



rural policy research institute

RUPRI Center for Rural Health Policy Analysis

NORC | **WALSH CENTER**
FOR RURAL HEALTH ANALYSIS

**A RURAL PERSPECTIVE REGARDING REGULATIONS
IMPLEMENTING TITLES I AND II OF THE MEDICARE PRESCRIPTION DRUG,
IMPROVEMENT, AND MODERNIZATION ACT OF 2003 (MMA)**

A Joint Publication of

The Walsh Center for Rural Health Analysis
National Opinion Research Center, University of Chicago
W Series • No. 6
and
The RUPRI Center for Rural Health Policy Analysis
University of Nebraska Medical Center
P2004-6

Authors:
Curt Mueller, Ph.D.
Keith Mueller, Ph.D.
Janet Sutton, Ph.D.

August 9, 2004

This study was funded under a cooperative agreement with the Federal Office of Rural Health Policy (ORHP), Health Resources and Services Administration, U.S. Department of Health and Human Services, Grant Numbers 7 UIC RH 02549-01-00 (Walsh Center) and 1 UIC RH 00025-01-00 (RUPRI Center). The conclusions and opinions expressed in this paper are the authors' alone; no endorsement by NORC, RUPRI, ORHP, or other sources of information is intended or should be inferred.

The Walsh Center is part of the Department of Health Survey, Program, and Policy Research, NORC, a national organization for research at the University of Chicago. To obtain a copy of the full report or for more information about the Walsh Center and its publications, please contact:

NORC Walsh Center for Rural Health Analysis

7500 Old Georgetown Road,
Suite 620, Bethesda, MD 20814-6133
Phone: (301) 951-5070
Fax: (301) 951-5082
www.norc.org

The RUPRI Center for Rural Health Policy Analysis is based at the University of Nebraska Medical Center, in the Department of Preventive and Societal Medicine, Section on Health Services Research and Rural Health Policy. For more information about the Center and its publications, please contact:

RUPRI Center for Rural Health Policy Analysis

University of Nebraska Medical Center
984350 Nebraska Medical Center
Omaha, NE 68198-4350
Phone: (402) 559-5260
Fax: (402) 559-7259
www.rupri.org/healthpolicy

Part 1: Medicare Prescription Drug Benefit - Comments

Curt Mueller, Ph.D.

Janet Sutton, Ph.D.

INTRODUCTION

In this portion of the Policy Paper, we provide some guidance regarding provisions in the Proposed Rule “Medicare Prescription Drug Benefit.” The benefit was enacted into law on December 8, 2003, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We reviewed the Proposed Rule (found at the CMS website given below) and have identified sections that might be of special concern to rural Medicare beneficiaries, medical care providers, and policymakers. Most of the sections identified below, however, are concerned with access to prescription drug coverage and whether there will be systematic differences between rural and urban areas and between areas that differ with respect to the number of sponsors of drug coverage. Several sections are also referenced out of concerns for impacts of the legislation on rural pharmacies. The primary focus of a number of Subparts (summarized in Section I of the Proposed Rule) is on rules that will affect providers of drug coverage; this Policy Paper does not focus on rural dimensions of coverage from the insurance provider’s perspective.

The Proposed Rule contains instructions for those wishing to comment, and can be found on either the CMS web site (www.cms.hhs.gov/medicarereform/) or in the *Federal Register* released on August 3, <http://www.gpoaccess.gov/fr/index.html>.

Citation	Statement in the Notice	Implications for Rural Health Services
Subpart B: Eligibility and Enrollment Eligibility to Enroll (§423.30)	The Secretary must ensure that each Part D eligible individual will have available a choice of enrollment in at least two qualifying plans, at least one of which must be a PDP; otherwise, a “fallback” plan will be made available. A “fallback” plan is a plan “offered by an eligible fallback entity that provides only standard prescription drug coverage (without supplemental benefits), provides access to negotiated prices” and meets other requirements for PDP sponsors.	Choice in rural areas may be more limited than in more urban areas, and “fallback” plans may be more likely to be offered in rural areas by default. How do expected benefits and costs under fallback plans compare with expected benefits and costs under regularly sponsored plans?

