CMS-4069-P-1

Submitter : **Dr. t tester** **Date & Time:** **08/05/2004 05:08:20**

Organization : **Dr. t tester**

Category : **Individual**

Issue Areas/Comments

Subparts J-M

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

asdfasdf

Subpart K--Application and Contract requirements for
MA organizations.

asfdasdf

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

asdfasdf

CMS-4069-P-1-Attach-1.doc

CMS-4069-P-1-Attach-1.doc

CMS-4069-P-1-Attach-1.doc

CMS-4069-P-2

Submitter : **Dr. clark newhall** **Date & Time:** **08/22/2004 03:08:25**

Organization : **law office of clark newhall md jd**

Category : **Individual**

Issue Areas/Comments

Subparts J-M

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

The NYT today 8/22 has a front page article describing how blue cross and other insurers have strenuously objected to the Bush plan to divide the country into ten or so large regions in which health insurers would compete for Medicare business. The motive of the Blues is obvious but let?s examines their excuses first. The Blues say that their current structure (60 or more plans divided by states or parts of a state) would not allow them to contract with groups of doctors and hospitals across state lines and would not allow uniform pricing in a region. They also say that they do not have the capitol to take on the risks of a multi-state region.
Both these arguments are specious. First, there are already many insurers that contract with doctors and hospitals across state lines, including some of the Blues that have been purchasing other Blues in other states. Regence, for instance, operates Blue plans in Oregon, Utah, Idaho and Washington. Anthem is even larger, having acquired the Blue operations in New Hampshire, Connecticut, Ohio, Maine, Colorado and 'Nevada. It also operates in other states where it is not the sole Blue insurer. Second, the risk of insurance pool is inversely related to the size of the pool. The larger the pool, the lower the risk, because the risk is spread over more individuals (and more capitol.) The Blues are right in that multi-state regions would require more capitol; that capitol has never been wanting in any other insurance expansion and would not be wanting when the Blues were forced into consolidation by the imposition of multi-state regions.
Why then would the Blues so strongly oppose multi-state regions? The answer lies as always in self-interest; in particular, in the Blues self-interest in preserving the weak regulation and toothless bureaucracies that now regulate them. Insurance companies, including Blues, are regulated by state insurance departments. With fifty state insurance departments, the regulation is so diverse and so fragmented that insurers, including the Blues, can get away with virtually any scheme for pumping up their influence and profits. The imposition of multi-state regions would eventually spell the end of state regulation of the insurance companies and the beginning of a coherent federal scheme to rein in health insurers' ability to operate their business in the least efficient way possible (as efficiency is measured in terms of return on invested dollar, rather than in terms of administrative costs paid out to executives.) Currently, the toothless state regulatory scheme allows health insurers to operate as "old-boy" clubs, perpetuating cozy relationships within the medical-industrial complex that guarantee high salaries to doctors, hospital administrators and insurance executives.
The second answer is closely allied to the first; the Blues and most other health insurers arose from and are still closely tied to the hospital-physician industry. The Blues themselves began as an effort by the hospital and medical industries to guarantee for themselves a steady income in a time when doctors and hospitals were mostly low-paid partly charitable workers. That relationship persists today and attempts to introduce market efficiencies into the medical industry are consistently resisted by the old-boy network (doctors, hospitals and insurers) all crying about how expensive it will be (in the short run.)
Those two reasons are the most cogent explanations for why the Blues are so strongly resisting an approach that in any other industry leads to efficiencies of scale, and in insurance, always decreases the risk by increasing the pool. There are other explanations and other arguments to expose the hollowness of the Blue's opposition, but these will suffice. I am strongly in favor of the imposition of multi-state regionalization of Medicare contracting and agree that such regionalization would lead to increased competition among insurers and enhanced efficiency for invested dollars.

CMS-4069-P-3

Submitter : Ms. elizabeth darrow **Date & Time:** 08/26/2004 03:08:16

Organization : Mount Carmel Health Plan

Category : Health Plan or Association

Issue Areas/Comments

Subparts A-I

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

We understand BBA requires establishment of "lock-in" however, we question the timing of the initiation of MA and Part D and lock in all in 2006. This will be a confusing time for beneficiaries and we are concerned that with lock in beneficiaries may be more reluctant to make changes or enter managed care plans. There will also be the added burden of educating the beneficiaries about lock in in addition to educating about Part D and the MA changes

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

Please clairify language with respect to participating/non-participating in Medicare and contracted/non-contracted with the MA organization. In addition, guidance is needed for the provider community with respect to the treatment of a benificiary who is entitled to Medicare regardless of payer. For example, Medicare participating providers could refuse to treat a MA enrollee because they are not contracted or seek higher payments either from the enrollee or the MA organization yet they are a Medicare participating provider. The PPO model, like the PFFS model will not work if proivders are allowed to refuse treatment based on MA enrollment. Many providers do not understand that they must accept what they would have received had the enrollee been on FFS. In other words, MA enrollees continue to have the same rights as FFS beneficiaries.

CMS-4069-P-4

Submitter : Ms. elizabeth darrow **Date & Time:** 08/31/2004 02:08:17

Organization : mount carmel health plan

Category : Health Plan or Association

Issue Areas/Comments

Subparts A-I

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

please clarify and define cost-sharing and provisions related to involuntary disenrollment. Cost sharing should include coinsurance, copayments, deductibles and premium. in the past health plans have been unable to take any action for failure to pay cost sharing other than premium and the burden of collecting other cost sharing has been the sole responsibility of the provider. if plans are to exercise this option we will need a detailed process to follow before steps are taken to disenroll a memeber. We also understand from our sources at CMS that the action of disenrolling a member for disruptive behavior has hardly, if ever, been used.

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

Please provide guidelines for identification of participants and measurements and detail regarding the monitoring for improvement.

CMS-4069-P-5

Submitter : **Mr. David DiGiuseppe** **Date & Time:** **09/03/2004 12:09:23**

Organization : **Community Health Plan of Washington**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-4069-P-5-Attach-1.doc

ATTACHMENT # 005

Comment on MMA Title II Proposed Regulations

Submitted by Community Health Plan of Washington, September 2, 2004

File code

CMS-4069-P

Issue Identifier

"Subpart A – General Provisions" §422.4 Types of MA Plans

and

"Subpart J – Special Rules for MA Regional Plans", §422.451 Moratorium on new local preferred provider organization plans

Summary

Community Health Plan of Washington is interested in applying to CMS in 2006 as a new Local HMO that would become operational in 2007. The operational model our Medicaid health plan follows is an HMO, requiring members to select a primary care physician who functions as a "gatekeeper" for referral services. However, we are licensed by the state of Washington as a "health care services contractor." We do not hold the state of Washington's licensure designation as a "health maintenance organization".

We are concerned that since we are not nominally licensed as an HMO, CMS may interpret the language of the proposed regulation in such a way that an organization like ours would not fit the definition of a Local HMO, and rather, would be forced to apply as a Local PPO, thus being subjected to the 2-year moratorium on Local PPOs.

We believe that the intent of the statute and the regulation would be to allow an organization like CHPW to apply as a Local HMO and we ask that CMS consider clarifying the language of §422.4(a)(1)(v) to ensure that an organization like ours would not fall subject to the moratorium.

Detail

Section 221(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA Act") (Pub.L. 108-173), in establishing the Medicare Advantage Program (the "MA program") to replace the Medicare+Choice program under Part C, establishes a 2-year (2006-2007) moratorium on the offering of any new local preferred

provider organization ("PPO") plans. The proposed regulation, at subpart J, §422.451, implements this moratorium.

Section 520(a)(3) of the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 ("BBRA") added Section 1852(e)(2)(D) defining PPO under the MA program for purposes of quality assurance requirements as including three elements: that the PPO (1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; (2) provides for reimbursement for all covered benefits regardless of whether those benefits are provided within the network of providers; and (3) is offered by an organization that is not licensed or organized under State law as a health maintenance organization ("HMO"). Subpart A of the Part 422, Medicare Advantage Program proposed regulations, at §422.4(a)(1)(v), in defining a coordinated care plan, has included this definition of PPO plan, revising it to read as follows:

"A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and, only for purposes of quality assurance requirements in § 422.152(e), is offered by an organization that is not licensed or organized under State law as an HMO."

As stated in the comments to the proposed regulations (FR Vol. 69, No. 148, page 46872), CMS's intent in proposing this language was to clarify that the application of the more limited quality assurance requirements of Section 1852(e)(2)(B) of the Act applied only to MA organizations not licensed or organized under State law as an HMO. What is not addressed in the comments is the extent to which this proposed definition of PPO plan, when read together with the 2-year moratorium on new local PPO plans, can be interpreted as preventing an organization not otherwise licensed under State law as an HMO from meeting the application requirements of §422.501 of the proposed regulations, i.e., documenting that the organization "is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract."

Given the proposed definition of PPO plan set forth above, we are concerned that unless an organization is licensed or organized under state law as an HMO, it will be presumed to be a PPO plan for purposes of submitting an application for contracting under the MA program, and, where it does not qualify as a Regional PPO plan, will be considered a Local PPO plan and, therefore, barred from applying during the 2-year moratorium.

In our case, we feel that our operational model of assigning members to a primary care clinic, whereby the clinic is capitated and at risk for primary and specialty care, and the primary care provider is responsible for making referrals for specialty care, does not meet the second criterion stating, "…provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers". Thus, we believe that an organization like ours should, in theory, be able to apply to CMS as a Local HMO. However, as noted above, we are licensed by the state of Washington as a "health care services contractor" (RCW 48.44.010). We do not hold the state of Washington's licensure designation as a "health maintenance organization" (RCW 48.46.020).

Based on an informal telephone conversation with CMS staff, we believe that the intent of the statute is to allow any managed care plan licensed by its state to accept risk the option of applying to CMS as a Local HMO. We ask that CMS consider clarifying the relevant language to ensure that an organization such as ours would not be precluded from applying to CMS as a Local HMO.

To that end, we have provided two suggestions for sentences that might be added to the regulation to clarify the issue:

- Any health plan that is licensed by its State to bear risk for primary and specialty care services, that assigns plan members to a primary care provider or primary care clinic, and exposes said provider/clinic to risk for primary and specialty care services may apply as a Local HMO.
- Any health plan that operates as a Medicaid managed care plan in its state and accepts capitation payments for primary and specialty care may apply as a Local HMO.

Thank you very much for your consideration. If you have any questions, please feel free to contact me:

David DiGiuseppe
Product Development Manager
Community Health Plan of Washington
720 Olive Way
Suite 300
Seattle, WA 98101
206-613-8946
ddigiuseppe@chpw.org

CMS-4069-P-6

Submitter : Michael Celayeta **Date & Time:** 09/04/2004 06:09:17

Organization : Clinic Pharmacy

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

1. MTMP are direct proactive interventions deisgned to enhance patiens' ability to take medicine correctly and increase patient medication compliance.
2. MTMP is a direct patient care service performed by a pharmacist interaction with a patient and theri medications.
3. MTMP include case management and patient counseling, customized packaging and refill management, and specialized patient medication reminders. Customized packaging must conform to United State Pharmacopoeia standards.
4. MTMP are generally of an ongoing nature, involving an initial patient in-take assessment, followed by routine patient monitoring at regular intervals.
5. MTMP must be reimbursed as a management fee, NOT as a dispensing fee. Costs associated with MTMP are separate and distinct from those costs associated with dispensing.
   *In-take assessment: 30 - 45 minutes of pharmacists' time per occurrence;
   *Monitoring and following up: 15 - 25 minutes of pharmacists' time per occurrence.

CMS-4069-P-7

Submitter : Mrs. Christine Bentley **Date & Time:** 09/08/2004 06:09:21

Organization : Mrs. Christine Bentley

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

How is CMS protecting enrollees from withdrawal by MA plans much as has been the case with Medicare+Choice? Mllions of enrollees were left high and dry, not knowing what to do next.

How can I trust CMA this time when there is no evidence that the MA providers will not "take the additional payments and run".

The burden is not being reduced for original Medicare enrollees who will bear a greater burden. Hence CMA is bringing undue duress on those of us enrolled in it to move to managed care. This will affect my relationships to trusted physicians. Dr. Mark McClelan will be putting his health economics before his medical ethics as he promotes poor continuity of care for many original M'care enrollees.

CMS-4069-P-8

Submitter : Mr. Doug Alfred **Date & Time:** 09/09/2004 05:09:30

Organization : Mount Carmel Health Plan

Category : Health Plan or Association

Issue Areas/Comments

Subparts A-I

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

Beneficiaries have sent many prior messages to legislators that they do not support the enrollment lock-in feature. Beneficiary backlash may result from the confusion of Part D and new plan choices in 2006 if they are paired with a feature like "lock-in". Movement of the beneficiary population from FFS Medicare to alternative coverage options may be slowed down in 2006 resulting from the confusion and fear of being "locked-in".

CMS-4069-P-9

Submitter : James W. Crisp **Date & Time:** 09/17/2004 10:09:49

Organization : James W. Crisp

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

I am very concerned about the new law that will allow my former employer to drop my coverage. I have been paying premiums since 1969 for insurance coverage for me and my wife. Since my wife will not be old enough to qualify for medicare for another 5 years, I am afraid that if my employer is allowed to drop my coverage, (because I am currently 65) they will also be allowed to terminate my wife's insurance coverage. This will leave her completly uninsured and put us in terrible perdicament.

CMS-4069-P-10

Submitter : **Mrs. earlyne moninger** **Date & Time:** **09/18/2004 11:09:53**

Organization : **Mrs. earlyne moninger**

Category : **Individual**

Issue Areas/Comments

Subparts A-I

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

This may not come under the above subpart. In a recent Kiplinger's Retirement Report, there was mention of an initial comprehensive physical exam for new beneficiaries, called the "Welcome to Medicare Physical". I have been a Medicare card carrier since March(this year), but have not used it. Would I come under the "new beneficiaries" now or ever? Would I need to wait until Jan.2005 to have a physical or did I miss the boat by being eligible 9mos too soon? Thank you.
Earlyne Moninger
thewiz37@aol.com

CMS-4069-P-11

Submitter : **Mr. Torelen Winbush** **Date & Time:** **09/19/2004 11:09:46**

Organization : **Mr. Torelen Winbush**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

It is important that you realize what you are doing to the standard of care that affects PLWA. If you decide to alter this program and put these type of restrictions then you will be setting yourself up for images of pre-care era in the 80's when hysteria and lack of empathy was the chief attitudes of citizens around the world. I propose that you realize what you are about to do. You are going to change the face of a movement and force communities to lose faith in an already frightening administration. We are voters too! Does our vote count and does our quest for a standard of care not part of the Bush agenda. Make me proud of being an american again! Rethink your position on this matter.

CMS-4069-P-12

Submitter : **Dr. Stephen Fadem** **Date & Time:** **09/22/2004 03:09:03**

Organization : **Kidney Associates, Houston**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

September 21, 2004

In the August 2, 2004 Federal Register HHS published rules governing the establishment of the Medicare Advantage Program. http://www.cms.hhs.gov/medicarereform/ . The comment period ends October 4, 2004. This will expand options such as HMOs, PPOs as well as medical savings and fee for service to many additional beneficiaries. Although at the highest level these plans have an intent of providing quality, the reality is different in that they only select certain nephrologists, certain surgeons and certain dialysis centers. New is the establishment of special needs plans that can exclusively enroll special needs individuals if they have targeted clinical programs for these individuals. ESRD patients are included. CMS is seeing comments on whether there are appropriate quality oversight mechanisms for these specialized plans appropriate to require ensuring these patients have increased quality, and rightfully this is a legitimate concern.

While these plans give patients a wide range of choices, they still are problematic because they will extend the same problems we now have with managed care:

1. Many patients are referred to nephrologists and dialysis units after looking around, and often seek the advice of other patients. Thus, they are often not referred by the plan primary physician. The nephrologists or dialysis center or both are often out of network ? and this creates problems for the patient who cannot go to the doctor of choice without either paying an extra premium or being refused altogether.
2. Credentialing in plans is not outcomes driven, and is based upon physician relationships. The only choice of a surgeon in a plan may not be the one who does av fistulae, insists on vessel mapping, or who has the best outcomes. If the patient cannot go out of network, he is stuck with a bad access, or a graft instead of a fistula.
3. The patients who sign up for these plans choose them because of the pharma benefits and their low cost, but they never dream that they are going to be the ones who require nephrology or oncology services that may be suboptimal in the plan they have chosen.
4. Trying to get single payer agreements and authorizations in these plans, and even trying to get paid, is often very staff intensive, and also non rewarding. Nephrologists are often put into the dilemma of choosing a surgeon they do not feel comfortable with or creating an issue by going out of network.

The proposal below is based upon clinical observation that outcomes have been adversely affected by IPA or HMO groups restricting the patients choice of nephrologist, dialysis center or surgeon. Expanding this may directly impact the health care quality outcomes we are all trying to improve. Letting the nephrologist and the patient determine the facility and surgeon choice is more in line with all of our efforts to empower and educate patients and take the sole choice out of the hands of the plan medical director or primary care physician who may not be as connected to dialysis outcomes management as we are.

Dr. McClellan, I strongly propose that these rules be modified: CMS should create waivers that will allow ESRD patients to be referred to nephrologists, dialysis centers or vascular surgeons who are out of network in the event that the patient prefers another physician or center, or the referring nephrologists feels that the vascular access outcomes will be better with the out of network surgeon. It will be the burden of the facility, surgeon and nephrologist to convince the patient (underlined) that they are making the right choice.

Thank you for considering the comments and proposal above. Feel free to contact me at any time regarding this very critical segment to this critical initiative.

Stephen Z. Fadem, M.D., FACP
Kidney Associates, PLLC
mailto:fadem@bcm.tmc.edu
cc: Brady Augustine, Barry Straub, MD

CMS-4069-P-13

Submitter : **Jean C. Work, L.M.T.** **Date & Time:** **09/23/2004 10:09:21**

Organization : **Milford Therapeutic Massage**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

It is absurd that Medicare is even considering that only P.T.s should be allowed to perform and be reimbursed for medical massage therapy. As a licensed professional, I, and most licensed massage therapists, are far more qualified to perform medical massage than a P.T. who has had only a few hours of massage training.

CMS-4069-P-14

Submitter : Ms. MayBelle McCormick **Date & Time:** 09/23/2004 07:09:45

Organization : answer to your request

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am trying to respond to a questionair sent to me by CMS regarding Medicare being my primary or secondary insurer. I tried to do this by phone and was disconnected, now please tell me how to respond by the website or give me a direct number by which I can do so.

sincerely,

MayBelle McCormick....e-mail/ maymccormick@msn.com

CMS-4069-P-15

Submitter : Mrs. Sybil Finken **Date & Time:** 09/26/2004 07:09:08

Organization : VOR

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

RE: Comments relating to Medicare Part D proposed regulations -
69 Fed. Reg. 46632 (Aug. 3, 2004).

I support the comments submitted by Voice of the Retarded (VOR). We feel strongly that:

* The definition of 'long term care facility' must include Intermediate Care Facilities for Persons with Mental Retardation (ICFs/MR).

* 'Institutionalized' should include all individuals eligible for ICF/MR placement, including current residents, home and community-based services (HCBS) waiver recipients, and eligible individuals on the waiting list for ICF/MR and HCBS waiver placements.

The regulations relating to Medicare Part D must, in all respects, allow for medication decisions based on individual need, not where someone lives.

Thank you for your consideration.

Sincerely,

Sybil Finken
parent/VOR Board member
24640 Jasmin Lane
Glenwood, IA 51534
712 527-3250
712 527-3334 (fax)
finkensrc@aol.com

CMS-4069-P-16

Submitter : **Mr. David Pearson** **Date & Time:** **09/28/2004 08:09:10**

Organization : **Texas Org. of Rural**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Subparts A-I

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

? 422 Subpart C?Benefits and Beneficiary Protections
As other stakeholders have likely reported, we caution against forming 50 separate regions that follow state boundaries, due to the fragmentation that would take place in the rural areas. State laws and access standards must be adhered to, but the only way to `shake-up? the current system will be to create multi-state regions that create a more collaborative environment.

We would also urge CMS to further clarify within the regulations that an ?Essential Hospital? is not a Critical Access Hospital. While CAHs are certainly viewed as essential hospitals within the rural policy community, they are never defined as such within the statute and/or these proposed regulations. This fact will cause substantial confusion and ongoing problems with the implementation of this proposal if not further clarified by CMS.

Subpart E--Relationships with providers.

? 422 Subpart E?Relationships with Providers
TORCH is also concerned about the manner in which specially designated rural hospitals will be reimbursed under Medicare Advantage. We were pleased recently to hear 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.? However, this is not true when they serve beneficiaries who access these services ?in network?. The payments for such hospitals will have to be negotiated and as with other managed care programs, large insurers often coerce rural providers to accept contracts with substantial discounts in order to retain patients and undermines the local infrastructure.

Furthermore, even if ?out of network? services are paid at cost, it will not be easy to administer with multiple payers and the current cost settlement process. 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. NRHA has suggested that 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, since these plans are not contracted with the hospital, they would not have a 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. Perhaps it could be communicated by the CAH and then verified by the Fiscal Intermediary.

CMS-4069-P-16-Attach-1.doc

CMS-4069-P-16-Attach-1.doc

CMS-4069-P-17

Submitter : **Mr. W. Ron Allen** **Date & Time:** **09/29/2004 05:09:05**

Organization : **Jamestown S'Klallam Tribe**

Category : **Other Government**

Issue Areas/Comments

GENERAL

GENERAL

Comments from the Jamestown S'Klallam Tribe, Sequim, WA are attached.

CMS-4069-P-17-Attach-1.doc

CMS-4069-P-18

Submitter : Mr. Richard Arnold **Date & Time:** 09/29/2004 08:09:40

Organization : Muenster Memorial Hospital

Category : Critical Access Hospital

Issue Areas/Comments

Subparts A-I

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

Although there are references to Essential Hospital in these proposed regulations, they are not defined in this document. There is no assurance that Critical Access Hospitals are included in the definition of Essential Hospital. Many Critical Access Hospitals have been established under essential provider classification guidelines developed within the state organization that worked with local community leader to develop Critical Access Hospitals in their communities.

Critical Access Hospitals and Provider Based Rural Health Clinics have been established in many communities across the country in an effort to assure that health care services are available in those small, rural communities. These proposed promulgations make no reference to the special reimbursement mechanisms that have been developed and that are currently in place for Critical Access Hospitals and Provider Based Rural Health Clinics.

Please add the appropriate definition for Critical Access HOspitals and Provider Based Rural Health Clinics. Levels of reimbursement for the services of Critical Access Hospitals and Provider Based Rural Health Clinics must continue as currently in effect in order to asure the continuation of these rural providers in the small, rural communities that they serve.

Subpart E--Relationships with providers.

Many rural physicians provide their services to rural communities through the hospital/provider based rural health clinic and through the Critical Access Hospital in the rural community. We have recently heard that providers who do not have contracts will be reimbursed the out-of-network; however, it is anticipated that the beneficiary may have to pay higher out-of-network deductible and co-insurance rates. This would be a negative incentive for the patient to use local providers who are out-of-network. If the provider is in-network there is no assurance that they will receive the level of reimbursement assured legislatively for Critical Access Hospitals and for Provider Based Rural Health Clinics. We would like to encourage the development of reimbursement mechanisms that assure the appropriate level of reimbursement while not penalizing the beneficiary for utilizing their local providers.

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

422.256 - Review, negotiation and approval of bids. (2) Noninterference -
"(i)" states that CMS may not require any MA organization to contract with a particular hospital, physician or other entity or individual to furnish items and services. We would like to suggest that it be mandated that special consideration be given to Critical Access Hospitals and Provider Based Rural Health Clinics by MA organizations to be included as in-network providers while being reimbursed at a level consistent with the current reimbursement rates. (Cost Based Reimbursement)

"(ii)" makes exceptions for the payment of a particular structure to Federally Qualified Health Centers. A similar exception could be granted for Critical Access Hospitals and Provider Based Rural Health Clinics in accordance with the "cost based" formulae that currently determine the reimbursement rates for these rural community providers.

Few beneficiaries will choose to be out-of-network. Local Critical Access Hospitals and Provider Based Rural Health Clinics provide a broad range of services at the "Primary" level of care. Patients who require a higher level of care must be in-network in order to access levels of care above the "Primary" level in secondary and tertiary level facilities and specialists clinics/offices. Local patients usually seek primary care in local Critical Access Hospitals and Provider Based Rural Health Clinics. They are then referred or transferred to facilities and providers that provide the required higher level of care and return to local primary level providers when released by the higher level provider (specialists.) A mechanism that recognizes the patients needs for the different levels of care must be developed in order to maintain a smooth continuum of care.

CMS-4069-P-18

CMS-4069-P-18-Attach-1.doc

CMS-4069-P-18-Attach-1.doc

CMS-4069-P-18-Attach-1.doc

CMS-4069-P-19

Submitter : **Ms. Joan Delabreau** **Date & Time:** **09/29/2004 08:09:59**

Organization : **Menominee Indian Tribe of Wisconsin**

Category : **Other Government**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4069-P-19-Attach-1.doc

CMS-4069-P-20

Submitter : **Ms. Joan Delabreau** **Date & Time:** **09/29/2004 08:09:35**

Organization : **Menominee Indian Tribe of Wisconsin**

Category : **Other Government**

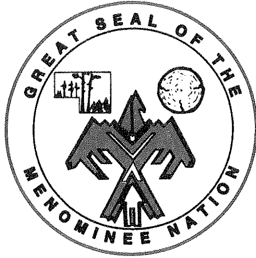
Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4069-P-20-Attach-1.pdf



MENOMINEE INDIAN TRIBE OF WISCONSIN

P.O. Box 910
Keshena, WI 54135-0910

September 29, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Comments on the Treatment of American Indians and Alaska Natives and Reimbursement to Tribal, Indian Health Service and Urban Indian Programs Under August 3, 2004 Proposed Rules for 42 CFR Parts 417 and 422, The Medicare Advantage Program

File Code CMS-4069-P

Dear Administrator:

The Menominee Indian Tribe of Wisconsin is concerned about the impact of the proposed regulations for Medicare Part C. The proposed regulations for the Medicare Advantage (MA) program published on August 3, 2004, do not mention American Indians, Alaska Natives, tribes, tribal organizations, tribal health services or the Indian Health Service.

The preamble to the regulations provides an analysis of the effects on small entities under the Regulatory Flexibility Act (RFA). The RFA analysis states: "We welcome comments on this approach and on whether we have missed some important category of effect or impact." We would like to state emphatically that you have missed an important category of effect and impact by omitting consideration of Tribal governments and Indian health care facilities.

We urge you to consult with Tribes to identify issues and workable solutions when new programs are being designed by the Centers for Medicare and Medicaid Services.

Sincerely yours,

Joan Delabreau/HJA

Joan R. Delabreau, Chairperson

Attachment

September 29, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Comments on the Treatment of American Indians and Alaska Natives and Reimbursement to Tribal, Indian Health Service and Urban Indian Programs Under August 3, 2004 Proposed Rules for 42 CFR Parts 417 and 422, The Medicare Advantage Program

File Code CMS-4069-P

Dear Administrator:

The Menominee Indian Tribe of Wisconsin is deeply concerned about the impact of August 3, 2004, proposed Medicare Modernization Act (MMA) rules regarding the **Medicare Advantage** program on American Indians and Alaska Natives (AI/AN) as well as the Indian Health Service, Tribal and urban (I/T/U) health programs that serve them. These comments and recommendations are submitted to the Centers for Medicare and Medicaid Services (CMS) with the very serious concerns of Tribes across the nation.

