

Submitter :  Date & Time:

Organization :

Category :

**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 examine 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.

Submitter :  Date & Time:

Organization :

Category :

**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 clarify 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 beneficiary 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 providers 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.

Submitter :  Date & Time:

Organization :

Category :

**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.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attachment.

## **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](mailto:ddigiuseppe@chpw.org)

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.

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? Millions 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 McClellan will be putting his health economics before his medical ethics as he promotes poor continuity of care for many original Medicare enrollees.

Submitter :  Date & Time:

Organization :

Category :

**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".

Submitter :  Date & Time:

Organization :

Category :

**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 completely uninsured and put us in terrible perdicament.

Submitter :  Date & Time:

Organization :

Category :

**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

Submitter :  Date & Time:

Organization :

Category :

**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.

Submitter :  Date & Time:

Organization :

Category :

**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 nephrologist 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

Submitter :  Date & Time:

Organization :

Category :

**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.

Submitter :  Date & Time:

Organization :

Category :

**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

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

Submitter :  Date & Time:

Organization :

Category :

**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**

Dear Dr. McLellan,

I am writing on behalf of the Texas Organization of Rural & Community Hospitals. Together we represent 160 rural hospitals across the great State of Texas. We appreciate the opportunity to submit comments in writing on this new and important enhancement to the Medicare program. Our comments regarding Medicare Advantage are focused on three areas: regional boundaries, hospital reimbursement and the term “Essential Access Hospital.”

§ 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.

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§ 422 Subpart E—Relationships with Providers

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We feel strongly that in order to attract rural hospitals that have special payment provisions, some guaranteed level of reimbursement needs to be assured. Much thought needs to go into the number and scope of the Advantage program regions and it would help to maintain terminology and processes that are familiar to the rural providers. We hope that CMS will offer a second comment period prior to implementation of a final rule. Please consider contacting us if you desire any further information.

Sincerely,  
David Pearson  
Vice-President, Advocacy/Communications  
TORCH

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

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

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

September 28, 2004

File Code CMS-4069-P

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8013  
Baltimore, MD 21244-8013

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

Dear Administrator:

The Jamestown S'Klallam Tribe is concerned about the impact of the proposed regulations for the Medicare Advantage (MA) program (Medicare Part C) published in the federal register on August 3, 2004. As drafted, these rules do not even mention American Indians/Alaska Natives (AI/AN), tribes, tribal organizations, tribal health services or the Indian Health Service, thus making Medicare Advantage plans virtually unavailable to AI/AN who depend on Indian health programs. We are especially concerned about potential negative impacts on AI/AN dual eligibles and tribes should States employ special needs T XIX MA plans.

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.

I strongly endorse the following comments, which have also been adopted by the CMS Tribal Technical Advisory Group and the National Indian Health Board.

### **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.<sup>1</sup> Pursuant to statutory directive,<sup>2</sup> 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 than most Americans. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights<sup>3</sup> 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.

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<sup>1</sup> See, e.g., 25 U.S.C. § 1601.

<sup>2</sup> 42 U.S.C. § 2001.

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

- 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<sup>4</sup>, 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 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.

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

A sizeable portion of the patient base for I/T/U pharmacies consists of dual eligibles. IHS estimates that there are between 25,963<sup>5</sup> and 30,544<sup>6</sup> 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.<sup>7</sup> 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.

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**<sup>8</sup> and **\$53.6 million**.<sup>9</sup> 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.

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<sup>5</sup> This number represents 85 percent of the three-year total of active users.

<sup>6</sup> This is the number of active users, defined as at least one visit in the past three years.

<sup>7</sup> 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.

<sup>8</sup> 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.

<sup>9</sup> This higher number uses the 30,544 number of dual eligibles in 2003 and the \$1,756 estimated spending in 2006.

## **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 choose 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.

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.<sup>10</sup>

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<sup>10</sup> 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.

- 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.
    - 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, copayments, 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 copayments 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.

Sincerely yours,

W. Ron Allen  
Chairman/Executive Director

Submitter :  Date & Time:

Organization :

Category :

**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 assure 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

## **Docket: CMS-4069-P**

Medicare Program; Establishment of the Medicare Advantage Program

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

Although there are references to Essential Hospitals they are not defined and there is no assurance that Critical Access Hospitals are included in this definition although many Critical Access Hospitals have been established under other essential provider classification guidelines.

Critical Access Hospitals and Provider Bases Rural Health Clinics have been established in many communities across the country in an effort to retain healthcare services available in those small, rural communities. These promulgations make no reference to the special reimbursement mechanism in place for Critical Access Hospital and Provider Based Rural Health Clinics currently in place.

Please add the appropriate definitions 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 should continue as currently in place in order to assure the continuation of these rural providers.

Subpart E – Relationship 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 rate; however, it is anticipated that the beneficiary may have to pay higher out of network deductibles 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 mechanism that assures 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 suggest that it be mandated that special consideration be given to Critical Access Hospitals and Provider Based Rural Health Clinics by MA organization to be included as in-network providers while being reimbursed at a level consistent with the current reimbursement rates.

“(ii)” makes exception for 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.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attached.

**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 Indians 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 R. Delabreau, Chairperson

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.<sup>1</sup> Pursuant to statutory directive,<sup>2</sup> 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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<sup>1</sup> See, e.g., 25 U.S.C. § 1601.

<sup>2</sup> 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<sup>3</sup> 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<sup>4</sup>, 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%

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

<sup>4</sup> 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<sup>5</sup> and 30,544<sup>6</sup> 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.<sup>7</sup> 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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<sup>5</sup> This number represents 85 percent of the three-year total of active users.

<sup>6</sup> This is the number of active users, defined as at least one visit in the past three years.

<sup>7</sup> 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<sup>8</sup>** and **\$53.6 million<sup>9</sup>**. 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 Medicare. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for affected 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 an 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 choose 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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<sup>8</sup> 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.

<sup>9</sup> 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.<sup>10</sup>
  - 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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<sup>10</sup> 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)(i) *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.

Submitter :  Date & Time:

Organization :

Category :

**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,

A handwritten signature in cursive script that reads "Joan R. Delabreau".

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:

- o 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.<sup>1</sup> Pursuant to statutory directive,<sup>2</sup> 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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<sup>1</sup> See, e.g., 25 U.S.C. § 1601.

<sup>2</sup> 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<sup>3</sup> 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<sup>4</sup>, 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%

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

<sup>4</sup> 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<sup>5</sup> and 30,544<sup>6</sup> 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.<sup>7</sup> 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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<sup>5</sup> This number represents 85 percent of the three-year total of active users.

<sup>6</sup> This is the number of active users, defined as at least one visit in the past three years.

<sup>7</sup> 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<sup>8</sup>** and **\$53.6 million.<sup>9</sup>** 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 Medicare. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for affected 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 choose 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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<sup>8</sup> 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.

<sup>9</sup> 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.<sup>10</sup>
  - 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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<sup>10</sup> 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)(i) *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.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attached.

**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, Executive Director

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 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.<sup>1</sup> Pursuant to statutory directive,<sup>2</sup> 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

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<sup>1</sup> See, e.g., 25 U.S.C. § 1601.

<sup>2</sup> 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<sup>3</sup> 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<sup>4</sup>, 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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<sup>3</sup> U.S. Commission on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System*, July 2, 2004 (staff draft).

<sup>4</sup> 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<sup>5</sup> and 30,544<sup>6</sup> 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.<sup>7</sup> 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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<sup>5</sup> This number represents 85 percent of the three-year total of active users.

<sup>6</sup> This is the number of active users, defined as at least one visit in the past three years.

<sup>7</sup> 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<sup>8</sup> and \$53.6 million.<sup>9</sup>** 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 Medicare. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for affected 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 an 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 choose 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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<sup>8</sup> 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.

<sup>9</sup> 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.<sup>10</sup>
  - 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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<sup>10</sup> 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.



**UNITED SOUTH AND EASTERN TRIBES, INC.**  
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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, Executive Director

Attachment

*"Because there is strength in Unity"*

September 29, 2004

Centers for Medicare & Medicaid Services  
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P.O. Box 8018  
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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.<sup>1</sup> Pursuant to statutory directive,<sup>2</sup> 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

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<sup>1</sup> See, e.g., 25 U.S.C. § 1601.

<sup>2</sup> 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<sup>3</sup> 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<sup>4</sup>, 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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<sup>3</sup> U.S. Commission on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System*, July 2, 2004 (staff draft).

<sup>4</sup> 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<sup>5</sup> and 30,544<sup>6</sup> 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.<sup>7</sup> 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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<sup>5</sup> This number represents 85 percent of the three-year total of active users.

<sup>6</sup> This is the number of active users, defined as at least one visit in the past three years.

<sup>7</sup> 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<sup>8</sup> and \$53.6 million.<sup>9</sup>** 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 Medicare. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for affected 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 an 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 choose 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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<sup>8</sup> 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.

<sup>9</sup> 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.<sup>10</sup>
  - 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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<sup>10</sup> 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)(i) *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.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attached.

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



**UNITED SOUTH AND EASTERN TRIBES, INC.**  
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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, 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.<sup>1</sup> Pursuant to statutory directive,<sup>2</sup> 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

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<sup>1</sup> See, e.g., 25 U.S.C. § 1601.

<sup>2</sup> 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<sup>3</sup> 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<sup>4</sup>, 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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<sup>3</sup> U.S. Commission on Civil Rights, *Broken Promises: Evaluating the Native American Health Care System*, July 2, 2004 (staff draft).

<sup>4</sup> 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<sup>5</sup> and 30,544<sup>6</sup> 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.<sup>7</sup> 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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<sup>5</sup> This number represents 85 percent of the three-year total of active users.

<sup>6</sup> This is the number of active users, defined as at least one visit in the past three years.

<sup>7</sup> 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<sup>8</sup> and \$53.6 million.<sup>9</sup>** 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 Medicare. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for affected 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 an 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 choose 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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<sup>8</sup> 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.

<sup>9</sup> 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.<sup>10</sup>
  - 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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<sup>10</sup> 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)(i) *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.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attached.

**THE EASTERN BAND OF CHEROKEE INDIANS**  
88 Council House Loop • P.O. Box 455 • Cherokee, N.C. 28719  
Telephone: (828) 497-2771 or 497-7000  
Telefax: (828) 497-7007

September 30, 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 Eastern Band of Cherokee Indians 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,

David Nash, Attorney General

Attachment

September 30, 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 Eastern Band of Cherokee Indians 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.<sup>1</sup> Pursuant to statutory directive,<sup>2</sup> 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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<sup>1</sup> See, e.g., 25 U.S.C. § 1601.

<sup>2</sup> 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<sup>3</sup> 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<sup>4</sup>, 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%

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

<sup>4</sup> 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<sup>5</sup> and 30,544<sup>6</sup> 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.<sup>7</sup> 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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<sup>5</sup> This number represents 85 percent of the three-year total of active users.

<sup>6</sup> This is the number of active users, defined as at least one visit in the past three years.

<sup>7</sup> 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<sup>8</sup>** and **\$53.6 million<sup>9</sup>**. 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 Medicare. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for affected 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 an 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 choose 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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<sup>8</sup> 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.

<sup>9</sup> 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.<sup>10</sup>
  - 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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<sup>10</sup> 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)(i) *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.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attached.

**THE EASTERN BAND OF CHEROKEE INDIANS**  
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Telefax: (828) 497-7007

September 30, 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 Eastern Band of Cherokee Indians 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,

David Nash, Attorney General

**Attachment**

September 30, 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 Eastern Band of Cherokee Indians 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.<sup>1</sup> Pursuant to statutory directive,<sup>2</sup> 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 than most Americans. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights<sup>3</sup> 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.

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<sup>1</sup> See, e.g., 25 U.S.C. § 1601.