Citation	Statement in the Notice	Implications for Rural Health Services
Subpart B: Eligibility and Enrollment Process (§423.34)	CMS is considering several approaches to enrolling dual eligibles, and seeks comment on the most appropriate method of performing automatic assignment and what entity (i.e., state, CMS) should perform assignments. Impacts will vary by state.	The size of the dual eligible population and details on administration of their coverage will vary by state, so rural dual eligibles in some states may be more adversely affected.
Subpart C: Benefits and Beneficiary Protections Definitions (§423.100)	The MMA does not define the term “dispensing fee.” CMS lists three alternative definitions that might be adopted. Under the second and third options, a definition is proposed that would improve Medicare coverage for home infusion of prescription drugs.	Because rural residents tend to be more isolated than urban residents, a broader definition that improves coverage of infusion expenses may be beneficial. How the dispensing fee is defined may also impact rural pharmacies.
Subpart C: Benefits and Beneficiary Protections Access to Covered Part D Drugs (§423.120)	PDPs and MA-PD plans will be required “to secure the participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by plan enrollees.” CMS is authorized “to use access rules no less favorable to enrollees than rules” under the TRICARE Retail Pharmacy Program. For designated rural areas (defined in the text), the rule would be that “at least 70 percent of Medicare beneficiaries in the plan’s service area, on average, live within 15 miles of a retail pharmacy participating in the prescription drug plan’s or MA-PD plan’s network.” CMS is proposing that PDPs serving more than one region meet access requirements within each region.	Rules to be defined by CMS will impact rural beneficiary access to pharmacy benefits and drugs and economics of rural pharmacies.

Citation	Statement in the Notice	Implications for Rural Health Services
Subpart C: Benefits and Beneficiary Protections Access to Covered Part D Drugs (§423.120)	CMS is proposing that PDPs serving more than one region meet access requirements within each region, and pharmacies that will be counted in the application of access requirements are to be retail pharmacies, i.e., pharmacies excluding those offering only limited access, such as in OPDs and clinics. An exception, however, is proposed for areas served by non-retail pharmacies administered by the IHS, Indian tribes and tribal organizations, and urban Indian organizations.	Rules to be defined by CMS will impact rural beneficiary access to pharmacy benefits and drugs and economics of rural pharmacies. Special rules are likely to be developed for tribal lands.
Subpart C: Benefits and Beneficiary Protections Access to Covered Part D Drugs (§423.120)	CMS is considering whether regulations are needed to address relationships between pharmacies administered by the IHS, Indian tribes and tribal organizations, and urban Indian organizations, and PDPs and MA-PDs.	Options for assuring access to these pharmacies may improve access to Part D drugs for many rural residents.
Subpart C: Benefits and Beneficiary Protections Access to Covered Part D Drugs (§423.120)	As CMS is “concerned about compromised access to network pharmacies by low-income beneficiaries who rely on FQHC and rural pharmacies for their health care,” CMS is seeking input on how to encourage plans to contract with FQHCs and rural pharmacies, including contracts in areas where drug plans would not have to contract with them to meet access requirements. CMS is expecting to require that PDP and MA-PD plans contract with “a sufficient number of home infusion pharmacies.”	Rural policy makers are encouraged to comment on how provisions affecting rural providers and the rural delivery system might be incorporated into Part D.
Subpart C: Benefits and Beneficiary Protections Access to Covered Part D Drugs (§423.120)	While plans must include retail pharmacies, mail-order can be offered as a delivery option by plan sponsors.	Trends toward mail order delivery in both urban and rural areas are expected to continue. These trends may adversely affect rural area pharmacies to the extent that their markets shrink.