INTRODUCTORY STATEMENT REGARDING INDIAN HEALTH SYSTEM

These comments address the implications of the proposed rules on the Indian health care delivery system and the changes that must be made to prevent Part C implementation from destabilizing the system responsible for providing health care to the approximately 1.3 million American Indians and Alaska Natives (AI/AN) served by the IHS system. In the form proposed by CMS, the rules will put in jeopardy significant revenues the Indian health system now collects from Medicaid for "dual eligibles". Since the loss of revenue to Indian health was **not** Congress's objective in enacting the Part C benefit, the rules must be revised in several respects to protect the Indian health system from what could be substantial harm. Furthermore, to enable voluntary enrollment by AI/AN in Part C requires substantial modifications to the proposed rules.

We ask that all CMS staff charged with reviewing comments and revising the proposed regulations be supplied with a copy of this introductory statement regarding the Indian health care system. Compliance with the dictates of notice and comment rulemaking requires that all relevant information supplied by commenters must be taken into account. Full consideration of the comments we offer on individual regulations can only be accomplished by a thorough understanding of the unique nature of the Indian health care system, and the responsibility of our steward, the Secretary of Health and Human Services, to assure that inauguration of Medicare Part C does not result in inadvertent and unintended harm to that system.

The regulations governing the Part C must be revised to achieve the following goals:

- Encourage MA enrollment by AI/AN by removing financial barriers and allowing AI/AN to voluntarily participate in Medicare Advantage plans, without financial penalty because of location of residence, selection of a plan that includes I/T/U, or use of I/T/U.

- Ensure that I/T/U, under all conditions, are held harmless financially and are fully reimbursed for covered services provided to AI/AN who enroll in a Medicare Advantage plan.

- Allow I/T/U the flexibility to sponsor AI/AN in Medicare Advantage plans, under a special group payer arrangement.

- Allow, in the future, the development of an AI/AN special Medicare Advantage plan that includes the active participation of Tribes in its design and implementation.

- Explicitly exempt AI/AN dual eligibles from mandatory participation in a State Title XIX MA or MA-PD Plan.

In order to fully comprehend the potential adverse impact Part C implementation will have on the Indian health care system -- particularly with regard to the dual eligibles it serves -- one must have an understanding of the way health care services are delivered to AI/ANs and the current state of Indian health. These considerations must be kept in mind as CMS reviews these comments in order to promulgate regulations that assure the inauguration of the Part C or Medicare Advantage (MA) program does not have negative consequences on the Indian health system by reducing the level of reimbursements from Medicaid or Medicare on which the system has come to rely.

Indian Health Care System and Indian Health Disparities

Overview. The Indian health care system does not operate simply as an extension of the mainstream health system in the United States. To the contrary, the Federal government has built a system that is designed specifically to serve American Indian and Alaska Native people in the context in which they live -- remote, sparsely-populated and, in many cases, poverty-stricken areas where the Indian health system is the only source of health care. Integral to that system are considerations of tribal cultures and traditions, and the need for culturally competent and sensitive care.

U.S. Trust Responsibility for Indian Health. The United States has a trust responsibility to provide health care to AI/ANs pursuant to federal laws and treaties with Indian Tribes.[1] Pursuant to statutory directive,[2] this responsibility is carried out by the Secretary of Health and Human Services, primarily through the Indian Health Service (IHS) with annual appropriations supplied by Congress. The IHS-funded health system follows the public health model in that it addresses the need for both medical care and preventive care. In order to perform this broad mission, the IHS funds a wide variety of efforts including: direct medical care (through hospitals, clinics, and Alaska Native Village health stations); pharmacy operations; an extensive (but underfunded) Contract Health Services program through which specialty care IHS cannot supply directly is purchased from public and private providers; health education and disease prevention programs; dental, mental health, community health and substance abuse prevention and treatment; operation and maintenance of hospital and clinic facilities in more than 30 states; and construction and maintenance of sanitation facilities in Indian communities.

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[1] *See, e.g.,* 25 U.S.C. § 1601.
[2] 42 U.S.C. § 2001.

Health Disparities. AI/ANs have a higher rate of disease and illness than the general population and consequently require more medications and incur higher prescription drug costs than most Americans. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights[3] reveals a number of alarming statistics such as:

- AI/ANs have the highest prevalence of Type II diabetes *in the world*, are 2.6 times more likely to be diagnosed with the disease than non-Hispanic whites, and are 420% more likely to die from the disease.
- The cardiovascular disease rate among AI/ANs is two times greater than the general population.
- AI/ANs are 770% more likely to die from alcoholism.
- Tuberculosis deaths are 650% higher among AI/ANs than the general population.
- AI/AN life expectancy is 71 years, five years less than the general U.S. population.
- The ratio of cancer deaths to new cancer cases is higher for Native Americans than the ratios for all other races, even though incidence rates are lower.
- The Indian suicide rate is 190 percent of the rate of the general population.

Composition of the Indian Health Care System. Operationally, health services to AI/ANs are delivered through the following entities:

- The Indian Health Service directly operates hospitals and clinics throughout Indian Country that are staffed by federal employees.
- Indian Tribes and tribal organizations may elect to assume management and control over IHS programs at the local tribal level through authority of the Indian Self-Determination and Education Assistance Act. At present, over one-half of the IHS budget is distributed to ISDEAA tribal programs.
- In 34 cities, urban Indian organizations operate limited health programs (largely referral services) for Indian people living in urban areas through grants authorized by the Indian Health Care Improvement Act.

Funding Sources. Indian health programs are supported primarily from annual federal appropriations to the Indian Health Service. Regardless of the operational form, all Indian health programs are severely underfunded. In a 2003 report[4], the U.S. Commission on Civil Rights found that the per-capita amount spent by the Indian Health Service for medical care was nearly 50% lower than spending for federal prisoner medical care and only slightly more than one-third of the average spending for the U.S. population as a whole. The Veterans Administration spends nearly three times as much for its medical programs as the Indian Health Service.

In an effort to improve the level of funding for Indian health programs, Congress, in 1976, made IHS/tribal hospitals eligible for Medicare Part A reimbursements, and enabled hospitals and clinics to collect Medicaid reimbursements, either as IHS facilities or as FQHCs. It was not until the 2000 BIPA that IHS facilities were authorized to collect for some Medicare Part B services. With enactment of the MMA, Congress authorized these facilities to collect for remaining Part B services for a five-year period.

Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by I/T/Us to Indians enrolled in Medicaid are reimbursed to the States at 100%

[3] U.S. Commission on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System*, July 2, 2004 (staff draft).

[4] U.S. Commission on Civil Rights, *A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country*, July 2003.

FMAP. Thus, the Federal government bears the full responsibility for these costs. If coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that the reimbursement of services for Indian dual eligibles continues without interruption and without reduction to I/T/U.

Indian health programs have become critically reliant on the third-party revenues, especially those supplied by Medicare and Medicaid. According to the IHS, Medicare, Medicaid and other third party collections can represent up to 50% of operating budgets at some facilities.

Scope of Services. The compliment of health services provided at a single site or by a Tribe varies from a single health station, common in Alaska, to comprehensive in and outpatient hospital services. Other health services provided directly by or through Indian health programs can include medical, dental, mental health, chemical dependency treatment, ambulance, pharmacy, home health, hospice, dialysis, public health and traditional healing.

The diversity of services provided through Indian health programs, and the generally limited size of the population they serve makes comprehensive contracting with private plans an expensive and challenging task.

Pharmacy Services for Dual Eligibles and Impact of Part D

Because most Indian health facilities are located in remote areas far distant from the mainstream health system, they must also operate pharmacies so their patients can access needed medications. IHS, Tribes, and urban Indian organizations operate 235 pharmacies throughout Indian Country. IHS and Tribes dispense pharmaceuticals to their Indian beneficiaries without charge, as is the case for all health services they offer.

A sizeable portion of the patient base for I/T/U pharmacies consists of dual eligibles. IHS estimates that there are between 25,963[5] and 30,544[6] individuals in the IHS patient database who are receiving both Medicare and Medicaid. Since this database does not include information from some tribally-operated facilities (those who do not use the IHS computerized data system) nor information about Indians served by urban Indian clinics, the number of dual eligibles system-wide is even greater than the IHS database reveals.

While there is no comprehensive data on the per-capita drug costs for dual eligibles in the Indian health system, we have been able to make some rough estimates by examining average state per-capita spending for this population. In 2002, the average per-capita spending for dual eligibles was $918.[7] We believe this is a very conservative figure for Indian Country, in view of the higher rates of illness that have expensive drugs associated with their treatment, including diabetes and mental illness. Furthermore, the IHS calculates that the cost of pharmaceuticals has increased by 17.6 percent per year between FY 2000 and FY 2003. This includes the cost of new drugs, increases in drug costs and population growth. Thus, if we trend the average out to the year 2006, the expected average per capita spending on drugs for dual eligibles would be $1,756.

[5] This number represents 85 percent of the three-year total of active users.
[6] This is the number of active users, defined as at least one visit in the past three years.
[7] From Table 2, "Full" Dual Eligible Enrollment and Prescription Drug Spending, by State, 2002, in "The 'Clawback:' State Financing of Medicare Drug Coverage" by Andy Schneider, published by the Kaiser Commission on Medicaid and the Uninsured, June 2004.

Using these population and per-capita spending data, we estimate that the Medicaid recovery for dual eligible drug costs in the Indian health system ranges between **$23.8 million**[8] **and $53.6 million.**[9] It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid for pharmacy services and placed into either an MA-PD or a Part D plan.

Part A and B Services for Dual Eligibles and the potential Impact of Medicare Advantage

As with Part D, the most serious concerns and most immediate reduction in Indian health program revenues are related to AI/AN who are dually eligible for Medicaid and Medicaid. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for effected Tribes. Although a financial analysis has not been conducted, potential revenue loss to I/T/U on a per patient basis would far exceed losses estimated for Part D alone.

The Secretary of Health and Human Services, as the principal steward of Indian health, has a responsibility to assure that the MMA, which was intended to benefit *all* Medicare beneficiaries, does not produce the opposite result for *Indian* Medicare beneficiaries who use the Indian health care system. He can guard against such an outcome by exercising the broad authority granted to the Secretary to assure access to Part C for AI/AN. We believe that Congress recognized that access for Indian beneficiaries means the ability to utilize Part C benefits through I/T/U and that AI/AN should be able to enjoy voluntary participation in Medicare Advantage plans on a equal basis with all other Medicare beneficiaries.

BACKGROUND FOR PART C ISSUES

There is a fundamental mismatch between the Indian health care system and the proposed rules to implement the MMA. The result of this flaw in the proposed regulations could result in a critical loss of revenue for the Indian health programs across the nation and will further contribute to an even greater disparity in health care between the AI/AN and the general population than already exists. In fact, the proposed rules for Part C make no mention of AI/AN or I/T/U at all. As written, it is unlikely that many AI/AN who receive health care through an I/T/U will be able to benefit from these important Medicare changes. If they do chose to participate in a Part C plan, it is unlikely that Indian health facilities will be able to obtain compensation for the services provided to those Medicare beneficiaries. Furthermore, to the extent that States require dual eligibles to enroll in Title XIX Medicare Advantage (MA) plans, I/T/U will experience significant reductions in revenue associated with these patients.

As sovereign nations and recognized governments, Tribes insist that HHS and CMS acknowledge the impact and financial burden MMA regulations have on Tribal governments and Indian people.

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[8] This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.
[9] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

Appropriately including AI/AN and I/T/U in MMA proposed regulations for Medicare Advantage first requires the recognition of key elements of this fragile health system.

- AI/AN are a unique political group guaranteed health care through treaties.
- The federal government has failed to meet this obligation and currently funds Indian health programs at only about 50% of need.
- The Department of Health and Human Services has and continues to develop Tribal consultation policies which have not been used in the process of drafting or assessing the impact of the proposed MMA rules.
- AI/AN, especially those living on or near reservations, suffer from the highest levels of poverty and disease burden in the United States.
- I/T/U, as culturally appropriate providers, have achieved great success in promoting preventive services and improving the health of AI/AN but still face daunting challenges.
- The IHS and Tribally-operated facilities do not charge AI/AN individuals for the health services provided to them, but they do rely upon third party payments, including Medicare and Medicaid.
- Unlike other populations, AI/AN are often reluctant to enroll in Medicaid and Medicare because they understand health care to be a right, thus premiums, and other cost sharing significantly discourages their participation and acts as an insurmountable barrier to program enrollment.
- Unlike other health care providers, I/T/U cannot charge AI/AN patients and therefore beneficiary "cost sharing" merely results in significant and inappropriate reimbursement reductions.
- Many I/T/U facilities provide services in remote areas where the size of the population is insufficient to support a private health care delivery system and where the market forces key to the implementation of this legislation do not exist.
- Private health and prescription drug plans often do not want to contract with I/T/U for many reasons including the health status and small size of the AI/AN population, the special contracting requirements, and the high administrative costs associated with developing and maintaining new contractual relationships with numerous small clinics.
- Resources spent by I/T/U to implement MMA by providing staff time for training, outreach, education, enrollment assistance, contract negotiation, and redesigning IT and administrative systems to accommodate new contracts with Medicare Advantage plans, further reduce funding for the health care of AI/AN.
- The number of AI/AN in the United States who are enrolled in Medicare and who use I/T/U is estimated to be 103,000. Approximately half of this group are thought to be dually eligible for Medicaid. Even if 20% of the remaining AI/AN Medicare population enrolls in a MA or MA-PD plan, the number of Indian enrollees in any MA plan will likely be very small and will have minimal impact on plans. However, because of the small and widely dispersed population, the per enrollee cost to plans (and I/T/U) to develop, negotiate, execute and implement contracts will be high.
- Although the impact of AI/AN enrollment in MA and MA-PD plans may seem insignificant to plans and CMS, the relative impact on individual Tribes could represent significant losses.

We hope CMS agrees that these regulations should minimize unintended consequences of MMA on I/T/U as well as promoting access to new Medicare options for AI/AN. There are two basic approaches to address Indian issues: 1) simple blanket policies requiring MA and MA-PD plans to pay I/T/U for covered services and limited exemptions for AI/AN; or, 2) numerous, extremely complex policies and exceptions to the proposed rules. **We challenge CMS to closely**

consider the issues presented here and assist in crafting language for the final rules that will "first do no harm" to Indian health programs and, second, step forward to actually improve access to Medicare for AI/AN and reimbursement for services provided to them by I/T/U.

Options for AI/AN MMA Policy

Five policy decisions to alleviate well-documented problems I/T/U have experienced contracting with private plans would address a majority of concerns raised by the proposed rules:

1. Encourage MA enrollment by AI/AN by removing financial barriers and allowing AI/AN to voluntarily participate in Medicare Advantage plans, without financial penalty because of location of residence, selection of a plan that includes I/T/U, or use of I/T/U.
    - Waive AI/AN cost sharing for all plans.
    - If AI/AN dual eligibles are required to enroll in an MA or MA-PD plan, establish the default enrollment for AI/AN to an MA or MA-PD plan for which the network includes local I/T/U facilities, or pays fully for out of network services.
    - Allow unlimited plan switching to facilitate enrollment in plans with culturally sensitive I/T/U providers. Exempt AI/AN from "lock-in" or "lock-outs".
    - Exempt AI/AN from cost differentials associated with selection of a plan that includes culturally appropriate I/T/U provider or more robust networks

2. Ensure that I/T/U, under all conditions, are held harmless financially and are fully reimbursed for covered services provided to AI/AN who enroll in a Medicare Advantage plan. We see three basic options to implement this policy:
    a. Require all MA (and MA-PD) plans to recognize I/T/U as in-network providers and reimburse at IHS Medicaid rates (as paid under the original or traditional Medicare), even without contracts. We believe this would be the desired option of plans and CMS because the minimal administrative burden and simplicity of regulations would reduce the cost of implementation.[10]
    b. Require MA (and MA-PD) plans to recognize I/T/U as in-network providers, even without contracts, and reimburse at Plan's standard Medicare rates. CMS provides "wrap-around" reimbursement to hold I/T/U harmless for difference between plan reimbursement and IHS Medicaid rate.
    c. Require all MA (and MA-PD) plans to contract with all willing I/T/U under similar special contract provisions terms as those used for the special endorsed Prescription Drug Discount Card contracts and using IHS Medicare rates. Also exempt I/T/U from plan credentialing, risk sharing, and other contracting requirements that are conducted or prohibited by federal or tribal statute, rule or policy. These contract provisions are outlined under 422.112 and are similar to those recommended for Part D.

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[10] Washington State Administrative Code provides a precedent and contains sample language for this provision. **WAC 284-43-200 Network adequacy.** (7) To provide adequate choice to covered persons who are American Indians, each health carrier shall maintain arrangements that ensure that American Indians who are covered persons have access to Indian health care services and facilities that are part of the Indian health system. Carriers shall ensure that such covered persons may obtain covered services from the Indian health system at no greater cost to the covered person than if the service were obtained from network providers and facilities. Carriers are not responsible for credentialing providers and facilities that are part of the Indian health system. Nothing in this subsection prohibits a carrier from limiting coverage to those health services that meet carrier standards for medical necessity, care management, and claims administration or from limiting payment to that amount payable if the health service were obtained from a network provider or facility.

3. Allow I/T/U the flexibility to sponsor AI/AN in Medicare Advantage plans, under a special group payer arrangement.
- Permit sponsorship of AI/AN with flexibility and adequate timelines to add and drop individuals
- Require plans and CMS to send sponsors information normally sent to enrollees so sponsors can respond quickly
- Add special plan disenrollment rule for sponsored AI/AN and require communication and problem resolution process between plan and sponsor prior to plan disenrollment of AI/AN

4. Allow, in the future, the development of an AI/AN special Medicare Advantage plan that includes the active participation of Tribes in its design and implementation.

5. Explicitly exempt AI/AN dual eligibles from mandatory participation in a State Title XIX MA or
MA-PD Plan.
- MMA should not reduce the funding currently going to support Indian health programs; however, the effect of mandatory AI/AN dual eligible enrollment would result in significant losses for effected I/T/U
- Sec. 1932 [42 U.S.C. 1396u-2] exempts AI/AN from mandatory Medicaid managed care plan enrollment, in recognition of the many difficulties facing I/T/U in interfacing with private plans. For these same reasons, we believe AI/AN dual eligibles should not be required to enroll in MA or MA-PD plans.
- Allow same options, or exemptions, for AI/AN as currently exists under state Medicaid plans.

Additional AI/AN policy issues that require changes in the proposed rules:

- Remedy potential reimbursement and Contract Health Services funding problems for I/T/U created by MSA without restricting as an option for AI/AN.

- Require consistency with Part D rules relative to AI/AN policy.

Recommended Revisions to August 3, 2004 Proposed Rules

Proposing specific section-by-section language changes to the proposed rules to accomplish the AI/AN policy objectives stated above would require time and resources beyond our current means. **We challenge CMS to come forward with comprehensive changes to the proposed rules that will appropriately allow access to MA for AI/AN and I/T/U as special populations and providers.** Listed here is a limited set of suggested revisions.

Subpart A – General Provisions

To enable an AI/AN specific MA or MA-PD plan in the future:

422.2 *Definitions*

Basic benefits add, "including covered services received through an Indian health service program."

Special needs individuals add "American Indians and Alaska Natives (AI/AN) are exempt from mandatory enrollment in Title XIX plans but would qualify for optional enrollment in an AI/AN specialized MA plan."

In establishing contracts with a national, statewide or regional MA or MAPD plans preference should be given to state licensed managed care organizations that are controlled by Indian Health Service funded Tribal and /or Urban Indian Health Programs which are funded to provide services in clients. This approach is the best means of assuring access to culturally competent and geographically proximal services to individual Indians.

To address the cost of implementation at the I/T/U level:

422.6 *Cost Sharing in Enrollment Related Costs*

We have commented to CMS on several occasions about the high cost to I/T/U for MMA implementation costs related to outreach, education and enrollment of AI/AN. We strongly encourage CMS to identify in this or another section the need for funding to support these activities be specifically directed to local I/T/U where the work is done and bearing the costs is most difficult. Unlike other Medicare populations, AI/AN are unlikely to enroll in MA plans without specific information from their I/T/U.

Subpart B – Eligibility, Election and Enrollment

To address potential intended loss of revenue to I/T/U:

422.52 *Eligibility to elect MA plan for special needs individual*

(b)(2) add, "except mandatory enrollment for AI/AN is prohibited."

To discuss and address unique issues related to AI/AN Medicare MSA:

422.56 *Enrollment in an MA MSA plan*

(c) The enrollment of AI/AN in MSAs presents unique challenges. Tribes would like an opportunity to discuss this issue with CMS to ensure it is implemented in a way that will improve access to services.

To accommodate I/T/U group payer arrangements:

422.60 *Election process*

Require MA and MA-PD plans to accept AI/AN enrollment, even if CMS has allowed the plan to close due to capacity limits. Rationale: AI/AN could enroll in MA plans under a variety of circumstances, including a group sponsorship. Because the number of AI/AN is small and the number of culturally appropriate plans available will be very limited, CMS should require plans to enroll AI/AN at anytime.

422.62 *Election coverage under an MA plan*

We request that CMS add the following provisions in an appropriate place:

- AI/AN may switch MA or MA-PD plan at any time if local I/T/U is not reimbursed by plan as in-network provider at original (or traditional) Medicare rate
- AI/AN who are in a sponsorship program may, with the consent of the sponsor, switch plans at any time
- Sponsors may add AI/AN enrollees to an MA plan at anytime under the following conditions: relocation to sponsor service area; loss of alternative health insurance coverage; change in sponsorship policies.
- AI/AN sponsored in a group payer arrangement are exempted from "lock-ins" and "lock-outs".

422.66 *Coordination of enrollment and disenrollment through MA organizations*

We request that CMS add the following provisions in an appropriate place:

- Establish a default enrollment process for AI/AN that uses a plan that reimburses local I/T/U at in-network rates
- Provide flexibility for switching plans under conditions AI/AN are likely to encounter
- Communicate directly with local I/T/U about patient enrollment/disenrollment

422.74 *Disenrollment by the MA organizations*

Add "Process for disenrolling an AI/AN under a sponsorship or group program must include direct communication with sponsor with adequate documentation of problem and steps taken to resolve as well as adequate timelines."

422.80 *Approval of marketing materials and election forms*

This language lists as prohibited marketing activities for MA Plans to *"Engage in any discriminatory activity, including targeted marketing to Medicare beneficiaries . . . and (iii) solicit Medicare beneficiaries door-to-door."* While the intent of this language is to prohibit aggressive enrollment practices that favor healthier individuals, the unintended consequence may be to limit the development of needed materials targeted to AI/AN. While MA Plan representative should be prohibited from soliciting business by going door-to-door, the outreach workers employed by tribal and IHS facilities should be encouraged to provide information about Medicare alternatives in the homes of AI/AN elderly. We ask that CMS clarify this issue.

Subpart C – Benefits and Beneficiary Protections

To address potential intended loss of revenue to I/T/U:

422.100 *General Requirements*

If not clearly addressed in another section, MA and MA-PD plans should be required to reimburse I/T/U at the original Medicare rate under all circumstances when the I/T/U provides a covered benefit.

To remove financial barriers for AI/AN enrollment:

422.101 (d) *Requirements relating to basic benefits special cost sharing rules*

Add (5) "Special rules for AI/AN. Covered services provided to AI/AN through I/T/U, including both direct care, contract health care and other payments, will be credited toward all AI/AN cost sharing including deductibles, co-payments, coinsurance and catastrophic limits."

To facilitate a special AI/AN MA or MA-PD plan and accommodate I/T/U group payer arrangements:

422.106 *Coordination of benefits with employer group health plans and Medicaid*

The discussion in the Federal Register states: "*Section 222(j)(2) of the MMA allows us to waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered by an employer, a labor organization. . .*" This type of waiver authority should also be used to create the flexibility to develop a national plan for AI/AN beneficiaries. We also ask CMS if this section could explicitly allow I/T/U or other entities to sponsor groups of AI/AN under a group plan. We assume this option to be exercised locally but could also envision a national AI/AN plan that would allow optional local sponsorship. We believe that few AI/AN who receive services through I/T/U will enroll in a MA plan on their own, therefore we ask CMS to develop an enabling option for I/T/U, or Tribes to enroll and pay for groups of AI/AN as sponsors.

As stressed above, we ask that dual eligible AI/AN be explicitly exempt from mandatory enrollment in MA or MA-PD plans.

To remove financial barriers for AI/AN enrollment:

422.111 *Disclosure requirements*

(e) *Changes to provider network* add "Changes to provider networks which affect AI/AN will provide cause for a AI/AN to switch to another plan at anytime without penalty."

422.122 *Access to Services*

Access to services for AI/AN requires the inclusion of I/T/U. All MA and MA-PD plans, including private fee-for-service plans referenced under 422.114 (c), should be required to include Indian health facilities as in-network providers to achieve network adequacy (without requiring the I/T/U to serve individuals who are not IHS beneficiaries), and AI/AN beneficiaries should be exempted from higher cost sharing if they use I/T/U. There are several reasons for this recommendation including: 1) AI/AN should be able to seek care at I/T/U as culturally appropriate services; 2) AI/AN could not be charged any cost sharing by I/T/U thus differences in premium or co-payments would only serve to further reduce revenue to tribal and Indian health facilities; 3) many I/T/U may be unable to contract with desirable MA or MA-PD plans for reasons already documented by CMS.

To enable I/T/U contracting with Part C plans:

Add "(a)(1)() *Access to IHS, tribal and urban Indian programs.* In order to meet access standards a Medicare Advantage plan or MA-PD plan must agree to contract with any I/T/U in its plan service areas.

(i) Such contracts shall incorporate, within the text of the agreement or as an addendum, provisions:

A. Acknowledging the authority under which the I/T/U is providing services, the extent of available services and the limitation on charging co-pays or deductibles.
B. Stating that the terms of the contract may not change, reduce, expand, or alter the eligibility requirements for services at the I/T/U as determined by the MMA; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal Regulations; and the terms of the contract, compact or grant issued to Provider by the IHS for operation of a health program, including one or more pharmacies or dispensaries.
C. Referencing federal law and federal regulations applicable to Tribes and tribal organization, for example, the Indian Self-Determination and Education Assistance Act, 25 U.S.C. §450 *et seq.* and the Federal Tort Claims Act, 28 U.S.C. §2671-2680.
D. Recognizing that I/T/Us are non-taxable entities.
E. Clarifying that Tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.
F. Confirming that a MA plan may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.
G. Including confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.
H. Recognizing that an I/T/U formulary cannot be restricted to that of the MA-PD plan.
I. Declaring that the Agreement may not restrict access the I/T/U otherwise has to Federal Supply Schedule or 340b drugs.
J. Stating that the I/T/U shall not be required to impose co-payments or deductibles on its Indian beneficiaries.
K. Authorizing I/T/U to establish their own hours of service.
L. Eliminating risk sharing or other provisions that conflict with federal, IHS or tribal laws, rules or policies."

We support the provision for payments to *"essential hospitals"* and request that I/T hospitals be explicitly identified by adding to (c)(6) "All hospitals operated by Tribes or the Indian Health Service will be considered essential under this provision."

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

To remove financial barriers for AI/AN enrollment and accommodate I/T/U group payer arrangements:

422.262 *Beneficiary Premiums*

AI/AN served by an I/T/U will most likely not elect to pay Part D premiums because these patients can access health care through the Indian Health Service (IHS) based on the Federal Government's obligation to federally recognized Tribes. It is our interpretation that the payment options cited to implement 422.262, Beneficiary Premiums, includes the IHS and Tribes. (Preamble, page 46651, "the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits"). We specifically ask CMS to remove barriers Tribes have encountered in paying Part B premiums for AI/AN under current CMS group payer rules (size of group and switching an individual from automatic deduction to group pay). Without these changes it is unlikely that AI/AN, who are entitled to health care without cost sharing, will enroll in MA plans.

