

October 1st, 2004

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P and CMS-4069-P
PO Box 8018
Baltimore, MD 21244-8018

Ref. File Code CMS-4068-P and CMS-4069-P

Dear Administrator McClellan:

The Rural Wisconsin Health Cooperative (RWHC) appreciates the opportunity to comment on the proposed rules implementing the new Medicare Drug Benefit and the Medicare Advantage Program published in the August 3, 2004, *Federal Register*. We appreciate your ongoing commitment to rural health care, and RWHC looks forward to working with you in our mutual goals of improving access and quality of health care for all rural Americans. These comments were prepared in collaboration with and, in part, abstracted from draft comments prepared by the National Rural Health Association as well as from discussions held at the Wisconsin Hospital Association.

RWHC, in its 25th year, is owned and operated by twenty-nine rural hospitals; in addition, three regional tertiary systems are non-voting affiliates. The RWHC vision is to support and enhance rural health and quality of care and that RWHC is a strong, innovative and mutually supportive network of hospitals with diversified services who combine their strengths to meet local community health needs through advocacy and high value products and services.

The proposed rule is exceedingly complex, with potentially, significant and unintended consequences for rural America. We support your efforts to ensure plan choice for all rural beneficiaries, and we also support your efforts to create regions which attempt to include all rural areas of the country. **However, it is absolutely critical for the Centers for Medicare & Medicaid Services (CMS) to assure the strict enforcement of existing CMS requirements intending to assure beneficiaries local access consistent with local community patterns of care.**

RWHC welcomed the recent CMS clarifications (your letter in response to Senator Russ Feingold's of April 8th) that cost-based providers operating within the Medicare Advantage program will be ensured proper reimbursement at their congressionally mandated cost-based levels when they serve beneficiaries who access them "out of network." **But it must be**

emphasized that this protection does not extend to cost-based providers when beneficiaries access these providers “in network.” As we have seen with Medicare+Choice, large insurers can and do coerce rural providers to accept contracts with substantial discounts in order to not lose the patients and undermine the local infrastructure. We understand that the definitive resolution of this issue will require an amendment to the current Medicare Advantage statute.

Because of the exceedingly complex nature of this proposed rule, and the fact that several key aspects of relevance to rural beneficiaries and providers have yet to be detailed in specific by CMS, we strongly urge CMS to issue a final rule with comment period prior to implementation of the regulations.

In our review of the potential impact of the proposed regulations in Wisconsin, we have two overriding concerns with the regulations as proposed.

- While the regulation addresses the perceived concern of rural providers having “monopoly power” in negotiations with MA plans, there are no provisions regarding the obvious potential for a Medicare Advantage plan to abuse its market power in a rural area. Although rural providers in most cases are unlikely to stop caring for their community’s rural elderly, a national Medicare Advantage health plan, operating without local community pressure, is quite likely to make a business decision not to contract with a local community provider. These regulations must clearly mandate that Prescription Drug plans and Medicare Advantage plans make a “good faith effort” to contract with local providers in order to minimize the number of beneficiaries who have to go “out of network” to access care locally.
- RWHC urge CMS to establish a requirement for each state Office of the Commissioner of Insurance be allowed the opportunity to offer comment on all Medicare Advantage plans to meet community access standards, before CMS approves such a proposal. These proposals should also be made available for public comment within each region.

We continue to believe, in concept, that the proposed Medicare Advantage program can enhance health care coverage and access for rural beneficiaries. But it must be implemented properly to ensure that both the beneficiaries, and providers, are not bypassed or ignored under the implementing regulations. **Ironically, if health plans are allowed to steer patients out of rural areas, CMS and the Medicare Trust Fund will still be responsible for increasingly higher per day and per visit costs at Critical Access Hospitals and other cost based providers as fixed costs are spread over fewer patients. Allowing plans to steer patients away from these providers will cost Medicare more than assuring that plans allow access to these facilities.**

