of having only one coordinated care appeals process for all plan types, all part 422 rules now apply to cost plans and HCCPs. All part 417 grievance and appeals provisions have been deleted and replaced by § 417.600(b) and § 417.840, requiring cost plans and HCCPs to apply the MA procedures under part 422, subpart M. FR 4680.



Part 422 grievance provisions and recent changes to the notice and appeal requirements for inpatient hospital, SNF, home health agency (HHA) and comprehensive outpatient rehabilitation facility services will apply to cost plans for the first time. These changes primarily involve § 422.564, § 422.620, § 422.622, § 422.624, and § 422.626. “The effect of those changes would be that the plans would have more specific guidelines for processing grievances, and enrollees would be entitled to the same notice and appeal rights in cases of termination of Medicare services furnished by hospitals, SNFs, HHAs, and CORFs.” FR 4679-80.

Cost plans and HCCPs must transition to the MA grievance and appeals process under part 422 by January 1, 2006. FR 4680.

Federal Preemption of Grievances and Appeals

Section 232(a) of MMA changes the presumption that state laws are not preempted to one in which State laws are presumed preempted unless they are licensing or solvency laws. In this context, CMS reexamined federal grievance requirements, and determined that it was desirable to adopt a uniform set of grievance procedures, in order to “reduce confusion and burden on MA organizations.” Section 422.564 implements the grievance provisions proposed in CMS’s January 24, 2001 proposed rule requiring MA organizations to establish notice and timeliness procedures. Enrollees will still have access to state remedies available when an issue in a case is not related to the MA organization’s status as a health plan. § 422.564; FR 4680-81.

Employer Sponsored Benefits and Appeals

Employers may establish group plans that are governed by Part 422 as well as ERISA and state law. Almost all commentators supported utilizing only the MA procedures for claims involving integrated ERISA and MA benefits. CMS consulted with the Department of Labor (DOL) to streamline the process and to avoid parallel appeals proceedings. CMS added § 422.560(c), which gives ERISA plans the option of electing the MA process instead of the procedures under CFR 2560.503-1 for claims involving supplemental benefits provided by contract with an MA organization. DOL must pass regulations before this provision can take effect. § 422.560; FR 4681.

Title II, Subpart N – Medicare Contract Determinations and Appeals

Kenneth M. Bruntel

This subpart adds only one subsection to the pre-existing regulations governing MA (formerly Medicare+Choice) contract determinations and appeals. Any determination favorable to an MA plan must be issued by July 15 in order for the determination to be effective for the next year. § 422.648(e). CMS received no comments on the proposed rule. FR 4681.

Title II, Subpart O – Intermediate Sanctions

Linda M. Lavache

Basis for Imposing Sanctions

The final rule is substantially unchanged from the proposed rule. The word “entity” is added to subsection (a)(8) of the regulation. This means that it is a violation for an MA organization to employ or contract with an individual *or entity* that is excluded from participation in Medicare under Section 1128 or 1128A of the Act. § 422.752(a)(8); FR 4681.

Although no other changes were in the proposed rules, the final rules modified the regulations for clarity and accuracy. One modification makes clear that CMS may impose one *or more* of the sanctions specified in 42 C.F.R. § 422.750(a)(2)-(4) if an MA organization were to violate any provision of subsection (a). § 422.752(a); FR 4682.

Subsection (b) was modified to incorporate references to provisions explaining the types of sanctions CMS may impose when it makes a determination under 42 C.F.R. § 422.510(a). The regulation previously referred to provisions detailing the procedures by which CMS may impose sanctions. § 422.752(b); FR 4682.



Civil Money Penalties

Subsection (c) was modified to clarify the grounds upon which CMS may impose civil money penalties on an MA organization. § 422.758(c); FR 4682.

Title II, Part 417 – Cost Plans

Shauna Alonge

Cost Plans Permitted Beyond January 1, 2008 in Limited Circumstances

CMS will not accept new cost plans, although expansion of service areas for existing cost plans will be considered under certain circumstances, so long as the applications are submitted to CMS on or before September 1, 2006. § 417.402(b); FR 4713. With respect to renewal of approved cost plans, the MMA provides for an initial extension of cost plans through December 31, 2007, with exceptions beyond that date permitted under certain circumstances. CMS adopted as final its proposed rule to permit cost plans to be extended beyond January 1, 2008 only when there are fewer than two competing coordinated care plans (either two local or two regional) of the same type available to Medicare beneficiaries in the same service area. Mandatory cost-plan non-renewal or service area reductions are triggered when two or more coordinated care plans meet certain minimum enrollment requirements for the entire previous calendar year. § 417.402(c); FR 4713. A single MA entity may offer more than one qualifying plan. FR 4593.

Beneficiary Grievances and Appeals for Cost Plans to Mirror Part 422 MA Rules

With few exceptions, CMS has adopted as final its proposed rule that the same rights, procedures, and requirements relating to appeals and grievances set forth in subpart M of Part 422 also apply to organizations offering Medicare cost plans. §§ 417.600(a)(3), (b); FR 4713. Cost plans have until January 1, 2006 to transition to the MA grievance and appeals process under Part 422. FR 4680.