<sup>2</sup> 42 U.S.C. § 2001.

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

- 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<sup>4</sup>, 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 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.

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

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<sup>5</sup> and 30,544<sup>6</sup> 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.<sup>7</sup> 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.

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<sup>8</sup>** and **\$53.6 million<sup>9</sup>**. 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 Medicare. 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.

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<sup>5</sup> This number represents 85 percent of the three-year total of active users.

<sup>6</sup> This is the number of active users, defined as at least one visit in the past three years.

<sup>7</sup> 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.

<sup>8</sup> 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.

<sup>9</sup> This higher number uses the 30,544 number of dual eligibles in 2003 and the \$1,756 estimated spending in 2006.

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 an 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 choose 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.

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.<sup>10</sup>

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<sup>10</sup> 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.

- 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.
    - 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)(i) *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.

Submitter :  Date & Time:

Organization :

Category :

**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.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attached.

**MISSISSIPPI BAND OF CHOCTAW INDIANS**

Tribal Office Building  
P.O. Box 6010  
Philadelphia, Mississippi 39350  
Telephone (601) 656-5251

September 30, 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 Mississippi Band of Choctaw Indians 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.

The National Indian Health Board (NIHB) has submitted comments on the Part C regulations and we endorse those comments.

Furthermore, 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,

Phillip Martin, Chief

Attachment

September 30, 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 Mississippi Band of Choctaw Indians 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.<sup>1</sup> Pursuant to statutory directive,<sup>2</sup> 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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<sup>1</sup> See, e.g., 25 U.S.C. § 1601.

<sup>2</sup> 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<sup>3</sup> 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<sup>4</sup>, 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%

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

<sup>4</sup> 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<sup>5</sup> and 30,544<sup>6</sup> 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.<sup>7</sup> 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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<sup>5</sup> This number represents 85 percent of the three-year total of active users.

<sup>6</sup> This is the number of active users, defined as at least one visit in the past three years.

<sup>7</sup> 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<sup>8</sup>** and **\$53.6 million<sup>9</sup>**. 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 Medicare. If States are allowed to mandate enrollment of these individuals in special MA or MA-PD plans, the result will be disastrous for affected 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 an 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 choose 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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<sup>8</sup> 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.

<sup>9</sup> 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.<sup>10</sup>
  - 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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<sup>10</sup> 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)(i) *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.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

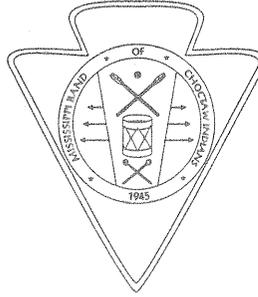
**GENERAL**

GENERAL

See attached.

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

MISSISSIPPI BAND OF CHOCTAW INDIANS



TRIBAL OFFICE BUILDING  
P. O. BOX 6010  
PHILADELPHIA, MISSISSIPPI 39350  
TELEPHONE (601) 656-5251

September 30, 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 Mississippi Band of Choctaw Indians 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.

The National Indian Health Board (NIHB) has submitted comments on the Part C regulations and we endorse those comments.

Furthermore, 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,

*Phillip Martin*  
Phillip Martin, Chief

Attachment

Submitter :  Date & Time:

Organization :

Category :

**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.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

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

# Indiana Pharmacists Alliance



729 N. Pennsylvania St.  
Indianapolis, IN 46204  
Phone 317-634-4968  
Fax 317-6321219  
[www.indianapharmacists.org](http://www.indianapharmacists.org)

September 23, 2004

## Comments on Proposed Medicare Part D Regulations

Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
**Attention: CMS-4068-P**  
Baltimore, MD 21244-8014

To Whom It May Concern:

I am writing on behalf of the Indiana Pharmacists Alliance (IPA). Our organization represents over 1400 pharmacists, students and technicians throughout the State of Indiana in all fields of the profession. We have several concerns and comments about the proposed Medicare Part D regulation as it relates to the practice of pharmacy.

### **Dispensing Fee**

The regulation provides for three possible definitions of dispensing fee. The first definition only allows for the net cost of delivering the drug to the patient. We believe that this fee should not only recognize the act of preparing a prescription but also includes overhead costs incurred prior to the actual filling of the prescription. The pharmacy is assuming the risks inherent in stocking the drug, maintaining a facility and staffing it, etc. Any dispensing fee should take these factors into account. According to the NACDS 2004 Industry Profile, the estimated cost of dispensing a single prescription in the State of Indiana during 2003 was \$7.27. It is the opinion of IPA that at minimum the dispensing fee should match this amount.

The second definition states that the fee should include amounts for supplies or devices necessary for administering covered drugs. The rule fails to state what "necessary" is. Without proper definitions of dispensing fees, the Prescription Drug Plans (PDPs) may deny patients access to devices such as nebulizers, inhaler spacers, since they are not a covered drug under Part D. These supplies or devices should be listed or defined.

The third definition includes monitoring by what is termed a "clinical pharmacist." With the exception of one state, there is no distinction drawn in any pharmacy practice acts between a pharmacist and a clinical pharmacist. All pharmacists take the same exam (NAPLEX) for

licensure in all states. We request that the term “clinical” be dropped and that the rule refer to a “pharmacist.”

### **Equal Access to Retail Pharmacies**

The proposed regulation requires that PDPs and Medicare Advantage-Prescription Drug Plans (MA-DPs) meet the minimum requirements of the Department of Defense’s TriCare pharmacy access- 90% of beneficiaries live within two (2) miles of a pharmacy in urban areas, 90% within five (5) miles in suburban areas and 70% within fifteen (15) miles in rural areas. The problem with this standard is that it is an average by region. Thus, members in one region could have greater access to pharmacies than those people living in an adjacent region. This requirement also does not take into consideration that a patient may live four miles from a pharmacy geographically, but has to drive seven miles to actually get there. IPA asks that this standard be calculated on a state-by-state basis using well-traveled, commercial roadways rather than geography.

### **Preferred Pharmacies**

Under the proposed rule, a PDP can avoid the minimum TriCare standard by creating networks of “preferred” pharmacies within a larger network. This could be accomplished by the PDP creating a network with the minimum number of pharmacies in it and then creating a smaller network of “preferred” pharmacies within that network, offering lower cost sharing or some other similar inducement to direct traffic to those “preferred” pharmacies. The rule doesn’t specify how many preferred pharmacies there will be or how large the difference in price sharing might be. Creating preferred pharmacies will likely have the following effects:

1. Pharmacies that are labeled as “non-preferred” could be seen as professionally sub-par.
2. The creation of preferred pharmacies accomplishes a single goal: to direct and control the flow of prescriptions and other purchases. The creation of these preferred pharmacies makes it possible for a PDP to discriminate against pharmacies within the larger network because the distinction will be made at the discretion of the Plan Sponsor.
3. Labeling a pharmacy as “preferred” could limit access to patients in impoverished or rural areas where multiple pharmacies do not exist. The net result will be the lowest-income patients having to pay higher prices simply because they cannot travel to a preferred pharmacy.

The concept of preferred pharmacies negates the “any willing provider” provision written into the law. IPA strongly objects to allowing PDPs to create these intra-network distinctions.

### **Level Playing Field**

Under the proposed regulation, a PDP cannot require patients to use a mail-order pharmacy. However, according to the proposed rule, a PDP that owns mail-order pharmacies can negotiate with manufacturers for rebates to increase benefits; retail pharmacies cannot. This could allow PDPs that own mail-order pharmacies to attempt to use these rebates, based on their entire book

of business, (including community pharmacy outlets) to offer lower prices through their owned mail order pharmacies. Rebates and discounts generated by business through all channels of retail pharmacy distribution could then be used to subsidize moving patients to mail order pharmacy. This will inevitably lead to negative effects on those patients with complex medication schedules, chronic diseases and those who self-administer certain drugs via devices. For these patients, face-to-face counseling with a pharmacist is not just preferred- it is necessary. Some things simply cannot be accomplished over the phone. It was not Congress's intent to allow the plans to coerce their patients into using certain pharmacies- as evidenced by Senators Grassley and Enzi's opposition.

IPA feels that the rebates PDPs receive should be applied equally to all drug-dispensing pharmacies- not just the PDP owned mail pharmacies. This will eliminate some of the difference in drug costs between preferred and non-preferred providers. Retail community pharmacies must be allowed to provide patients with 90 day supplies of their medications, if the patients so desire.

We also feel that the proposed rule is too vague regarding the term "negotiated price." We ask for a clarification or more exact definition of the term.

### **Electronic Prescribing**

IPA is in support of the use of electronic prescribing given the following conditions:

1. The prescribing of medications through electronic means complies with all State laws and regulations.
2. Electronic prescribing is performed through a uniform and reliable system such as ProxyMed or SureScripts.
3. Incentives are provided to help pharmacists and pharmacies prepare to receive prescriptions electronically. There are software and other technical issues that will require solutions before implementation can be accomplished.
4. Any electronic prescription is sent to the pharmacy of the patient's choice.

### **Cost Effective Drug Utilization Management**

IPA supports the goal of reducing medication errors and increasing cost-effectiveness. We advocate the adoption of quality assurance standards and criteria. We recommend using standards and criteria developed by NCQA as a reference.

If PDPs are to use formularies, IPA supports the creation of P&T Committees, and that they are required to have pharmacists in an equal number to other committee members. Our preference is that pharmacists should make up a majority of the committee's members- given the acknowledged expertise of pharmacists with the proper use of prescription drugs.

### **Medication Therapy Management**

The regulation requires that each PDP and MA-PD provide a MTM program for Medicare patients with high drug costs, chronic medical conditions and chronic medications. However, there is no standard service that each PDP will have to offer. The regulation does not define “chronic medications” or “chronic medical conditions.” The inevitable result will be patients in one region qualifying for services and identical patients in another region being denied those same benefits. We believe that the rules should define a standard for services that must be offered by PDPs, so that there is not a patchwork of differing services offered by different plans.

The regulation does not specify the amount of a minimum payment to be made. IPA believes the fee should be paid to the pharmacist and should be high enough as to encourage pharmacists to provide these services.

IPA wishes to stress that MTM’s primary goal is the proper utilization of drugs. Therefore we are of the opinion that MTM should be available to ANY patient with high drug costs and/or chronic medical conditions who is taking two (2) or more drugs, regardless of OTC or Rx status. Pharmacists are the ideal health care professionals to provide MTM services and to determine which services each beneficiary needs. Plans should be encouraged to use our services- to let us help our patients make the best use of their medications. We are concerned that leaving that decision to the PDPs may allow plans to choose less qualified providers of MTM services.

### **Coordination of Benefits**

IPA believes that Part D should not automatically cover drugs not covered in Medicare Part B due to a lack of Medicare Supplier Number. Rather, an incentive for obtaining a Medicare Supplier Number should be made available. If pharmacists are going to be required to perform the coordination of benefits, there must be a standardized process for all plans to use, and the pharmacist should be compensated for performing this service.

### **Self-Referral Prohibition**

IPA supports the rule preventing referrals for Part B drugs when a financial relationship exists between the physician and the entity furnishing the drugs. We also feel that PDPs should NOT be allowed to refer patients to their own mail-order pharmacies. IPA supports the inclusion of Part D outpatient prescription drugs into this rule to curb the risk of anticompetitive and unethical behavior.

### **Home Infusion Pharmacies**

Patients should always have access to home infusion pharmacies. It is the opinion of the IPA that the PDPs and MA-DPs not include home infusion pharmacies in their routine community pharmacy access standards. Rather, a new standard should be created specifically for home infusion pharmacies.