The Medicare + Choice program was not a successful scheme for rural America. The RWHC will oppose any policies that duplicate the failed methodologies of M+C within the new Medicare Advantage program. Our specific comments include the following:

Title I (Medicare Drug Benefit), Subpart C:

Definition of Rural

The definition of rural in the implementation of this section is a substantial concern for RWHC. The proposed rural definition (utilizing the Department of Defense's TRICARE's methodology) must not be used. The TRICARE methodology is simply too broad a definition for rural for the use of determining access standards. The broader the area that is defined as rural, and therefore the more beneficiaries that are identified as living in a rural area, the easier it will be for plans to exclude rural communities from access standards. **The proposed rule allows regional plans to exclude up to 30% of beneficiaries from local access standards; this could encompass as many as 7.8 million beneficiaries under the TRICARE methodology, a number higher than the total number of beneficiaries who reside in non-metropolitan areas.** (Source: "Definition of Rural in the Context of MMA Access Standards for Prescription Drug Plans," A Joint Publication of the RUPRI Center for Rural Health Policy Analysis Policy Paper P2004-7 and the North Carolina Rural Health Research and Policy Analysis Center Working Paper No. 79)

While the "70% of beneficiaries having access within 15 miles" proposal may be good in determining whether a Plan is allowed into a region, it must not be allowed to prevent beneficiaries from accessing a local pharmacy at "in-network" cost sharing rates. In any event, if miles are to be used in any computation of appropriate access, it must be considered as "15 road miles."

CMS should use one (or a combination) of several of its currently used definitions for rural. The federal definition of rural and related access standard should be applied to each state, even if CMS creates multi-state regions.

In any application of the access standard, we are concerned about the 30 percent of beneficiaries who may have difficulty in gaining access to network pharmacies. **We believe that it is appropriate to adopt the same "community standard" used in the Title II authority,** which include travel times and distances consistent with current usage as measures of access, provide a good model for this definition.

The RWHC recognizes the challenge will be finding the balance between the goals of expanding plan coverage into rural areas, while still retaining access at a local level. **We believe that balance is best maintained by requiring plans to serve larger rather than smaller regions while not relaxing access standards that respect existing community travel patterns.**

Pharmacy Care

Beneficiaries must have the ability to receive pharmacy care from non-contracted providers (at network cost sharing levels) in order to maintain community patterns of care. The provisions in Title II regarding essential hospitals should be applied to essential pharmacies; and the same out-of-network protections for beneficiaries should apply. Beneficiaries should not be required to pay differential charges when using non-network providers for legitimate reasons related to access.

Under the proposed regulations, while plans must include retail pharmacies, mail order can be offered as a delivery option by plan sponsors. Although the use of mail order may result in cost-saving for rural beneficiaries, and ease access problems in some cases, if this provision results in financial problems for rural pharmacies, it will have a harmful impact on access to care. Rural beneficiaries must have access to medications in emergency situations and access to the informational services provided by local pharmacies, services that mail order prescription companies simply can not provide. CMS must ensure that essential rural pharmacies remain in business, so that mail order is not the only option for the rural elderly.

Also, it is often the case that very small rural hospitals do not have a pharmacist and rely on the pharmacy in the local community for delivery of inpatient acute care. If the pharmacy service provider closes, then the community hospital loses its pharmacists and its local pharmacy as well. CMS must ensure that this situation will not occur within this proposal. Therefore, plans must be mandated to contract with local rural pharmacies that serve as essential community providers by providing clinical services and/or working with local hospitals.

RWHC urges CMS to assure that plans contract with at least one pharmacy in each community service area. In order to ensure this is feasible, the plan must be required to waive those portions of their standard contract that the pharmacy cannot reasonably be expected to meet. For example, if a plan's standard contract requires that a pharmacy carry private malpractice insurance, an FQHC pharmacy can not reasonably be expected to carry private malpractice insurance.