Citation	Statement in the Notice	Implications for Rural Health Services
<p>Subpart C: Benefits and Beneficiary Protections Access to Covered Part D Drugs (§423.120)</p>	<p>PDPs and MA-PD plans “would be required to permit the participation in their plan networks of any pharmacy that was willing to accept the plan’s terms and conditions,” but “(M)odification of contracting terms and conditions might be necessary, for example, to assure access in remote rural areas ...” In fact, CMS is open to not mandating “a single set of terms and conditions for participation in a pharmacy network” to help encourage participation. CMS appears to favor that PDPs and MA-PD plans not be restricted from “varying cost-sharing not only based on type of drug or formulary tier, but also on a particular pharmacy’s status within the plan’s pharmacy network – in essence authoring distinctions between ‘preferred’ and ‘non-preferred’ pharmacies.” At the same time, CMS recognizes “the possibility that plans could effectively limit access in portions of their service areas by using the flexibility ... in designing its network...” and that this flexibility might “discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that plan.” CMS intends to review “the design of proposed prescription drug plan and MA-PD plan designs to ensure that they are not likely to substantially discourage enrollment by certain Part D eligible individuals.”</p>	<p>There appears to be interest within CMS to encourage participation in Part D by pharmacies. Encouraging plans and pharmacies to seek mutually acceptable terms defining participation in Part D, however, would seem to work best in competitive markets that may not be as common in rural as in urban settings.</p>

Citation	Statement in the Notice	Implications for Rural Health Services
<p>Subpart C: Benefits and Beneficiary Protections Special Rules for Access to Covered Part D Drugs at Out-of-Network Pharmacies (§423.124)</p>	<p>CMS expects to guarantee out-of-network access to Part D drugs under certain conditions, including ‘cases in which a Part D enrollee cannot obtain a covered Part D drug in a timely manner within his or her service areas because, for example, there is no network pharmacy within a reasonable driving distance that provides 24-hours-a-day/7-day-per-week service’ and when a particular Part D drug ‘is not regularly stocked at accessible network retail or mail-order pharmacies.’ At the same time, plans may ‘establish reasonable rules to assure that enrollees use out-of-network pharmacies appropriately.’ Although the enrollee ‘would be responsible for any difference in price between the out-of-network pharmacy’s usual and customary (U&C) price and the plan allowance for that covered Part D drug,’ CMS encourages comments on how to define U&C price to ensure that that the U&C price is not used in such instances by pharmacies ‘to increase total reimbursement.’</p>	<p>Out-of-network provisions are being debated, permitting input from rural policymakers.</p>
<p>Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans Cost and Utilization Management (§423.153)</p>	<p>This section identifies elements of quality assurance systems that are viewed as desirable for PDP sponsors and MAs. These include electronic prescribing systems, clinical decision support systems, and bar coding.</p>	<p>Although, presumably, each of these systems may assist in reducing prescribing errors and promoting quality improvement, it is not clear whether rural providers and pharmacies (at least ones that are not part of a larger chain) have access to the technology or resources to implement these systems. Information on the technical and resource requirements necessary to implement these quality assurance systems to ensure that rural residents also benefit from patient safety interventions would be useful.</p>

Citation	Statement in the Notice	Implications for Rural Health Services
<p>Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans Electronic Prescription Program (§423.159)</p>	<p>PDP sponsors and MA organizations are required to have the capacity for electronic prescribing, although it does not appear that providers are required to prescribe electronically. With regard to physicians, the regulations allow MA-PD plans to reimburse physicians different amounts depending upon whether they do or do not transmit prescriptions electronically.</p>	<p>It is not clear whether rural providers will have access to the technology or resources to transmit prescriptions electronically. To the extent that they do not, rural beneficiaries may not benefit from these patient safety interventions. Small rural physician practices are likely to be financially disadvantaged if they do not have access to the software or hardware required for adoption of this technology.</p>
<p>Subpart F: Submission of Bids and Monthly Beneficiary Premiums National Average Monthly Bid Amount (§423.279)</p>	<p>CMS would establish an appropriate methodology for adjusting the national average monthly bid amount to take into account any significant differences in prices for covered Part D drugs among PDP regions. CMS is seeking comments on the existence of regional price variation in drug prices and any factors affecting variation. CMS “may not implement a geographic adjuster for the first few years of the program” because time is needed to “have acquired sufficient information on pricing to accurately characterize that variation.” If implemented, the geographic adjuster would be implemented in a budget neutral manner.</p>	<p>Information on price variation in rural versus urban areas is needed for CMS to consider geographic adjustment of payments under Part D.</p>