Lawrence J. Sage  
Executive Vice President  
Indiana Pharmacists Alliance

Submitter :  Date & Time:

Organization :

Category :

**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

# Community Pharmacies of Indiana

729 N. Pennsylvania St.  
Indianapolis, IN 46204  
Phone 317-634-4968  
Fax 317-6321219  
cpi@indianapharmacists.org

September 23, 2004

## Comments on Proposed Medicare Part D Regulations

Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
**Attention: CMS-4068-P**  
Baltimore, MD 21244-8014

To Whom It May Concern:

I am writing on behalf of the Community Pharmacies of Indiana (CPI). Our organization represents over 200 independent pharmacies throughout the State of Indiana. We have several concerns and comments about the proposed Medicare Part D regulation as it relates to the practice of pharmacy.

### **Dispensing Fee**

The regulation provides for three possible definitions of dispensing fee. The first definition only allows for the net cost of delivering the drug to the patient. We believe that this fee should not only recognize the act of preparing a prescription but also includes overhead costs incurred prior to the actual filling of the prescription. The pharmacy is assuming the risks inherent in stocking the drug, maintaining a facility and staffing it, etc. Any dispensing fee should take these factors into account. According to the NACDS 2004 Industry Profile, the estimated cost of dispensing a single prescription in the State of Indiana during 2003 was \$7.27. It is the opinion of CPI that at minimum the dispensing fee should match this amount.

The second definition states that the fee should include amounts for supplies or devices necessary for administering covered drugs. The rule fails to state what "necessary" is. Without proper definitions of dispensing fees, the Prescription Drug Plans (PDPs) may deny patients access to devices such as nebulizers, inhaler spacers, since they are not a covered drug under Part D. These supplies or devices should be listed or defined.

The third definition includes monitoring by what is termed a "clinical pharmacist." With the exception of one state, there is no distinction drawn in any pharmacy practice acts between a pharmacist and a clinical pharmacist. All pharmacists take the same exam (NAPLEX) for

licensure in all states. We request that the term “clinical” be dropped and that the rule refer to a “pharmacist.”

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### **Preferred Pharmacies**

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1. Pharmacies that are labeled as “non-preferred” could be seen as professionally sub-par.
2. The creation of preferred pharmacies accomplishes a single goal: to direct and control the flow of prescriptions and other purchases. The creation of these preferred pharmacies makes it possible for a PDP to discriminate against pharmacies within the larger network because the distinction will be made at the discretion of the Plan Sponsor.
3. Labeling a pharmacy as “preferred” could limit access to patients in impoverished or rural areas where multiple pharmacies do not exist. The net result will be the lowest-income patients having to pay higher prices simply because they cannot travel to a preferred pharmacy.

The concept of preferred pharmacies negates the “any willing provider” provision written into the law. CPI strongly objects to allowing PDPs to create these intra-network distinctions.

### **Level Playing Field**

Under the proposed regulation, a PDP cannot require patients to use a mail-order pharmacy. However, according to the proposed rule, a PDP that owns mail-order pharmacies can negotiate with manufacturers for rebates to increase benefits; retail pharmacies cannot. This could allow PDPs that own mail-order pharmacies to attempt to use these rebates, based on their entire book

of business, (including community pharmacy outlets) to offer lower prices through their owned mail order pharmacies. Rebates and discounts generated by business through all channels of retail pharmacy distribution could then be used to subsidize moving patients to mail order pharmacy. This will inevitably lead to negative effects on those patients with complex medication schedules, chronic diseases and those who self-administer certain drugs via devices. For these patients, face-to-face counseling with a pharmacist is not just preferred- it is necessary. Some things simply cannot be accomplished over the phone. It was not Congress's intent to allow the plans to coerce their patients into using certain pharmacies- as evidenced by Senators Grassley and Enzi's opposition.

CPI feels that the rebates PDPs receive should be applied equally to all drug-dispensing pharmacies- not just the PDP owned mail pharmacies. This will eliminate some of the difference in drug costs between preferred and non-preferred providers. Retail community pharmacies must be allowed to provide patients with 90 day supplies of their medications, if the patients so desire.

We also feel that the proposed rule is too vague regarding the term "negotiated price." We ask for a clarification or more exact definition of the term.

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CPI is in support of the use of electronic prescribing given the following conditions:

1. The prescribing of medications through electronic means complies with all State laws and regulations.
2. Electronic prescribing is performed through a uniform and reliable system such as ProxyMed or SureScripts.
3. Incentives are provided to help pharmacists and pharmacies prepare to receive prescriptions electronically. There are software and other technical issues that will require solutions before implementation can be accomplished.
4. Any electronic prescription is sent to the pharmacy of the patient's choice.

### **Cost Effective Drug Utilization Management**

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If PDPs are to use formularies, CPI supports the creation of P&T Committees, and that they are required to have pharmacists in an equal number to other committee members. Our preference is that pharmacists should make up a majority of the committee's members- given the acknowledged expertise of pharmacists with the proper use of prescription drugs.

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The regulation requires that each PDP and MA-PD provide a MTM program for Medicare patients with high drug costs, chronic medical conditions and chronic medications. However, there is no standard service that each PDP will have to offer. The regulation does not define “chronic medications” or “chronic medical conditions.” The inevitable result will be patients in one region qualifying for services and identical patients in another region being denied those same benefits. We believe that the rules should define a standard for services that must be offered by PDPs, so that there is not a patchwork of differing services offered by different plans.

The regulation does not specify the amount of a minimum payment to be made. CPI believes the fee should be paid to the pharmacist and should be high enough as to encourage pharmacists to provide these services.

CPI wishes to stress that MTM’s primary goal is the proper utilization of drugs. Therefore we are of the opinion that MTM should be available to ANY patient with high drug costs and/or chronic medical conditions who is taking two (2) or more drugs, regardless of OTC or Rx status. Pharmacists are the ideal health care professionals to provide MTM services and to determine which services each beneficiary needs. Plans should be encouraged to use our services- to let us help our patients make the best use of their medications. We are concerned that leaving that decision to the PDPs may allow plans to choose less qualified providers of MTM services.

### **Coordination of Benefits**

CPI believes that Part D should not automatically cover drugs not covered in Medicare Part B due to a lack of Medicare Supplier Number. Rather, an incentive for obtaining a Medicare Supplier Number should be made available. If pharmacists are going to be required to perform the coordination of benefits, there must be a standardized process for all plans to use, and the pharmacist should be compensated for performing this service.

### **Self-Referral Prohibition**

CPI supports the rule preventing referrals for Part B drugs when a financial relationship exists between the physician and the entity furnishing the drugs. We also feel that PDPs should NOT be allowed to refer patients to their own mail-order pharmacies. CPI supports the inclusion of Part D outpatient prescription drugs into this rule to curb the risk of anticompetitive and unethical behavior.

### **Home Infusion Pharmacies**

Patients should always have access to home infusion pharmacies. It is the opinion of the CPI that the PDPs and MA-DPs not include home infusion pharmacies in their routine community pharmacy access standards. Rather, a new standard should be created specifically for home infusion pharmacies.

George Maurer  
President  
Community Pharmacies of Indiana

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**Subparts J-M**

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

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

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

Subpart K—Contracts with Medicare Advantage Sponsors  
Comment on the proposed rule for establishment of the Medicare Advantage Program  
October 1, 2004

Dear Sirs:

This comment applies to the proposed subpart K, subsection on “Requirements of other laws and regulations” under the existing CFR, and other related requirements as described below. I propose that this subsection be removed in its entirety and that these others be removed or significantly modified. I am sending a similar comment on the parallel sections in the Prescription Drug Plan (PDP) regulation.

1. In your proposed rule you retain verbatim a subsection from the Medicare+Choice regulation that would require MA plans to comply with “all Federal, State, and local laws and regulations” (your preamble language on proposed Title II regulations) which in its regulatory text requires compliance with “all other applicable laws and regulations.” On its face, this requirement would continue an additional enforcement sanction to potential violations of thousands of Federal laws and regulations. These would include the DOJ and FTC antitrust rules, DOL minimum wage rules, IRS tax enforcement, NLRB labor relations requirements, OSHA safety requirements, SEC securities laws, FEC campaign finance laws, EPA environmental rules, government-wide debarment regulations, EEOC and DOJ civil rights rules, and innumerable others. Likewise, state and local governments enforce thousands of laws and regulations, including zoning laws, gun control laws, tax laws, traffic laws, and a host of others.

The origin of this “any law” requirement lies in language that then-HCFA regulations drafters routinely included in Conditions of Participation (CoP) regulations two and three decades ago. During the 1990s, and since then, these provisions have been removed piecemeal as CoP regulations were revised, by agreement of CMS drafters and OS regulations reviewers. Today, few if any remain outside of the M+C regulation.

The bloated interim final Medicare+Choice regulation issued in 1998 did not receive the normal intensity of scrutiny applied previously and subsequently to HCFA regulations, and included among its many gratuitous requirements this “any law” provision carried over into the proposed MA and PDP regulations. (So poorly drafted was that regulation that within a year an amended rule was issued to remove requirements that HCFA admitted were impossible for any health plans to meet.) The provision was not explained or defended in the preamble, and health plans commenting on the regulation did not realize its implications.

This provision has a halo feel. Who could object to a provision simply stating the obvious fact that companies are expected to obey all laws? But in fact it is a radical provision. It presumes that CMS has the expertise and resources to review company compliance with statutes for which CMS has no statutory responsibility or expert competence. It further presumes that CMS has some form of Solomonic wisdom and may exact an additional penalty (loss of an MA contract) if in CMS’s subjective judgment the company has not

paid a high enough penalty under some other law or fails to comply with some other law. And it presumes that CMS has competence and legal authority to impose this penalty even though another Federal or State agency was assigned exclusive authority to administer that law, to determine compliance under that law, and to determine applicable penalties. In cases where the company remains in alleged noncompliance after an initial adverse finding by another agency, under appeal by the company, it assumes that CMS should be allowed to intervene in the middle of a case under the stewardship of another agency and exact a draconian penalty before all other legal procedural avenues are exhausted.

No coherent reason, let alone evidence, has ever been advanced (and no reason is advanced in this preamble other than that of “copy catting” the MA regulations) why any Federal agency, under any program, should ever have such powers to unilaterally impose its subjective notions of justices for its own interpretations of alleged or adjudicated violations of other laws. Nor has any Medicare-specific reason ever been advanced as to why only Medicare’s MA and PDP programs (not even other Medicare programs) need this power, alone among the entire panoply of thousands of Federal programs issuing grants and contracts that choose not to impose such a requirement. Certainly the other major Federal health insurance programs that contract with health plans, including FEHBP and TriCare, have never felt the need to impose such a requirement.

On its face, this provision violates the legal obligation on CMS, imposed by EO 12866, to “promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need.”

This proposal also violates settled Administration policy. In 2001 the Bush Administration identified as a candidate for repeal, and subsequently repealed (FR pages 66984-86, December 27, 2001), the so-called “blacklisting rule” under which all Federal contractors were required to comply with any applicable law or lose eligibility for future contracts. The stated reasons for repeal included some of those above, e.g. lack of contracting officials’ competence to deal with laws administered by other agencies. In addition, the unstated reason for repeal was the very issue that prompted virulent opposition from Federal contractors: the “blank check” given to contracting officials to use their own subjective judgment in determining whether companies were in satisfactory compliance with tax, labor, employment, environmental, antitrust, etc. laws, and to “blacklist” companies they unilaterally determined to warrant additional penalties.

By conflicting with government-wide contracting policy and other insurance agencies’ policy, this provision also violates the EO 12866 directive that “each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies, ” and is potentially a significant regulatory action by virtue of creating “a serious inconsistency ... with an action taken or planned by another agency.”

For the same reasons that this provision should be eliminated, and for additional reasons discussed below, any policy that MA organizations commit themselves and have a

compliance plan “to comply with all applicable Federal and State standards” should also be deleted.