Subpart G – Payments to Medicare Advantage Organizations

To discuss and address unique issues related to AI/AN Medicare MSA:

422.314 *Special rules for beneficiaries enrolled in MA MSA plans*

The enrollment of AI/AN in MSAs presents unique challenges. Tribes would like an opportunity to discuss this issue with CMS to ensure it is implemented in a way that will improve access to services.

To address potential intended loss of revenue to I/T/U:

422.316 *Special rules for payments to federally qualified health centers*

Add "Tribal FQHCs are not required to contract with MA or MA-PD plans as a condition for reimbursement. CMS will pay tribal FQHC at the same rate they would receive under original Medicare."

Conclusion

We understand that some of the MMA proposed rules related to point of service options and coverage of areas without adequate networks are intended to encourage the availability of MA and MA-PD plans in rural areas. However, because I/T/U operate in a diverse range of environments, the patient populations tend to be small and the array of possible local options is unknown, proposing complex policies to shoehorn in AI/AN seems ill advised. Our assessment of the negative impact on AI/AN and their access to MA plans is based on years of experience under implementation of State Medicaid managed care waivers. While the experience of Tribes and AI/AN under these private health plans was frequently disastrous, a number of Indian policy models have emerged which can be adopted for MMA implementation. In fact, to acknowledge these problems, a July 17, 2001 "Dear State Medicaid Director" letter was issued by CMS directing states to notify and communicate with Tribes during a waiver or renewal and inform Tribes of "the anticipated impact on Tribal members." We encourage CMS to consult with Tribes in a similar manner, and although it has, by default, fallen on Tribes themselves to assess the impact of MMA proposed regulations, we expect CMS to seriously consider remedies for all of the issues raised in this letter.

Again we urge CMS to consider eliminating unnecessary administrative cost burdens to all involved (AI/AN, I/T/U, CMS, Tribes, Indian Health Service and MA plans) and adopt simple

blanket policies for AI/AN and I/T/U that will promote access to these new benefits as well as guarantee Medicare reimbursements from the MA and MA-PD plans.

CMS-4069-P-21

Submitter : **Mr. James Martin** **Date & Time:** **09/29/2004 08:09:16**

Organization : **United South and Eastern Tribes, Inc.**

Category : **Other Government**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4069-P-21-Attach-1.doc

UNITED SOUTH AND EASTERN TRIBES, INC.
711 Stewarts Ferry Pike • Suite 100 • Nashville, TN 37214
Telephone: (615) 872-7900 • Fax: (615) 872-7417

September 29, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Comments on the Treatment of American Indians and Alaska Natives and Reimbursement to Tribal, Indian Health Service and Urban Indian Programs Under August 3, 2004 Proposed Rules for 42 CFR Parts 417 and 422, The Medicare Advantage Program

File Code CMS-4069-P

Dear Administrator:

The United South and Eastern Tribes, Inc. is concerned about the impact of the proposed regulations for Medicare Part C. The proposed regulations for the Medicare Advantage (MA) program published on August 3, 2004, do not mention American Indians, Alaska Natives, tribes, tribal organizations, tribal health services or the Indian Health Service.

The preamble to the regulations provides an analysis of the effects on small entities under the Regulatory Flexibility Act (RFA). The RFA analysis states: "We welcome comments on this approach and on whether we have missed some important category of effect or impact." We would like to state emphatically that you have missed an important category of effect and impact by omitting consideration of Tribal governments and Indian health care facilities.

We urge you to consult with Tribes to identify issues and workable solutions when new programs are being designed by the Centers for Medicare and Medicaid Services.

Sincerely yours,

James T. Martin/HJH

James T. Martin, Executive Director

Attachment

"Because there is strength in Unity"

September 29, 2004

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8018
Baltimore, MD 21244-8018

RE: Comments on the Treatment of American Indians and Alaska Natives and Reimbursement to Tribal, Indian Health Service and Urban Indian Programs Under August 3, 2004 Proposed Rules for 42 CFR Parts 417 and 422, The Medicare Advantage Program

File Code CMS-4069-P

Dear Administrator:

The United South and Eastern Tribes, Inc. is deeply concerned about the impact of August 3, 2004, proposed Medicare Modernization Act (MMA) rules regarding the **Medicare Advantage** program on American Indians and Alaska Natives (AI/AN) as well as the Indian Health Service, Tribal and urban (I/T/U) health programs that serve them. These comments and recommendations are submitted to the Centers for Medicare and Medicaid Services (CMS) with the very serious concerns of Tribes across the nation.

INTRODUCTORY STATEMENT REGARDING INDIAN HEALTH SYSTEM

These comments address the implications of the proposed rules on the Indian health care delivery system and the changes that must be made to prevent Part C implementation from destabilizing the system responsible for providing health care to the approximately 1.3 million American Indians and Alaska Natives (AI/AN) served by the IHS system. In the form proposed by CMS, the rules will put in jeopardy significant revenues the Indian health system now collects from Medicaid for "dual eligibles". Since the loss of revenue to Indian health was **not** Congress's objective in enacting the Part C benefit, the rules must be revised in several respects to protect the Indian health system from what could be substantial harm. Furthermore, to enable voluntary enrollment by AI/AN in Part C requires substantial modifications to the proposed rules.

We ask that all CMS staff charged with reviewing comments and revising the proposed regulations be supplied with a copy of this introductory statement regarding the Indian health care system. Compliance with the dictates of notice and comment rulemaking requires that all relevant information supplied by commenters must be taken into account. Full consideration of the comments we offer on individual regulations can only be accomplished by a thorough understanding of the unique nature of the Indian health care system, and the responsibility of our steward, the Secretary of Health and Human Services, to assure that inauguration of Medicare Part C does not result in inadvertent and unintended harm to that system.

The regulations governing the Part C must be revised to achieve the following goals:

- Encourage MA enrollment by AI/AN by removing financial barriers and allowing AI/AN to voluntarily participate in Medicare Advantage plans, without financial penalty because of location of residence, selection of a plan that includes I/T/U, or use of I/T/U.

- Ensure that I/T/U, under all conditions, are held harmless financially and are fully reimbursed for covered services provided to AI/AN who enroll in a Medicare Advantage plan.

- Allow I/T/U the flexibility to sponsor AI/AN in Medicare Advantage plans, under a special group payer arrangement.

- Allow, in the future, the development of an AI/AN special Medicare Advantage plan that includes the active participation of Tribes in its design and implementation.

- Explicitly exempt AI/AN dual eligibles from mandatory participation in a State Title XIX MA or MA-PD Plan.

In order to fully comprehend the potential adverse impact Part C implementation will have on the Indian health care system -- particularly with regard to the dual eligibles it serves -- one must have an understanding of the way health care services are delivered to AI/ANs and the current state of Indian health. These considerations must be kept in mind as CMS reviews these comments in order to promulgate regulations that assure the inauguration of the Part C or Medicare Advantage (MA) program does not have negative consequences on the Indian health system by reducing the level of reimbursements from Medicaid or Medicare on which the system has come to rely.

Indian Health Care System and Indian Health Disparities

Overview. The Indian health care system does not operate simply as an extension of the mainstream health system in the United States. To the contrary, the Federal government has built a system that is designed specifically to serve American Indian and Alaska Native people in the context in which they live -- remote, sparsely-populated and, in many cases, poverty-stricken areas where the Indian health system is the only source of health care. Integral to that system are considerations of tribal cultures and traditions, and the need for culturally competent and sensitive care.

U.S. Trust Responsibility for Indian Health. The United States has a trust responsibility to provide health care to AI/ANs pursuant to federal laws and treaties with Indian Tribes.[1] Pursuant to statutory directive,[2] this responsibility is carried out by the Secretary of Health and Human Services, primarily through the Indian Health Service (IHS) with annual appropriations supplied by Congress. The IHS-funded health system follows the public health model in that it addresses the need for both medical care and preventive care. In order to perform this broad mission, the IHS funds a wide variety of efforts including: direct medical care (through hospitals, clinics, and Alaska Native Village health stations); pharmacy operations; an extensive (but underfunded) Contract Health Services program through which specialty care IHS cannot supply directly is purchased from public and private providers; health education and disease prevention programs; dental, mental health, community health and substance abuse prevention and treatment; operation and maintenance of hospital and clinic facilities in more than 30 states; and construction and maintenance of sanitation facilities in Indian communities.

Health Disparities. AI/ANs have a higher rate of disease and illness than the general population and consequently require more medications and incur higher prescription drug costs

[1] *See, e.g.,* 25 U.S.C. § 1601.
[2] 42 U.S.C. § 2001.

than most Americans. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights[3] reveals a number of alarming statistics such as:

- AI/ANs have the highest prevalence of Type II diabetes *in the world*, are 2.6 times more likely to be diagnosed with the disease than non-Hispanic whites, and are 420% more likely to die from the disease.
- The cardiovascular disease rate among AI/ANs is two times greater than the general population.
- AI/ANs are 770% more likely to die from alcoholism.
- Tuberculosis deaths are 650% higher among AI/ANs than the general population.
- AI/AN life expectancy is 71 years, five years less than the general U.S. population.
- The ratio of cancer deaths to new cancer cases is higher for Native Americans than the ratios for all other races, even though incidence rates are lower.
- The Indian suicide rate is 190 percent of the rate of the general population.

Composition of the Indian Health Care System. Operationally, health services to AI/ANs are delivered through the following entities:

- The Indian Health Service directly operates hospitals and clinics throughout Indian Country that are staffed by federal employees.
- Indian Tribes and tribal organizations may elect to assume management and control over IHS programs at the local tribal level through authority of the Indian Self-Determination and Education Assistance Act. At present, over one-half of the IHS budget is distributed to ISDEAA tribal programs.
- In 34 cities, urban Indian organizations operate limited health programs (largely referral services) for Indian people living in urban areas through grants authorized by the Indian Health Care Improvement Act.

Funding Sources. Indian health programs are supported primarily from annual federal appropriations to the Indian Health Service. Regardless of the operational form, all Indian health programs are severely underfunded. In a 2003 report[4], the U.S. Commission on Civil Rights found that the per-capita amount spent by the Indian Health Service for medical care was nearly 50% lower than spending for federal prisoner medical care and only slightly more than one-third of the average spending for the U.S. population as a whole. The Veterans Administration spends nearly three times as much for its medical programs as the Indian Health Service.

In an effort to improve the level of funding for Indian health programs, Congress, in 1976, made IHS/tribal hospitals eligible for Medicare Part A reimbursements, and enabled hospitals and clinics to collect Medicaid reimbursements, either as IHS facilities or as FQHCs. It was not until the 2000 BIPA that IHS facilities were authorized to collect for some Medicare Part B services. With enactment of the MMA, Congress authorized these facilities to collect for remaining Part B services for a five-year period.

Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by I/T/Us to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. If coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that

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[3] U.S. Commission on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System*, July 2, 2004 (staff draft).

[4] U.S. Commission on Civil Rights, *A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country*, July 2003.

the reimbursement of services for Indian dual eligibles continues without interruption and without reduction to I/T/U.

Indian health programs have become critically reliant on the third-party revenues, especially those supplied by Medicare and Medicaid. According to the IHS, Medicare, Medicaid and other third party collections can represent up to 50% of operating budgets at some facilities.

Scope of Services. The compliment of health services provided at a single site or by a Tribe varies from a single health station, common in Alaska, to comprehensive in and outpatient hospital services. Other health services provided directly by or through Indian health programs can include medical, dental, mental health, chemical dependency treatment, ambulance, pharmacy, home health, hospice, dialysis, public health and traditional healing.

The diversity of services provided through Indian health programs, and the generally limited size of the population they serve makes comprehensive contracting with private plans an expensive and challenging task.

Pharmacy Services for Dual Eligibles and Impact of Part D

Because most Indian health facilities are located in remote areas far distant from the mainstream health system, they must also operate pharmacies so their patients can access needed medications. IHS, Tribes, and urban Indian organizations operate 235 pharmacies throughout Indian Country. IHS and Tribes dispense pharmaceuticals to their Indian beneficiaries without charge, as is the case for all health services they offer.

A sizeable portion of the patient base for I/T/U pharmacies consists of dual eligibles. IHS estimates that there are between 25,963[5] and 30,544[6] individuals in the IHS patient database who are receiving both Medicare and Medicaid. Since this database does not include information from some tribally-operated facilities (those who do not use the IHS computerized data system) nor information about Indians served by urban Indian clinics, the number of dual eligibles system-wide is even greater than the IHS database reveals.

While there is no comprehensive data on the per-capita drug costs for dual eligibles in the Indian health system, we have been able to make some rough estimates by examining average state per-capita spending for this population. In 2002, the average per-capita spending for dual eligibles was $918.[7] We believe this is a very conservative figure for Indian Country, in view of the higher rates of illness that have expensive drugs associated with their treatment, including diabetes and mental illness. Furthermore, the IHS calculates that the cost of pharmaceuticals has increased by 17.6 percent per year between FY 2000 and FY 2003. This includes the cost of new drugs, increases in drug costs and population growth. Thus, if we trend the average out to the year 2006, the expected average per capita spending on drugs for dual eligibles would be $1,756.

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[5] This number represents 85 percent of the three-year total of active users.

[6] This is the number of active users, defined as at least one visit in the past three years.

[7] From Table 2, "Full" Dual Eligible Enrollment and Prescription Drug Spending, by State, 2002, in "The 'Clawback:' State Financing of Medicare Drug Coverage" by Andy Schneider, published by the Kaiser Commission on Medicaid and the Uninsured, June 2004.

Using these population and per-capita spending data, we estimate that the Medicaid recovery for dual eligible drug costs in the Indian health system ranges between **$23.8 million**[8] **and $53.6 million.**[9] It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid for pharmacy services and placed into either an MA-PD or a Part D plan.

Part A and B Services for Dual Eligibles and the potential Impact of Medicare Advantage

As with Part D, the most serious concerns and most immediate reduction in Indian health program revenues are related to AI/AN who are dually eligible for Medicaid and Medicaid. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for effected Tribes. Although a financial analysis has not been conducted, potential revenue loss to I/T/U on a per patient basis would far exceed losses estimated for Part D alone.

The Secretary of Health and Human Services, as the principal steward of Indian health, has a responsibility to assure that the MMA, which was intended to benefit *all* Medicare beneficiaries, does not produce the opposite result for *Indian* Medicare beneficiaries who use the Indian health care system. He can guard against such an outcome by exercising the broad authority granted to the Secretary to assure access to Part C for AI/AN. We believe that Congress recognized that access for Indian beneficiaries means the ability to utilize Part C benefits through I/T/U and that AI/AN should be able to enjoy voluntary participation in Medicare Advantage plans on a equal basis with all other Medicare beneficiaries.

BACKGROUND FOR PART C ISSUES

There is a fundamental mismatch between the Indian health care system and the proposed rules to implement the MMA. The result of this flaw in the proposed regulations could result in a critical loss of revenue for the Indian health programs across the nation and will further contribute to an even greater disparity in health care between the AI/AN and the general population than already exists. In fact, the proposed rules for Part C make no mention of AI/AN or I/T/U at all. As written, it is unlikely that many AI/AN who receive health care through an I/T/U will be able to benefit from these important Medicare changes. If they do chose to participate in a Part C plan, it is unlikely that Indian health facilities will be able to obtain compensation for the services provided to those Medicare beneficiaries. Furthermore, to the extent that States require dual eligibles to enroll in Title XIX Medicare Advantage (MA) plans, I/T/U will experience significant reductions in revenue associated with these patients.

As sovereign nations and recognized governments, Tribes insist that HHS and CMS acknowledge the impact and financial burden MMA regulations have on Tribal governments and Indian people.

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[8] This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.

[9] This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.

Appropriately including AI/AN and I/T/U in MMA proposed regulations for Medicare Advantage first requires the recognition of key elements of this fragile health system.

- AI/AN are a unique political group guaranteed health care through treaties.
- The federal government has failed to meet this obligation and currently funds Indian health programs at only about 50% of need.
- The Department of Health and Human Services has and continues to develop Tribal consultation policies which have not been used in the process of drafting or assessing the impact of the proposed MMA rules.
- AI/AN, especially those living on or near reservations, suffer from the highest levels of poverty and disease burden in the United States.
- I/T/U, as culturally appropriate providers, have achieved great success in promoting preventive services and improving the health of AI/AN but still face daunting challenges.
- The IHS and Tribally-operated facilities do not charge AI/AN individuals for the health services provided to them, but they do rely upon third party payments, including Medicare and Medicaid.
- Unlike other populations, AI/AN are often reluctant to enroll in Medicaid and Medicare because they understand health care to be a right, thus premiums, and other cost sharing significantly discourages their participation and acts as an insurmountable barrier to program enrollment.
- Unlike other health care providers, I/T/U cannot charge AI/AN patients and therefore beneficiary "cost sharing" merely results in significant and inappropriate reimbursement reductions.
- Many I/T/U facilities provide services in remote areas where the size of the population is insufficient to support a private health care delivery system and where the market forces key to the implementation of this legislation do not exist.
- Private health and prescription drug plans often do not want to contract with I/T/U for many reasons including the health status and small size of the AI/AN population, the special contracting requirements, and the high administrative costs associated with developing and maintaining new contractual relationships with numerous small clinics.
- Resources spent by I/T/U to implement MMA by providing staff time for training, outreach, education, enrollment assistance, contract negotiation, and redesigning IT and administrative systems to accommodate new contracts with Medicare Advantage plans, further reduce funding for the health care of AI/AN.
- The number of AI/AN in the United States who are enrolled in Medicare and who use I/T/U is estimated to be 103,000. Approximately half of this group are thought to be dually eligible for Medicaid. Even if 20% of the remaining AI/AN Medicare population enrolls in a MA or MA-PD plan, the number of Indian enrollees in any MA plan will likely be very small and will have minimal impact on plans. However, because of the small and widely dispersed population, the per enrollee cost to plans (and I/T/U) to develop, negotiate, execute and implement contracts will be high.
- Although the impact of AI/AN enrollment in MA and MA-PD plans may seem insignificant to plans and CMS, the relative impact on individual Tribes could represent significant losses.

We hope CMS agrees that these regulations should minimize unintended consequences of MMA on I/T/U as well as promoting access to new Medicare options for AI/AN. There are two basic approaches to address Indian issues: 1) simple blanket policies requiring MA and MA-PD plans to pay I/T/U for covered services and limited exemptions for AI/AN; or, 2) numerous, extremely complex policies and exceptions to the proposed rules. **We challenge CMS to closely consider the issues presented here and assist in crafting language for the final rules that will**

"first do no harm" to Indian health programs and, second, step forward to actually improve access to Medicare for AI/AN and reimbursement for services provided to them by I/T/U.

Options for AI/AN MMA Policy

Five policy decisions to alleviate well-documented problems I/T/U have experienced contracting with private plans would address a majority of concerns raised by the proposed rules:

1. Encourage MA enrollment by AI/AN by removing financial barriers and allowing AI/AN to voluntarily participate in Medicare Advantage plans, without financial penalty because of location of residence, selection of a plan that includes I/T/U, or use of I/T/U.
    - Waive AI/AN cost sharing for all plans.
    - If AI/AN dual eligibles are required to enroll in an MA or MA-PD plan, establish the default enrollment for AI/AN to an MA or MA-PD plan for which the network includes local I/T/U facilities, or pays fully for out of network services.
    - Allow unlimited plan switching to facilitate enrollment in plans with culturally sensitive I/T/U providers. Exempt AI/AN from "lock-in" or "lock-outs".
    - Exempt AI/AN from cost differentials associated with selection of a plan that includes culturally appropriate I/T/U provider or more robust networks

2. Ensure that I/T/U, under all conditions, are held harmless financially and are fully reimbursed for covered services provided to AI/AN who enroll in a Medicare Advantage plan. We see three basic options to implement this policy:
    a. Require all MA (and MA-PD) plans to recognize I/T/U as in-network providers and reimburse at IHS Medicaid rates (as paid under the original or traditional Medicare), even without contracts. We believe this would be the desired option of plans and CMS because the minimal administrative burden and simplicity of regulations would reduce the cost of implementation.[10]
    b. Require MA (and MA-PD) plans to recognize I/T/U as in-network providers, even without contracts, and reimburse at Plan's standard Medicare rates. CMS provides "wrap-around" reimbursement to hold I/T/U harmless for difference between plan reimbursement and IHS Medicaid rate.
    c. Require all MA (and MA-PD) plans to contract with all willing I/T/U under similar special contract provisions terms as those used for the special endorsed Prescription Drug Discount Card contracts and using IHS Medicare rates. Also exempt I/T/U from plan credentialing, risk sharing, and other contracting requirements that are conducted or prohibited by federal or tribal statute, rule or policy. These contract provisions are outlined under 422.112 and are similar to those recommended for Part D.

3. Allow I/T/U the flexibility to sponsor AI/AN in Medicare Advantage plans, under a special group payer arrangement.

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[10] Washington State Administrative Code provides a precedent and contains sample language for this provision. **WAC 284-43-200 Network adequacy.** (7) To provide adequate choice to covered persons who are American Indians, each health carrier shall maintain arrangements that ensure that American Indians who are covered persons have access to Indian health care services and facilities that are part of the Indian health system. Carriers shall ensure that such covered persons may obtain covered services from the Indian health system at no greater cost to the covered person than if the service were obtained from network providers and facilities. Carriers are not responsible for credentialing providers and facilities that are part of the Indian health system. Nothing in this subsection prohibits a carrier from limiting coverage to those health services that meet carrier standards for medical necessity, care management, and claims administration or from limiting payment to that amount payable if the health service were obtained from a network provider or facility.

- Permit sponsorship of AI/AN with flexibility and adequate timelines to add and drop individuals
- Require plans and CMS to send sponsors information normally sent to enrollees so sponsors can respond quickly
- Add special plan disenrollment rule for sponsored AI/AN and require communication and problem resolution process between plan and sponsor prior to plan disenrollment of AI/AN

4. Allow, in the future, the development of an AI/AN special Medicare Advantage plan that includes the active participation of Tribes in its design and implementation.

5. Explicitly exempt AI/AN dual eligibles from mandatory participation in a State Title XIX MA or
MA-PD Plan.

- MMA should not reduce the funding currently going to support Indian health programs; however, the effect of mandatory AI/AN dual eligible enrollment would result in significant losses for effected I/T/U
- Sec. 1932 [42 U.S.C. 1396u-2] exempts AI/AN from mandatory Medicaid managed care plan enrollment, in recognition of the many difficulties facing I/T/U in interfacing with private plans. For these same reasons, we believe AI/AN dual eligibles should not be required to enroll in MA or MA-PD plans.
- Allow same options, or exemptions, for AI/AN as currently exists under state Medicaid plans.

Additional AI/AN policy issues that require changes in the proposed rules:

- Remedy potential reimbursement and Contract Health Services funding problems for I/T/U created by MSA without restricting as an option for AI/AN.

- Require consistency with Part D rules relative to AI/AN policy.

Recommended Revisions to August 3, 2004 Proposed Rules

Proposing specific section-by-section language changes to the proposed rules to accomplish the AI/AN policy objectives stated above would require time and resources beyond our current means. **We challenge CMS to come forward with comprehensive changes to the proposed rules that will appropriately allow access to MA for AI/AN and I/T/U as special populations and providers.** Listed here is a limited set of suggested revisions.

Subpart A – General Provisions

To enable an AI/AN specific MA or MA-PD plan in the future:

422.2 *Definitions*

Basic benefits add, "including covered services received through an Indian health service program."

Special needs individuals add "American Indians and Alaska Natives (AI/AN) are exempt from mandatory enrollment in Title XIX plans but would qualify for optional enrollment in an AI/AN specialized MA plan."

In establishing contracts with a national, statewide or regional MA or MAPD plans preference should be given to state licensed managed care organizations that are controlled by Indian Health Service funded Tribal and /or Urban Indian Health Programs which are funded to provide services in clients. This approach is the best means of assuring access to culturally competent and geographically proximal services to individual Indians.

To address the cost of implementation at the I/T/U level:

422.6 *Cost Sharing in Enrollment Related Costs*

We have commented to CMS on several occasions about the high cost to I/T/U for MMA implementation costs related to outreach, education and enrollment of AI/AN. We strongly encourage CMS to identify in this or another section the need for funding to support these activities be specifically directed to local I/T/U where the work is done and bearing the costs is most difficult. Unlike other Medicare populations, AI/AN are unlikely to enroll in MA plans without specific information from their I/T/U.

Subpart B – Eligibility, Election and Enrollment

To address potential intended loss of revenue to I/T/U:

422.52 *Eligibility to elect MA plan for special needs individual*

(b)(2) add, "except mandatory enrollment for AI/AN is prohibited."

To discuss and address unique issues related to AI/AN Medicare MSA:

422.56 *Enrollment in an MA MSA plan*

(c) The enrollment of AI/AN in MSAs presents unique challenges. Tribes would like an opportunity to discuss this issue with CMS to ensure it is implemented in a way that will improve access to services.

To accommodate I/T/U group payer arrangements:

422.60 *Election process*

Require MA and MA-PD plans to accept AI/AN enrollment, even if CMS has allowed the plan to close due to capacity limits. Rationale: AI/AN could enroll in MA plans under a variety of circumstances, including a group sponsorship. Because the number of AI/AN is small and the number of culturally appropriate plans available will be very limited, CMS should require plans to enroll AI/AN at anytime.

422.62 *Election coverage under an MA plan*

We request that CMS add the following provisions in an appropriate place:

- AI/AN may switch MA or MA-PD plan at any time if local I/T/U is not reimbursed by plan as in-network provider at original (or traditional) Medicare rate
- AI/AN who are in a sponsorship program may, with the consent of the sponsor, switch plans at any time
- Sponsors may add AI/AN enrollees to an MA plan at anytime under the following conditions: relocation to sponsor service area; loss of alternative health insurance coverage; change in sponsorship policies.
- AI/AN sponsored in a group payer arrangement are exempted from "lock-ins" and "lock-outs".

422.66 *Coordination of enrollment and disenrollment through MA organizations*

We request that CMS add the following provisions in an appropriate place:

- Establish a default enrollment process for AI/AN that uses a plan that reimburses local I/T/U at in-network rates
- Provide flexibility for switching plans under conditions AI/AN are likely to encounter
- Communicate directly with local I/T/U about patient enrollment/disenrollment

422.74 *Disenrollment by the MA organizations*

Add "Process for disenrolling an AI/AN under a sponsorship or group program must include direct communication with sponsor with adequate documentation of problem and steps taken to resolve as well as adequate timelines."

422.80 *Approval of marketing materials and election forms*

This language lists as prohibited marketing activities for MA Plans to *"Engage in any discriminatory activity, including targeted marketing to Medicare beneficiaries . . . and (iii) solicit Medicare beneficiaries door-to-door."* While the intent of this language is to prohibit aggressive enrollment practices that favor healthier individuals, the unintended consequence may be to limit the development of needed materials targeted to AI/AN. While MA Plan representative should be prohibited from soliciting business by going door-to-door, the outreach workers employed by tribal and IHS facilities should be encouraged to provide information about Medicare alternatives in the homes of AI/AN elderly. We ask that CMS clarify this issue.

Subpart C – Benefits and Beneficiary Protections

To address potential intended loss of revenue to I/T/U:

422.100 *General Requirements*

If not clearly addressed in another section, MA and MA-PD plans should be required to reimburse I/T/U at the original Medicare rate under all circumstances when the I/T/U provides a covered benefit.