We applaud CMS for seeking input on how best to encourage plans to contract with Federally Qualified Health Centers and Rural Health Clinic pharmacies under these regulations, and we look forward to working with CMS on this particular concern.

Independent Pharmacists

The RWHC is very concerned about the impact on independent pharmacists under this proposal. PBMs in many cases also run mail order companies. Therefore, there is a built-in bias within this proposal towards mail order, which could result in the elimination of independent pharmacists, which are a primary source of pharmacy care in rural America.

Dispensing fee

Under the proposed rule, CMS lists three possible definitions that might be adopted for "dispensing fee." RWHC urges the adoption of either of the second or third approach, which provides a broader definition that would improve coverage of infusion expenses. This broad approach is necessary to address the isolated nature of rural beneficiaries.

Title I (Medicare Drug Benefit), Subpart F:

Fallback Plans

The proposed rule clearly states that the beneficiaries must have a choice of enrollment in at least two qualifying plans, or a "fallback" plan will be made available providing only standard prescription drug coverage, (without supplemental benefits.) RWHC anticipates that for regions

that are composed primarily of rural states, “fallback” plans will be the plans of choice. Therefore, we have great reservations, concerns, and questions about the expected benefits and costs under these fallback plans in comparison with options that are likely to be available in regions with large urban areas. **RWHC strongly encourages CMS to fully detail costs and benefits of these “fallback plans” prior to implementation.**

Title I (Medicare Drug Benefit), Subpart D:

Cost Control and Quality Improvement

Excellent quality in healthcare is the goal of all providers. The main objective of quality assessment/quality improvement programs is to ensure that the health care system achieves the goal of optimizing the health of the people for whom it is responsible. **As the context of health care delivery can vary significantly between urban and rural areas, there needs to be rural appropriate quality healthcare standards and benchmarks that factor in these differences.**

If CMS intends to rely solely on new systems of information technology (under the proposed regulation) to improve quality, which some rural providers do not currently utilize, this is problematic. Appropriate funding to rural providers to allow building of an information infrastructure must accompany any such proposal. Any proposed scheme to link rural physician reimbursement to electronic prescribing without appropriate federal assistance is inappropriate, and detrimental to rural health care. RWHC encourages CMS to seek full funding for the grant program in Section 108 of the MMA.

Title II (Medicare Advantage Program) Subpart C:

Community Access Standard

Under no circumstance should the existing community access standard be relaxed.

Therefore, the current CMS access requirements must be strictly enforced: “Maintain and monitor a network of appropriate providers, supported by written arrangements, that is sufficient to provide adequate access to covered services to meet the needs of the population served. This involves ensuring that services are geographically accessible and consistent with local community patterns of care.”

The proposed access language, when applied to rural portions of a region, is particularly disturbing. It appears to contradict the access standard noted above of “ensuring that services are geographically accessible and consistent with local community patterns of care.” The following language appears to allow rural access to be less than that assured by the “community patterns of care” rule above but falls short of assuring that the beneficiary cost sharing is at “in network” levels. I.e. it allows “less robust” networks to charge higher cost-sharing than charged those “in network,” albeit less high than more “robust” networks.”

“We propose to permit MA regional plans with lower out-of network cost sharing to have less robust networks of contracted providers. While we propose to permit MA regional

plans with more robust networks of contracted providers to impose higher cost sharing charges on individuals going out-of-network. This is because if the plans' networks were robust, we would not expect beneficiary access to be unduly limited by higher cost-sharing requirements when they seek care from out-of-network providers. We could require MA regional plans that have less than 20, 50, or 70 percent of hospital beds in the service area (or portion of the service area) under contract to charge lower out-of-network cost sharing to individuals accessing non-network hospitals.”

Maintaining and enforcing the existing community access standard is paramount to the success of this program in rural America.

Essential Access Hospital

We would urge CMS to further clarify that due to the language of the Medicare Modernization Act, the proposed rule's reference to “Essential Access Hospitals” does not include Critical Access Hospitals. While CAHs are certainly viewed as essential access hospitals within the rural policy community, they are not defined as such within the statute and these proposed regulations. This fact has led to substantial confusion, and will likely cause additional problems within the implementation of this proposal if not further clarified by CMS.