2. It might be argued that HHS has not proposed to amend these provisions and the others discussed below, and that they are not, as a result, a proper subject of regulatory comment or change in the Final rule. In fact, HHS states repeatedly in its proposed MA rule and in particular in its Regulatory Impact and Regulatory Flexibility Analyses that it is seeking comments on other changes to the existing M+C rules that would reduce burden on MA plans.

In fact, this existing provision would newly apply to hundreds of PPO and HMO plans newly entering the MA market and to plans in many new States (the existing M+C market covering less than one half of Medicare beneficiaries and a small fraction of US geography). Furthermore, this and related provisions would impose potentially hundreds of millions of dollars in compliance and paperwork costs on these newly covered entities, costs never addressed in the original M+C regulation or in this proposed MA regulation. The Administrative Procedure Act and EO 12866 are not to be interpreted as allowing unexplained expansions of dubious regulatory requirements without the opportunity for change, and immediate remedy, once identified by public comment as contrary to sound public policy.

Should anyone doubt that these provisions (and all those others not specifically named as proposed for change) are properly subject to review and revision under the MA NPRM, I request that their argument as to why HHS may not undertake additional deregulatory actions be raised to the personal attention of the CMS Administrator, the Secretary of HHS, and the OIRA Administrator at OMB.

3. Subsection (v) of this subsection would require new MA PPO plans to comply with “other laws applicable to *recipients of Federal funds*” (emphasis added). Doesn’t that include every recipient under every Federal and State law? This provision is unclear in intent, but appears to be subject to all the debilities above. In addition, it essentially duplicates the proposed provision that MA organizations commit themselves and have a compliance plan “to comply with all applicable Federal and State standards” (existing section 422.501) It also appears to contradict the regulatory provision, itself unclear, that “CMS may enter into contracts under this part ... without regard to Federal and Departmental acquisition regulations” (also in existing 422.501).

Most fundamentally, it conflates two entirely separate bodies of regulations. Under longstanding legal and practical distinctions, the Federal government, HHS, and CMS distinguish between Federal rules applied to “grantees” and “contractors.” A huge *corpus* of statutes and rules apply to contractors (for example, the Federal Acquisition Regulations, or FAR), and another huge and distinct *corpus* applies to grantees. This provision lumps the two sets of laws and rules together under the rubric of “recipients of Federal funds.” There is no legal or policy justification for subjecting MA plans to Federal grant rules. These plans will be Federal contractors, and the FAR rules

encompass the relevant universe of potential applicability under the rubric of receipt of funds.

Astoundingly, these two requirements in effect impose the entire panoply of FAR requirements on MA plans. But Section 1857(c) of Title 18 of the SSA gives CMS explicit authority to waive the applicability of all FAR rules to PDP and MA contractors. Nothing in the preamble indicates what CMS intends, or why. The explanation, of course, is simple. CMS retained longstanding, contradictory, and mindless M+C regulatory language without considering its implications. CMS surely does not want all FAR rules to apply to MA plans. Luckily, the preamble invites comments on, and CMS promises to fix, existing M+C provisions like these that impose unnecessary or burdensome requirements.

What is even worse, the proposed regulation would retain the existing requirement for “written policies, procedures, and standards of conduct that articulate the organization’s commitment to comply with *all* applicable Federal and State standards” (emphasis added). This clearly implies that MA plans identify each of the tens of thousands of applicable statutes and regulations and write a compliance procedure dealing with each. How else would plans even know what standards apply? Nothing in the Regulatory Analysis or Paperwork Reduction Act analysis in this NPRM or in the original M+C rule even hints at the potential costs involved. A serious effort to comply would cost millions of dollars for each participating plan. This provision alone would create an economically “significant” rule. And nothing in this provision meets EO 12866 standards. Surely CMS has intended no such result, a consequence of careless drafting rather than policy intent.

The policy conclusion is simple. HHS should eliminate all of this expansive language. None of it serves any demonstrable purpose, or meets any demonstrated need. It all violates EO 12866 standards, and the stated goals of the CMS Administrator.

I have two additional suggestions. First, since HHS has the authority to selectively determine which FAR standards apply, HHS should add one simple requirement to replace the existing proposal. HHS should not allow firms to participate that have been debarred under the FAR standards. Debarment is a simple and clear standard that will prevent fraudulent firms from obtaining MA contracts. It is inexcusable for HHS to have left this loophole while imposing mindlessly expansive and empty standards.

Second, a simple fix will eliminate 99 percent of the ambiguity and cost of the provision on “written policies, procedures, and standards,” while focusing it on the only demonstrably important concern central to the administration of Medicare. HHS should limit this provision to compliance with “Federal standards aimed at preventing or ameliorating waste, fraud, and abuse.” This change will not only eliminate excessive requirements of no real world relevance, but also focus plan efforts where they belong: on prevention of fraud and abuse.

4. Existing sections 422.502(h)(i) through (iv) would require MA plans to comply with four specifically named Federal laws. Nothing in the preamble indicates any conceivable

reason why these four laws, out of thousands, should be emphasized by specific naming. As written, these provisions are on their face entirely duplicative of the “any law” standard discussed above. On that ground alone, these provisions should be eliminated along with the “any law” standard, simply as a matter of parsimony in drafting.

These cited laws include four civil rights statutes (amazingly, unlike the NPRM for Title I, they do not include the HIPAA Administrative simplification rules that HHS said should be include to “update” the list in the identical section of the PDP rule). Nothing in the administrative record regarding Federal health insurance contractors suggests that these laws should have been singled out as of particular concern from among the thousands of applicable Federal statutes, and dozens of applicable civil rights statutes. Under the Administrative Procedure Act, and normal regulatory drafting practice, nothing requires that regulations list, or “update,” the myriad other laws and regulations that apply to contracting firms. This is an entirely gratuitous and unnecessary provision.

This argument applies most obviously to the listing of the Americans with Disabilities Act. This statute applies to employers of 15 or more persons and providers of public accommodations in interstate commerce. It no doubt applies to MA plans. Nothing in Federal regulatory procedures requires that HHS list in this NPRM the ADA as one of the myriad laws applying to MA plans. In no other HHS regulation is the ADA pointedly listed as a requirement that contractors or recipients must agree to comply with. This is also an entirely unnecessary provision (unless, unknown to me, there is an issue of coverage as described below).

The remaining three laws are all civil rights statutes that apply, in their own terms, to “recipients of Federal financial assistance.” Nothing in the preamble of this NPRM or the 1998 M+C interim final rule indicates why they are listed, and potential MA PPO and MSA sponsors and health care providers have no reason to suspect a deceit, but that is indeed what is going on, perhaps unknown to the original drafters and current reviewer of this provision. To only slightly oversimplify, all Federal civil rights statutes apply either to firms operating in interstate commerce, to the Federal government itself, or to Federal grantees as recipients of Federal “assistance.” Nothing in standard delegation and governance procedures requires or even encourages individual regulations to name other regulations that may apply to Federal contractors. Why then, are these statutes specifically named?

None of the three cited statutes, title VI of the Civil Rights Act of 1964, the Age Discrimination Act, and section 504 of the Rehabilitation Act applies on its face to Federal contractors. Under Federal administrative law, Federal contractors are never or almost never recipients of “assistance;” rather, they carry out Federal functions on a contractual basis that does not include any purpose or intent to provide “financial assistance” to the contractor. In sharp contrast, Federal grantees, who are given funds with an assistance purpose (and likewise recipients of Federally subsidized loans) are recipients of “assistance.” For example, States receiving Medicaid funds, and universities receiving NIH research grants, are recipients of “assistance.” However, nothing in the MMA indicates any purpose to provide MA plans Federal financial assistance. They are

subject to civil rights and other laws that apply to interstate commerce and to Federal contractors, but not to laws applicable only to Federal grantees and other recipients of “assistance.” Accordingly, the three referenced statutes are among the subset of Federal laws that most clearly do **NOT** apply to MA plans. I do not believe that there exists today a single legal memorandum arguing that the MMA or the predecessor M+C program creates a program of financial “assistance.” Absent any such justification, and its presentation to the public in an NPRM requesting comment, the proposed expansion of these statutes to even more entities that were never contemplated as subject to them, would be a badly flawed rulemaking.

In this context, the issue takes on a serious interagency dimension. Any line of reasoning that MA contractors are receiving “assistance” is likely to be a line of reasoning that would apply to all or most Federal contracts. That would be a radical change in interpretation of these civil rights law, one with government-wide implications and potentially very substantial costs. (In this regard it is important to note that most hospitals, physicians, and pharmacies are already subject to these statutes as subrecipients of Medicaid funds. But the vast majority of Federal contractors are not grantee subrecipients and would face an entirely new panoply of requirements and costs. And the hundred thousand or more physicians newly covered through participation in new MA plans would face costs due to the self-assessments and other paperwork requirements of the existing civil rights regulations, costs that were omitted from the NPRM’s Regulatory Impact, Regulatory Flexibility, and Paperwork Reduction analyses.)

It is possible that some in HHS may have a different view. If so, you still have a simple alternative in accommodating these comments without lengthy debate that might delay the final rule. Explain the legal issue as to “assistance” in the final rule preamble, eliminate the proposed regulatory language from the final rule, and explain that you will at a later time consider issuing a proposed rule dealing specifically, and in detail, with the possible applicability of these and other laws to PDPs (the three named statutes are not the only ones that hinge on the term “financial assistance”). In that proposed rule, should it ever be issued, present a Regulatory Impact Analysis laying out estimated compliance costs, and alternatives. In that NPRM include written opinions from the civil rights and administrative law components of the Justice Department and other affected agencies (e.g., OPM and the Federal Acquisition Regulatory Council). But do not retain these requirements in regulation without a candid and complete APA rulemaking presenting the issues squarely and fairly, or without an analysis complying with EO 12866.

5. The preceding comments are complex. But you have a truly simple expedient. You need only delete the “requirements of other laws” subsection in its entirety (and make the accompanying changes discussed above), explaining in a preamble paragraph or two that the existing regulation presents unforeseen problems, is not necessary to implement Title II, and that any issues will be attended to in the future if necessary. You can take this simple step even if you do not agree with all of the specific arguments made above, and without creating a lengthy and complex analysis of your own.

Some might argue that in practice these provisions have caused little or not problem or burden in the M+C, because they have been unused or unenforced. That argument leads to an inexorable conclusion under EO 12866: eliminate unused and unenforced provisions as obviously unnecessary.

To implement this “just say no” policy decision, you need not wait until the final stages of regulatory clearance or even resolve any legal questions. Inclusion of the regulatory language I criticize in these comments was never required by law, but a voluntary policy decision. The language can be removed on the same basis it was included: by policy fiat. Instead, you should explain your intention of accepting these comments to relevant HHS components (Inspector General, Planning and Evaluation, Administrative Law Division, and Civil Rights) and OMB. You should tell OMB that if it wishes to subject these changes to interagency review it should do so immediately (in October), and require any dissenting view to be presented in October. No last minute vetoes by HHS components or other agencies should be allowed. In other words, these burdensome and unnecessary regulatory provisions should be disposed of immediately, so that serious work on the many substantive issues can proceed and the MMA regulations can be issued timely at the end of December or early January.

I have sent a copy of this comment to OMB, because of the serious regulatory policy and burden issues that it raises under EO 12866. I recommend that OMB take steps to assure that any interagency policy issues not be allowed to delay promulgation of the final rule.