To remove financial barriers for AI/AN enrollment:

422.101 (d) *Requirements relating to basic benefits* special cost *sharing rules*

Add (5) "Special rules for AI/AN. Covered services provided to AI/AN through I/T/U, including both direct care, contract health care and other payments, will be credited toward all AI/AN cost sharing including deductibles, co-payments, coinsurance and catastrophic limits."

To facilitate a special AI/AN MA or MA-PD plan and accommodate I/T/U group payer arrangements:

422.106 *Coordination of benefits with employer group health plans and Medicaid*

The discussion in the Federal Register states: *"Section 222(j)(2) of the MMA allows us to waive or modify requirements that hinder the design of, the offering of, or the enrollment in an MA plan offered by an employer, a labor organization. . ."* This type of waiver authority should also be used to create the flexibility to develop a national plan for AI/AN beneficiaries. We also ask CMS if this section could explicitly allow I/T/U or other entities to sponsor groups of AI/AN under a group plan. We assume this option to be exercised locally but could also envision a national AI/AN plan that would allow optional local sponsorship. We believe that few AI/AN who receive services through I/T/U will enroll in a MA plan on their own, therefore we ask CMS to develop an enabling option for I/T/U, or Tribes to enroll and pay for groups of AI/AN as sponsors.

As stressed above, we ask that dual eligible AI/AN be explicitly exempt from mandatory enrollment in MA or MA-PD plans.

To remove financial barriers for AI/AN enrollment:

422.111 *Disclosure requirements*

(e) *Changes to provider network* add "Changes to provider networks which affect AI/AN will provide cause for a AI/AN to switch to another plan at anytime without penalty."

422.122 *Access to Services*

Access to services for AI/AN requires the inclusion of I/T/U. All MA and MA-PD plans, including private fee-for-service plans referenced under 422.114 (c), should be required to include Indian health facilities as in-network providers to achieve network adequacy (without requiring the I/T/U to serve individuals who are not IHS beneficiaries), and AI/AN beneficiaries should be exempted from higher cost sharing if they use I/T/U. There are several reasons for this recommendation including: 1) AI/AN should be able to seek care at I/T/U as culturally appropriate services; 2) AI/AN could not be charged any cost sharing by I/T/U thus differences in premium or co-payments would only serve to further reduce revenue to tribal and Indian health facilities; 3) many I/T/U may be unable to contract with desirable MA or MA-PD plans for reasons already documented by CMS.

To enable I/T/U contracting with Part C plans:

Add "(a)(1)() *Access to IHS, tribal and urban Indian programs.* In order to meet access standards a Medicare Advantage plan or MA-PD plan must agree to contract with any I/T/U in its plan service areas.

(i) Such contracts shall incorporate, within the text of the agreement or as an addendum, provisions:

A. Acknowledging the authority under which the I/T/U is providing services, the extent of available services and the limitation on charging co-pays or deductibles.
B. Stating that the terms of the contract may not change, reduce, expand, or alter the eligibility requirements for services at the I/T/U as determined by the MMA; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal Regulations; and the terms of the contract, compact or grant issued to Provider by the IHS for operation of a health program, including one or more pharmacies or dispensaries.
C. Referencing federal law and federal regulations applicable to Tribes and tribal organization, for example, the Indian Self-Determination and Education Assistance Act, 25 U.S.C. §450 *et seq*. and the Federal Tort Claims Act, 28 U.S.C. §2671-2680.
D. Recognizing that I/T/Us are non-taxable entities.
E. Clarifying that Tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.
F. Confirming that a MA plan may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.
G. Including confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.
H. Recognizing that an I/T/U formulary cannot be restricted to that of the MA-PD plan.
I. Declaring that the Agreement may not restrict access the I/T/U otherwise has to Federal Supply Schedule or 340b drugs.
J. Stating that the I/T/U shall not be required to impose co-payments or deductibles on its Indian beneficiaries.
K. Authorizing I/T/U to establish their own hours of service.
L. Eliminating risk sharing or other provisions that conflict with federal, IHS or tribal laws, rules or policies."

We support the provision for payments to *"essential hospitals"* and request that I/T hospitals be explicitly identified by adding to (c)(6) "All hospitals operated by Tribes or the Indian Health Service will be considered essential under this provision."

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

To remove financial barriers for AI/AN enrollment and accommodate I/T/U group payer arrangements:

422.262 *Beneficiary Premiums*

AI/AN served by an I/T/U will most likely not elect to pay Part D premiums because these patients can access health care through the Indian Health Service (IHS) based on the Federal Government's obligation to federally recognized Tribes. It is our interpretation that the payment options cited to implement 422.262, Beneficiary

Premiums, includes the IHS and Tribes. (Preamble, page 46651, "the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits"). We specifically ask CMS to remove barriers Tribes have encountered in paying Part B premiums for AI/AN under current CMS group payer rules (size of group and switching an individual from automatic deduction to group pay). Without these changes it is unlikely that AI/AN, who are entitled to health care without cost sharing, will enroll in MA plans.

Subpart G – Payments to Medicare Advantage Organizations

To discuss and address unique issues related to AI/AN Medicare MSA:

422.314 *Special rules for beneficiaries enrolled in MA MSA plans*

The enrollment of AI/AN in MSAs presents unique challenges. Tribes would like an opportunity to discuss this issue with CMS to ensure it is implemented in a way that will improve access to services.

To address potential intended loss of revenue to I/T/U:

422.316 *Special rules for payments to federally qualified health centers*

Add "Tribal FQHCs are not required to contract with MA or MA-PD plans as a condition for reimbursement. CMS will pay tribal FQHC at the same rate they would receive under original Medicare."

Conclusion

We understand that some of the MMA proposed rules related to point of service options and coverage of areas without adequate networks are intended to encourage the availability of MA and MA-PD plans in rural areas. However, because I/T/U operate in a diverse range of environments, the patient populations tend to be small and the array of possible local options is unknown, proposing complex policies to shoehorn in AI/AN seems ill advised. Our assessment of the negative impact on AI/AN and their access to MA plans is based on years of experience under implementation of State Medicaid managed care waivers. While the experience of Tribes and AI/AN under these private health plans was frequently disastrous, a number of Indian policy models have emerged which can be adopted for MMA implementation. In fact, to acknowledge these problems, a July 17, 2001 "Dear State Medicaid Director" letter was issued by CMS directing states to notify and communicate with Tribes during a waiver or renewal and inform Tribes of "the anticipated impact on Tribal members." We encourage CMS to consult with Tribes in a similar manner, and although it has, by default, fallen on Tribes themselves to assess the impact of MMA proposed regulations, we expect CMS to seriously consider remedies for all of the issues raised in this letter.

Again we urge CMS to consider eliminating unnecessary administrative cost burdens to all involved (AI/AN, I/T/U, CMS, Tribes, Indian Health Service and MA plans) and adopt simple blanket policies for AI/AN and I/T/U that will promote access to these new benefits as well as guarantee Medicare reimbursements from the MA and MA-PD plans.

CMS-4069-P-22

Submitter : **Mr. James Martin** **Date & Time:** **09/29/2004 08:09:55**

Organization : **United South and Eastern Tribes, Inc.**

Category : **Other Government**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4069-P-22-Attach-1.pdf

CMS-4069-P-23

Submitter : **Mr. David Nash** **Date & Time:** **09/30/2004 02:09:26**

Organization : **The Eastern Band of Cherokee Indians**

Category : **Other Government**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4069-P-23-Attach-1.doc

CMS-4069-P-23

Submitter : **Mr. David Nash** **Date & Time:** **09/30/2004 02:09:26**

Organization : **The Eastern Band of Cherokee Indians**

Category : **Other Government**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4069-P-23-Attach-1.doc

CMS-4069-P-24

Submitter : Marie Sieloff **Date & Time:** 09/30/2004 03:09:13

Organization : Marie Sieloff

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

My concern is the people who use government incentives like Medicaid buy-in and PASS. These people are mostly poor and disabled, who depend on these programs to make sure that they and their families have coverage on doctor's and hospital visits.

CMS-4069-P-25

Submitter : **Mr. Phillip Martin** **Date & Time:** **09/30/2004 07:09:34**

Organization : **Mississippi Band of Choctaw Indians**

Category : **Other Government**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4069-P-25-Attach-1.doc

CMS-4069-P-26

Submitter : Mr. Phillip Martin **Date & Time:** 09/30/2004 07:09:37

Organization : Mississippi Band of Choctaw Indians

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4069-P-26-Attach-1.pdf

CMS-4069-P-27

Submitter : NARGES SOHRABI **Date & Time:** 10/01/2004 01:10:43

Organization : UNIVERSTIY OF TOLEDO

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

WHEN BEING INFORMED OF THE OPPORTUNITY TO VOICE MY OPINION REGARDING THE MEDICATION THERAPY MANAGEMENT SERVICES OUTCOMES, I WAS DELIGHTED TO BE A PART OF THIS BILL. I HAVE A FEW GENERAL COMMENTS ON THIS ISSUE:

I BELIEVE THAT AS A STUDENT PHARMACIST AND ENDURING ALL THE DRUG THERAPY AND PHARMACOLOGY COURSES IN PHARMACY SCHOOL, MAKES PHARMACISTS THE MOST ELIGIBLE CANDIDATE FOR PROVIDING MEDICATION THERAPY TO INDIVIDUALS.

I BELIEVE THAT THE PATIENT SHOULD BE ABLE TO GO TO ANY PHARMACY AND RECEIVE THESE BENEFITS WITHOUT BEING RESTRICTED BY THEIR INSURANCE WITH REGARDS TO A PREFERRED PROVIDER OR PHARMACY. THE PATIENT-PHARMACIST RELATIONSHIP SHOULD BE UNDISTURBED, ALLOWING FOR A RESPECTFUL AND CONSISTENT PARTNERSHIP.

LASTLY, THE SERVICES PROVIDED SHOULD FOREMOST INCLUDE A ONE-ON-ONE INITIAL MEETING WITH PATIENT AND PHARMACIST?A FACE TO FACE CONFERENCE IS IMPORTANT IN ESTABLISHING TRUST, CREDIBILITY, AND A GREATER UNDERSTANDING OF WHAT IS AT STAKE FOR THE PATIENT AND HOW THE PHARMACIST CAN HELP.

I SUPPORT THE MEDICATION THERAPY MANAGEMENT SERVICES DEFINITION AND PROGRAM CRITERIA DEVELOPED AND ADOPTED BY 11 NATIONAL PHARMACY ORGANIZATIONS IN JULY 2004.

CMS-4069-P-28

Submitter : Mr. Lawrence Sage **Date & Time:** 10/01/2004 02:10:40

Organization : Indiana Pharmacists Alliance

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I have attached a file which contains the general comments from the Indiana Pharmacists Alliance.

CMS-4069-P-28-Attach-1.doc

CMS-4069-P-29

Submitter : **Mr. George Maurer** **Date & Time:** **10/01/2004 02:10:26**

Organization : **Community Pharmacies of Indiana**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I have attached a file that contains the general comments of the Community Pharmacies of Indiana Inc.

CMS-4069-P-29-Attach-1.doc

CMS-4069-P-30

Submitter : **Mr. W.J. Francis** **Date & Time:** **10/01/2004 05:10:34**

Organization : **Public Policy Network**

Category : **Individual**

Issue Areas/Comments

Subparts J-M

Subpart K--Application and Contract requirements for
MA organizations.

Dear Sirs, I am attaching comments on Suppart K as a Word file.

CMS-4069-P-30-Attach-1.doc

CMS-4069-P-31

Submitter : **Mr. W.J. Francis** **Date & Time:** **10/01/2004 05:10:39**

Organization : **Public Policy Network**

Category : **Individual**

Issue Areas/Comments

Subparts A-I

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

Dear Sirs: I am attaching a Word file containing comments on Network requirements.

CMS-4069-P-31-Attach-1.doc

CMS-4069-P-32

Submitter : **Karen Bullock** **Date & Time:** **10/01/2004 05:10:00**

Organization : **Community Health Partnership, Inc.**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached Word File.

CMS-4069-P-32-Attach-1.doc

CMS-4069-P-33

Submitter : Mr. Walter K. Moore **Date & Time:** 10/01/2004 06:10:13

Organization : Genentech, Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Genentech, Inc. appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services? (CMS) Medicare Program; Establishment of the Medicare Advantage Program. As you are aware, Genentech is a leading biotechnology company headquartered in South San Francisco, California. Our primary mission is to develop, manufacture and market breakthrough biologics that address significant unmet medical needs, including cancer and heart disease, and immunological diseases. A number of our therapies will be eligible for coverage under the Medicare Advantage (MA) program, as well as those plans that participate in the Medicare Part D program. We expect MA and their respective Part D plans to allow access to these therapies for Medicare beneficiaries.

Genentech appreciates the effort that CMS has invested in the difficult task of creating the proposed MA program. We recognize the complexity of renovating this significant program and if done properly, with the help of the Managed Care community, Genentech believes that the MA Program will allow greater and more affordable access to healthcare among Medicare beneficiaries.

However, Genentech does not believe that the proposed MA program fulfills the statutory directive of Congress. While we are supportive of the development of MA plans, we are specifically concerned about: (i) the utility of disease-specific specialized plans and their formularies; (ii) ensuring patient cost sharing is appropriately calculated and reported, and credited; (iii) the need for guidance around the negotiations between MCOs, physicians, Pharmacy Benefit Managers (PBMs), and drug manufacturers; and (iv) plans to release utilization data from the Medicare Demonstration Project in regards to Part D and its implications to beneficiaries and MCOs.

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

The proposed rule provides little guidance on the feasibility of specialized plans and their formularies. Although the intent of creating special needs plans is to better serve the subpopulation of Medicare beneficiaries who require more specialized and resource intensive treatment, these plans actually create discrimination in the marketplace by allowing MCOs in the same area/region to restrict service to beneficiaries that fall under the ?severe and disabling? label. Genentech urges CMS to be mindful that some beneficiaries may choose to remain in their current plan rather than elect to enroll in a special needs plan. CMS must take the necessary steps to continue providing an appropriate level of treatment to these individuals within their current plan, as well as, provide educational assistance to the beneficiary if it is in his/her best interest to switch plans.

Genentech also would like the Final Rule of the MA program to direct plans to release utilization data from the Medicare Demonstration Project and its Part D implications to beneficiaries and MCOs. The experience of Medicare beneficiaries who chose to participate in the Demonstration Project may provide significant weight in the decision making process of those who may elect to switch to an MA plan and/or a Part D providing plan.

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

The proposed rule provides considerable discussion regarding MCO estimation of beneficiary premium and cost sharing, but does not seek bids and comments on how MCOs will internally calculate and report patient out of pocket (OOP) cost sharing attributed to Part D spend. Genentech suggests that each plan keep detailed electronic records of patient co-payment and coinsurance at the pharmacy and/or physician level in order to ensure beneficiary spend is recorded and calculated appropriately. These records should be available at the point of purchase so that patient co-payment amount is calculated appropriately. Genentech also suggests that an ?indicator? be created, allowing the beneficiary to know when or how close they are to reaching their out-of-pocket maximum under Part D, (e.g. monthly or quarterly statements to the beneficiary detailing MCO and out-of-pocket spend on beneficiary care). Allowing information to be shared across plans if the beneficiary elects to switch is essential to ensuring

beneficiary access to care.

Genentech is surprised that although the proposed rule provides significant discussion on MCO bidding for plan participation under MA, little guidance around the negotiations between MCOs, physicians, Pharmacy Benefit Managers (PBMs), and drug manufacturers is given to support the calculation of such bids, especially for those MCOs who will offer a Part D pharmacy benefit plan. It is crucial that CMS provide general direction regarding this process, ensuring that patient access not be negatively impacted in the process.

CMS-4069-P-33-Attach-1.pdf

CMS-4069-P-33-Attach-1.pdf

CMS-4069-P-33-Attach-1.pdf

CMS-4069-P-34

Submitter : | **Date & Time:** 10/01/2004 07:10:47

Organization : America's Health Insurance Plans

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

attached

CMS-4069-P-35

Submitter : **Mr. Michael Honda** **Date & Time:** **10/01/2004 07:10:39**

Organization : **Congressional Asian Pacific American Caucus**

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

Enclosed please find comments and recommendations regarding 42 CFR Parts 403, 411, 417, and 423, the Medicare Program; Medicare Prescription Drug Benefit; Proposed Rule, which was released on August 3, 2004 from members of the Congressional Asian Pacific American Caucus.

CMS-4069-P-35-Attach-1.pdf

Submitter : Ms. Heidi Margulis **Date & Time:** 10/01/2004 08:10:37

Organization : Humana Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached please find comments from Humana Inc. regarding the CMS proposed rules to establish the Medicare Prescription Drug Benefit and the Medicare Advantage (MA) Program.

CMS-4069-P-36-Attach-1.doc

CMS-4069-P-37

Submitter : **Mr. John Hopkins** **Date & Time:** **10/01/2004 10:10:18**

Organization : **Rocky Mountain Health Plans**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attached File

CMS-4069-P-37-Attach-1.doc

CMS-4069-P-38

Submitter : **Dr. Robert L. Brandt, Jr., MD** **Date & Time:** **10/02/2004 12:10:45**

Organization : **Health Care Interventions**

Category : **Physician**

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

All Medicare recipiants who have a diagnosis of HIV/AIDS (042) must have complete access to all antiretroviral therapy in any shape, form or combination as prescribed by their physician who is credentialed as an HIV/AIDS specialist through the American Academy of HIV Medicine. It is the HIV/AIDS specialist who is most knowledgable regarding their appropriate HIV antiretroviral medication regimen. Such ability will ensure the patients' utmost care and potential for recovery and return to the work force as productive citizens. Please allow the patients this access and their specialicist's ability to treat them unencombered.

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

Any person diagnosed with HIV infection, regardless of their immune status should be eligible for access to all treatment and any medication regimen that their HIV/AIDS doctor recommmends.

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

There should be no restrictions in terms of access to care or to medications as determined by the patient's HIV/AIDS physician.

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

I would recommend that all quality care and monitoring requirements be undertaken by the American Acvademy of HIV Medicine so that uniform treatment codes and procedures would be common place across the country in order to equalize and improve access and improve treatment outcomes to all patients.

Subpart E--Relationships with providers.

There should be no restrictions in a patient's ability to access an HIV/AIDS specialist. All specialists should be credentialed and certified by the American Academy of HIV Medicine. HIV/AIDS diagnosis,treatment and care should be qualified as a speciality area of medicine as other areas are under the American Medical Association (AMA).

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

Should be goverened under current requirements.

Subpart G--Payments for MA organizations.

Should be governed under current Medixcare/Medicaid policy.

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

Should be goverend under current Meicare/Medicaid regulations.

CMS-4069-P-39

Submitter : Dr. jay harrington **Date & Time:** 10/02/2004 12:10:36

Organization : senior whole health

Category : Health Care Industry

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

The proposed regulations define Specialized MA Plans as MA Plans that exclusively serve special needs individuals. Is is suggested that this defination be retained.

The four or more chronic conditions for an enrollee to present a complex medical condition seen reasonable. The criteria employed by the PACE programs would be another acceptable option
Criteria should be established to validate that specialized MA Plans have incorporated processes or clinical programs that are designed to address the unique needs of enrolled special needs beneficiaries. It is doubtful that the complex medical needs of these populations could be met if such programs were not available
We support the proposal that specialized MA Plans should provide part D coverage. However the plans should be allowed to implement their owm pharmacy benefit program.
Specializoed MA Plans should be allowed to exclusively enroll certain sub groups of Medicad or institutionalized beneficaries. The appropoiate sub groups are those CMS has identified, the dually eligible, beneficiaries with severe or chronic conditions, institutionilized beneificiaries and End Stage Renal Disease patients.
Quality oversight mechanisms for specialized MA Plans should be adopted from standards used by PACE programs.

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

We support the suggestion that individuals with a disabiling condition who are not in an institution but require a similar level of care be eligible for enrollment in specialized MA Plans. We also support the inclusion of ESRD beneficiaries in populations eligible for enrollment in specialized MA Plans.
Beneficiaries enrolled in specialized MA Plans should be given "continued eligibility" status that beneficiaries in PACE programs have been granted
Individuals enrolled in specialized MA Plans should be allowed to remained enrolled in the Plan even if they no longer meet the special need criteria if they would again meet eligibilty criteria within six months.
Specialized MA Plans should be defined as an MA Plan which exclusively serves special needs individuals
If CMS decides not to use the "exclusive" standard then it should require specialized MA plans to have at least 85% of their enrollment be from special populations
We support the extension of the File and Use program to specialized MA Plans

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

Specialized MA Plans shold be given the same fragility adjustment that PACE programs receive

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

We support the suggestion to revise 422.402 to clearly state that MA standards supersede State law and regulation with the exception of licensing laws related to Plan solvency

CMS-4069-P-39-Attach-1.wpd

CMS-4069-P-39

CMS-4069-P-39-Attach-1.wpd

CMS-4069-P-39-Attach-1.wpd

CMS-4069-P-39-Attach-1.wpd

CMS-4069-P-40

Submitter : **Ms. Thelma Matthews** **Date & Time:** **10/02/2004 01:10:52**

Organization : **Helping Hand Ministry Foundation, Inc**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

[Thelma Matthews/ Helping Hand Ministry Foundation, Inc.]
[P.O. Box 7846
Spanish Fort, AL 36577]

Centers for Medicare and Medicaid Services Department of Health
and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

To Whom It May Concern:

I am responding to the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am concerned that the current rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit.

CMS must designate people living with HIV/AIDS as a "special population" and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.

Many of the people who are affected/infected by HIV/AIDS are not able to obtain care for their illnesses without the assistance of medicare. Please donot take away that link that is so vitally needed.

Thank you for considering my comments as you finalize the regulations.

Sincerely,

Thelma Matthews, program coordinator
for Helping Hand Ministry Foundation, Inc.

CMS-4069-P-41

Submitter : Mr. Harry Wolin **Date & Time:** 10/02/2004 06:10:21

Organization : Mason District Hospital

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

Dear Administrator McClellan:

On behalf of Mason District Hospital, a Critical Access Hospital located in Mason County, Illinois, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) proposed rule establishing the Medicare Advantage Program.
____

Title II (Medicare Advantage Program)
Relationship Of MA Plans to Critical Access Hospitals:

____

We have significant concern that the proposed rule does not adequately address the relationship that will exist between MA Plans and rural areas served by Critical Access Hospitals. Due to the complexity of the proposed rule, this relationship is impacted both directly and indirectly by several sections of the rule.

Because Critical Access Hospitals are reimbursed by Medicare for treatment to beneficiaries on a cost-based methodology, the rule should include a requirement that MA plans provide reimbursement on a similar cost-based methodology to Critical Access Hospitals.

The reasons that Critical Access Hospitals are reimbursed their cost is the result of policy and legislative action to assure access to services in isolated rural areas. By definition, Critical Access Hospitals are providing service to geographically remote rural communities. Although MA geographic areas have yet to be defined, it is easy to see how small, remote, under-served rural communities could be implicitly excluded as was the case with Medicare+ Choice Plans.

As such, if the MA plans are not required to participate in the Critical Access Program, Medicare Beneficiaries in these areas will be denied the opportunity to obtain the enhanced benefits of the MA program, or alternately, be lured to joining MA Plans that include no local providers. The irony of this scenario is that the cost to the Medicare program would be increased while beneficiaries established local patterns of care would be disrupted.

If MA 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 as fixed costs are spread over fewer patients, i.e., allowing plans to steer patients away from Critical Access Hospitals will cost Medicare more than assuring that plans allow access to these facilities.____

Mason District Hospital appreciates the opportunity to submit these comments on the proposed rule. If you have any questions regarding the comments, please feel free to contact me at (309) 543-8575

Subparts A-I

Subpart E--Relationships with providers.

There is an issue of the default payment to Critical Access Hospitals if the beneficiary is out-of-network. It is easy to say that a Critical Access Hospital 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 Critical Access Hospital that would approximate cost while still allowing for timely settlement of claims. We support the proposal that has been suggested to have the payment rate be the Medicare

interim rate in effect at the time that service was rendered. 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 Critical Access Hospital and verified by the Fiscal Intermediary.

CMS-4069-P-41-Attach-1.doc

CMS-4069-P-41-Attach-1.doc

CMS-4069-P-42

Submitter : Mr. W.J. Francis **Date & Time:** 10/02/2004 09:10:18

Organization : Public Policy Network

Category : Individual

Issue Areas/Comments

Subparts A-I

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

Dear Sirs: here is a comment on subparts I and K.

CMS-4069-P-42-Attach-1.doc

Submitter : Mr. W.J. Francis **Date & Time:** 10/02/2004 09:10:27

Organization : Public Policy Network

Category : Individual

Issue Areas/Comments

Subparts J-M

Subpart K--Application and Contract requirements for
MA organizations.

Dear Sirs: here is an additional comment on subparts I and K.

CMS-4069-P-43-Attach-1.doc

CMS-4069-P-44

Submitter : **Mr. W.J. Francis** **Date & Time:** **10/02/2004 09:10:00**

Organization : **Public Policy Network**

Category : **Individual**

Issue Areas/Comments

Subparts A-I

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

Dear Sirs: here is a corrected comment on network requirements. Please replace my comment of yesterday with this one, which is marked October 2 and "revision." Thank you, W.J. Francis

CMS-4069-P-44-Attach-1.doc

CMS-4069-P-45

Submitter :

Date & Time: 10/03/2004 08:10:25

Organization :

Category : Health Plan or Association

Issue Areas/Comments

Subparts A-I

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

Subpart B.2. Eligibility to Elect a Special Needs MA Plan (Section 422.52(b)) - Basic Eligibility Requirements
Issue: This section identifies dually eligible individuals as among those eligible to elect an MA special needs plan. In the Interim Guidance on MA Special Needs Plans, CMS broadly defines dually eligible individuals to include all of the following: those entitled to Medicare Part A and Part B and full Medicaid benefits, Qualified Medicare Beneficiaries, Special Low-income Medicare Beneficiaries, QI-1s, etc. This would include both dual eligibles with full Medicaid benefits, as well as dual eligibles without full Medicaid benefits, such as QMB only, SLMB only, QDWIs, QI-1s, and QI-2s. MA Special Needs Plans serving dual eligibles would be required to enroll all categories of dual eligibles.

There are a number of Medicaid plans nationally that provide Medicaid benefits on a managed care basis to dual eligibles with full Medicaid benefits, but not to QMBs/SLMBs without full Medicaid benefits. To provide coordinated and integrated care for dual eligibles, MA Special Needs plans must offer a unified benefit package that consolidates both Medicare and Medicaid covered services. However, if required to serve all classes of dual eligibles, such plans would also have to offer Medicaid covered benefits (such as long-term care benefits) to dual eligibles currently are not eligible for full Medicaid benefits.

Proposed Revision to Rule: To address this problem, we recommend that CMS clarify that MA Special Needs plans can indicate that certain benefits, if covered by Medicaid (such as long-term care services), are not uniformly available to all classes of dual eligibles. Instead, MA Special Needs plans may indicate that such benefits may be available for those dually eligible individuals who qualify for them under the applicable state Medicaid program.

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

Subpart C.6. Coordination of Benefits with Employer Group Health Plans and Medicaid (Section 422.106)
Issue: This section indicates that the MMA allows CMS to waive or modify requirements to promote better coordination of benefits with employer group plans and Medicaid programs. This section appears to allow for the restriction and conversion of enrollment to individuals who are already part of the employer group or Medicaid plan.
This section could also apply to dually eligible individuals who are already enrolled in Medicaid managed care plans that are potential MA Special Needs plans. Such individuals currently receive Medicaid benefits on a managed care basis through potential MA special needs plans, and continued enrollment in such plans would allow for continuity of care and improved coordination with their Medicaid benefits. This would be similar to the current EGHP process with existing Medicare Advantage plans that convert commercial enrollment as they achieve Medicare eligibility.