Citation	Statement in the Notice	Implications for Rural Health Services
<p>Subpart Q: Guaranteeing Access to a Choice of Coverage Assuring Access to a Choice of Coverage (§423.859)</p>	<p>The prescription drug access standard and how “fallback” plans will be used if the access standard has not been met are discussed. Fallback plans will be used in areas in which a choice of at least two qualifying plans is not available. Fallback plans offer basic benefits and sponsors do not assume financial risk. Because sponsors would be reimbursed based on costs, it is expected that these plans will have less incentive or ability to negotiate drug discounts. Although options for performance-based payment, which encourage fallback plans to obtain discounts, are being considered, it is possible that the premiums associated with these plans could be higher than for other types of plans.</p>	<p>It is important to examine how the fallback plans will be designated and incentives that will be used to promote cost savings by these plans. Rural residents may be more likely than urban residents to obtain fallback plan coverage, which may increase out-of-pocket expenses for rural residents.</p>

Part 2: The Medicare Advantage Program

Keith Mueller, Ph.D.

INTRODUCTION

The material in this part of the Policy Paper is organized to provide the reader with guidance regarding provisions in the Proposed Rule “Establishment of the Medicare Advantage Program,” which implements Title II of the MMA. The focus here is specifically on those statements in the Rule that may affect the delivery of health services in rural areas. The Proposed Rule contains instructions for those wishing to comment, and can be found on either the CMS web site (www.cms.hhs.gov/medicarereform/) or from the *Federal Register* released on August 3, <http://www.gpoaccess.gov/fr/index.html> (enter Medicare Modernization Act in the search space and submit). The Proposed Rule includes a Preamble and an Analysis of the regulation. Citations in this paper are to either a Subpart of the Preamble (with reference to a section of the regulation) or the Analysis.

AVAILABILITY OF PLAN CHOICES AND SERVICES FOR RURAL BENEFICIARIES

There are multiple provisions in the MMA intended to attract competing health plans to rural areas. These provisions accept a premise that competition will result in access to more enhanced benefits at affordable costs to the beneficiaries and to the Medicare program.

Citation in the Proposed Rule	Statement in the Notice (N) or From the Regulatory Analysis (R)	Implication for Rural Health Services
Subpart B—Eligibility, Election and Enrollment 5. Election Process (§ 422.60)	(N) MA organizations can request restrictions on enrollment capacity at any time during the year. This is related to what happens when a large competitor withdraws from the market and there could be a subsequent large increase in enrollment that is beyond the capacity of the remaining MA organization(s) to handle, or what can happen if an MA organization loses a contract with a large regional provider.	While the scenario could occur anywhere rural areas are especially susceptible to the phenomenon the Notice describes, since there is a stronger likelihood there would be low enrollment local MA organizations in rural areas. Instances of this market phenomenon occurred when large urban-based plans withdrew from rural markets between 1999 and 2003, sometimes leaving small plans as the only M+C plans available.