Sincerely, W.J. Francis  
Public Policy Network  
703-278-0041

Submitter :  Date & Time:

Organization :

Category :

**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.

Subpart C—Benefits and Beneficiary Protections  
Comment on the proposed rule for establishment of the Medicare Advantage Program  
October 1, 2004

Dear Sirs:

Your proposed rule requires regional plans to “provide reimbursement for all covered benefits” in and out of network, while allowing “differential cost sharing” for out of network benefits. This creates several potential problems; potentially preventing attainment of the Congressional objective that MA plans function similarly to private health plans, such as those participating in the FEHBP. This comment is to provide you my suggestions for sensible legal and practical interpretations to prevent these problems from arising, while ensuring the broad Congressional objective that enrollees have access to medical providers in- and out-of-network.

“Covered benefits” can be grouped into several categories, only one of which seems likely to have been intended for mandating participation of non-network providers.

First, there are core benefits where *enrollees would typically have provider choices* but might prefer a non-network provider even at increased cost sharing. Provider types in this category would include physicians, hospitals, and drug stores. Without question, the Congress intended that these benefits allow use of in- and out-of-network providers. This legislative choice was not a chimera. Many preferred provider plans in the private sector, such as the Blue Cross Basic plan in the FEHBP, limit choices more severely. These models were certainly known to, and rejected by, the Congress.

Second, there are a few benefits that are provided on a contractual basis through a *single provider for all plan enrollees*. These include mail order drugs and nurse hotlines (other examples in some plans would be behavioral management and disease management). These contracts are typically predicated on obtaining **all** of the plan’s business, and the contractual arrangements and bid prices reflect that. It would be impossible to administer a health plan if every mail order drug firm or nurse hotline firm were eligible to participate on the same terms as the firm that signed up for a guaranteed volume of business, and the Congress could not be presumed to have intended to prevent the very kinds of volume discounts on which it relied for obtaining deep discounts on drugs in each plan. Put another way, no second firm could in fact meet the contractual terms and conditions that were designed for one firm, because that the first firm would not agree to the same discounts if it were not the exclusive provider. Requiring plans to allow non-network providers for these services would present a Catch-22, since the original sole contractor would not have agree to those terms in the first place. Furthermore, establishing such contracts, integrating provision of those services, and informing enrollees of those services are expensive functions, and a second (or third, or fourth) contract would impose significant expense and inconvenience on plans, thereby increasing cost to the government, to plans, and to enrollees.

Third, there are *ancillary single provider benefits*. These arrangements are for services not normally paid through health insurance, and provide benefits such as gym discounts, eyeglass discounts, and dental discounts. The scope and diversity of these kinds of benefits is staggering. A network called GlobalFit is used by Aetna, Kaiser, CareFirst, and others to provide discounts at a number of gym chains. Some plans offer discounts on massage, acupuncture, and weight control programs. For example, CareFirst gives its enrollees discounts to Weight Watchers. And Cigna provides discounts to health-related magazines. In these arrangements, there is typically no payment by the plan, and no cost sharing by the enrollee. Instead, the enrollee obtains a discount from the retail price he would otherwise have paid. Typically, the plan negotiates an agreed discount with a particular firm or chain, and that firm or its members (who may be franchised rather than owned, or even a provider pool) profit from the larger volume of business that the plan members bring to it rather than to competing providers. These business arrangements cannot survive entry on equal terms by other firms, since their entire economic basis is exclusivity. Indeed, to subject these contracts to free entry would also be to create a Catch-22, since one of the usual contractual provisions is that only one firm or group of firms will obtain the favored arrangement. By definition, this deal cannot be provided simultaneously to more than additional entrants without altering the expected economic return. Note that this business model is common, and not limited to the world of health insurance. Similar arrangements (e.g., for eyeglass discounts at a particular chain) are often made by affinity organizations.

Although the conference agreement is silent on the rationale for its non-network reimbursement requirement, the Congress cannot have intended to render impossible the normal practices of private health insurance, or to deprive enrollees of otherwise desirable services on favorable terms to enrollees. The sweeping statutory language reflects, instead, the failure of the drafters to consider explicitly the second and third situations described above.

There is no question as to what result HHS should seek on policy grounds. The only issue arises as to the rationale for interpreting the unintentionally broad statutory language to prevent a result the Congress could not have intended. I propose several lines of interpretation and explanation below. It may be equally as important to provide preamble examples as to provide regulatory language, and I deal with both.

Preferably, HHS should create a principled distinction between the kinds of benefits reasonably subject to the statutory provision, and the kinds of benefits that would be thwarted if subject to the provision. Using the typology above, the applicability of the statutory provision would be limited to the broad types of benefits for which health plan enrollees normally have multiple provider choices, namely retail providers of hospital, physician, device, and pharmacy services. Core and ancillary benefits normally provided through a single provider for all plan enrollees would be exempted on the grounds that the Congress did not intend to create a Catch-22 situation. Indeed, when a statute is drafted in a way that, read literally, would thwart its implementation it is common for regulations to create the kinds of reasonable interpretations that allow a sensible result.

(Elsewhere in your proposed regulations a statutory error in using the word “not” is overridden by your through just this kind of reasoning.)

Another potential line of reasoning is to focus on the statutory terminology that the plan “provides for reimbursement” regardless of whether the benefit is provided in or out of network. The benefits at issue here normally do not involve reimbursable arrangements of the kind referenced by the statute. The statute is clearly aimed at services that are reimbursed for a unit of service, such as a physician visit or drug prescription. It specifically allows for higher enrollee cost sharing for these services, which presupposes a charge for these services. Most of the services at issue here are normally provided “free” to the enrollee and hence would not involve any cost sharing to vary. (Note, however, that although most are “free” to enrollees there is direct plan to contractor payment for nurse hotlines. These hotlines might, however, be exemptible on the grounds that they are part of the internal operation of the plan, like plan appeal process and benefit payments, and hence not a “covered benefit.” Nor does this approach work for mail order drugs.)

Yet another possibility might be to use the distinction between “basic” and “supplemental” benefits that the statute uses throughout.

If your attorneys cannot agree that the Congress did not intend to nullify the normal panoply of single-contractor benefits offered by private health plans, as articulated above, then a fallback position is to take the approach used under the FEHBP. That program has created a category called “non-FEHB benefits available to plan members.” Under this approach, plans provide benefits that:

“Are neither offered nor guaranteed under the contract with the FEHB Program, but are made available to all enrollees and family member of this Plan. The cost of the benefits described on this page is not included in the FEHB premium and any charge for these services do not count toward any FEHB deductibles, out-of-pocket maximum copay charges, etc. These benefits are not subject to the FEHB disputed claims review procedure.”

This approach is well suited for benefits such as gym, eyeglass, and dental discounts. If applied to MA, plans would be allowed to offer certain services that are not “covered benefits” under the statute. Because these services are not provided as contractual guarantees, the entire panoply of MA requirements is avoided. All that CMS need do to facilitate these arrangements is to allow plan brochures and other informational materials to include information on non-contractual benefits. Since the kinds of benefits involved typically involve no plan payments, but simply discounts for volume, the statutory payment systems are compromised in no way. Unfortunately, this approach will not work for mail order drugs, which are in covered benefits.

If your attorneys cannot agree to this entirely reasonable alternative, as endorsed by a sister agency operating a comparable program, then it may be that only one option is left. This option requires little or no change in regulatory text, but the addition of a substantial

preamble explanation in the final rule. You would explain that any plan could avoid the seemingly draconian limitation using the method explicitly endorsed by the Congress. Under this approach, you would explain, plans may charge for out-of-network services on a copayment, coinsurance, or deductible basis, and distinguish between hospital, medical, and drug benefits on the one, and these other services on the other. These amounts, HHS should explain, could be set at levels that would, as a practical matter, prevent non-network firms from applying, or at any rate from obtaining any consequential volume of business, and hence prevent undercutting the discounts that the plan arranged on the basis most favorable to enrollees.

Relatedly, you should address the point that nurse hotlines, and vision and other discount arrangements, need not be, and in the world of private insurance never are, subject to deductibles. However, nothing in the statute precludes plans from establishing a high deductible (perhaps \$500 or more) for using non-network firms, a deductible so high that none would apply. (Hospital and medical services are subject to a unified deductible, and drugs to another deductible, but note of these services except mail order drugs would fall under those deductibles). Thus, these ancillary services could be provided with no deductible using the contractual single firm, and a high deductible if using a “non-network” firm.

The fact that plans have these tools available to solve the problem should not, however, dissuade you from taking the simpler approach of distinguishing between benefits where choice is expected and the use of non-network providers sometimes very important to enrollee access, and services requiring use of a single provider, and directly allowing the use of “one firm only” contracts for the latter.

Another complication arises if these ancillary services were interpreted by CMS to be beneficiary spending subject to the catastrophic limit on out-of-pocket expenditures. Clearly the Congress did not intend that gym fees would count toward this limit.

I trust that you will find these comments helpful in drafting your final rule. Whatever approach(es) you take to dealing with this issue, be sure to discuss specifically the consequences for (a) mail order drugs, (b) nurse hotlines, and (c) discount arrangements, and please provide specific examples of the kinds of cost sharing that would be appropriate to protect these benefits, and implications for the catastrophic limit. For example, would a plan be able to impose a \$500 gym deductible before it allowed a discount for a non-network gym, and exclude beneficiary gym costs from the limit?

Sincerely, W.J. Francis  
Public Policy Network  
703-278-0041

Submitter :  Date & Time:

Organization :

Category :

Issue Areas/Comments

**GENERAL**

GENERAL

Please see attached Word File.

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



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October 1, 2004

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

Attention: **CMS-4069-P**

Community Health Partnership, Inc. is one of the four Wisconsin Partnership Program demonstration sites. We are a managed care program that integrates Medicare, Wisconsin Medicaid, and community long-term care services for a small population (600) of high-need, low-income disabled adults and frail elderly. Our plan exclusively serves high-need, high-risk beneficiaries, nearly 90% of who are dually eligible. We would fall under the "Special Needs Plan" (SNP) category of MMA. Our plan targets dually eligible Medicare beneficiaries at the high end of the "risk bell curve" of the full Medicare population – those with the highest cost and highest needs. Because our risk is spread in a narrow band with small numbers (and with already noted potential for underpayment at this end of the curve), we are more vulnerable to elements of these rules that pertain to a much broader population to spread the risk across. We have great concerns about the potential adverse impact the proposed regulation would have on our small plan.

The proposed legislation as a whole is inconsistent with the integrated care concept the WPP projects demonstrate. We are successfully demonstrating that for our high-needs service population, the intense levels of case management services we provide reduces primary and acute medical utilization and costs, while improving beneficiary satisfaction and quality outcomes. MMA legislation specifically prohibits the type of "cost shifting" we engage in.

The new legislation also presents significant administrative burden on our program. Our past and current practice is to identify the most appropriate and efficacious services our beneficiaries need, and provide those services in a timely manner, regardless of funding source. We have attained cost efficiencies in the claims processing, accounting, reporting/analysis, and underwriting functions of our plan. We would also like to address the following concerns:

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*Branch Offices:*

475 Chippewa Mall Drive, Suite 418, Chippewa Falls, WI 54729 *Ph:* (715) 720-1865 or (866) 720-1865 *Fax:* (715) 720-4763



October 1, 2004

Page Two

## **Subpart A – General Provisions**

### **1. Definitions (§422.2)**

Section 1859(b)(6)(B) identifies three types of Special Needs Plans for individuals that are institutionalized, entitled to Medical Assistance, or have severe or disabling chronic conditions. We believe that each type of plan should not be mutually exclusive. For instance, a plan could be established to serve both Medical Assistance eligible individuals that are institutionalized.

If they are mutually exclusive, as it appears to read in the proposed regulations, a number of demonstration programs including Wisconsin Partnership Program would encounter capacity issues and would be forced to enroll individuals that it is not designed to serve. We support Medicare Policy Coalition's position with regards to "special needs" definition.

## **Subpart A – General Provisions**

### **2. Definitions (§422.2) *continued***

We would also seek clarification of what defines "Medical Assistance eligible individuals".