Proposed Revision to Rule: We recommend that existing dually eligible individuals who are enrolled in Medicaid managed care plans that are subsequently designated as MA Special Needs plans remain enrolled in such plans. Such individuals could remain enrolled or choose to elect other MA plans during the appropriate election periods.

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

Subpart D - Quality Improvement Program (Section 422.152)
Issue: This section delineates the requirements set forth for quality improvement projects that could have a favorable effect on health outcomes and enrollee satisfaction.

Proposed Revision to Rule:
We recommend that metrics developed to compare plans be tailored to the specific plan type, particularly MA Special Needs plans, and that the QI program's size and scope be proportionate to the plan size. Because they will serve dual eligible individuals, MA Special Needs plans will likely enroll individuals with more complex health care conditions than the average Medicare beneficiary. As a result, CMS may want to adjust the QI metrics to account for populations served.

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

Subpart F: Submission of Bids, Premiums and Related Information and Plan Approval
Issue: While risk adjustment will help to ensure that plans are paid more accurately for the health status of their members, risk adjustment may only partially recognize the health needs of the dually eligible members. Dually eligible members are significantly more likely to be frail elderly, nursing home certifiable or to reside in a nursing home than the average Medicare enrollee. This issue is of significant concern for those potential MA special needs plans that currently provide Medicaid benefits to dual eligibles, which may attract a greater proportion of frail elderly and nursing home residents.

Proposed Revision to Rule: We recommend that CMS implement a frailty adjuster specifically for MA Special Needs plans. Without a frailty adjuster, it will still be difficult for MA Special Needs Plans to enroll large numbers of frail dually eligible persons, and those dually eligible individuals residing in nursing homes. A frailty adjuster will help to ensure that all dually eligible individuals can be enrolled in MA Special Needs plans.

CMS-4069-P-46

Submitter : | **Date & Time:** 10/03/2004 08:10:05

Organization :

Category : **Health Plan or Association**

Issue Areas/Comments

Subparts A-I

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

Subpart B.2. Eligibility to Elect a Special Needs MA Plan (Section 422.52(d)) - Deeming Continued Eligibility
Issue: This section would deem eligible an enrollee who no longer meets the 'special needs' criteria if the dually eligible enrollee would meet the special needs criteria of the plan within 6 months.

Proposed Revision to Rule: We strongly concur with the deeming language in this section of the proposed rule. Dually eligible individuals often temporarily lose their Medicaid eligibility. We recommend that CMS allow a six-month grace period of continuing enrollment for enrollees to regain their Medicaid eligibility. If, after six months, the enrollee is still no longer Medicaid eligible, then the individual's enrollment in the MA Special Needs plan would be terminated. If eligibility is established retroactively, payment is made to the Special Needs Plans accordingly.

CMS-4069-P-47

Submitter : | **Date & Time:** 10/03/2004 08:10:49

Organization :

Category : **Health Plan or Association**

Issue Areas/Comments

Subparts A-I

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

Subpart B.7. Coordination of Enrollment and Disenrollment Through MA Organizations (Section 422.66) -
Issue: Some potential MA Special Needs plans currently provide the full range of health care benefits to Medicaid beneficiaries on a managed care basis. When these Medicaid beneficiaries turn age 65, they will gain Medicare eligibility and become dually eligible for both programs. As currently drafted, these new dual eligibles would revert to the unmanaged Medicare fee-for-service program if they do not make a positive election into an MA plan.

Proposed Revision to Rule: To avoid the reversion of significant numbers of new dual eligibles back into an unmanaged fee-for-service environment, we recommend that such newly converted dually eligible individuals remain enrolled in the MA special needs plan if that plan provides their Medicaid managed care coverage at the time they gain Medicare eligibility. Such individuals could remain enrolled or choose to elect other MA plans during the appropriate election periods. This proposed revision would minimize potential disruption to the dually eligible enrollee, preserve continuity of care, and reduce the potential significant reversion to unmanaged fee-for-service Medicare and would be consistent with the 'age-in' rule applicable to commercial plans when a worker becomes eligible for Medicare and is a MA member.

CMS-4069-P-48

Submitter : **Dr. Ronald Harlander** **Date & Time:** **10/03/2004 11:10:57**

Organization : **U of Minnestoa**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The passing of a drug benefit card is a great benefit for seniors. This will provide better access to medications. However, the inactment of an medication management program which is open to any health care provider would be an injustice. Very few health care providers are able to adequate answer medication questions. I feel it should be restricted to pharmacist and maybe physicians. By allowing any provider to provide this service would do more harm than good. I hope you take my comments to heart! I appreaciate you allowing me the time to state them. Thanks and take care!

CMS-4069-P-49

Submitter : Mr. Eli Camhi **Date & Time:** 10/04/2004 01:10:28

Organization : NewYork-Presbyterian System SelectHealth

Category : Health Plan or Association

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

Subpart A--General Provisions

The provision of HIV primary care must include access to prescription medications including antiretroviral therapies. Specialized MA plans serving the Medicare-eligible population living with HIV/AIDS should not be required to pay for medications. Such medications should be covered directly by Medicare and/or, when recipients are dually insured, by Medicaid when such prescription coverage is sufficient. In New York State, Medicaid recipients with HIV/AIDS receive their medications through Medicaid whether they are enrolled in HIV Special Needs Plans, Medicaid Managed Care Plans or remain in fee for service.

Specialized MA plans should be permitted to enroll the dually eligible Medicaid population living with HIV/AIDS. Ideally, an HIV Specialist should serve as the Primary Care Provider. However, in some cases, a co-management model consisting of a Primary Care Provider and an HIV Specialist could be acceptable.

Regarding quality oversight mechanisms NYPSSH suggests consideration of the New York State HIV Quality of Care Program described below:

NEW YORK STATE HIV QUALITY OF CARE PROGRAM
The AIDS Institute's program is responsible f or monitoring and improving the quality of medical care and support services provided to people with HIV infection in New York State.

http://www.hivguidelines.org/public_html/center/quality-of-care/quality_of_care_program.htm

HIVQUAL PROJECT
Created to improve the quality of HIV care through building capacity and capability to sustain quality improvement in HIV care.

http://www.hivguidelines.org/public_html/center/quality-of-care/hivqual-project/hivqual-project.htm

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

Subpart B--Eligibility, Election and Enrollment

The current HIV SNP model restricts enrollment solely to Medicaid covered individuals who are HIV infected and their dependent children regardless of HIV status. The complex and chronic care needs of the HIV population justify an exclusive model that insures that resources are aligned with patient care.

Medicaid HIV Special Needs Plans should be allowed to also become MA Specialized Plans serving the HIV/AIDS Medicare population.

CMS-4069-P-49-Attach-1.doc

CMS-4069-P-49-Attach-1.doc

CMS-4069-P-50

Submitter : **Ms. Jane Andrews** **Date & Time:** **10/04/2004 12:10:29**

Organization : **CMS**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

This is a test

CMS-4069-P-50-Attach-1.doc

CMS-4069-P-51

Submitter : **Dr. Daniel Lyons** **Date & Time:** **10/04/2004 12:10:25**

Organization : **Independence Blue Cross**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Comments regarding enrollment of Dual Eligibles

CMS-4069-P-51-Attach-3.doc

CMS-4069-P-51-Attach-2.doc

CMS-4069-P-51-Attach-1.txt

CMS-4069-P-52

Submitter :	Dr. Daniel Lyons	Date & Time:	10/04/2004 12:10:04

Organization : Independence Blue Cross

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached letter

CMS-4069-P-52-Attach-1.doc

CMS-4069-P-53

Submitter : **Ramona Stevens** **Date & Time:** **10/04/2004 01:10:59**

Organization : **Ramona Stevens**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I support the bill but would like to see the following included in the bill ,1.drug plans must carryall the drugs people with AIDS need.2.Meidcare should treatpeople with AIDS as as 'specialneeds poultion'and requrie drug plans to offer them an 'open formulary'3.CMS should ensure that new benefts are of equal or greater quality then those provided by Medicaid 4.Dual eligibles with HIV/AIDS can not risk a gap in coverage during the transition form Medicaid to Meidcare.5Grievance and appeal processes must be effective and easy to use and include the right to getan emergency supply of medications while an appeal is underway.6.Drug plans should not violate the privacy of people with HIV/AIDS and other Medicare beneficiaries

CMS-4069-P-54

Submitter : Mrs. Karen Allenbach **Date & Time:** 10/04/2004 02:10:38

Organization : Mount Carmel Health Plan

Category : Health Plan or Association

Issue Areas/Comments

Subparts A-I

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

We would recommend that there be more definition to whether members can be disenrolled for lack of making their copayments. If we choose do disenroll a member for this reason we would like clear language to enforce this.

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

1)If PPO's are able to waive the conitinuity of care requirement, will there be some allowance for local hmo's to do the same given regional health plans have increased reimbursement and the local hmos have to to more with less. 2) Can there be clarification as to whether making a payment determination of observation is actually a denial or a determination of level of payment.

Subpart G--Payments for MA organizations.

Referring to PM 2880(Modifier and Condition Code for Providers to use when billing for Implantable Automatic Defibrillators for Beneficiaries in a MA Plan), we have had significant problems operationalizing this. We educate providers to bill Medicare, and then the member is charged 20%. Our benefit reads 100% coverage for inpatient care so we have to pay the 20% ourselves. Our reimbursement from Medicare doesn't take this into account. We have had issues with providers not billing Medicare when they should and payment being delayed as a result. We recommend reimbursement rates be adjusted mid-year to reimburse for newly covered procedures as that coverage changes rather than asking providers to bill Medicare....the plan ends up paying the price. Thanks for considering this.

Submitter : Mr. Brandin Hay **Date & Time:** 10/04/2004 02:10:47

Organization : Mr. Brandin Hay

Category : Individual

Issue Areas/Comments

Subparts J-M

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

See attached.

CMS-4069-P-55-Attach-1.doc

CMS-4069-P-56

Submitter : **Nancy Fisher** **Date & Time:** **10/04/2004 02:10:40**

Organization : **Erickson Retirement Communities**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

We are attaching a document that relates to the definition of "special needs individuals," as well as eligibility and election specific to residents of Continuing Care Retirement Communities.

CMS-4069-P-56-Attach-1.doc

CMS-4069-P-57

Submitter : Dr. Lloyd Smith **Date & Time:** 10/04/2004 02:10:26

Organization : American Podiatric Medical Association

Category : Physician

Issue Areas/Comments

Subparts A-I

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

October 4, 2004

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4069-P
P.O. Box 8018
Baltimore, MD 21244-8018

RE: CMS-4069-P
Comments on Medicare Program; Establishment of the Medicare Advantage Program; Proposed Rule (69 Fed. Reg. 46866, August 5, 2004)

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA) is pleased to provide comments on the proposed rule that would create the Medicare Advantage program. Several areas of the rule are of concern to the APMA, the national association representing more than 11,000 doctors of podiatric medicine. We offer the following comments:

Subpart B - Eligibility, Election, and Enrollment (69 Fed. Reg. 46877)

The APMA recognizes the burden of increased regulatory oversight but worries that the proposed streamlined approval of marketing materials will allow Medicare beneficiaries to be confused. Marketing for Medicare + Choice plans was a problem because plans misled beneficiaries or sought to include the healthiest patients while excluding the sickest ones. While we understand that the new streamlined approval process applies to organizations that have consistently demonstrated compliance with established marketing guidelines, we remain concerned that a five-day approval process may not be sufficient to avoid a repeat of previous problems. We recommend that CMS require more stringent review than an automatic approval after five days would allow.

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

Subpart C - Benefits and Beneficiary Protections (69 Fed. Reg. 46878)

The APMA supports the extension of billing protections to beneficiaries enrolled in Medical Savings Accounts (MSAs). We believe that the fee-for-service billing limits that applied to charges that providers could impose ? when providing covered services to enrollees in Medicare Advantage (MA) coordinated care plans where there is no agreement in place governing payment ? should likewise be extended to MSA plan enrollees.

We are concerned with the proposal that would permit MA regional plans to elect any one of the local coverage determinations that applies to original Medicare fee-for-service beneficiaries in any part of an MA region to apply to its enrollees in all parts of an MA region. According to CMS, if the plan chooses to exercise this option, it must elect a single fee-for-service contactor?s local coverage determination (LCD) that it will apply to all members of an MA regional plan. It appears to us that CMS does not intend to require plans electing this option to use all LCDs of a single contractor to apply to all members of the plan. As a result, the injection policy of contractor X may be used while the ulcer debridement policy of contractor Y may be used. We would appreciate confirmation that our understanding of the proposal is accurate.

The APMA believes that this proposal will result in confusion among those who must adhere to the LCD since the MA region may employ a policy that differs from the existing local carrier policy. In recent years, CMS has focused on consolidating local Medicare carriers and in achieving greater consistency in carrier policies among the states governed by a single carrier. The APMA supports local carrier variability and recognizes that standards of care may vary depending upon the geographical area in question and that local policies should reflect local practices. The APMA, along with the podiatric Carrier Advisory Committee (CAC) representatives, has invested significant time and effort in recent years in better educating members about existing LCDs.

We believe that the policies of the MA plan must be identical to the policies of the local Medicare carrier. It is unreasonable to expect physicians and providers to follow different policies for the same service just because a beneficiary is in an MA plan instead of fee-for-service Medicare. Rather than allow the MA plan to select a single contractor?s LCD to apply to all members of the plan, the MA plan should be required to adhere to each of the policies of the local carriers that exist within the MA region, even if they differ. To do otherwise places an undue burden on physicians and providers.

We are supportive of CMS?s clarification on the ?point-of-service?(POS) option, provided this change is properly and sufficiently communicated to plan providers. Providers must be informed of the policy that members cannot be held financially liable when contracting providers fail to follow or adhere to plan referral or pre-authorization policies before providing covered services.

42 CFR Chapter IV Section 422.112 requires Medicare + Choice plans to have provider networks that make all covered services available to enrollees, and Section 422.205 prohibits discrimination based on the degree of the practitioner. Podiatric physicians provide a wide variety of services, both surgical and non-surgical, to Medicare beneficiaries. We believe that all plans must be required to include podiatric physicians in their networks to ensure that the necessary and vital services provided by these physicians continue to be available to patients.

Subparts J-M

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

Subpart M - Grievance, Organization Determinations, and Appeals (69 Fed. Reg. 46911)

CMS is soliciting comments on whether to permit or require network and non-network providers to furnish a type of advance beneficiary notice (ABN) for use when managed care enrollees access non-Medicare covered services. The APMA does not support the required use of an ABN for non-covered services. When services may or may not be covered, then the use of an ABN is appropriate. When a service is non-covered, the additional regulatory burden of completing an ABN should not be imposed on providers.

Within the last couple of years, the APMA worked cooperatively with CMS staff in developing a Notice of Exclusion from Medicare Benefits (NEMB) for non-covered Medicare services. Our members understand that the use of this form is optional and that it may assist them in communicating with Medicare beneficiaries about services that are not covered by Medicare. We believe that providers should be given the option of using a form of this type with beneficiaries, but that to require its use with non-covered services is unreasonable and burdensome.

Conclusion

The APMA appreciates the opportunity to offer these comments. If you require additional information, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

Lloyd S. Smith, DPM
President

CMS-4069-P-57

CMS-4069-P-57-Attach-1.doc

CMS-4069-P-57-Attach-1.doc

CMS-4069-P-57-Attach-1.doc

CMS-4069-P-58

Submitter : | **Date & Time:** 10/04/2004 03:10:59

Organization : AAPPO

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Aee attached files.

CMS-4069-P-58-Attach-1.doc

CMS-4069-P-58-Attach-2.doc

CMS-4069-P-59

Submitter : | **Date & Time:** 10/04/2004 03:10:35

Organization : AAPPO

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached files.

CMS-4069-P-59-Attach-1.doc

CMS-4069-P-59-Attach-2.doc

CMS-4069-P-60

Submitter : Stacy Dixon

Date & Time: 10/04/2004 03:10:35

Organization : Susanville Indian Rancheria

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-4069-P-60-Attach-1.pdf

CMS-4069-P-60-Attach-2.rtf

CMS-4069-P-61

Submitter : **Ms. Debra Ness** **Date & Time:** **10/04/2004 03:10:49**

Organization : **National Partnership for Women**

Category : **Consumer Group**

Issue Areas/Comments

Subparts A-I

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

42 CFR 422
CMS has requested comments on the desirability of either using the same performance metrics across all plan types or tailoring the metrics to specific plan types. The former would permit consumers to compare performance on a given measure among the various types of plans. For example, the consumer could see which plan or plans, whether an HMO or PPO, performs well on preventive care measures, or on treatment of diabetes. The latter would permit comparison only with other plans of the same type.

The National Partnership urges CMS to use the same standardized set of measures for all plans and to report results using the same metrics across all plan types. The measures commonly in use ? HEDIS, CAHPS, the Health Outcomes of Seniors survey ? can be applied in a variety of plan structures. State Medicaid agencies have been measuring performance across plan types for years. Massachusetts and Colorado, for example, have been using the HEDIS measures for both the HMOs that contract with the state to enroll Medicaid beneficiaries and the state?s Primary Care Case Manager (PCCM) program. In both states all the HMO scores (by individual plan) and the PCCM scores are publicly reported, giving consumers readily available data to inform their choice. The New York State annual managed care quality report calculates statewide benchmarks across all plans (commercial and Medicaid), and also reports the scores of each individual plan so separate commercial or Medicaid benchmarks can be developed. Their collective experience suggests, however, that the public reporting of the information is the most critical element, as that permits the data to be tailored for optimum use by its multiple audiences consumers, providers, purchasers, and researchers.

CMS-4069-P-61-Attach-1.doc

CMS-4069-P-62

Submitter : **Ms. Valerie Sellers** **Date & Time:** **10/04/2004 03:10:55**

Organization : **New Jersey Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Subparts A-I

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

Subpart C - Benefits and Beneficiary Protections

422.113 Special rules for emergency services

NJHA supports the proposed change to distinguish between emergency services provided in the emergency department and post-stabilization services that may be provided after admission. The change in definition from emergency services to emergency department services should help both beneficiaries and providers better understand the cost-sharing requirements associated with these services.

Subpart G--Payments for MA organizations.

Subpart G - Payments to Medicare Advantage Organizations

422.318 Special rules for coverage that begins or ends during hospital stay

NJHA supports the addition of language that clarifies MA organizations? responsibility for payment when an enrollee?s coverage begins or ends while the beneficiary is an inpatient in an acute care, rehabilitation or long tern care hospital. We believe it is appropriate for a plan that covered an individual at the time of admission to continue coverage until the patient?s discharge.

Subparts J-M

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

Subpart M - Grievances, Organization Determinations and Appeals

422.566 Organization determinations

NJHA supports CMS?s clarification that reductions in service are organization determinations and as such are appealable if the enrollee disputes the reduction. Providers consider a health plan?s reduction in service to be a medical necessity decision based on the patient?s condition, and have long treated decisions and utilization management determinations that are appealable. The proposed rule is consistent with industry practice.

422.568 Notice requirements for organization determinations

NJHA supports the elimination of the practitioner?s notice requirement. We have long believed that it is the plan?s responsibility to notify the patient regarding any decision by the plan to deny or reduce a service. Placing this responsibility on the provider is not only administratively burdensome for physicians and hospitals but absolves plans from accountability for their utilization management determinations.

422.620 Notice of noncoverage of inpatient hospital care

NJHA supports the concept that CMS is addressing by modifying the rule to remove the requirement that a physician concur with a plan?s decision to deny or reduce care prior to supplying the patient with a written notice of the denial. However, the proposed modification continues to tie physician concurrence with the plan?s decision to discharge or change the level of care. This proposed amendment does not reflect existing industry

practice and assumes an association that simply does not exist.

First, only a physician can discharge a patient or order a change in the treatment of an individual to a lower level of care. The provision as proposed suggests that the plan is discharging or changing the level of care; however, in reality the only role a plan has related to these actions is to notify the provider and/or enrollee that it will no longer pay for additional acute care days.

Second, it will continue to cause confusion for physicians and hospitals to tie physician concurrence to any action by a plan. This was demonstrated by the earlier requirement to obtain physician concurrence prior to supplying a patient with a denial notice. The reality is that physicians may often disagree with a plan?s determination, since the physician who sees the patient daily is in the best position to determine the needs of the patient. By requiring physician concurrence to issue a notice, the earlier rule's provision effectively prevented any number of notices from being issued, simply because the physician did not agree with the plan's decision. The result was the enrollee's inability to begin the appeal process. The proposed change may result in the same unintended consequences: no notice regarding a change in service being issued to the patient because the physician does not concur, and therefore the appeal process cannot begin.

NJHA requests that the entire paragraph related to physician concurrence be eliminated and that plans simply be required to issue a notice of noncoverage to an enrollee at the time it makes a determination to no longer pay for acute care ? without any physician concurrence required for the plan to make its decision. This would greatly simplify the process and allow for the timely initiation of appeals in an enrollee disagrees with the decision to discontinue or reduce the service.

CMS-4069-P-63

Submitter : | **Date & Time:** 10/04/2004 03:10:57

Organization :

Category : **Congressional**

Issue Areas/Comments

Subparts A-I

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

October 4, 2004

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

Dear Dr. McClellan:

We are writing to comment on the CMS Proposed Rule: Medicare Program-Establishment of the Medicare Advantage Program (CMS-4069-P) to encourage you to support the inclusion of specific information regarding the scope of home health coverage provided by Medicare Advantage (MA) plans in any educational or comparative information published by CMS, CMS contractors, and/or by the MA plans.

We believe that Medicare beneficiaries should have adequate information on all Medicare benefits, including home health care, in order to make an informed choice based on their current and potential medical needs. Unfortunately, in the area of home health care, Medicare managed care plans typically do not specify the range of home health coverage that is offered to enrollees. Rather, the plans may simply state that they ?offer home health coverage.? In reality, the actual number (or type) of clinical visits provided for a particular medical condition varies widely among plans.

Seniors or people with disabilities who enroll in a Medicare managed care plan often operate under the assumption that the coverage under their new plan will be the same as what was provided under the traditional Medicare benefit. When the need for home health care arises, they are often surprised to learn that their Medicare managed care plan only covers a few home health visits (compared to an average 16.5 visits per episode of care under the traditional Medicare home health benefit).

For example, an individual recently discharged from a hospital to receive post-surgery home health nursing and therapy for the recovery from a broken hip may receive one to three nursing visits as authorized under his or her Medicare managed care plan, whereas another individual with the same need has coverage for a combination of ten nursing, home health aide, and physical therapy as authorized under a different plan.

To address this disparity that already exists in the Medicare managed care marketplace, we urge you to include a provision in the Final Rule to require both CMS and MA plans to inform beneficiaries of:

? The average number and type of home health visits per episode of patient care that was covered by the Medicare Advantage plan during the prior year;

? The beneficiary?s cost sharing requirements; and

? The names of home health providers who are included in the plan?s network and the number of years that they have operated as a Medicare-certified home health provider

CMS has indicated that it will embark on a significant beneficiary education campaign with respect to the new outpatient prescription drug benefit and the new regional MA plans. It is just as important that beneficiaries receive from CMS complete and accurate information about Medicare

home health coverage. The specificity of medical information and scope of coverage can make a significant difference to the clinical outcomes of these individuals.

Thank you for considering our request.

Sincerely,

Judy Biggert, Member of Congress
Ed Towns, Member of Congress
Vito Fossella, Member of Congress
Eliot Engel, Member of Congress
Chris Smith, Member of Congress
John McHugh,Member of Congress
Henry Hyde, Member of Congress
Frank Pallone, Member of Congress
Ron Paul, Member of Congress
Ted Strickland, Member of Congress
Rosa DeLauro, Member of Congress
Amo Houghton, Member of Congress

CMS-4069-P-63-Attach-1.pdf

CMS-4069-P-64

Submitter : | **Date & Time:** 10/04/2004 03:10:16

Organization : **Medicare Cost Contractors Alliance**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

The Medicare Cost Contractors Alliance is pleased to submit the attached comments on the proposed rule concerning the Medicare Advantage program.

CMS-4069-P-64-Attach-1.doc

CMS-4069-P-65

Submitter : Ms. Hewett Ashbridge **Date & Time:** 10/04/2004 04:10:39

Organization : University of Pennsylvania

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4069-P-65-Attach-2.doc

CMS-4069-P-65-Attach-1.doc

CMS-4069-P-65-Attach-3.doc

CMS-4069-P-66

Submitter : Dr. Margaret P. Moss (Hidatsa/Lakota **Date & Time:** 10/04/2004 04:10:53

Organization : University of MN, Sch of Nursing

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4069-P-66-Attach-1.wpd

CMS-4069-P-67

Submitter : | **Date & Time:** 10/04/2004 04:10:57

Organization :

Category : State Government

Issue Areas/Comments

Subparts A-I

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

Please refer to Word document for comment.

CMS-4069-P-67-Attach-1.doc

CMS-4069-P-68

Submitter : **Mr. Kenneth Hansen** **Date & Time:** **10/04/2004 04:10:30**

Organization : **Samish Indian Nation**

Category : **Other Government**

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-4069-P-68-Attach-1.doc

CMS-4069-P-69

Submitter : **Mr. Dave Baldridge** **Date & Time:** **10/04/2004 04:10:35**

Organization : **National Indian Project Center**

Category : **Individual**

Issue Areas/Comments

Subparts A-I

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

The Medicare Advantage Program contains provisions that will harm Indian clients, who are already receiving "covered" services at no charge through the Indian health care delivery system. In particular, proposed regulations could cause a significant loss of Medicare Part A and Part B reimbursement revenue for Indian health programs. Medicare Advantage plans will be run by private companies who may charge elderly and disabled Indian clients significant premiums and prescription drug costs for health services which are now available without charge through Indian health programs.

CMS-4069-P-69-Attach-1.doc

CMS-4069-P-70

Submitter : Mr. Kevin Costello **Date & Time:** 10/04/2004 05:10:36

Organization : Community Legal Services

Category : Attorney/Law Firm

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

Please see attached document for comments on the proposed Medicare Advantage regulations.

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

Please see attached document for comments on the proposed Medicare Advantage regulations.

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

Please see attached document for comments on the proposed Medicare Advantage regulations.

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

Please see attached document for comments on the proposed Medicare Advantage regulations.

Subpart E--Relationships with providers.

Please see attached document for comments on the proposed Medicare Advantage regulations.

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

Please see attached document for comments on the proposed Medicare Advantage regulations.

Subpart G--Payments for MA organizations.

Please see attached document for comments on the proposed Medicare Advantage regulations.

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

Please see attached document for comments on the proposed Medicare Advantage regulations.

Subparts J-M

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

Please see attached document for comments on the proposed Medicare Advantage regulations.

Subpart K--Application and Contract requirements for
MA organizations.

CMS-4069-P-70

Please see attached document for comments on the proposed Medicare Advantage regulations.

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

Please see attached document for comments on the proposed Medicare Advantage regulations.