Citation in the Proposed Rule	Statement in the Notice (N) or From the Regulatory Analysis (R)	Implication for Rural Health Services
Subpart C (§ 422.112 and § 422.101(d)(2))	(N) CMS proposes “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.” The new standards would apply only in counties where MA plans are unable to secure contracts with an adequate number of providers to satisfy comprehensive network adequacy requirements. Plan enrollees could be provided the opportunity to see a non-contracted provider at the in-plan cost sharing levels. MA plans would still be required to have a high percentage of the necessary providers under contract. Beneficiaries would be held harmless, financially, from the plan’s inability to secure contracts. Presumably, as a non-contract provider, any rural providers affected by this regulation would be compelled to accept as payment in full from the MA plan the amount that would otherwise have been paid by Medicare.	This approach represents an effort to retain access to local providers, but without imposing additional costs on beneficiaries. It also has implications for providers, since MA plans would not need contracts with all the providers in a service area in order to meet access standards. The subsequent payment may be more or less than rural providers could expect through a negotiation process. Would MA Plans be expected to pay the current Medicare amount, including special payments for Critical Access Hospitals, Sole Community Hospitals, bonus payments for physicians, and other special payments? If providers are expected to accept MA plan payment or not accept the enrollees in that plan, will providers simply decline to accept new Medicare patients? While the discussion in the Notice begins with the discussion of hospital payment, what are the implications for other rural providers? <i>CMS is requesting comment on measures to assess robustness of contracted provider networks, and on thresholds to adopt relative to cost-sharing limits.</i>
Overall Impact 1. Objectives of the Proposed Rule Promoting Competition	(R) One of the purposes of the MMA is to promote competition, which is expected to result in greater efficiency among plans and more benefits for enrollees. This expectation is confirmed by evidence from research literature. CMS acknowledges a relationship between competition and spending that could result in lower payments inducing plan exit, which in turn undermines competition. Therefore, the Federal Government has an interest in safeguarding and promoting competition independent of payment rates.	Rural areas are perhaps the most likely places to experience the scenario of prices driving competition down because of low volume. In areas with only a modest number of Medicare beneficiaries there would be fewer competing plans, so an exit by even one plan could undermine competition.

FINANCIAL LIABILITY OF BENEFICIARIES

Regulations governing activities of MA organizations could affect the financial liability of rural beneficiaries.

Citation in the Proposed Rule	Statement in the Notice (N) or From the Regulatory Analysis (R)	Implication for Rural Health Services
II. Subpart C: Benefits and Beneficiary Protections (§ 422.101(d))	(N) MA regional plans would be responsible for tracking beneficiary out-of-pocket limits (incurred rather than paid) and for notifying members when they are met.	Rural beneficiaries in regional plans will have access to this information. This could be an advantage of regional plans for rural beneficiaries. It could be a burden for regional plans serving predominantly rural areas because they may not have the same economies of scale as regional plans in more populous areas.
Subpart C (§ 422.112 (b))	(N) This section addresses the continuity of care standard in the MA program, which requires “specific methods by which MA organizations are to ensure an effective continuity and integration of health care services.” CMS is considering eliminating or modifying many of the requirements for local PPOs and regional MA (PPOs) plans. They are also considering the appropriateness of the requirements for all coordinated care plans.	There may be special challenges assuring continuity of care in geographically large rural areas. Rural beneficiaries may need special protection from possibly disjointed services. <i>CMS is inviting comments on these considerations, especially comparisons to what is required of commercial insurers.</i>
Regulatory Analysis B. Basis for Estimating Impacts Issues in Beneficiary Behavior	(R) Beneficiaries in M+C plans in 2003 experienced out-of-pocket medical expenses that were \$667 lower, on average, than similar expenses for beneficiaries in fee-for-service Medicare. Beneficiaries in poor health find MA plans attractive.	Rural beneficiaries are on average lower-income than urban beneficiaries, and there is evidence that rural beneficiaries are more likely to be of poor health. Will the lower out-of-pocket experiences of beneficiaries in MA plans be valid for rural beneficiaries if plans expand into rural areas?