As provided for in the regulations, Special Needs Plans will be required to offer Part D coverage. We support this provision because it promotes a less fragmented health delivery system for our high-risk individuals. However, we are concerned about our ability as a small specialized plan that focuses on high-cost and high-utilization individuals to offer a competitive bid. We believe the risk adjustment methodology for pharmacy must have separate component similar to the frailty factor to account for high-risk individuals.

Additionally, most special needs plans will be smaller in size than local or regional plans and will lack the ability to secure substantial pharmacy discounts compared to larger plans. We would like CMS to explore pharmacy purchasing options for Special Needs Plans such as the 340B Program for FQHCs.

### **3. Disenrollment by the MA Organization (§422.74)**

We believe the regulations need to address the disenrollment issues that special need plans for dual eligible individuals are likely to experience. For many enrolled individuals, Medical Assistance qualification can change at any time during a plan year. We would like to see special needs plans given the authority to choose to continue to provide the Medicare services until the next enrollment period or terminate the individual's participation in the plan at the plan's discretion. Many states have retroactive adjustments and error corrections that can make immediate termination for dual eligible individuals an unnecessary action and a disruption to their continuity of care.



October 1, 2004

Page Three

**Subpart C - Benefits and Beneficiary Protections**

**11. Access to Services (§422.112)**

CMS has invited response regarding the reimbursement of Critical Access Hospitals by Medicare Advantage Plans. As a rural program, Community Health Partnership, Inc. has a strong interest in the outcome of this portion of the regulation.

Because Critical Access Hospitals are not governed by a competitive framework, our payments will be significantly higher without a wraparound payment that has been proposed by CMS. We support a methodology similar to the proposal for Federally Qualified Health Centers. The problem that CMS has asked for comments on is the lack of a non-CAH facility specific rate under section 1886 for these Critical Access Hospitals.

We believe that it is not possible to determine an exact non-CAH facility specific rate without adding undue burden to either the Medicare Advantage health plan or the Critical Access Hospital. However, we believe an estimated rate is attainable and is necessary to allow local MA plans to penetrate the rural markets.

For all outpatient services and lab it would be possible to reimburse the CAHs under PPS methodologies adjusted for wage index variations. We believe the administrative burden would be minimal for both MA plans and providers.

Inpatient and swing bed services should be reimbursed based on the last PPS rate available for each hospital adjusted for inflation. The long-term solution is to modify the CAH cost reports and billing procedures to determine both the facility PPS rate and CAH rate. This would require DRG grouping. Not only does this alleviate issues with MA plans, it would also facilitate CAH program evaluation. We believe the administrative burden would be minimal to CAHs.

We are unable to judge the adequacy of \$25 million for the “essential” hospitals. If MA plans do succeed in penetrating rural markets, we believe that \$25 million will be inadequate. If the program for “essential” hospitals encounters a shortfall, CAHs should bear the reduction in their wraparound payment. MA plans could not adequately account for the possible shortfall in their bidding process. Additionally, we believe it would also serve as a deterrent for CAHs to control their escalating cost structures.

Finally, Rural Health Clinics (RHC) should also be addressed in the regulation. It would seem appropriate to have similar procedures as FQHCs.



October 1, 2004

Page Four

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

### **1. Submission of Bids (§422.254)**

The proposed regulation suggests that Congress intended to exempt PACE organizations from the bid process with exception of Part D coverage. In our view, integrated special needs, dual eligible plans should also be exempted from the A/B bidding process.

Demonstration projects like Wisconsin Partnership Program were designed to integrate Medicare and Medicaid funding to facilitate a unified care approach that does not fragment the health care delivery system. The goal is to provide higher quality of care with better outcomes at lower cost than the current fragmented Medicare and Medicaid delivery systems. Community Health Partnership, Inc. has demonstrated we are able to attain substantial cost savings. The savings are accomplished by significant reduction in acute medical costs (traditional Medicare Part A & B) which are partially offset by increased expenses in pharmaceutical and home-based long-term care (traditional Medicaid services). The bidding process will have an adverse affect on the health care delivery behavior of these programs.

For instance, if we spend \$80 dollars on a non-Medicare covered service with the goal to save \$100 in Medicare acute care services, the integrated plan has theoretically saved \$20 dollars net. Currently, the Wisconsin Partnership Program is actively performing this very function. However, if dual eligible special needs plans are required to bid for their capitation, their behavior will change drastically. If the above example was done under the bidding rules, the plan would be a net loss of \$5 (\$100 savings less 25% government retention less the \$80 spent on a non Medicare covered service = \$5 deficit). While this example is simplified, over time care decisions will be affected by the 25% retention. Any non-Medicare service that saves Medicare acute dollars will not be done unless it saves greater than the 25% retention even though it may be in the best interests of the patient and the taxpayers. We believe this anticipated outcome is contrary to intention for dual eligible special needs plans and we believe this portion of the bill hampers long-term care strategies for dual eligible special needs plans.

## **Subpart G – Payments to Medicare Advantage Organizations**

### **4. Adjustment to Capitation Rates, Benchmarks, Bids, and Payments**

The Wisconsin Partnership Program is currently being paid capitation payments that are blended for the phase-in of the HCC risk adjustment model. We are currently one year behind MA organizations and receiving the PACE risk adjuster and frailty factor. For 2006, Wisconsin Partnership Programs will be 50% risk adjusted and 50% Pace methodology. However, unlike PACE organizations, we are not exempt from the A/B bidding process. We would like to receive clarification as to how the Wisconsin Partnership Program will be treated during this transition.



October 1, 2004  
Page Five

If you have any questions or require additional clarification, please contact Brent Bauman at (715) 858-7012. We appreciate the opportunity to share our concerns with you and would also like to convey our support of the comments submitted by the Medicare Policy Coalition.

Sincerely,

A handwritten signature in black ink that reads "Karen A. Bullock". The signature is written in a cursive style.

Karen A. Bullock  
Chief Executive Officer

c: Brent Bauman  
Dan Jones

Submitter :  Date & Time:

Organization :

Category :

**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



1399 New York Ave, NW Suite 300  
Washington, DC 20005  
Phone: (202) 296-7272  
Fax: (202) 296-7290

October 1, 2004

Mark McClellan, Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W. – Room 445-G  
Washington, D.C. 20201

**Re: Comments on CMS-4069-P; Medicare Program;  
Establishment of the Medicare Advantage Program**

Dear Administrator McClellan:

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.

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## **Provisions of the Medicare Advantage Program**

### ***Subpart A – General Provisions; Eligibility to Elect a Special Needs MA Plan***

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.

### ***Subpart F – Submissions 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.

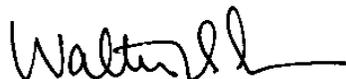
Genentech also would like the Final Rule of the MA program to direct plans to release utilization data from the Medicare Demonstration Project and its Part D implications to beneficiaries and MCOs. The experience of Medicare beneficiaries who chose to participate in the Demonstration Project may provide 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.

### ***Conclusion***

Genentech urges CMS and the Managed Care community to further define the Medicare Advantage program by further defining: (i) the utility of disease-specific specialized plans and their formularies; (ii) ensuring patient cost sharing is appropriately calculated and reported; (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.

Again, Genentech appreciates this opportunity to comment. We look forward to working with CMS and the managed care community toward a more effective and feasible system for the benefit of Medicare beneficiaries.

Sincerely,

A handwritten signature in black ink, appearing to read "Walter K. Moore". The signature is fluid and cursive, with a long horizontal stroke at the end.

Walter K. Moore, Vice President  
Government Affairs

Submitter :  Date & Time:

Organization :

Category :

Issue Areas/Comments

**GENERAL**

GENERAL

attached

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
DEPARTMENT FOR REGULATIONS & DEVELOPMENT

Please note, the attachment to this document has not been attached for several reasons, such as:

1. Improper format or,
2. The submitter did not follow through when attaching the document, or submitted only one file or,
3. The document was protected file and would not allow for CMS to attach the file to the original message.

We are sorry that we cannot provide this attachment to you at this time electronically, but you can view them here at CMS by calling and scheduling an appointment at 1-800-743-3951.

Submitter :  Date & Time:

Organization :

Category :

**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

# Congress of the United States

Washington, DC 20515

October 1, 2004

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

Attention: File Code CMS-4069-P

Dear Dr. McClellan:

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.

We, the members of the Congressional Asian Pacific American Caucus, are writing to bring to your attention a serious flaw in the Draft Model Guidelines proposed by the United States Pharmacopeia to guide the design of drug formularies for Medicare beneficiaries. We urge CMS to use its discretion outlined in §423.120b to require revisions to the current Draft Model Guidelines. The flaw arises from the failure to properly categorize certain classes of hypertension medications in a manner that would require their inclusion for coverage, and it could have particular impact on members of the Asian American community.

The issue involves the anti-hypertensives known as ACEs (angiotensin-converting enzyme inhibitors) and ARBs (angiotensin receptor blockers). ACEs and ARBs are recognized as different classes of drugs by leading medical professional groups (e.g., American Heart Association, American College of Cardiology), government organizations (e.g., World Health Organization), and in current treatment guidelines (e.g., Joint National Committee for the Prevention, Diagnosis, Evaluation and Treatment of High Blood Pressure). Their different mechanisms of action offer physicians important choices in prescribing medications that best meet the needs of their individual patients. That flexibility is extremely important for elderly patients, whose responses to medications vary considerably, either because of their frailty, other illnesses, multiple medications, or as sometimes is the case, because of their ethnic heritage.

One of the side effects associated with ACEs is cough, and the existence and persistence of chronic cough can play a role in patients' ability to continue to take their blood pressure medications. Research has shown that the incidence of this ACE-associated cough is particularly high among people of Chinese descent (up to 54% of these patients compared with 19% of Caucasians).<sup>1,2,3</sup> Hence, for Chinese

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<sup>1</sup> Ding PYA, Hu OYP, Pool PE, et al. Does Chinese ethnicity affect the pharmacokinetics and pharmacodynamics of angiotensin-converting enzyme inhibitors? *J Hum Hypertens* 2000;14:163-170.

<sup>2</sup> Chan WK, Chan TY, Luk WK, et al. A high incidence of cough in Chinese subjects treated with angiotensin converting enzyme inhibitors. *Eur J Clin Pharmacol.* 1993;44(3):299-300.

<sup>3</sup> Woo KS, Norris RM, Nicholls G. Racial difference in incidence of cough with angiotensin-converting enzyme inhibitors (A tale of two cities). *Am J Cardiol* 1995;75:967-968.

Americans in particular, as for many others with hypertension as well, physicians may prescribe an ARBs because they are not associated with troubling cough.

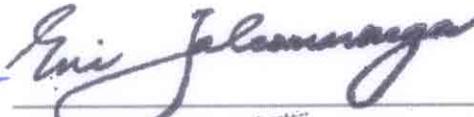
The current Draft Model Guidelines, however, don't provide the guarantee that patients and their physicians will have access to ACEs and ARBs as needed. In fact, the current version of the Model Guidelines could create a situation that would allow formularies to exclude either ARBs or ACEs entirely from coverage. Such a situation would surely be a blow to all Medicare beneficiaries who suffer from hypertension, but Asian Americans all the more since they respond so differently to the ACE inhibitors.

That inequity can be eliminated by reclassifying the ACEs and ARBs in the Model Guidelines at the level of Pharmacologic Class (currently they are designated at the level of Recommended Subdivision, which would not guarantee availability). With that change, formularies would be required to provide coverage to two or more drugs from each of these different classes, thus assuring access to all of the medications Medicare beneficiaries and their physicians need to provide them with the best and proper care.