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-70-Attach-1.doc

CMS-4069-P-71

Submitter : **Mr. Brent Bauman** **Date & Time:** **10/04/2004 05:10:42**

Organization : **Community Health Partnership, Inc.**

Category : **Health Plan or Association**

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

Subpart A ? General Provisions

Definititions (?422.2)

Importance of Frailty Factor for Special Needs Plans

Currently CMS has recognized the limitations of the HCC risk model for independent frail elderly that are members of PACE organizations or the Wisconsin Partnership Program by reimbursing them an additional frailty factor based on ADLs. We wish to extend our support of the current methodology. While the HCC risk model works very well in general, it does not adequately predict costs for non-institutionalized frail elderly.

We believe the argument for the frailty factor for special needs plans is exactly the same as for the PACE program. The expansion of smaller special needs plans for dual eligible elderly individuals depends on the additional reimbursement from the frailty component. Without it, non-PACE plans cannot focus on non-institutionalized frail elderly, a result that we believe Congress did not intend.

CMS-4069-P-72

Submitter : Ms. Nancy Davidson **Date & Time:** 10/04/2004 05:10:33

Organization : Lash Group Healthcare Consultants

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

It is with great pleasure that Lash Group Healthcare Consultants present comments to the Medicare Program; Establishment of the Medicare Advantage Program [CMS - 4069 -P] Fed. Reg. 46866 (August 3, 2004). We appreciate CMS' efforts to move forward with this historic addition to the Medicare Program. Please feel free to contact us if you have any comments or concerns about our attached comment letter.

Sincerely,

Nancy J. Davidson

CMS-4069-P-72-Attach-1.wpd

CMS-4069-P-73

Submitter : **Ms. Karen Whittington** **Date & Time:** **10/04/2004 05:10:47**

Organization : **Campell University - School of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Subparts A-I

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

Subpart C: Benefit & Beneficiary Protections
Pharmacy Access Standards

Convenience for patients is one of the most important aspects in healthcare, especially in terms of pharmacies. As part of this convenience, it is critical that TRICARE requirements are meet to serve local communities. In communities that are suburban, pharmacies are located virtually on every corner, however this is not the case in rural communities. Without these requirements rural communities may ?slip through the cracks? with the disadvantage of patients having to drive many miles to a pharmacy. It is noted that only 70% of the patients living in rural areas will benefit from this plan in comparison to the 90% patient benefit of those living in urban areas. Fair access would include every type of community for the incentives of this program to be equally advantageous among different groups.

Any Willing Provider

Allowing plans to choose between ?preferred? and ?nonpreferred? pharmacies, may steer business from other pharmacies, which in fact contradicts Congress?s intent on fair access. Although this plan could reduce copayments, it is again an inconvenience for patients who would prefer to keep their same pharmacy and pharmacist.

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

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

I believe that the Medication Management Therapy service will bring about a greater and more respected role for pharmacists. This service will allow pharmacists to make assessments and changes for the medication that the patient is taking. This service is extremely important in monitoring the geriatric community, where harsh drug interactions could occur due to the numerous medications that the patient may be taking. Although doctors play a major role in diagnosis, the pharmacist can identify and improve the quality of drug therapy.

Some of my concerns to help make this program work effectively:

? Define the length of time the beneficiary can use the service (Time per visit and number of visits)
? Remove ?preferred? and ?non-preferred? distinctions for pharmacies so that fees will be the same for all MTMS providers.
? Prepare pharmacists by offering more Continuing Education classes geared toward these services, as well as put in force an initial training program
? Clarify how the payment will be reimbursed
? Clarify if consultation rooms will be added in the pharmacies, so that patients can participate in the confidential service since most pharmacies lack private areas
? Make a schedule where pharmacists are doing consultations at maximum 2-3 days a week for MTM patients. This factor is important because most retail pharmacists are overwhelmed with the number of scripts and consulting would take away from filling prescriptions and consulting non-MTM patients. An alternative would be, hiring consulting pharmacists to provide this service to each region. These traveling consulting pharmacists may help to reduce the overwhelming load that the local pharmacists face everyday. These consulting pharmacists could go to different pharmacies depending on the day or the appointments made by the beneficiaries of the MTM plan.

In conclusion, I urge CMS to reevaluate the following regulations:

1) Require that plans meet the local requirement for TRICARE

2) Remove the ?preferred? and ?non-preferred? definitions for pharmacies
3) Add training requirements, above and beyond those of Continuing Education
4) Add consulting rooms to pharmacies for MTM beneficiaries

Thank you for considering my views

CMS-4069-P-73-Attach-1.doc

CMS-4069-P-73-Attach-1.doc

CMS-4069-P-74

Submitter : **Mrs. Nancy Muller** **Date & Time:** **10/04/2004 05:10:39**

Organization : **National Association For Continence**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

CMS-4069-P-74-Attach-1.doc

CMS-4069-P-75

Submitter : **Ms. Vickie Keys-Lydic** **Date & Time:** **10/04/2004 06:10:58**

Organization : **John Deere Health Care, Inc.**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached comment file.

CMS-4069-P-75-Attach-1.txt

CMS-4069-P-75-Attach-2.txt

CMS-4069-P-76

Submitter : | **Date & Time:** 10/04/2004 06:10:18

Organization : Aetna

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

please see attached two documents

CMS-4069-P-76-Attach-1.doc

CMS-4069-P-76-Attach-2.doc

CMS-4069-P-77

Submitter : | **Date & Time:** 10/04/2004 06:10:41

Organization :

Category : **Other Government**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4069-P-77-Attach-1.doc

CMS-4069-P-78

Submitter : **Mr. Robert Clark** **Date & Time:** **10/04/2004 06:10:29**

Organization : **Bristol Bay Area Health Corporation**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-4069-P-78-Attach-1.pdf

CMS-4069-P-78-Attach-2.rtf

CMS-4069-P-79

Submitter : **Dr. Meghan Gerety** **Date & Time:** **10/04/2004 06:10:36**

Organization : **American Geriatrics Society**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached file

CMS-4069-P-79-Attach-1.doc

CMS-4069-P-79-Attach-2.doc

CMS-4069-P-80

Submitter : **Ms. Deborah Madson** **Date & Time:** **10/04/2004 06:10:07**

Organization : **Blue Cross Blue Shield of Minnesota**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4069-P-80-Attach-1.doc

CMS-4069-P-80-Attach-2.doc

Submitter : Dr. David Scrase **Date & Time:** 10/04/2004 06:10:45

Organization : Presbyterian Health Plan

Category : Health Plan or Association

Issue Areas/Comments

Subparts J-M

Subpart K--Application and Contract requirements for
MA organizations.

The section on which we are commenting is 42 CFR 422.503(b)(4)(vi)(G). Included in this section of the proposed rule are additional requirements for a Medicare Advantage organization?s compliance plan, under ?[P] rocedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization?s MA contract.?

Our comments are directed to the proposed language mandating that:

(2) If, after reasonable inquiry, the MA organization has determined that the misconduct may violate criminal, civil or administrative law, the sponsor must report the existence of the misconduct to the appropriate Government authority within a reasonable period, but not more than 60 days after the determination that a violation may have occurred. If the potential violation related to Federal criminal law, the civil False Claims Act, Federal Anti-Kickback provisions, the civil monetary penalties authorities (primarily under section 1128A and 1857 of the Social Security Act), or related statutes enforced by the HHS Office of the Inspector General, the report must be made to that Office.

PLEASE NOTE: The requirement to self-report was considered, then discarded, during rulemaking for the Medicare + Choice program, between 1997 and 2000.

Two reasons cited for opposing self-reporting, detailed in the preamble to the Final Rule for the Medicare + Choice (M+C) program, are as relevant today as they were in June 2000, when the M+C Final Rule was published:

1. Vagueness: The M+C proposed rule failed to specify what information must be reported. The MA proposed rule does not further clarify this; it only states that the ?existence of the misconduct? must be reported. Given the gravity of the act of reporting suspected violations, it seems highly uncautious for CMS to propose a rule that lacks specificity as to the conditions under which reporting would occur.

2. Unfairness: The essential unfairness of requiring self-reporting requirements for one section of the health care industry, and not all sectors. The objection to self-reporting on the basis of unfairness is self-evident, and, readily acknowledged by authors of the M+C Final Rule in June 2000.

Additional reasons exist to remove the requirement for MA organization to self-report:

1. Absence of data to support the need for this additional compliance requirement: To our knowledge, there has been no indication, from either the Office of the Inspector General nor the Centers for Medicare and Medicaid Services, of widespread industry noncompliance of a degree that would warrant self-reporting by all Medicare Advantage organizations.

2. Administrative burden:. Given the rising cost of health care products and services, including insurance, and federal spending for Medicare, can the cost to companies and oversight agencies for self-reporting be justified, particularly in the absence of data to support the need for self-reporting? We believe it cannot.

3. Existing compliance requirements: We believe existing compliance requirements, addressing virtually every area and operation of our industry, and the programs and initiatives our industry has designed to meet those requirements, have resulted in a set of comprehensive, meaningful and effective safeguards to protect the integrity of Medicare managed care.

CMS-4069-P-82

Submitter : **Helen Spencer** **Date & Time:** **10/04/2004 06:10:17**

Organization : **Helen Spencer**

Category : **Attorney/Law Firm**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4069-P-82-Attach-1.doc

CMS-4069-P-83

Submitter : **Mr. Eben Hopson** **Date & Time:** **10/04/2004 06:10:25**

Organization : **Arctic Slope Native Association, Ltd.**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter and comments.

CMS-4069-P-83-Attach-1.doc

CMS-4069-P-84

Submitter : John Folkemer **Date & Time:** 10/04/2004 07:10:12

Organization : Maryland Dept. of Health and Mental Hygiene

Category : State Government

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

Regarding the definition of Medicare Advantage regional plans in ?422.2, Maryland believes that the purpose of the regional plan designation is to encourage plans to enter or re-enter the market by providing special rules and incentives. Encouraging Medicare Advantage participation is particularly important in Maryland, where almost all Medicare+Choice plans have withdrawn from the market. CMS will establish regions that may include multiple states. Plans may be reluctant to take on multiple states as a specialized Medicare Advantage plan with enrollment limited to Medicaid eligibles for the entire region. To encourage organizations to offer specialized Medicare Advantage plans, a new definition should be added to afford specialized Medicare Advantage plans the status of regional Medicare Advantage plans for most purposes (including special rules and incentives applicable to Medicare Advantage regional plans) without having to cover multiple states.

With regard to whether CMS should allow specialized Medicare Advantage plans to exclusively enroll certain subgroups of Medicaid or institutionalized beneficiaries, requiring a specialized Medicare Advantage plan to be open to all beneficiaries who are members of the relevant special needs category precludes establishment of a specialized Medicare Advantage plan with enrollment limited to Medicaid-eligible institutionalized or dually-eligible beneficiaries who are fully Medicaid-eligible. State Medicaid programs that are developing managed/capitated long-term care projects intended to interface with specialized Medicare Advantage plans are likely to limit enrollments initially to dual-eligibles who are fully-eligible for Medicaid whether in community or institutional settings. The States? ability to recruit organizations that agree to participate in Medicaid special needs programs will be undermined if enrollment in the specialized Medicare Advantage plan cannot be limited to subsets of the dually-eligible and institutional populations served by the State Medicaid programs. This is particularly important in States that have few or no Medicare Advantage plans, but have organizations that are willing to offer specialized Medicare Advantage plans in conjunction with managed Medicaid long-term care programs.

As part of this provision, it is imperative that States be given the authority to auto-enroll certain dual-eligible individuals into specialized Medicare Advantage plans that serve special needs individuals. Maryland is developing a Medicaid ?1115 waiver request that seeks to establish a managed care program(called `CommunityChoice?) for dual-eligible individuals who require long-term care services. These services would be provided through Medicaid managed care organizations (to be known as `community care organizations?) that are also certified as Medicare Advantage plans. The program is scheduled to be implemented at the same time as the Medicare Part D prescription drug benefit. Maryland is seeking the authority to passively enroll individuals eligible for both Medicare and Medicaid in the Medicare Advantage plan that is the same as the Medicaid community care organization, and allow them to change plans during a special election period established under ?423.36.

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

?422.52 (Eligibility to Select a Medicare Advantage Plan for Special Needs Individuals) identifies populations that may enroll in a specialized Medicare Advantage plan (beneficiaries who are ?institutionalized? or ?entitled to medical assistance?). CMS? comments on the proposed regulation indicate that specialized plans will not be allowed to limit enrollment to any subsets of these populations. This means a specialized plan would have to take all comers in an identified special needs category, including institutionalized beneficiaries who are not Medicaid-eligible and duals whose Medicaid eligibility is only partial. This would add additional complexities and serve as a disincentive for participation by a plan whose specific purpose in Medicare Advantage participation would be to complement a specialized State Medicaid program. Unless specialized Medicare Advantage plan enrollment can be limited to beneficiaries with full Medicaid eligibility ? with specified exclusions as included in Maryland?s ?1115 waiver ? the rule will hinder States? development of specialized Medicaid programs that complement coverage by specialized Medicare Advantage plans, and plan recruitment will suffer.

Maryland also believes that the initial and recurring enrollment periods provided in ?422.62 (Election of Coverage Under a Medicare Advantage Plan) will complicate coordination of enrollment in a specialized Medicare Advantage plan and complementary Medicaid managed care plans. A special provision allowing easy entry into specialized Medicare Advantage plans is needed to accommodate States? efforts to implement such complementary programs, and to assist specialized Medicare Advantage plans to reach a viable level of enrollment. A flexible election rule for beneficiaries entering specialized Medicare Advantage plans should be added. Once enrolled in a specialized Medicare Advantage plan, individuals

with special needs can be subject to the usual rules governing Medicare Advantage plan enrollment and dis-enrollment.

Finally, Maryland believes that the rule in ?422.62 (a)(6) (Open Enrollment Period for Institutionalized Individuals) allowing institutionalized beneficiaries to enroll and dis-enroll from Medicare Advantage plans at-will may encourage Medicare Advantage plans to adopt high standards of quality for their network nursing home providers, thereby protecting an especially vulnerable population. It will, however, make it harder for specialized Medicare Advantage plans serving this population to project future enrollment, service costs and provider network needs. Therefore, withdrawal of this special open enrollment provision for institutionalized beneficiaries is recommended. If our previous recommendation is adopted, institutionalized individuals who are not already enrolled in a specialized Medicare Advantage plan would be permitted to enroll in a specialized Medicare Advantage plan at any time. Considered together, these provisions will encourage care continuity and coordination for vulnerable special needs populations.

CMS-4069-P-84-Attach-1.doc

CMS-4069-P-84-Attach-1.doc

CMS-4069-P-85

Submitter : Jack Scott **Date & Time:** 10/04/2004 07:10:25

Organization : UPMC Health Plan/ UPMC Health Network

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached file

CMS-4069-P-85-Attach-1.doc

CMS-4069-P-86

Submitter : **Ms. Deborah Washington-McNeill** **Date & Time:** **10/04/2004 06:10:36**

Organization : **PARTNERS National Health Plans of NC, Inc.**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached file

CMS-4069-P-86-Attach-1.doc

CMS-4069-P-87

Submitter :	**Dr. Mary Hager**	**Date & Time:**	**10/04/2004 07:10:10**
Organization :	**The American Dietetic Association**		
Category :	**Dietitian/Nutritionist**		

Issue Areas/Comments

GENERAL

GENERAL

The American Dietetic Association (ADA) is pleased to make comments about the proposed establishment of the Medicare Advantage (MA) Program published August 3, 2004 in 69CFR46865. The ADA represents nearly 67,000 food and nutrition professionals serving the public through the promotion of optimal nutrition, health and well being.

ADA commends CMS for recognizing the importance of prevention and disease management in containing healthcare costs and in improving the quality of care for Medicare beneficiaries. ADA supports the concept of integrated health plan approaches such as disease prevention, disease management and other care coordination techniques that combine the traditional Parts A and B of Medicare and the new Part D drug benefit and that apply innovative techniques such as telehealth. Coordinated care that includes MNT best serves beneficiary self care management goals that can result in better clinical outcomes, a reduced burden on the healthcare system, and a saving of Medicare dollars.

Comments:
An issue related to all MA programs, including specialized MA plans, is the availability of and access to medical nutrition therapy (MNT). MNT can control severe or disabling chronic conditions and is currently a Medicare covered service for those individuals with diabetes and renal disease. However, there are other chronic conditions, specifically dyslipidemia and hypertension, for which the evidence supports Medicare MNT coverage as stated in the 2004 Report to Congress on Medical Nutrition Therapy from Secretary of Health and Human Services, Tommy Thompson. MA programs have the discretion and legal authority to expand coverage for MNT to other diseases and conditions. We encourage CMS to support MA?s expansions of other evidence-based services such as MNT. The Medical Savings Accounts (MSA) offer beneficiaries an additional way to pay for medically-indicated MNT services for additional diseases and conditions.

We applaud the Secretary for recognizing the value of prevention within Medicare services. We urge coverage for preventive MNT treatment services for individuals who are diagnosed with pre-diabetes, pre-hypertension, and borderline dyslipidemia, which can be accomplished within the MA framework. There is evidence that nutrition interventions can significantly reduce the risk of developing diabetes mellitus in individuals diagnosed with pre-diabetes by reversing disease progression before life-threatening complications develop.

Regarding innovative technologies, ADA requests that Registered Dietitians (RD) be added to the list of Medicare telehealth services as CMS reviews the additional sites and settings, geographic areas, and practitioners that may be reimbursed for the provision of telehealth services. The delivery of Medical Nutrition Therapy through telehealth would promote access to services by underserved populations and support the chronic care model as envisioned in the Chronic Care Improvement Program. MNT telehealth services provided by RDs are currently being utilized by many healthcare systems to optimize clinical and financial outcomes.

ADA urges CMS to ensure that the MNT benefits for diabetes and renal diseases, now incorporated as an integral component of the ?Welcome to Medicare? exam and the Chronic Care Improvement Program, extend to Medicare Advantage programs. We look forwarding to partnering with CMS in educating beneficiaries, physicians, and other qualified non-physician practitioners about accessing and making referrals to MNT benefits covered under Medicare Part B and MA.

Please do not hesitate to call Dr. Mary Hager, Senior Manager, Regulatory Affairs for the American Dietetic Association, at (202) 775-8277 with any questions or requests for additional information.

Best regards,

Pam Michael, MBA, RD
Director of Quality, Outcomes and Coverage

Mary H. Hager, PhD, RD

Senior Manager, Regulatory Affairs

CMS-4069-P-88

Submitter : Ms. Gale Pearce **Date & Time:** 10/04/2004 07:10:27

Organization : Passport Health Plan

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Comments from Passport Health Plan

CMS-4069-P-88-Attach-1.doc

CMS-4069-P-89

Submitter : **Ms. Leslie Fried** **Date & Time:** **10/04/2004 07:10:09**

Organization : **Alzheimer's Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see our attached comments.

CMS-4069-P-89-Attach-1.doc

CMS-4069-P-90

Submitter : **Mr. Keith Pugliese** **Date & Time:** **10/04/2004 07:10:27**

Organization : **Brown and Toland Medical Group**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Brown and Toland Medical Group is an Independent Practice Association ('IPA') of approximately 1,500 physicians providing medical care to approximately 200,000 patients in the San Francisco Bay Area, about 10,000 of whom are enrolled under the Medicare Advantage ('MA') program. Brown & Toland is recognized as a prestigious leader of quality initiatives and disease management programs. As an IPA fully delegated by health plans, Brown & Toland's financially strong and clinically integrated medical services model ensures an enhanced physician-patient relationship and a stable network of providers.

As requested by CMS, our comments on the proposed MA regulations have been included in the appropriate sections below. However, in addition to these comments, we'd like to express a general concern about what we feel is a bias in CMS's policy approach to MA Preferred Provider Organizations ('PPOs'). While we fully support the policy to offer additional choices to Medicare beneficiaries, it is imperative that CMS implement this policy in a way that does not cut quality, network adequacy, or other corners to entice private sector PPOs to join the Medicare program. We provide detail below related to these concerns.

Beyond policies addressed by the proposed MA regulations, we call on CMS to develop and conduct activities to educate and inform Medicare beneficiaries on the differences in the various MA options. This is particularly important in communities where a beneficiary may choose among traditional Medicare, MA coordinated care plans (e.g. Health Maintenance Organizations ('HMOs'), regional and local PPOs), Medical Savings Accounts ('MSAs') and private fee-for-service plans. The education of beneficiaries is critical in understanding these options.

Subparts A-I

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

Subpart C - Benefits and Beneficiary Protection

CMS has solicited comments on its proposal to eliminate most of the continuity and coordination of care requirements under 422.112(b) for MA private fee-for-service plans, MSAs and local and regional PPOs. While we believe elimination of continuity and coordination of care requirements may be appropriate for non-coordinated care MA plans, such as private fee-for-service plans and MSAs, we do not believe that this is appropriate for local and regional PPOs. Medicare beneficiaries typically are cared for by multiple care givers, which requires significant coordination of care to be most effective. To that end, instead of considering the elimination of the coordination and continuity of care requirements, we call on CMS to require all MA PPOs to provide continuity and coordination of care to beneficiaries. To do otherwise leaves the beneficiary with the daunting and complex task of coordinating the care provided to him/her by multiple providers, which will likely result in lower quality and more costly care.

CMS has proposed to relax network adequacy requirements for MA PPOs. Brown & Toland would support this strategy on a very limited basis, such as in rural areas that do not have adequate provider networks. However, MA PPOs operating in areas with sufficient numbers of providers should be held to the same standard as other MA coordinated care plans. Beneficiaries enrolled in a MA PPO without an adequate network of providers will bear the burden of finding care and will face out-of-pocket costs that other MA beneficiaries will not confront.

CMS has proposed to allow MA regional PPOs to elect a local Medicare coverage decision that applies in any part of its region to apply to its beneficiaries in all parts of its region. Brown & Toland recommends that CMS not adopt this strategy as it will create significant problems for beneficiaries and out-of-network providers. If this provision were enacted, a MA regional PPO beneficiary in a region with multiple local medical review policies will not know which local coverage decision is applicable. Similarly, their out-of-network care giver will lack this important information. This will be particularly true in areas where there are several MA plans. A beneficiary or out-of-network provider may believe that a particular local coverage decision applies, only to learn the MA regional PPO has adopted a different coverage decision. This will lead to complex disputes over whether the care should be covered and will likely result in the beneficiary having to pay for care that would otherwise have been

covered. The rule should allow for a beneficiary to receive coverage for a service that is covered by a local coverage decision, regardless of whether the service is not covered by another local coverage decision in the MA regional PPO's service area.

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

Subpart D - Quality Improvement Program

Brown & Toland recommends that CMS add a provision to this section to explicitly allow MA plans to delegate quality improvement activities to capitated IPAs and medical groups that meet CMS's standards for such activities. While utilization management activities are typically delegated to capitated IPAs and medical groups, quality improvement activities are not. Many IPAs and medical groups have developed robust and comprehensive quality improvement and chronic care programs in an effort to improve the health of beneficiaries; however, the lack of delegation of quality improvement activities by MA plans results in inefficiencies when both the MA plan and the IPA/medical group provide similar services to the same beneficiary. Allowing for delegation of quality improvement activities will allow for better coordination of quality improvement services between the MA plan and the IPA/medical group, which will result in higher quality and more cost effective care for the beneficiary.

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

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

In addition to permitting MA plans to use the 75% rebate for reductions in beneficiary cost sharing and premiums, Brown & Toland recommends that CMS modify 422.266 of the proposed regulations to permit MA plans to also use the rebate for stabilizing their provider networks. Recent improvements in provider compensation are not sufficient to ensure stable provider networks. Permitting a portion of the rebate to be used for provider compensation increases will result in increased provider participation in MA products and a more stabilized network, both of which will have an overall positive outcome for beneficiaries.

Additionally, Brown & Toland recommends that CMS modify 422.266 of the proposed regulation to allow MA plans to improve benefits mid-year, as long as these improvements do not result in increased cost to the beneficiary or the Medicare program. Disallowing mid-year benefit improvements is contrary to CMS's efforts, throughout the regulations, to protect beneficiaries.

Subpart G--Payments for MA organizations.

Subpart G - Payment to Medicare Advantage Organizations

Brown & Toland recommends that CMS modify 422.310(d)(4) of the proposed regulations to allow MA plans to include financial incentives in their contracts with providers, not financial penalties. Brown & Toland recognizes the importance of complete data submissions for risk adjustment; however, we believe that incentives are more effective in helping to ensure proper submissions. The health care industry in California has had great success in a pay-for-performance program that provides financial incentives to IPAs and medical groups to encourage outstanding quality health care, including the submission of encounter data. We recommend that CMS use a similar strategy in its efforts to obtain complete risk adjustment data submissions.

Subparts J-M

Subpart K--Application and Contract requirements for
MA organizations.

Subpart K - Contracts with Medicare Advantage Organizations

Section 422.520 of the proposed regulations requires MA plans to meet certain claim prompt payment standards related to fee-for-service claims. This helps to protect fee-for-service providers that provide care to MA beneficiaries. However, the regulations do not set forth any comparable protections for capitated IPAs and medical groups. Brown & Toland recommends that CMS include the following in the final MA regulations:

1) Establish timely payment requirement for capitation that is paid by MA plans to capitated IPAs and medical groups.

2) Set forth requirements for documentation that must be included with the capitation payment. At a minimum, this documentation must be electronic and include all reasonable information that is needed by the capitated IPA or medical group to confirm that the capitation payment from

the MA plan is correct (including disclosing how the plan is paid by CMS).

3) Set a 90-day limitation on a MA plan's ability to retroactively assign/terminate beneficiaries to/from a capitated IPA or medical group.

4) MA plans often use what is called a 'capitation deduction' from its capitation payment to a capitated IPA or medical group as a means of reconciling what the MA plan perceives as a payment dispute or discrepancy. CMS must establish requirements for capitation deductions made by MA plans. All capitation deductions must include reasonable detail so that the capitated IPA or medical group can verify that the deduction is appropriate. Additionally, MA plans should be prohibited from making any retroactive capitation deductions that pertain to issues older than 12 months.

5) Require MA plans to allow their capitated IPAs and medical groups to renegotiate their capitation rate if new benefits are either required by law or added by the MA plan.

6) Require MA plans to provide capitated IPAs and medical groups, on a quarterly basis, with a detailed accounting of the status of any risk arrangements or risk pools (e.g. hospital, pharmacy, etc.) included in the agreement between the MA plan and the capitated IPA or medical group. The detailed accounting must be in a mutually agreed upon electronic format and must include at least the following: a., the total number of member months; b., the total budget allocation for the member months; c., the total expenses paid during the period; d., a description of the incurred but not reported (IBNR) claims methodology used for incurred expenses during the period; and, e., a description of each and every expense allocated to the risk arrangement, including at least beneficiary identification number, date of service, description of service by claim codes, billed charge, net payment amount and date of payment. Additionally, the MA plan should be required to make any risk-sharing payments to an IPA or medical group no later than 180 days after the close of the contract year or contract termination date, whichever occurs first.

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

Subpart M - Grievance, Organization Determinations, and Appeals

CMS has requested guidance on the appropriateness of requiring network and non-network providers to furnish beneficiaries with an 'advanced beneficiary notice' ('ABN') in certain situations, such as when a MA beneficiary accesses non-Medicare covered services. Brown & Toland recommends that CMS not adopt this requirement. Physicians are already overwhelmed with managed care requirements and are not adequately compensated; an ABN requirement would create confusion and add to this burden.

CMS-4069-P-91

Submitter : Mary Kennedy **Date & Time:** 10/04/2004 07:10:53

Organization : Minnesota Department of Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

The attached Word file contains comments on the proposed regulations governing Medicare Advantage, from Mary Kennedy, Medicaid Director, Minnesota Department of Human Services.