Citation in the Proposed Rule	Statement in the Notice (N) or From the Regulatory Analysis (R)	Implication for Rural Health Services
<p>Regulatory Analysis E. Effects on Beneficiaries</p>	<p>(R) “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. ... The Medgap effects can potentially have a greater impact on rural areas in a State. 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 areas(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.”</p>	<p>The following scenario could adversely affect rural beneficiaries:</p> <ul style="list-style-type: none"> • Regional plans are able to offer a more generous set of benefits than local area rural plans because urban benchmark rates make the regional rate higher than local area rural rates. Urban rates which are above the rural floor rates would be weighted in a regional calculation based on numbers of beneficiaries in the affected counties, thereby making the urban rates the dominant component of a regional calculation. • Regional plans are able to offer more generous packages than Medigap plans. • Local area urban plans are able to offer more generous packages than regional plans, because their rates are not lowered by any consideration of the lower rural rates. • Local urban markets may be most attractive markets to potential MA plans, which may mean most organizations developing those plans restrict themselves to urban areas (new plans would need to do so before January 1, 2006). Those decisions, in turn, would limit competition within the remainder of the region to the minimum number of plans required by law, meaning at least two Prescription Drug Plans (PDPs). Local MA plans, though, would not receive incentive payments. • Choices in rural areas are limited to regional plans (which may be limited if most MA plans remain exclusively local urban area plans) and Medigap plans because local rural plans cannot compete with regional plans that have higher revenues based on higher rates. • Medigap plans attract only high risk beneficiaries in urban areas, thereby driving up the premiums for all Medigap enrollees in the region. • Rural beneficiaries pay a higher premium to enroll in Medigap plans, but the alternatives are limited to whatever regional plans are offered. Therefore, if rural beneficiaries see Medigap as the choice that assures selection of local providers, they will pay a higher premium than otherwise available in regional plans. <p>The scenario just presented might be altered by attractive regional plans that use local providers, thereby mitigating the likelihood of Medigap plans being the alternative of choice, or by assuring a competitive position for local area plans.</p>

INCLUSION OF RURAL PROVIDERS IN PPOS, AND PAYMENT TO THOSE PROVIDERS

Rural providers are expected to negotiate with MA plans and to subsequently be incorporated into provider networks. MA plans will seek contracts with rural providers in order to meet access standards in the regulation.

Citation in the Proposed Rule	Statement in the Notice (N) or From the Regulatory Analysis (R)	Implication for Rural Health Services
Subpart C (§ 422.112 (c))	(N) MA plans can designate as “essential hospitals” acute care general hospitals needed to meet access requirements, but who will not accept Medicare prospective payment as contracted payment. The statute sets aside \$25 million to use to supplement MA plan payment for those hospitals. The MA plan must demonstrate it negotiated in good faith, and the essential hospital must demonstrate costs that exceed amounts normally payable under Medicare fee-for-service.	This provision affects rural acute care hospitals. It does not include critical access hospitals, which are currently reimbursed by Medicare on the basis of cost rather than diagnosis related groups. This regulatory notice presents an opportunity to ask questions about negotiations between MA plans and CAHs. <i>CMS is inviting specific comments: how to ensure payments are limited to the \$25 million specified; how to ensure that a good faith effort to contract has occurred; the best way to determine a hospitals’ actual costs for services when the amount normally payable is insufficient to cover costs; and how to minimize the burden associated with implementing the provision while ensuring the accuracy and integrity of the process.</i>
Regulatory Analysis K. Analysis of Effects on Small Entities 4. Hospitals	(R) The essential hospital provision is more likely to occur in small towns and rural areas. Over 700 rural hospitals are already paid at rates higher than would otherwise be applicable under Medicare. They are in sparsely inhabited rural areas and account for only one percent of Medicare hospital payments.	As stated in the analysis, these are rural hospitals which are the only hospitals in their immediate area.