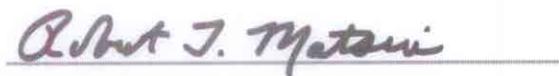
Sincerely,



Rep. Michael M. Honda, Chair  
Congressional Asian Pacific American  
Caucus



Rep. Eni Faleomavaega, Vice-Chair  
Congressional Asian Pacific American  
Caucus



Rep. Robert Matsui  
Congressional Asian Pacific American  
Caucus



Rep. Neil Abercrombie  
Congressional Asian Pacific American  
Caucus



Rep. Madeleine Bordallo  
Congressional Asian Pacific American  
Caucus



Rep. Xavier Becerra  
Congressional Asian Pacific American  
Caucus

CC: Roger Williams, M.D.  
Chief Executive Officer  
United States Pharmacopeia  
12601 Twinbrook Parkway  
Rockville, MD 20852

Submitter :  Date & Time:

Organization :

Category :

**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.

**Humana Inc.**  
500 West Main Street  
Louisville, KY 40202

October 1, 2004



The Honorable Mark McClellan, MD, Ph.D.  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8018  
Baltimore, MD 21244-8018

**Attn: CMS 4068-P and CMS-4069-P**

Dear Dr. McClellan:

The purpose of this letter is to comment on the Centers for Medicare and Medicaid Services' (CMS's) proposed rules to establish the Medicare Prescription Drug Benefit and the Medicare Advantage (MA) Program enacted in Title I and Title II of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). We have also attached a recent letter Humana submitted to you regarding the regional PPO program.

Humana Inc., headquartered in Louisville, Kentucky, is one of the nation's largest publicly traded health benefits companies, with approximately 5.8 million medical members located primarily in 15 states and Puerto Rico. We offer coordinated health insurance coverage and related services - through traditional and Internet-based plans - to employer groups, government-sponsored plans, and individuals. As of January 2004, Humana serves over 350,000 Medicare beneficiaries in markets across the nation.

Humana is also a member of America's Health Insurance Plans (AHIP), the principal national trade association representing companies that provide health benefits to consumers and employers throughout the United States. We provided technical input into the AHIP's comments regarding the proposed rules for the Medicare Prescription Drug Benefit and the MA Program, and want to express our support for and agreement with the comments and recommendations submitted to CMS by this organization. Additionally, we are appending a copy of our recent letter to you reiterating our support for considering participation in the regional PPO program should there be fewer than 50 regions and our belief that the Secretary must use his authority to ensure that seniors, no matter where they live, have access to coverage choices with adequate provider networks.

As a strong supporter of the MMA, we commend the CMS' efforts to expeditiously issue proposed rules for both these programs as well as your outreach efforts to explain the provisions and seek guidance. Given the short timeframe for many of the Act's program effective dates, we urge CMS to promulgate the final regulations as quickly as possible to ensure that interested entities can make the kinds of decisions necessary for operational implementation. We believe the law and subsequent final regulations should strengthen the Medicare program and should protect and provide seniors with meaningful choices of affordable, quality health care coverage.

We appreciate the opportunity to provide these comments. Humana has enjoyed a long partnership with the federal Medicare program, and we look forward to working with you to strengthen the Medicare program for today's seniors and future generations. If you have any questions, please do not hesitate to contact me.

Sincerely,

**Heidi Margulis**

Heidi Margulis  
Senior Vice President, Government Relations  
Humana Inc.

Submitter :  Date & Time:

Organization :

Category :

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attached File

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



October 1, 2004

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

Dear Dr. McClellan:

Rocky Mountain Health Plans (“RMHP”) has participated continuously in the Medicare program under a reasonable cost contract with the Center for Medicare & Medicaid Services (CMS) for more than 28 years, and is currently the only Medicare managed care plan that operates on a statewide basis -- encompassing both rural and urban areas -- in Colorado. RMHP is a community-based, not-for-profit managed care organization that delivers benefits to over 20,000 Medicare beneficiaries throughout the State of Colorado. RMHP was the fastest growing Medicare plan in every county in which we operate during 2003, and has continued to achieve substantial membership growth throughout 2004.

RMHP welcomes the opportunity to comment on the proposed regulations regarding “Establishment of the Medicare Advantage Program” (69 FR 46866). Our main focus with regard to the proposed regulations is to continue to serve our Medicare members in the decades to come.

RMHP’s comments pertain to the language regarding Extension of Reasonable Cost Contracts set forth at 42 CFR 417.402 of the proposed regulations. The final statutory interpretation adopted by CMS in this area will have a profound impact on the ability of RMHP to continue serving Medicare beneficiaries throughout its entire service area. It may also affect the ability of CMS to achieve the basic policy objectives established by Congress under the Medicare Modernization Act (“MMA”).

We confine our comments to our greatest concern: the proposed regulations cited above interpret section 234 of the MMA originally sponsored at our behest by Colorado Senator Wayne Allard and Congressman Scott McInnis. This provision permits cost plans to continue operations after January 1, 2008 only under certain circumstances. Specifically, the statute states that reasonable cost contracts “may not be extended or renewed for a service area insofar as such area during the entire previous year was within the service area” of two or more Medicare Advantage (“MA”) plans (Section 1876(h)(5) of the Social Security Act).

In section 417.402(c) of the proposed regulations, CMS interprets the statute to require mandatory non-renewal of contracts *in any area* in which there are two or more MA plans meeting minimum enrollment requirements (“original interpretation”). However, CMS also invites comment on another possible interpretation of the statute, which “would permit a cost plan to continue operating in its entire service area until all parts of the cost plan’s service area are subject to MA competition meeting applicable thresholds” (69 FR 46869) (“alternate interpretation”).

RMHP believes that the alternate interpretation described by CMS is better supported by the plain language of the statute, when applied in the real world.

For example, as noted above, RMHP is the only managed care organization in Colorado to offer Medicare plans on a statewide basis. As such, RMHP’s service area does not fall *within* the service area of any competing MA organizations at the present time. Rather, the urban service areas of competing MA organizations fall *within* RMHP’s service area, which encompasses both urban and rural counties.

RMHP also believes that the alternate interpretation described by CMS is more likely to promote the basic purpose of the MMA: to expand beneficiary choice of plan and access to needed benefits, nationwide. RMHP asks that CMS consider the following points in the development of final implementing regulations for the MMA.

- **Cost plans have a proven track record of creating value and choice for beneficiaries in rural areas. The efforts of CMS to expand risk plans should be done without jeopardizing options that now exist for beneficiaries.**

The MMA includes financial and other contractual incentives for the expansion of managed care into markets that have not traditionally been served by Medicare risk plans. Substantial increases in reimbursement are presently budgeted by Congress for both local and regional MA plans. Additional flexibility has been afforded in rate-setting arrangements for regional plans, and federal bonus provisions create further incentives for the development of national plans.

These incentives are necessary to facilitate the expansion of risk plans into non-traditional markets. However, they may not be sufficient, because the fundamental economics that drive rural health care systems will not change under the MMA. Specifically, competition among hospitals and other providers for health plan contracts, a basic principle of risk contracting in urban markets, will not increase in rural areas as a result of the MMA. Non-competitive markets for provider services will remain non-competitive. Additionally, the total volume of members available in rural areas will remain unchanged and will be diluted by the option of beneficiaries and providers to continue participation in the original Medicare program. Finally, unlike local Medicare plans, regional plans are statutorily prohibited from adjusting beneficiary premium and cost-sharing levels in rural areas to reflect these economic factors. As such, regional plans will face significant costs in establishing region-wide delivery systems and will not be able to sustain them without substantial, ongoing reimbursement guarantees by CMS.

All of this is not to say the expansion of managed care will not work, but that it may not work in some areas. The question, then, is whether CMS will adopt rules that will remove cost contracts as an option for beneficiaries.

Cost plans have much greater flexibility to deliver services and create value for rural beneficiaries. Specifically, cost plans have the ability to manage the delivery of original and supplemental Medicare benefits without assuming financial risk for Part A services, which are reimbursed directly by the fiscal intermediary. The cost of Part B services is audited by CMS to ensure that the plan operates as a prudent purchaser in delivering Medicare services, while competition with supplemental insurers and other plans creates incentives for cost plans to keep beneficiary premiums low. An additional option for beneficiaries under cost contracts is their ability to use out of network providers by retaining original Medicare benefits. Finally, cost plans have significant flexibility to tailor benefit designs that reflect the preferences of rural enrollees and other market factors. RMHP's stability and consistent presence in rural markets provides evidence that the reasonable cost model is a time-tested and effective means of creating managed care options for beneficiaries who would otherwise have none.

- **Cost plans may not be able to convert to MA-risk status or operate with hybrid cost / risk service areas:**

Unlike its MA competitors in Colorado, RMHP is an independent, non-profit health plan that operates solely for the benefit of the local communities it serves. Creation of a "hybrid" plan, in which a local MA plan is embedded in the urban portion of a broader cost-plan service area, would create significant confusion for beneficiaries and providers and be problematic for any statewide employer plans with retirees. In such a scenario, beneficiary choice of provider would be more limited in risk areas than it would be in cost areas because Medicare would deny reimbursement for any non-network claims. Additionally, providers would need to differentiate billing procedures for plan members on the basis of beneficiary residence in the cost- or risk-based service area.

Reasonable cost reimbursement has enabled RMHP to compete effectively with much larger MA plans in urban markets, while providing affordable coverage for beneficiaries in rural areas.

We appreciate that, CMS would like to encourage cost plans to consider the benefits of transferring to Medicare Advantage and RMHP is undertaking the detailed analysis required for that business decision. This is not a transformation that can be made without significant effort. For example, small plans like RMHP must carefully consider the difficulty of meeting capitalization requirements for the responsible assumption of Medicare risk. CMS's original interpretation would make it difficult for RMHP to convert to MA plan status in local urban markets and nearly impossible to do so on a state- or region-wide basis.

- **Cost plans may not be able to continue providing coverage in rural areas if excluded from urban areas or to re-enter markets at a later date:**

Exclusion of cost plans from the Medicare program will disrupt coverage for thousands of urban and rural beneficiaries. Even if the exclusion occurs only in competitive urban markets where MA plans have historically participated, the resulting loss of membership will jeopardize the ability of cost plans to continue service in rural areas. Administrative costs and risk for supplemental coverage would be spread over a much smaller membership base, thereby reducing the efficiency and stability of the plan.

Further, it is clear beneficiaries and providers have limited tolerance for volatility in health plan coverage. The rapid entry and withdrawal of M+C plans in the years following the implementation of the Balanced Budget Act of 1997 created chaos, confusion and breaks in continuity for Medicare beneficiaries throughout the United States. In Colorado, health plans that exited the M+C program in urban markets face significant obstacles to re-entry, despite reimbursement increases by CMS. Barriers to re-entry are even more pronounced in rural areas. Such exits breach the trust of beneficiaries. Maintenance of rural provider agreements requires a reservoir of good will and extensive, ongoing administrative support. Given their relative resource limitations, it may not be possible for cost-plans to re-establish rural Medicare networks, even if re-entry becomes possible at a later date.

RMHP recognizes that the MMA contains several provisions that are designed to support and encourage the expansion of Medicare risk plans. However, many of the assumptions regarding the design of the new MA program remain untested. In contrast, the reasonable-cost model has consistently enabled organizations such as RMHP to deliver the benefits of managed care to rural beneficiaries. CMS should exercise its administrative latitude to balance the risks associated with the implementation of the new MA programs with the proven success of cost plans. Interpretation of the cost-plan extension statutes in a manner that would require competition by two or more MA organizations throughout an entire cost-plan service area, before excluding the cost plan from *any* portion of its service area, would substantially mitigate these risks.

RMHP appreciates this opportunity to comment on the proposed regulations. If you have any questions about RMHP's comments or the impact of proposed policies on Medicare cost plans, please contact me at 970-244-7775 or by e-mail at [jhopkins@rmhp.org](mailto:jhopkins@rmhp.org).