CMS-4069-P-92

Submitter : **Mr. Jack Ebeler** **Date & Time:** **10/04/2004 07:10:45**

Organization : **Alliance of Community Health Plans**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

A letter from the Alliance of Community Health Plans' (ACHP), containing comments in a number of issue areas, is attached to this electronic submission.

CMS-4069-P-92-Attach-1.doc

CMS-4069-P-93

Submitter : Ms. Ghita Worcester **Date & Time:** 10/04/2004 07:10:37

Organization : UCare Minnesota

Category : Health Plan or Association

Issue Areas/Comments

Subparts J-M

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

Section 417.402 Extension of Reasonable Cost Contracts: UCare strongly supports the CMS interpretation of the statute requiring cost plan service area reduction where there are two or more MA plans of the same type meeting minimum enrollment requirements that overlap with a portion of the cost plan?s service area. Further, we agree that cost plans be required to operate under the same provisions as other private plans that enter the cost plan?s service area.

It is clear, from both the statutory language and the Conference Committee report, that Congress intended a phase-out of cost contracts under specified circumstances. By setting enrollment thresholds and requiring either two local or two regional MA plans to meet those thresholds, Congress sought to insure that beneficiaries had an adequate number of choices available to them in this event.
Cost contracts are an example of an uneven playing field with MA risk plans. Even though the intent of cost plans is that plans recoup only their administrative costs for running the program, this has not been the experience in the Minnesota market and other areas. Cost products hold many advantages over their risk product counterparts, including not being held financially accountable for the majority of benefits they offer. While they budget for their enrollees at the beginning of a year, if costs exceed budgeted allotments, the health plan is reimbursed for their losses in the settlement process with CMS. In addition to creating a competitive disadvantage, there is little incentive for cost plans to hold down expenses and ensure that care is delivered in an efficient method. Over the past three years, one of our competitors has had a minimum of 17% profit for their cost product as shown in state filings. The current situation not only creates a competitive disadvantage but also discourages the most efficient delivery of health care. Scrutiny to cost plans premium justification should be similar to what is taking place for risk plans.
Section 422.458 MA organizations must be licensed to bear risk in each state within a region: The MMA give CMS the authority to temporarily waive state licensure requirements to facilitate plans in regions encompassing multiple states; however, in this situation, a plan must be licensed in at least one state. UCare would like clarification to determine whether CMS can use its authority to grant the same waiver to local plans seeking service area expansion to bordering states. We would argue that in providing this flexibility to regional plans, Congress intends to facilitate plan choices for beneficiaries. This would apply as well to local plans seeking to become another option for enrollees in neighboring states.

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

Advance beneficiary notices (Preamble, p. 46911-46912): CMS invites comment regarding whether network and non-network providers should be required or permitted to issue a type of advance beneficiary notices (ABNs) to MA enrollees in two situations: when managed care enrollees access non-Medicare covered services and in order to alert MA enrollees to their possible liability for out-of-network services that would otherwise be payable by the MA plan if proper referral were obtained. ABN requirements are difficult to enforce with non-par providers and notices are difficult to operationalize when they pertain only to a small sub-set of the physician practice.

CMS-4069-P-93-Attach-1.doc

CMS-4069-P-93-Attach-1.doc

Submitter : Mr. Guy King **Date & Time:** 10/04/2004 07:10:41

Organization : King Associates

Category : Individual

Issue Areas/Comments

Subparts A-I

Subpart G--Payments for MA organizations.

Comments on Proposed Regulations (file code CMS-4069-P)

There is a deficiency in the proposed regulations that I believe prevents an MSA from being viable under the MA program. The total MA payment on behalf of a beneficiary enrolled in an MSA (the sum of the deposit to the MSA account and the payment to the MSA plan) is not equal to the risk adjusted capitation (benchmark) amount, as it would be for any other local MA plan. Because of this deficiency, beneficiaries and insurance companies cannot be reasonably sure that the Medicare payment will be adequate to cover the cost of care. This deficiency arises because the payment to the MSA plan is risk-adjusted and the deposit to the MSA account is not.

I understand that the problem described above arises because the contribution to the MSA account is, by law, not risk-adjusted. Special Rules for beneficiaries enrolled in MA MSA plans (?422.314) requires, in accordance with subsection 1853(c) of the Act, that the deposit in the MA MSA for each month of enrollment is calculated as the difference between the MSA premium and 1/12 the benchmark amount (annual capitation rate). By definition, the benchmark amount, equivalent to the ?annual Medicare+Choice capitation rate? in subsection 1853(c) of the law (which was not amended by the MMA) is not risk-adjusted. Likewise, the monthly MSA premium is not risk-adjusted because subsection 1854(c) requires that the monthly MSA premium be uniform among individuals, thus precluding risk-adjustment.

I believe that the MSA requirements should be written so that (1) the deposit to the MA MSA account is the difference between the risk-adjusted benchmark amount (annual capitation rate) and the risk-adjusted MSA premium, and (2) the payment to the MSA plan is equal to the risk-adjusted MSA premium. This requirement would result in the total payment (deposit plus payment to MSA insurance plan) being equal to the risk-adjusted benchmark, the same as other MA plan payments. I recognize this change may possibly require legislation. Specifically, subsection 1853(c) of the Act might have to be amended to provide for risk adjustment to the contribution to the MSA account.

As the regulations are currently written, the total MA payment to an MSA plan could be substantially higher or lower than the risk-adjusted benchmark. The attached worksheet illustrates how the total Medicare Advantage payment for a beneficiary enrolled in an MSA does not equal the Medicare Advantage payment for the same beneficiary enrolled in any other plan.

CMS-4069-P-95

Submitter :

Date & Time: 10/04/2004 07:10:54

Organization : New York State Dept. of Health

Category : State Government

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

The New York State Department of Health (Department) has reviewed the proposed rule for the Medicare Program, Establishment of the Medicare Advantage Program (CMS-4069.P). The Department is responsible for regulating managed care organizations in the state and for the implementation and operation of the Medicaid managed care program under the state?s Section 1115 waiver. We offer the following comments:

Subpart-A General Provisions

New York State is well along the way in planning for enrollment of dual eligibles beginning in January 2005 and our program design relies on enrolling dual eligibles in managed care plans that participate in both Medicaid managed care in the state and Medicare Advantage. The Special Needs Plans (SNPs) are of great interest to us and to the plans that serve nearly 2 million Medicaid recipients in New York State. We offer the following comments related to the SNPs based on our recent experience in planning to enroll dual eligibles:

? We would strongly encourage CMS to permit SNPs to enroll a subgroup of dual eligibles. For administrative reasons, there are some subgroups of duals that we will not be enrolling under our dual eligible initiative, for example, those with Medicaid eligibility subject to a spenddown and those without full Medicaid benefits. We believe that allowing a health plan to have the flexibility to limit enrollment in the SNP to a subgroup of dual eligibles will further CMS? stated goal of expanding the availability of private health plan options to Medicare beneficiaries.

? One of the primary challenges New York has faced in implementing its dual eligible program is reconciling the differences in health plan marketing requirements for the Medicare and the Medicaid programs. October 2003 guidance from CMS attempted to clarify this issue by stating that, ?the Medicaid State Agency marketing requirements must be adhered to any time a Medicare Advantage organization conducts marketing activity that is intended to also sell a Medicaid managed care product to the beneficiary.? Marketing requirements for the state Medicaid program and the Medicare Advantage program can be fundamentally different and, in practice, it will not be possible to distinguish the Medicare Advantage marketing encounter with a dual eligible from the Medicaid marketing encounter. We would urge CMS to take this opportunity to set forth workable rules for SNPs and other Medicare Advantage plans to follow when marketing to persons who are dual eligible. We believe that the best approach would be to specify that the Medicare requirements supercede the state Medicaid requirements or, alternatively, to specify that the Medicaid requirements apply only when the marketing staff is solely dedicated to marketing the plan?s Medicaid product.

? Another challenge of implementing the dual-eligible initiative has been the coordination of grievances and appeals for dually eligible enrollees. We urge CMS to take this opportunity to clarify through the rule-making process the grievance and appeals rights of dual-eligible individuals who enroll in a Special Needs Plan or a Medicare Advantage Plan for both their Medicare and Medicaid coverage. We would suggest that the clarification include that Medicare appeal rules would prevail except where Medicaid is the primary payer for the benefit.

? Finally, we support CMS? proposed approach to require SNPs to provide Part D prescription drug coverage. Prescription drug coverage is critical for this population and we believe that it is beneficial to the member to receive such coverage through the same MA plan as they receive the rest of their medical care. For the same reason, we would also encourage CMS to adopt policies and procedures that would auto-assign dually eligible beneficiaries who do not select a Part D prescription drug plan to the Medicare Advantage Plan in which they are enrolled.

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

Subpart I - Organization Compliance with State Law and Preemption by Federal Law

Federal preemption of state laws governing managed care organizations is a long-standing and complicated issue. We appreciate the preamble clarifying that state licensing laws are limited to the requirements for becoming state licensed (for example, filing of articles of incorporation with the appropriate state agency or satisfying state governance requirements) and does not extend to the requirements that a state may impose on

licensed health plans that absent federal preemption must be met as a condition for keeping a state license. We urge CMS to make this clarification in Section 422.402 of the rule.

Subparts J-M

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

Subpart J - Special Rules for MA Regional Plans

The statute requires that CMS establish between 10 and 50 regions within the 50 states and the District of Columbia. Although we have no specific recommendation concerning the appropriate number of regions or the specific factors that should be considered in selecting the MA regions, we wish to inform the decision making process by offering the following information about the insurance marketplace in New York State. Of the over 40 health maintenance organizations certified in New York State, none have developed provider networks that serve the entire state. Moreover, when seeking to implement the state?s Medicaid expansion program for adults, known as Family Health Plus, market review showed that only one Preferred Provider Organization had a provider network that covered a substantial portion of the state.

CMS-4069-P-96

Submitter : | **Date & Time:** 10/04/2004 07:10:12

Organization : **Medicare Payment Advisory Commission**

Category : **Congressional**

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4069-P-96-Attach-1.pdf

CMS-4069-P-97

Submitter : Ms. Judith Mears

Date & Time: 10/04/2004 07:10:54

Organization : Kaiser Permanente

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached comments

CMS-4069-P-97-Attach-1.doc

CMS-4069-P-98

Submitter : **Mr. John Warren** **Date & Time:** **10/04/2004 07:10:21**

Organization : **Colorado Access**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4069-P-98-Attach-1.doc

CMS-4069-P-99

Submitter : **Mr. William Ilgenfritz** **Date & Time:** **10/04/2004 07:10:47**

Organization : **Keystone Health Plan Central**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached

CMS-4069-P-99-Attach-1.doc

CMS-4069-P-100

Submitter : **Kristin Bass** **Date & Time:** **10/04/2004 08:10:17**

Organization : **WellPoint**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attached Files

CMS-4069-P-100-Attach-1.doc

CMS-4069-P-100-Attach-4.doc

CMS-4069-P-100-Attach-2.doc

CMS-4069-P-100-Attach-3.doc

CMS-4069-P-101

Submitter : **Mr. Timothy Teynor** **Date & Time:** **10/04/2004 08:10:53**

Organization : **Aultman Health Foundation - AultCare Health Plana**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached file

CMS-4069-P-102

Submitter : | **Date & Time:** **10/04/2004 09:10:21**

Organization : **America's Health Insurance Plans**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments

CMS-4069-P-102-Attach-1.doc

CMS-4069-P-103

Submitter : **Miss. Heather Olson** **Date & Time:** **10/04/2004 08:10:35**

Organization : **Iowa Hospital Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Attached please find IHA's comments on the Medicare proposed rule to Establish the Medicare Advantage Program.

Heather Olson

CMS-4069-P-103-Attach-1.doc

CMS-4069-P-103-Attach-2.doc

CMS-4069-P-104

Submitter : **Ms. Ghita Worcester** **Date & Time:** **10/04/2004 08:10:10**

Organization : **UCare Minnesota**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached letter for UCare Minnesota's comments on Title II

CMS-4069-P-105

Submitter : Steve Tucker **Date & Time:** 10/04/2004 08:10:57

Organization : PacifiCare Health Systems, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Attached are two documents. One is a cover letter for our comments. The second is our detailed comments.

CMS-4069-P-105-Attach-1.doc

CMS-4069-P-105-Attach-2.doc

CMS-4069-P-106

Submitter : Mr. Steven Lieberman **Date & Time:** 10/04/2004 08:10:11

Organization : The Moran Company

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See attached document.

CMS-4069-P-106-Attach-1.doc

CMS-4069-P-107

Submitter : **Ms. Mary Dewane** **Date & Time:** **10/04/2004 08:10:30**

Organization : **Schaller Anderson**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached document

CMS-4069-P-107-Attach-1.doc

CMS-4069-P-108

Submitter : | **Date & Time:** 10/04/2004 08:10:23

Organization : Parrish, Moody

Category : Other

Issue Areas/Comments

Subparts A-I

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

This comment serves as a response to the 'Establishment of the Medicare Advantage Program' published in the Federal Register on August 3, 2004. Of these proposed implementation provisions we are specifically concerned with the impact of the Medicare Advantage program in rural communities.

Our firm, Parrish, Moody & Fikes, pc, is a public accounting firm located in central Texas that specializes in healthcare. We currently service more than 80 rural hospitals located throughout Texas. The majority of these hospitals are dependent on the Medicare program.

The proposed implementation of the Medicare Advantage program would require MA organizations to contract with local providers in order to ensure that beneficiaries will have access to services. Due to the large number of enrollees, the MA regional plan will be able to secure contracts with providers at substantially discounted rates. Rural hospitals that either must accept a substantially discounted contract with an MA plan or lose patients will be faced with a no win situation- insolvency from low fees or insolvency due to decreased patient volume.

A hospital that is unable to reach a contract agreement with an MA plan may be deemed an 'essential hospital' if the hospital's participation is necessary for the MA plan to meet the provider access requirements; however, 'essential hospital' and 'access requirements' have not been defined.

These proposed rules implementing the Medicare Advantage Program threaten the continued existence of rural hospitals, thus causing the future of rural healthcare to be questionable. Prior legislation has been enacted to protect availability and access to healthcare for rural populations by allowing rural hospitals that meet certain other conditions to elect a designation that provides for more equitable payment. Because of low population densities, high levels of poverty, and large elderly populations, rural hospitals are dependent on Medicare for survival. A designation such as Critical Access, Sole Community or Medicare Dependant allows a hospital to receive enhanced reimbursement, making its survival more viable.

By allowing any patient to be transferred from a Critical Access Hospital (CAH) or possibly even a Sole Community Hospital (SCH) or Medicare Dependant Hospital (MDH) because of the volume decline adjustment, the overall cost will not change in the hospital, but the per day cost will increase because of having less patients. Therefore, the overall cost to Medicare (cost of the CAH plus the new Medicare Advantage cost) will be more than if Medicare did not allow the patient to transfer. Additionally, by having less patients, you could significantly affect access to care because many of these low volume hospital are very unstable and even the slightest decrease could cause the hospital to close.

We urge CMS to protect Critical Access, Sole Community and Medicare Dependent hospitals in rural areas by defining an essential hospital under section 422.112 as a CAH, SCH, and Medicare Dependent or by requiring MA plans to reimburse these special designated hospitals at their current enhanced rates.

Subparts J-M

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

This comment serves as a response to the 'Establishment of the Medicare Advantage Program' published in the Federal Register on August 3, 2004. Of these proposed implementation provisions we are specifically concerned with the impact of the Medicare Advantage program in rural communities.

CMS-4069-P-108

Our firm, Parrish, Moody & Fikes, pc, is a public accounting firm located in central Texas that specializes in healthcare. We currently service more than 80 rural hospitals located throughout Texas. The majority of these hospitals are dependent on the Medicare program.

The proposed implementation of the Medicare Advantage program would require MA organizations to contract with local providers in order to ensure that beneficiaries will have access to services. Due to the large number of enrollees, the MA regional plan will be able to secure contracts with providers at substantially discounted rates. Rural hospitals that either must accept a substantially discounted contract with an MA plan or lose patients will be faced with a no win situation- insolvency from low fees or insolvency due to decreased patient volume.

A hospital that is unable to reach a contract agreement with an MA plan may be deemed an 'essential hospital' if the hospital?s participation is necessary for the MA plan to meet the provider access requirements; however, 'essential hospital' and 'access requirements' have not been defined.

These proposed rules implementing the Medicare Advantage Program threaten the continued existence of rural hospitals, thus causing the future of rural healthcare to be questionable. Prior legislation has been enacted to protect availability and access to healthcare for rural populations by allowing rural hospitals that meet certain other conditions to elect a designation that provides for more equitable payment. Because of low population densities, high levels of poverty, and large elderly populations, rural hospitals are dependent on Medicare for survival. A designation such as Critical Access, Sole Community or Medicare Dependant allows a hospital to receive enhanced reimbursement, making its survival more viable.

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We urge CMS to protect Critical Access, Sole Community and Medicare Dependent hospitals in rural areas by defining an essential hospital under section 422.112 as a CAH, SCH, and Medicare Dependent or by requiring MA plans to reimburse these special designated hospitals at their current enhanced rates.

CMS-4069-P-109

Submitter : **Ms. Mimi Haley** **Date & Time:** **10/04/2004 08:10:29**

Organization : **Group Health Cooperative**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached file.

CMS-4069-P-109-Attach-1.doc

CMS-4069-P-110

Submitter : Mr. Robert Tracy **Date & Time:** 10/04/2004 08:10:59

Organization : Independent Health

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

see attached file

CMS-4069-P-111

Submitter : **Paul Lee** **Date & Time:** **10/04/2004 08:10:19**

Organization : **National Coalition of Local Health Plans**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attached document.

CMS-4069-P-111-Attach-1.pdf

CMS-4069-P-112

Submitter : **Mr. Rick Pollack** **Date & Time:** **10/04/2004 08:10:11**

Organization : **American Hospital Association**

Category : **Association**

Issue Areas/Comments

GENERAL

GENERAL

There is an attached Word file with the AHA's comment letter on this issue. Thank you.

CMS-4069-P-112-Attach-1.doc

CMS-4069-P-113

Submitter : Mrs. Tara Flippin **Date & Time:** 10/04/2004 08:10:42

Organization : OSF HealthPlans, Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

OSF HealthPlans is providing comment to 42 CFR Parts 417 and 422, proposed rule. These comments are to supplement comments, questions and suggestions made directly to CMS staff and administration regarding specific areas of this rule.

OSF HealthPlans is a MA Organization with both an HMO and PPO demonstration plan. We exclusively serve rural and small urban markets in northern and central Illinois. We are very concerned about our ability to continue to participate in the MA program beginning in 2006. We hope that you will consider the impact the rule may have on organizations such as ours.

We want seniors to have viable Medicare options. To help assure this, there must be a level playing field for all Medicare Advantage plans. Unless local health plans are given the opportunity to participate on an equitable basis with new Regional PPOs, hundreds of thousands of seniors will never get a meaningful choice.

The Medicare Payment Advisory Commission has suggested for several years that beneficiaries? choice of delivery system should be financially neutral to the Medicare program. We agree that neutrality between traditional Medicare and private plan offerings in Medicare was not the short term result of the Medicare Modernization Act; however, we do not believe the Congress? intent was to create a financial incentive for beneficiaries to chose a new regional PPO over a local MA plan that has been serving the beneficiaries in its community for many years. Adding another level of disparity between the various types of delivery systems moves us further from the goal of a budget-neutral choice for the Medicare program and its beneficiaries.
The fundamental purpose of Regional PPOs was to assure that seniors not presently served by a private health plan would have an option in addition to traditional Medicare. Many local Medicare Advantage plans currently serve markets that have been shunned by large national corporations. Local plans in these areas have worked hard to develop networks and offer beneficiaries services that exceed the traditional FFS benefit. This effort has not been easy nor lacking in investment of many resources.

Unfortunately, the financial advantages of the regional PPO bidding and payment methodology that the agency proposes will allow these plans to drive us out of the market by offering better benefit packages and better prices. If local MA plans had the same advantages as the regional PPOs, we could compete with them on price and benefits. Unfortunately, the rules as drafted do not create such a level playing field.

We appreciate the fact that you have been working with local health plans on ways to address these inequities. We encourage you to examine all possible ways to provide incentives that will ensure the viability of local health plans that provide services to seniors. In lieu of available regulatory changes, we propose that you consider the development of a Demonstration Project that would result in fair and equitable treatment of local health plans and Regional PPOs. This initiative will give seniors as much choice as possible.

Subparts A-I

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

6. Election of Coverage Under an MA Plan

Consider allowing a special election period to beneficiaries in markets with MA market penetration below 20%. This will allow time for educating beneficiaries as to what MA plans are, the key component to the sales and enrollment process. Our internal data, supported by external analysis, suggests that most beneficiaries in markets where MA market penetration is low and total managed care market penetration is low, enrollment in an MA plan is foreign.

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

11. Access to Services, last paragraph, page 46883

Contracting in rural markets is difficult for ALL MA plans. Make the following exception available to ALL MA plans: ?offer beneficiaries reasonable access to in-network cost-sharing, even if there are no contracted providers of a specific type available in a geographic location within the service area.? ?We propose to permit relaxation of comprehensive network adequacy requirements for MA regional plans, but only to the extent that beneficiaries are not put at risk for high cost sharing related to services received from non-network providers.?

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

5. Requirements for MA Regional Plans and MA Local Plans that are PPOs as Defined in ?422.152(e)

Consideration should be made to remove ?422.152(f)(4) for all MA organizations, making this initiative either 1) voluntary, or 2) only apply to those organizations that serve areas with racial and ethnic minorities of more than 10% of the total population.

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

Please consider and analyze the impact of the differences between the Regional Plan Benchmark and the Local Plan Benchmark, taking special notice of Local Plan Benchmarks exclusively rural and small urban markets.

Local Benchmark $599 !V Local Bid $588 = $11 x .75 = $8.25 rebate to offer mandatory supplemental benefits.

Regional Benchmark $654 !V Regional Bid $605 = $49 x .75 = $36.75 rebate to offer mandatory supplemental benefits.

This results in a significant competitive advantage on behalf of the Regional Plan. This is irregardless of payments made to the plan. The requirement is that a uniform benefit package at a uniform price be offered to all beneficiaries through out the region.

?{ If payments to the Regional Plan are not close enough to the benchmark, then enrollment in rural areas will be compromised.
?{ If payments to the Local Plans are not adjusted, to raise the benchmark, then rural plans will not be able to compete, thus eliminating choice to beneficiaries. (The benefits that can be offered for $36.75 in the example above are far greater than those that can be offered for $8.25).

Subpart G--Payments for MA organizations.

4. Adjustments to Capitation Rates, Benchmarks, Bids, and Payments

Adjustments for intra-area variations, proposed ?422.308 (d)(1) would implement section 1853(a)(1)(F)(i) of the Act, requires CMS to adjust payments for local and regional MA plans to account for variations in ?local payment rates? within each region the plan is serving .

This should be considered by CMS as a tool to use in adjusting the local payment rates, in rural markets, where competing with a regional plan would be cost prohibitive. An adjustment to the payment rate could bring the local plan benchmark to a level play field when competing with benefits offered/calculated from the Regional benchmark. Adjustments may be calculated based upon costs associated with offering similar benefits or a localized derivation of the regional benchmark. Adjustments to the payment rates may be required to be used as benefits, either through decreased cost sharing or increased coverage, to beneficiaries.

CMS-4069-P-113-Attach-1.doc

CMS-4069-P-113

CMS-4069-P-113-Attach-1.doc

CMS-4069-P-113-Attach-1.doc

CMS-4069-P-113-Attach-1.doc

CMS-4069-P-113-Attach-1.doc

CMS-4069-P-113-Attach-1.doc

CMS-4069-P-114

Submitter : Tim Teynor **Date & Time:** 10/04/2004 08:10:20

Organization : Aultman Health Plan, Aultcare

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See attached document.

CMS-4069-P-114-Attach-1.doc

CMS-4069-P-115

Submitter : **Ms. Marcia Stein** **Date & Time:** **10/04/2004 08:10:52**

Organization : **Senior Whole Health, LLC**

Category : **Health Plan or Association**

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

Senior Whole Health, LLC is a Senior Care Organization in MA, formed specifically to address the health and functional needs of dually eligible and MassHealth only seniors. As such, SWH is pleased that the MA legislation specifically addresses the needs of this frail population.

Our comments:

SWH agrees with the need to include Medicare Part D benefits as part of the benefit package for these populations because pharmacy management and compliance is an integral part of medically stablizing this population and controlling cost. However, pharmacy utilization must be risk adjusted to reflect anticipated high utilization in this segment.

On the definition of 'severe or disabiling chronic condition' - if CMS chooses to enroll disabled Medicare dually eligible recipients in special plan - plans must have the ability to limit the age of recipients. The disabled population below the age of 21 requires significantly different provider and service delivery networks which correspond to the different disabling conditions in the population (eg. congential abnormalities, spina bifida, muscular dystrophy).

SWH agrees with CMS decision to enroll specifice subgroups of Medicaid or institutionalized enrollees. On the Medicaid side, we believe the criteria should be community versus institutional corresponding to the PACE program.

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

Subpart B Part 2. - SWH believes that the ability to enroll individuals with disabling conditions will enhance care for these recipients in special plans

We also agree with the proposal to allow recipients to remain in the program if they no longer meet special needs criteria but absent care from the program would be expected to need special needs within the succeeding 6 month period.

SWH believes that the "File and Use" approval process would definitely streamline present processes.

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

SWH believes that special metrics need to be created in order to evaluate special needs plans given the fact that many of the plans will serve diverse populations.

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

SWH believes that adequate reimbursement for services provided is critical for the success of the special plans. The bidding methodology really only addresses the needs of non special MA plans who service a more uniformly distributed population. SWH believes very strongly that the special plans should follow the PACE and SCOs rating methodologies until an adequate risk adjustment methodology can be developed to accurately predict costs in these frail and high cost populations.

CMS-4069-P-116

Submitter : **Barbara Edwards** **Date & Time:** **10/04/2004 08:10:00**

Organization : **Ohio Department of Job and Family Services**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments from the Ohio Department of Job and Family Services Office of Ohio Health Plans regarding the proposed regulations for the Medicare Advantage plans.

CMS-4069-P-116-Attach-1.doc

CMS-4069-P-117

Submitter : Mr. Patrick Killeen **Date & Time:** 10/04/2004 09:10:30

Organization : Gundersen Lutheran Health Plan, Inc.

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4069-P-117-Attach-1.doc

Submitter : Dr. David Scrase **Date & Time:** 10/04/2004 08:10:00

Organization : Presbyterian Health Plan

Category : Health Plan or Association

Issue Areas/Comments

Subparts J-M

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

RE: File code CMS ? 4069 - P
(Proposed Rule: Establishment of the Medicare Advantage Program)

Presbyterian Health Plan (CMS contract H3204) is writing to comment on provisions within the Medicare Prescription Drug, Improvement and Modernization Act (MMA), establishing regional Medicare Advantage preferred provider organizations (MAPPOs), per 42 CFR 422.455(b).

The MMA calls for the creation of a fixed number of MAPPOs within the 50 States, and the District of Columbia, by January 1, 2005. On this issue, Presbyterian offers the following comments:

1. The CMS should make available MA Regional PPOs to Medicare beneficiaries throughout the country by maximizing the number of private sector organizations that have the opportunity to participate in the new MA Regional PPO programs.

2. The CMS should use the individual 50 state boundaries in establishing MAPPO regions to recognize existing business practices and retain existing markets. This allows private entities to: make use of existing provider networks and state licensure; consider the unique socio-economic characteristics within each state; consider state-specific employer group markets and business practices.