Citation in the Proposed Rule	Statement in the Notice (N) or From the Regulatory Analysis (R)	Implication for Rural Health Services
II. Subpart C—Benefits and Beneficiary Protection 1. General Requirements (§ 422.100)	(N) “A physician or other entity that does not have a contract with an MSA plan is now required to accept as payment in full ... the amount the physician or other entity could have collected had the individual not been enrolled in the MSA plan.”	Rural providers would be compelled to accept current levels of Medicare payment as payment in full for beneficiaries insured through an MSA plan. Does the amount the provider could have collected include special payments to specific providers such as Critical Access Hospitals and physicians practicing in shortage areas? Does this provision lock in payment levels that are inadequate and/or contribute to geographic inequity?
II. Subpart C 11. Access to Services (§ 422.112)	(N) There are no new access standards, but the law and regulation try to deal with the situation of hospitals having “monopoly power” in negotiations with MA plans.	The perception of hospitals holding out in negotiations with MA plans has merit, but the Notice is silent regarding any similar posture held by MA plans.
Subpart D – Quality Improvement Program <u>Adjustment for intra-area variations</u> (§ 422.308(d)(1))	(N) Section 1853(a)(1)(F)(i) of the MMA requires that CMS “adjust payments for local and regional MA plans to account for variations in ‘local payment rates’ within each region the plan is serving.” CMS assumes this requirement means methods other than using county AAPCC rates can be applied. CMS will review MedPAC’s study on MA payments, which will include analysis of the reason for variation in costs among different areas before determining the basis for adjustment.	Differentiating rates within a region may affect negotiations with rural providers.

QUALITY IMPROVEMENT

Citation in the Proposed Rule	Statement in the Notice (N) or From the Regulatory Analysis (R)	Implication for Rural Health Services
Subpart D – Quality Improvement Program 2. Quality Improvement Program 3. Chronic care improvement program requirements 4. Quality Improvement Projects (§ 422.152)	(N) The heading of Section 422.152 is changed from “quality assessment and performance improvement program” to “quality improvement program.” Each MA plan except private fee-for-service and MSA plans will be required to have an ongoing quality improvement program.	The specifics of quality improvement programs remain to be determined, but there are models cited in the Notice. MA plans could select their own means of implementing a quality improvement program. This may create flexibility for implementing appropriate programs in rural areas, or if regional MA plans are creating the programs it could impose programs developed in one part of the region on the entire region. <i>CMS is requesting comments on whether or not to require comparable measures across plans and making QI program size and scope proportionate to plan size; and on guidance for plans on criteria and mechanisms that might help them identify and monitor enrollees that are participating in chronic care improvement programs.</i>

DEFINING REGIONS FOR MA PLANS AND EFFECTS ON COMPETITION

The MMA requires CMS to establish between 10 and 50 regions within which regional plans would be required to make services available to all beneficiaries regardless of residence. The regional MA plans would be preferred provider organizations (PPOs). Local area plans would continue to be allowed as well. However, no new local area plan could be established as a PPO from January 1, 2006 through December 31, 2007. The definition of regions will be an important element in implementing the MMA.

Citation in the Proposed Rule	Statement in the Notice (N) or From the Regulatory Analysis (R)	Implication for Rural Health Services
Subpart J – Special Rules for MA Regional Plans 1. Establishment of the MA regions (§ 422.455)	(N) The regions will be determined after a market study has been completed. Factors CMS is considering in selecting regions: number of eligible beneficiaries in each region, similarity in regional payment rates, balance within each region of rural and urban, inclusion of health markets within regions, and having MA and PPO regions be the same to the greatest extent possible.	One reason for developing regions is to achieve a goal of making alternative health plans available to rural beneficiaries. The size of regions will have implications for the ability of health plans to participate in the program, and therefore for the choices available to rural beneficiaries. <i>CMS is requesting comments on how to best address the considerations they specified, and comments related to other factors they should consider in defining regions.</i>
Subpart D--- Quality Improvement Program 5. Calculation of benchmarks (§ 422.258)	(N) The calculation of the benchmark (determines if plans are above or below what would otherwise be paid, representing costs or savings) for local plans is based on the county rate as determined by historic fee-for-service expenditures on behalf of the beneficiaries in that county. “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 benchmark is in effect a target expectation for Medicare payment for health plans. Within the same rural area there could be two benchmarks, one local based on previous Medicare policies (in effect the floor payment) and one that is a blend of a regional rate and the bids submitted by MA plans. As discussed in the Notice, until there is more experience we cannot determine which rate will be more attractive in specific instances. Local plans may be advantaged if competitive pressures drive bids down while local benchmarks remain high, or disadvantaged if the floor payment is far below the regional rate.