Adjustment for Intra-Area Variations

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. This provision could allow health plans to segregate rural providers within their region and offer them a substantially lower payment rate. While RWHC certainly opposes any methodology that would not improve the current payment disparities within the Medicare program, we recognize the need to further correct payment disparities in the future. Therefore, we urge CMS to seek further data on the historical causes for these disparities, and to seek additional public comment on this particular proposal.

It is unfortunate that Wisconsin beneficiaries, plans and providers continue to be disadvantaged as the proposed benchmarks for the health plans are significantly effected by our state's historically lower utilization rates. Medicare+Choice was rightly criticized for making available extra benefits in regions of the country that had high Medicare utilization which could not be made available in regions with more appropriate utilization.

Title II (Medicare Advantage Program), Subpart D

Comparable Plan Quality Measures

In response to calls for comments concerning, “comparable measures across plans,” RWHC urges CMS to collect and review quality data from plans annually. This annual review is necessary as this program is implemented, and certainly can not be viewed as a one-time occurrence if quality is to be truly measured and ensured.

Lastly, the quality of care delivered in Wisconsin has traditionally been among the highest in the country. Contributing to that level of quality have been the integrated delivery systems and their related health plans. In fact, several of them have been recognized by the National Committee on Quality Assurance and the Baldrige National Quality Program. Our concern is that the regional PPO plans be held to the same high standards as those achieved by our local plans. Because of the monetary incentives provided them, regional plans have the potential of driving local plans from the marketplace. In that event, Medicare beneficiaries should not have to accept a lower level of quality care.

Medigap

The RWHC is concerned that the proposal could adversely affect rural beneficiaries in the following ways:

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 weighed 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. While the payment will be below historic urban-only rates, it will still enable plans to offer additional benefits, as has been the experience of M+C plans even when rate increases did not keep pace with cost increases. Further, regional plans have other payment advantages, including additional payment within risk corridors when targeted expenses are exceeded, bonus payments up to 3% of the benchmark rate, and assistance in paying essential hospitals.

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. Those decisions, in turn, would limit competition within the remainder of the region to the minimum number of plans required by law. Local MA plans, though, would not receive incentive payments.

Choices in rural areas are limited to regional plans and Medigap plans because local rural plans can not compete with regional plans that have higher revenues based on higher rates and financial incentives to induce participation by regional plans. 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.

CMS needs to reconsider its analysis of the potential effects on beneficiaries in lieu of the analysis just presented which indicates the possibility for a negative effect on rural beneficiaries as a result of market segmentation.

Title II (Medicare Advantage Program), Subpart E

Relationships with Providers

There is an issue of the default payment to CAHs if the beneficiary is out-of-network. It is easy to say that a CAH should be paid at cost, it is not easy to administer with multiple payers and the extended nature of Medicare cost report settlements. We encourage CMS to determine if there is an acceptable alternative rate that a plan could pay a CAH that would approximate cost while still allowing for timely settlement of claims. One thought would be to have the payment rate be the Medicare interim rate in effect at the time that service was rendered. This puts both parties at some risk that a payment will be more or less than actual cost. However, we are talking about plans that are not contracted with the hospital, and presumably these plans would not have significant volume with the CAH. If there is a contract in place, then the CAH would be paid at the contracted rate. If the interim rate is used, there is still a question of how the plan will know the appropriate rate. Maybe it could be communicated by the CAH and verified by the Fiscal Intermediary.

RWHC appreciates the opportunity to submit these comments on the proposed rule. Please do not hesitate to contact me at 608-643-2343 if you have any questions about our comments. Thanks.

Sincerely,

A handwritten signature in black ink that reads "Tim Size". The signature is written in a cursive, slightly slanted style.

Tim Size
Executive Director