3. Regions numbering 24 or less due to the proposed significant and disparate funding, as portrayed in the consultant?s model, are not acceptable to MA Local plans due to the proposed significant and disparate funding allocated across some regional markets. The additional funding to MA Regional PPOs would improve benefits and provider payments over what MA Local plans could provide, if future funding levels for MA Local plans reflect past patterns and amounts.

4. The CMS must allow existing Local MA plans to compete on a level playing field with new MA Regional PPOs by providing financially viable opportunities, CMS mediation with Essential Hospitals, and service area expansion opportunities for MA Local plans (HMO and PPO).

5. To facilitate the offering of MAPPO plans in multiple states, the CMS should streamline administrative processes to avoid duplicative program submissions and marketing material reviews, thereby creating efficiencies and cost-effectiveness crucial to the long-term health of the Medicare Trust Fund.

CMS-4069-P-119

Submitter : Mrs. Mary Ninos **Date & Time:** 10/04/2004 08:10:34

Organization : Coventry Health Care

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached Word document

CMS-4069-P-119-Attach-1.doc

CMS-4069-P-120

Submitter : Mr. Daniel Hilferty **Date & Time:** 10/04/2004 08:10:34

Organization : AmeriHealth Mercy Health Plan

Category : Health Plan or Association

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

comments from AmeriHealth Mercy Health Plan

CMS-4069-P-120-Attach-1.doc

CMS-4069-P-120-Attach-2.doc

CMS-4069-P-121

Submitter : **Melanie Bella** **Date & Time:** **10/04/2004 09:10:29**

Organization : **Indiana - Medicaid Policy and Planning**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

See Attached.

CMS-4069-P-121-Attach-1.pdf

CMS-4069-P-122

Submitter : Ms. Carla Jackson **Date & Time:** 10/04/2004 08:10:17

Organization : Magellan Health Services

Category : Health Plan or Association

Issue Areas/Comments

Subparts J-M

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

COMMENTS ON AUGUST 3, 2004 PROPOSED RULE
MEDICARE PROGRAM; ESTABLISHMENT OF THE MEDICARE ADVANTAGE PROGRAM ? CMS 4069-P

Magellan Behavioral Health, a subsidiary of Magellan Health Services, is the industry leader in comprehensive behavioral care delivery management, serving over 58.7 million lives in all 50 states. Magellan is a subcontractor to several Medicare Advantage Plans.

The following comments refer to Subpart M ? Grievances, Organization Determinations and Appeals.

Magellan Health Services suggests that the Centers for Medicare & Medicaid Services (CMS) consider making a distinction between treatment for physical illness and behavioral health needs for the purpose of requiring the physician who is responsible for the enrollee?s inpatient care to concur with the decision to discharge the enrollee prior to the Medicare Advantage (MA) organization issuing a Notice of Discharge and Medical Appeal Rights (NODMAR) to the enrollee. See Section 422.620. Magellan Health Services believes that the MA organization making a benefit determination based on medical necessity guidelines to discontinue unnecessary inpatient coverage for a behavioral health service scenario should not require the physician?s concurrence.

The scenario here is the enrollee has been admitted under medically necessary or emergency guidelines. The enrollee?s care no longer meets medically necessary guidelines. The MA organization believes the enrollee is in a position to transition to a lower level of care or is stable to transfer to a participating facility based on the enrollee?s clinical presentation, medical necessity guidelines and member benefit plan requirements. However, the physician does not agree. The physician insists on inpatient care and, in turn, consumes the enrollee?s benefits. Therefore, the MA is unable to ensure the enrollee?s benefits are used in the best interest of the enrollee.

If the patient is admitted for treatment related to a physical illness, the payment to the physician or facility is based on a Diagnosis Related Grouping (DRG). This is a very established manner of using the enrollee?s benefits. However, if the patient is admitted for treatment related to a behavioral health need, there is no prescribed regimen. Additionally, the physician and facility are paid on a per diem basis, not a DRG basis, and therefore, there is no incentive on the part of the physician to discharge the patient. Treatment for behavioral health services usually involves varying sequences of treatment, drugs and dosages of drugs. Because this process varies for each person and there is no incentive for the physician to discharge the enrollee, Magellan Health Services is recommending that CMS consider making a distinction between physical illnesses and behavioral health services in Sec. 422.620 and permitting the MA organization to base the discharge on medical necessity guidelines without the physician?s concurrence.

Were the MA organization permitted to base the discharge on medical necessity guidelines without the physician?s concurrence, there is an appeal process in place to protect the enrollee if the physician disagrees with the MA organization. The enrollee may request a Quality Improvement Organization (QIO) review. Additionally, Magellan Health Services is recommending that CMS permit an MA organization to initiate a QIO review to allow for optimal management of the enrollee?s benefits.

Magellan Health Services is recommending that CMS strongly consider making a distinction between physical illness and behavioral health needs in Sec. 422.620 and permitting the MA organization to base the discharge on medical necessity guidelines without the physician?s concurrence. Additionally, Magellan Health Services is recommending that CMS permit an MA organization to initiate a QIO review to allow for optimal management of the enrollee?s benefits.

CMS-4069-P-122

CMS-4069-P-123

Submitter : **Mrs. Ann Berkey** **Date & Time:** **10/04/2004 09:10:27**

Organization : **McKesson Corporation**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

On behalf of McKesson Corporation, I am pleased to submit comments regarding the proposed rule to create the new Medicare Prescription Drug Benefit.

CMS-4069-P-123-Attach-1.doc

CMS-4069-P-124

Submitter : **Valrie Wilbur** **Date & Time:** **10/04/2004 09:10:19**

Organization : **Medicare Policy Coalition**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

The Medicare Policy Coalition for High Risk Beneficiariesis pleased to submit the attached comments.

Submitter : Valrie Wilbur **Date & Time:** 10/04/2004 09:10:09

Organization : Medicare Policy Coalition

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

National Health Policy Group

Improving Payment and Performance for High-Risk Beneficiaries

October 4, 2004

Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

ATTENTION: CMS - 4069- P

Dear Sirs:

The National Health Policy Group appreciates the opportunity to submit comments on the Notice for Proposed Rule Making, which will establish requirements for the Medicare Advantage Program, on behalf of the Medicare Policy Coalition for High Risk Beneficiaries (MPC).

The Medicare Policy Coalition is an alliance of Medicare Advantage Plans and providers that have made a unique commitment to serving high-risk beneficiaries such as the frail elderly and adult disabled. MPC members have a strong interest in the Special Needs Plan designation and other aspects of the Medicare Advantage proposed rule affecting high-risk Medicare beneficiaries as they all currently offer special programs of care for these beneficiaries, many under Medicare demonstrations. Special Needs Plans offer a potential vehicle for the demonstrations to transition to permanent plan status and for non-demonstrations to intensify their focus on targeted beneficiary groups. They also provide a vehicle for more traditional plans and provider networks to develop a specialization in serving special needs beneficiaries.

Thank you for your consideration of our views on the implementation of the Medicare Modernization Act of 2003. If you have any questions regarding the attached comments, please do not hesitate to contact us at 202-264-1508.

Sincerely,

Richard J. Bringewatt Valerie S. Wilbur
President Vice President
Chair, Medicare Policy Coalition Co-chair, Medicare Policy Coalition

801 Pennsylvania Avenue, Suite 245, Washington DC 20004 (202) 624-1516 Fax: (202) 737-6462 www.nhpg.org

CMS-4069-P-126

Submitter : Ms. Christina Metzler **Date & Time:** 10/04/2004 09:10:44

Organization : American Occupational Therapy Association

Category : Health Care Professional or Association

Issue Areas/Comments

Subparts A-I

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

AOTA has received comments and concerns from our members about their relationships with current Medicare+Choice (soon to be Medicare Advantage) contractors and, while our one of our issues is not addressed in the proposed rule, would like to take this opportunity to inform CMS of those problems and express AOTA?s questions about some policies that have had a negative impact on our members and their patients.

The most important issues of concern in the current and future Medicare managed care program to AOTA relate to two issues. First, according to our members, CMS is not requiring current Medicare+Choice contractors to provide certain types of covered services. The above referenced proposed rule does not address this issue specifically and we are writing to ask for clarification and, if indeed full access to covered services is not required, asking for correction in the regulations or manuals.

The experience of AOTA members is that Medicare +Choice plans deny coverage of outpatient occupational therapy solely because of site of service. The site of service in question is the home of the beneficiary. This is separate from coverage of the home health benefit which has completely different rules. Under 42USC1861(g), which refers to 42USC1861(p), outpatient occupational therapy is a covered benefit when furnished by an occupational therapist in his office or the beneficiary?s home. This requirement is, AOTA believes, a basic parameter of the Medicare benefit. It may also be a critical component of quality care as home-based services, such as an evaluation for safety and function post-stroke, may be able to be provided only in the actual place where the individual is at risk, i.e., their home environment. Denials based only on site of service, AOTA would argue, are a denial of the full scope of benefits. AOTA understands that according to personnel in CMS regional offices, site of service is not considered a component of coverage; however, AOTA cannot find reference to this in CMS Manuals.

AOTA urges CMS to provide clarification on the availability of benefits, including outpatient occupational therapy, to beneficiaries in their homes, separate and distinct from the home health benefit. AOTA believes that the availability of ?house calls? by providers who are willing to accept the financial reimbursement of a particular plan should not be arbitrarily discouraged by CMS policy.

In addition, AOTA is very concerned about the new allowance for regional PPOs at 422.101(b)(4) to choose a local medical review policy (LMRP) or local coverage determination (LCD) from among all of those applicable in the regional area without any oversight or review from CMS or the public. At present, other Medicare Advantage plans must submit their choice of LMRP or LCD to CMS for review under existing section 422.101(b)(3)(i) and (ii).

AOTA would urge CMS to change both Sec 422.101(b)(3) and (4) to require public comment on the choice of LCD or LMRP by regional and other Medicare Advantage plans to assure that the most appropriate, contemporary and clinically valid requirements are used to determine coverage of services.

But at a minimum, regional plans should be required to obtain approval from CMS for their choice of coverage guideline just as other Medicare Advantage plans will be required to do.

CMS-4069-P-127

Submitter : | **Date & Time:** 10/04/2004 09:10:37

Organization :

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

test

CMS-4069-P-128

Submitter : **Mr. Herbert Fritch** **Date & Time:** **10/04/2004 09:10:17**

Organization : **HealthSpring, Inc.**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

HealthSpring, Inc.

CMS-4069-P-128-Attach-1.doc

CMS-4069-P-128-Attach-2.doc

CMS-4069-P-129

Submitter : Dr. Harvey Neiman **Date & Time:** 10/04/2004 09:10:06

Organization : American College of Radiology

Category : Radiologist

Issue Areas/Comments

GENERAL

GENERAL

The American College of Radiology (ACR) represents 32,000 Radiologists, Interventional Radiologists, Radiation Oncologists, Nuclear Medicine physicians and Medical Physicists. We appreciate the opportunity to comment on the August 3, 2004 proposed rule on the establishment of the Medicare Advantage program (42 CFR Parts 417 and 422). Please see our comments, attached.

CMS-4069-P-129-Attach-1.pdf

CMS-4069-P-130

Submitter : | **Date & Time:** 10/04/2004 09:10:51

Organization :

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

Comments from Medica Health Plan

CMS-4069-P-130-Attach-1.doc

Submitter : | **Date & Time:** 10/04/2004 09:10:06

Organization :

Category : Health Care Industry

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

Please see attached

CMS-4069-P-131-Attach-1.doc

CMS-4069-P-131-Attach-2.doc

CMS-4069-P-132

Submitter : Valerie Wilbur **Date & Time:** 10/04/2004 09:10:01

Organization : The Social HMO Consortium

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The Social HMO Consortium

October 4, 2004

Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

ATTENTION: CMS - 4069- P

Dear Sirs:

The Social HMO Consortium appreciates the opportunity to submit comments on the Notice for Proposed Rule Making, which will establish requirements for the Medicare Advantage Program.

The Social HMO Consortium represents the four Social HMO demonstration sites including Elderplan, Inc., SCAN Health Plan, Senior Advantage II of the Kaiser Permanente Northwest Division and Sierra Health Services/Health Plan of Nevada. The Comments herein are limited to the proposed rules for Specialized Medicare Advantage Plans for Special Needs Individuals and selected provisions related to bidding, payment, the dually eligible and issues of special interest to specialty plans serving high-risk Medicare beneficiaries.

Thank you for your consideration of our views on the implementation of the Medicare Modernization Act of 2003. If you have any questions regarding the attached comments, please do not hesitate to contact us or Valerie Wilbur, our senior policy advisor, at 202-624-1508.

Sincerely,

Eli Feldman
President & CEO
Elderplan

Ronnie Grower
Vice President for Quality Improvement
And Reporting
Sierra Health Services/
Health Plan of Nevada

Lucy Nonnenkamp
Project Director
Senior Advantage II

Kaiser Foundation Health Plan of the Northwest

Timothy Schwab, M.D.
Chief Medical and Information Officer
SCAN Health Plan

Social HMO Consortium Members

Eli Feldman
President & CEO
Metropolitan Jewish Health System
6323 Seventh Avenue, 3rd Floor
Brooklyn, NY 11220-4711
Phone: (718) 921-8066
Fax: (718) 921-1616

Ronnie Grower
Vice-President for Quality Improvement
and Reporting
Health Plan of Nevada
PO Box 15645
Las Vegas, NV 89114-5645
702-242-7356

Lucy Nonnenkamp
Kaiser Permanente Northwest Division
2701 NW Vaughn, Suite 160
Portland, OR 97210
(503) 499-5794
(503) 499-5719-fax

Tim Schwab, M.D.
Chief Medical/Information Officer
SCAN Health Plan
3800 Kilroy Airport Way, Suite 100
Long Beach, CA 90801-5616
Phone: (562) 989-8309
Fax: (562) 989-9439

CMS-4069-P-132-Attach-1.doc

CMS-4069-P-133

Submitter : Dr. William E Mitch **Date & Time:** 10/04/2004 09:10:06

Organization : American Society of Nephrology

Category : Health Care Professional or Association

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

American Society of Nephrology
1725 I Street, N.W., Suite 510
Washington, D.C. 20006
202-659-0599

October 4, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4069-P
PO Box 8018
Baltimore, MD 21244-8018

RE: Proposed Rule: Medicare Program Establishment of the Medicare Advantage Program

Dear Sir or Madam:

The American Society of Nephrology (ASN) is a professional association with approximately 8,500 members. Of this membership, about 95% are physicians, with the remaining members basic scientists with a primary interest in renal disease. Virtually every licensed nephrologist in the United States is a member of the ASN, with an additional 3,000 nephrologists from 82 other countries comprising the remainder of our membership. The Society is focused on promulgating innovative research related to renal disease, and on providing continuing medical education to physicians and scientists dedicated to the improved understanding and treatment of renal disease.

The ASN welcomes the opportunity to respond to the Notice of Proposed Rule Making (42 CFR Parts 417 & 422), published in the Federal Registrar on August 3, 2004. ASN comments focus on your request for comments on whether Medicare beneficiaries with End Stage Renal Disease (ESRD) should be allowed to enroll in Medicare Advantage programs for patients with specialized needs.

The ASN joins with the renal community in (its historic) opposition to attempts to repeal the prohibition contained in 42 USC section 1395 w-21. The ASN recognizes the critical role of nephrologists in the care of dialysis patients. Our opposition to enrolling ESRD patients in managed care is based on the following arguments:

1. Managed care plans disrupt existing relationships between patients and health care providers, forcing patients to switch to network doctors and clinics forfeiting established institutions and health care personnel;

2. Nephrologists are not considered `primary care physicians? in the managed care setting, which hampers the ability to care for ESRD/renal patients secondary to the need for referrals and pre-approval for certain diagnostic tests;

3. Managed care plans have an incentive to restrict access to more costly specialized services that ESRD Medicare beneficiaries require;

4. If ESRD patients decide to join a managed care plan and ultimately decline or drop Medigap insurance, they will be permanently locked into managed care; ESRD patients could not switch back to Medicare fee-for-service because ESRD is considered a pre-existing condition and would make them ineligible for Medigap coverage;

5. Presently, there is no way for CMS to monitor the quality of care provided to dialysis patients who are enrolled in managed care plans. CMS ESRD Clinical Performance Measures data are extracted from billing information dialysis providers submit to Medicare, which then become part of the Medicare common working file. Additionally, dialysis providers do not bill Medicare for the services they provide to ESRD beneficiaries covered by a Medicare risk plan.

In the March 2004 Medicare Payment Advisory Commission (MedPac) Report to Congress they state a special needs Medicare Advantage program tailored for ESRD patients should be more attuned to their needs than a Medicare Advantage plan in which ESRD patients constitute an insignificant percentage of enrollees.

The continuity of ESRD patient care is essential given its complex nature. Existing ESRD patient ? physician relationships should not be disrupted unnecessarily. Patients and family members and friends depend upon the comfort provided by physicians and health care workers they know and trust. MedPac argues that ESRD patients should have the same ability to choose managed care that other Medicare beneficiaries have. Conversely, protections should be provided by statute or regulation to assure that ESRD patients

CMS-4069-P-133-Attach-1.txt

CMS-4069-P-133-Attach-2.txt

CMS-4069-P-134

Submitter : **Ms. trisha kurtz** **Date & Time:** **10/04/2004 09:10:01**

Organization : **jcaho**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-4069-P-134-Attach-1.doc

CMS-4069-P-135

Submitter : | **Date & Time:** 10/04/2004 09:10:33

Organization : NCQA

Category : Health Care Industry

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

See attached

CMS-4069-P-136

Submitter : Mr. Jerrold Hercenberg **Date & Time:** 10/04/2004 09:10:44

Organization : BeneSolutions, LLC

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4069-P-136-Attach-1.pdf

Submitter : Valerie Wilbur **Date & Time:** 10/04/2004 09:10:19

Organization : Medicare Policy Coalition High Risk Beneficiaries

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

National Health Policy Group

Improving Payment and Performance for High-Risk Beneficiaries

October 4, 2004

Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

ATTENTION: CMS - 4069- P

Dear Sirs:

The National Health Policy Group appreciates the opportunity to submit comments on the Notice for Proposed Rule Making, which will establish requirements for the Medicare Advantage Program, on behalf of the Medicare Policy Coalition for High Risk Beneficiaries (MPC).

The Medicare Policy Coalition is an alliance of Medicare Advantage Plans and providers that have made a unique commitment to serving high-risk beneficiaries such as the frail elderly and adult disabled. MPC members have a strong interest in the Special Needs Plan designation and other aspects of the Medicare Advantage proposed rule affecting high-risk Medicare beneficiaries as they all currently offer special programs of care for these beneficiaries, many under Medicare demonstrations. Special Needs Plans offer a potential vehicle for the demonstrations to transition to permanent plan status and for non-demonstrations to intensify their focus on targeted beneficiary groups. They also provide a vehicle for more traditional plans and provider networks to develop a specialization in serving special needs beneficiaries.

Thank you for your consideration of our views on the implementation of the Medicare Modernization Act of 2003. If you have any questions regarding the attached comments, please do not hesitate to contact us at 202-264-1508.

Sincerely,

Richard J. Bringewatt Valerie S. Wilbur
President Vice President
Chair, Medicare Policy Coalition Co-chair, Medicare Policy Coalition

801 Pennsylvania Avenue, Suite 245, Washington DC 20004 (202) 624-1516 Fax: (202) 737-6462 www.nhpg.org

CMS-4069-P-137

CMS-4069-P-137-Attach-1.doc

CMS-4069-P-138

Submitter : Valerie Wilbur **Date & Time:** 10/04/2004 09:10:50

Organization : Social HMO Consortium

Category : Health Plan or Association

Issue Areas/Comments

GENERAL

GENERAL

The Social HMO Consortium

October 4, 2004

Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

ATTENTION: CMS - 4069- P

Dear Sirs:

The Social HMO Consortium appreciates the opportunity to submit comments on the Notice for Proposed Rule Making, which will establish requirements for the Medicare Advantage Program.

The Social HMO Consortium represents the four Social HMO demonstration sites including Elderplan, Inc., SCAN Health Plan, Senior Advantage II of the Kaiser Permanente Northwest Division and Sierra Health Services/Health Plan of Nevada. The Comments herein are limited to the proposed rules for Specialized Medicare Advantage Plans for Special Needs Individuals and selected provisions related to bidding, payment, the dually eligible and issues of special interest to specialty plans serving high-risk Medicare beneficiaries.

Thank you for your consideration of our views on the implementation of the Medicare Modernization Act of 2003. If you have any questions regarding the attached comments, please do not hesitate to contact us or Valerie Wilbur, our senior policy advisor, at 202-624-1508.

Sincerely,

Eli Feldman
President & CEO
Elderplan

Ronnie Grower
Vice President for Quality Improvement
And Reporting
Sierra Health Services/
Health Plan of Nevada

Lucy Nonnenkamp
Project Director
Senior Advantage II

Kaiser Foundation Health Plan of the Northwest

Timothy Schwab, M.D.
Chief Medical and Information Officer
SCAN Health Plan

Social HMO Consortium Members

Eli Feldman
President & CEO
Metropolitan Jewish Health System
6323 Seventh Avenue, 3rd Floor
Brooklyn, NY 11220-4711
Phone: (718) 921-8066
Fax: (718) 921-1616

Ronnie Grower
Vice-President for Quality Improvement
and Reporting
Health Plan of Nevada
PO Box 15645
Las Vegas, NV 89114-5645
702-242-7356

Lucy Nonnenkamp
Kaiser Permanente Northwest Division
2701 NW Vaughn, Suite 160
Portland, OR 97210
(503) 499-5794
(503) 499-5719-fax

Tim Schwab, M.D.
Chief Medical/Information Officer
SCAN Health Plan
3800 Kilroy Airport Way, Suite 100
Long Beach, CA 90801-5616
Phone: (562) 989-8309
Fax: (562) 989-9439

CMS-4069-P-138-Attach-1.doc

CMS-4069-P-139

Submitter :	**Ms. Margaret O'Kane**	**Date & Time:**	**10/04/2004 09:10:50**

Organization : **National Committee for Quality Assurance**

Category : **Health Care Industry**

Issue Areas/Comments

Subparts A-I

Subpart A--General provisions, establishment of the
Medicare Advantage program, definitions, types of MA plans, and user fees.

Please see attached

CMS-4069-P-139-Attach-1.doc

CMS-4069-P-140

Submitter : **Mr. Beau Washington** **Date & Time:** **10/04/2004 09:10:13**

Organization : **Mr. Beau Washington**

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-4069-P-140-Attach-1.rtf

CMS-4069-P-141

Submitter : Senators Dole and Reed **Date & Time:** 10/04/2004 09:10:04

Organization : United States Senate

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

October 4, 2004

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

Dear Dr. McClellan:

We are writing to comment on the CMS Proposed Rule: Medicare Program-Establishment of the Medicare Advantage Program (CMS-4069-P) to encourage you to support the inclusion of specific information regarding the scope of home health coverage provided by Medicare Advantage (MA) plans in any educational or comparative information published by CMS, CMS contractors, and/or by the MA plans.

We believe that Medicare beneficiaries should have adequate information on all Medicare benefits, including home health care, in order to make an informed choice based on their current and potential medical needs. Unfortunately, in the area of home health care, Medicare managed care plans typically do not specify the range of home health coverage that is offered to enrollees. Rather, the plans may simply state that they ?offer home health coverage.? In reality, the actual number (or type) of clinical visits provided for a particular medical condition varies widely among plans.

Seniors or people with disabilities who enroll in a Medicare managed care plan often operate under the assumption that the coverage under their new plan will be the same as what was provided under the traditional Medicare benefit. When the need for home health care arises, they are often surprised to learn that their Medicare managed care plan only covers a few home health visits (compared to an average 16.5 visits per episode of care under the traditional Medicare home health benefit).

For example, an individual recently discharged from a hospital to receive post-surgery home health nursing and therapy for the recovery from a broken hip may receive one to three nursing visits as authorized under his or her Medicare managed care plan, whereas another individual with the same need has coverage for a combination of ten nursing, home health aide, and physical therapy as authorized under a different plan.

To address this disparity in the Medicare managed care marketplace, we urge you to include a provision in the Final Rule to require both CMS and MA plans to inform beneficiaries of:

? The average number and type of home health visits per episode of patient care that was covered by the Medicare Advantage plan during the prior year;

? The beneficiary?s cost sharing requirements; and

? The names of home health providers included in the plan?s network and the number of years they have operated as a Medicare-certified home health provider.

CMS has indicated that it will embark on a significant beneficiary education campaign with respect to the new outpatient prescription drug benefit and the new regional MA plans. It is just as important that beneficiaries receive from CMS complete and accurate information about Medicare home health coverage. The specificity of medical information and scope of coverage can make a significant difference to the clinical outcomes of

these individuals.

Thank you for considering our request.

Sincerely,

Senator Elizabeth Dole
Senator Jack Reed
Senator Wayne Allard
Senator James Jeffords
Senator Susan Collins
Senator Lincoln Chafee
Senator Ben Nighthorse Campbell
Senator Hillary Rodham Clinton
Senator Charles Schumer
Senator Jon Corzine
Senator Russell D. Feingold
Senator Ron Wyden
Senator Frank R. Lautenberg
Senator Jon Kyl
Senator Barbara A. Mikulski

CMS-4069-P-141-Attach-1.pdf

CMS-4069-P-142

Submitter : Robert Pascasio **Date & Time:** 10/04/2004 10:10:04

Organization : Bayside Community Hospital

Category : Critical Access Hospital

Issue Areas/Comments

Subparts A-I

Subpart E--Relationships with providers.

The federal government, and our local community, have invested heavily these past few years to insure the long-term viability of our institution. Please do not allow anything to occur that would undermine those efforts, including allowing managed care organizations to contract CAH facilities such as ours for less than cost. It is bad enough that we can not recover cost in the commercial market, please do not allow it to occur in the governmental market as well. There is no doubt in my mind that allowing such to occur will spell the end of rural hospitals across America.

CMS-4069-P-143

Submitter : Lee Olson **Date & Time:** 10/04/2004 10:10:34

Organization : Southcentral Foundation

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-4069-P-144

Submitter :	**Mr. David Schulke**	**Date & Time:**	**10/04/2004 10:10:37**
Organization :	**American Health Quality Association**		
Category :	**Association**		

Issue Areas/Comments

Subparts A-I

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

Document Attached

CMS-4069-P-144-Attach-1.doc

CMS-4069-P-145

Submitter : Ifeoma Achusim **Date & Time:** 10/05/2004 03:10:24

Organization : APhA-Academy of Student Pharmacists

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

PROVIDER OF MTM AND PAYMENT.
Iam glad for the opportunity afforded me as a pharmacy student to comment on the medicare part D rule. In my capacity as a pharmacy student I believe, Pharmacists should play a key role in determining medication therapy management (MTM) services providers for this is the area they know very well. For this program to be successful, the center for medicare and medicaid services (CMS) should exploit the expertise of the pharmacists to improve the patients medication therapy outcomes not just for the total cost contentment but better health for the patient to enjoy. CMS rules must allow for all the Pharmacists to participate in the program at all healthcare settings for medicare patient including but not limited to rurual area, Suburban and urban areas.
Adequate reimbursement plans should be made on how to pay the pharmacists that participated in providing the MTM services promptly.
In summary Pharmacist should be the main component of the new medicare benefit, as these patients mostly depend on their Pharmacist for advice and counsel. This is also the opportunity for the CMS to tap into the wealthy knowledge of Pharmacist for the good of the general public. The willing Pharmacist should be given the chance to participate and adequately paid to keep the ball rolling. Thanks!