Citation in the Proposed Rule	Statement in the Notice (N) or From the Regulatory Analysis (R)	Implication for Rural Health Services
Regulatory Analysis E. Effects on Beneficiaries	(R) Beneficiaries in private plans have already seen reduced expenditures and increased benefits. In New Jersey the average monthly M+C premium declined from \$56 to \$15 and in all 21 of the state’s counties a prescription drug benefit was added. The generosity in benefits has been less in rural counties, in 1999 the average M+C premium was \$5 per month, but in rural areas it was \$14. There could be disparities in the generosity of benefits across regions.	The generosity of benefits available to rural beneficiaries will be a function of the designation of regions and participation of competing plans in those regions.
Regulatory Analysis K. Alternatives Considered 1. Designation of Regions	(R) CMS wants to hear from plans and potential plans regarding the factors that are important in promoting plan participation. Using an attractive state such as New Jersey as part of a multi-state region might increase the opportunities in the other states. States with the smallest Medicare populations tend to have the highest proportion of rural beneficiaries as a percent of the total Medicare population in those states. Should such states be combined? Would a regional plan be viable when the geography becomes immense?	The designation of regions may determine whether or not there will be competing regional plans in rural areas. <i>CMS is asking for specific comments from any plans with experience in attracting enrollees on a regional basis.</i>

Citation in the Proposed Rule	Statement in the Notice (N) or From the Regulatory Analysis (R)	Implication for Rural Health Services
Regulatory Analysis B. Basis for Estimating Impacts Issues in Predicting Plan Behavior	(R) Medicare regional plans have an opportunity to participate in Medicare at less risk than local HMO and PPO plans because of potentially higher payment levels. The market opportunity is also related to expected growth in the number of potential enrollees. A major goal of promoting regional plans is to increase access to competing health plans in rural areas. Reasons plans have not entered rural markets include difficulty in establishing provider networks, too small an enrollment base, and few rural areas consume large amounts of health care which limits ability to achieve efficiency gains. The designation of regions will be a factor affecting which rural areas may have plans participating.	The assumptions in this analysis support assumptions that the designation of regions under the authority of the MMA will enhance benefits available to rural beneficiaries. To the extent any of them are not valid, the aspired gains for rural beneficiaries may not be realized. If regional plans have competitive advantages over local plans, will there be net gains in competition in rural areas where local plans now operate? If local plans are forced out of the market by regional plans, will access to local services and/or quality (including provider and patient satisfaction) be affected? If the assumptions about reasons for lack of competition in some areas are true, how will they be overcome in rural areas? Federal Government oversight and regulation may serve to assure competition in rural areas.
Regulatory Analysis F. Effect on Health Plans and Insurers	(R) “Local plans have the advantage of being able to selectively market to Medicare beneficiaries in that they can make decisions on a county basis.” The ability of plans to bid above and below the benchmark and be paid by Medicare for amounts above the benchmark should smooth out revenue streams.	Local rural plans may be able to compete successfully and offer local options to beneficiaries.
Regulatory Analysis K. Analysis of Effects on Small Entities 2. The local MA Market and Small Entities	(R) Local plans will be competing with regional MA plans, and with regional PDPs. Regional plans have access to the stabilization fund and to risk sharing with the government. Local plans have advantages in marketing and offering integrated benefits (as compared to PDPs). Local plans operate, for the most part, in urban areas with higher rates.	Local <u>rural</u> plans would not have an advantage in rates, but would have the marketing advantage and the integrated services advantage (as compared to regional PDPs). What are the implications for local rural plans, and in turn for beneficiary access? <i>CMS requests suggestions for steps to ameliorate any problems created by the regional structure.</i>