Sincerely,



John P. Hopkins  
President and CEO

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 recipients 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 knowledgeable 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 specialist's ability to treat them unencumbered.

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 recommends.

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 Academy 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 governed under current requirements.

Subpart G--Payments for MA organizations.

Should be governed under current Medicare/Medicaid policy.

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

Should be governed under current Medicare/Medicaid regulations.

Submitter :  Date & Time:

Organization :

Category :

**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. It is suggested that this definition 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 own pharmacy benefit program.

Specialized MA Plans should be allowed to exclusively enroll certain sub groups of Medicaid or institutionalized beneficiaries. The appropriate sub groups are those CMS has identified, the dually eligible, beneficiaries with severe or chronic conditions, institutionalized beneficiaries 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 disabling 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 remain enrolled in the Plan even if they no longer meet the special need criteria if they would again meet eligibility 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 should 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-Attach-1.wpd

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

Reference #: CMS4069-P  
42 –CRF Parts 417 and 422  
Re: Comments  
From: Jay Harrington  
Chief Development Officer  
Senior Whole Health  
Cambridge Massachusetts

#### Sub Part A – General Provisions

The proposed regulations define Specialized MA Plans are defined as MA Plans that exclusively serve special needs individuals. It is suggested that this definition be retained. If the definition is changed to plans which serve “disproportionately” special needs beneficiaries it would necessitate complex calculations to determine when an appropriate threshold was reached to determine when a regular MA Plan would qualify as a Specialized MA Plan.

The four or more chronic conditions for an enrollee to represent a complex medical condition seem reasonable. The criteria employed by the PACE programs would be another 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 readily available.

We support the proposal that special needs plans provide part D coverage. However special needs plans should be allowed to implement their own internal pharmacy program.

MA Plans should be allowed to exclusively enroll certain subgroups of Medicaid or institutionalized beneficiaries. The appropriate sub groups are those CMS has identified, i.e. the dually eligible, beneficiaries with severe or chronic conditions, institutionalized beneficiaries and End Stage Renal Disease patients.

Quality oversight mechanisms for specialized MA plans should be adopted from standards used for PACE programs.

## Sub Part B – Eligibility, Election and Enrollment

We support the suggestion that individuals with a disabling 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 enrolled in PACE programs having been granted.

Individuals enrolled in specialized MA Plans should be allowed to remain enrolled in the Plan even if they no longer meet the special needs criteria if they would again meet the eligibility criteria for that MA Plan. This provision is vital in order to avoid a cycle of enrollment and disenrollment as the health status of the beneficiary fluctuates.

Specialized MA Plans should be defined as an MA Plan which exclusively serves special needs individuals. The medical care needs of these populations demands that organizations have an exclusive focus on developing the clinical programs necessary to serve these populations.

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.

## Sub Part F Submission of Bids, Premiums, and related Information and Plan approval

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

## Subpart 1 – Organization Compliance with State Law and Preemption by Federal Law

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

Submitter :  Date & Time:

Organization :

Category :

**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.

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.

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

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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

**CMS-4069-P-41**

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



**MASON DISTRICT HOSPITAL**  
615 N. Promenade  
P.O. Box 530  
Havana, Illinois 62644-0530  
Phone (309) 543-4431 Fax (309) 543-8523

October 1, 2004

**VIA: Electronic Submission**

Mark McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4069-P  
PO Box 8014  
Baltimore, MD 21244-1814

**Ref. File Code CMS-4069-P**

**Re: Medicare Program; Establishment of the Medicare Advantage Program; Proposed Rule, Federal Register, Volume 69, No. 148, Tuesday, August 3<sup>rd</sup>, 2004**

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.

Mark McClellan, M.D., Ph.D.

October 1, 2004

Page 2

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.

### **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.

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

Sincerely,  
Mason District Hospital

Harry Wolin  
Administrator, Chief Executive Officer

Submitter :  Date & Time:

Organization :

Category :

**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.

Subparts I Preemption and K Contracts with Medicare Advantage Sponsors  
Comment on CMS-4069-P; Proposed rule for establishment of the Medicare Advantage  
Program  
October 2, 2004

Dear Sirs:

This comment applies to the proposed subparts I (preemption) and the existing subpart K (contracts), and any other related requirements that I have not identified that present similar problems of regulatory excess. I propose that subpart K's "requirements of other laws" and "Federal and State standards" subsections be removed in their entirety. I have submitted a similar comment on the proposed PDP regulation.

Your proposed rule retains verbatim a subsection from the Medicare+Choice regulation that would require MA plans to comply with "all Federal, State, and local laws and regulations" (as explained in your preamble language describing how your proposed Title I regulations simply copy those of Title II). This subsection's regulatory text requires compliance with "all other applicable laws and regulations" and is retained from the existing M+C regulation. You would also retain verbatim a subsection requiring a compliance plan dealing with all Federal, State, and local laws. On its face, these requirements would make denial of MA contract eligibility an enforcement sanction for potential violations of thousands of Federal laws and regulations as well as thousands of State and local laws and regulations. The retained regulatory text makes no exception for State insurance laws, and hence HHS seems to be proposing to retain all existing State insurance standards as MA standards.

However, Section 232 of the MMA specifically preempts State law and regulations (and local law, which is necessarily authorized by State law). It says that the standards established under the MMA "shall supersede any State law or regulation ... with respect to MA plans which are offered by MA organizations under this part."

Accordingly, your proposed retention of 422.502(h)(1)(vi), and 422.501(b)(3)(vi)(A) [existing CFR numbering system], requiring respectively that an MA plan agrees to comply with "all other applicable laws and rules" and has a compliance plan including "written policies, procedures, and standards of conduct ... to comply with all applicable Federal and State standards" are in direct contradiction of the MMA preemption clause and Congressional intent. This is clearly an area where you should have revised existing regulatory language to reduce potential burden and confusion on MA plans.

The proper fix is to eliminate these subsections in their entirety. Nothing in the MMA authorizes you to impose any State requirements (other than licensure and solvency) on MA plans. Nor is there any reason for HHS to seek to impose on MA plans an enforcement requirement for all State laws other than those that apply to health insurance. What a bizarre policy decision that would be—all State laws other than those related to health insurance as such would be enforced by HHS.

The States can enforce their own laws without any help from HHS, and you should be ashamed of not having eliminated these ridiculous regulatory provisions in your proposed rule.

In this respect, has the Congress appropriated a dime to fund HHS enforcement of Federal, State, and local laws not under the direct jurisdiction of HHS, and assigned by statute to other agencies? Has HHS ever requested an appropriation for this purpose? This looks like bureaucratic and legal empire building on a massive scale. What savings might be possible if HHS eliminated its enforcement of Federal, State, and local laws under the existing M+C program? Alternatively, if there are no potential savings because HHS spends nothing enforcing these provisions, they would appear to be pure regulatory bloat and bloviation.

Were you to retain these subsections you would be in apparent violation of laws and Executive Orders dealing with Federalism, which require you to respect States' primacy in enforcement of their own laws, except for those preempted. Nothing in your preamble suggests that you gave the slightest thought to the radical proposition that HHS might enforce State zoning, criminal, labor, property tax, automotive, and other laws, and nothing in your preamble provides the legally requisite justification.

I have sent a copy of this comment to OMB, because of the serious regulatory policy and burden issues that it raises under EO 13132 on Federalism.

Sincerely, W.J. Francis  
Public Policy Network  
703-278-0041

Submitter :  Date & Time:

Organization :

Category :

**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.

Subparts I Preemption and K Contracts with Medicare Advantage Sponsors  
Comment on CMS-4069-P; Proposed rule for establishment of the Medicare Advantage  
Program  
October 2, 2004

Dear Sirs:

This comment applies to the proposed subparts I (preemption) and the existing subpart K (contracts), and any other related requirements that I have not identified that present similar problems of regulatory excess. I propose that subpart K's "requirements of other laws" and "Federal and State standards" subsections be removed in their entirety. I have submitted a similar comment on the proposed PDP regulation.

Your proposed rule retains verbatim a subsection from the Medicare+Choice regulation that would require MA plans to comply with "all Federal, State, and local laws and regulations" (as explained in your preamble language describing how your proposed Title I regulations simply copy those of Title II). This subsection's regulatory text requires compliance with "all other applicable laws and regulations" and is retained from the existing M+C regulation. You would also retain verbatim a subsection requiring a compliance plan dealing with all Federal, State, and local laws. On its face, these requirements would make denial of MA contract eligibility an enforcement sanction for potential violations of thousands of Federal laws and regulations as well as thousands of State and local laws and regulations. The retained regulatory text makes no exception for State insurance laws, and hence HHS seems to be proposing to retain all existing State insurance standards as MA standards.

However, Section 232 of the MMA specifically preempts State law and regulations (and local law, which is necessarily authorized by State law). It says that the standards established under the MMA "shall supersede any State law or regulation ... with respect to MA plans which are offered by MA organizations under this part."

Accordingly, your proposed retention of 422.502(h)(1)(vi), and 422.501(b)(3)(vi)(A) [existing CFR numbering system], requiring respectively that an MA plan agrees to comply with "all other applicable laws and rules" and has a compliance plan including "written policies, procedures, and standards of conduct ... to comply with all applicable Federal and State standards" are in direct contradiction of the MMA preemption clause and Congressional intent. This is clearly an area where you should have revised existing regulatory language to reduce potential burden and confusion on MA plans.

The proper fix is to eliminate these subsections in their entirety. Nothing in the MMA authorizes you to impose any State requirements (other than licensure and solvency) on MA plans. Nor is there any reason for HHS to seek to impose on MA plans an enforcement requirement for all State laws other than those that apply to health insurance. What a bizarre policy decision that would be—all State laws other than those related to health insurance as such would be enforced by HHS.

The States can enforce their own laws without any help from HHS, and you should be ashamed of not having eliminated these ridiculous regulatory provisions in your proposed rule.

In this respect, has the Congress appropriated a dime to fund HHS enforcement of Federal, State, and local laws not under the direct jurisdiction of HHS, and assigned by statute to other agencies? Has HHS ever requested an appropriation for this purpose? This looks like bureaucratic and legal empire building on a massive scale. What savings might be possible if HHS eliminated its enforcement of Federal, State, and local laws under the existing M+C program? Alternatively, if there are no potential savings because HHS spends nothing enforcing these provisions, they would appear to be pure regulatory bloat and bloviation.

Were you to retain these subsections you would be in apparent violation of laws and Executive Orders dealing with Federalism, which require you to respect States' primacy in enforcement of their own laws, except for those preempted. Nothing in your preamble suggests that you gave the slightest thought to the radical proposition that HHS might enforce State zoning, criminal, labor, property tax, automotive, and other laws, and nothing in your preamble provides the legally requisite justification.

I have sent a copy of this comment to OMB, because of the serious regulatory policy and burden issues that it raises under EO 13132 on Federalism.

Sincerely, W.J. Francis  
Public Policy Network  
703-278-0041

Submitter :  Date & Time:

Organization :

Category :

**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

Subpart C—Benefits and Beneficiary Protections  
Comment on the proposed rule for establishment of the Medicare Advantage Program  
CMS-4069-P  
Revised October 2, 2004

Dear Sirs:

Your proposed rule requires MA regional plans to “provide reimbursement for all covered benefits” *in and out of network*, while allowing “differential cost sharing” for out of network benefits. This creates several potential problems; potentially preventing attainment of the Congressional objective that MA plans function similarly to private health plans, such as those participating in the FEHBP. This comment is to provide you my suggestions for sensible legal and practical interpretations to prevent these problems from arising, while ensuring the broad Congressional objective that enrollees have access to medical providers in- and out-of-network.

“Covered benefits” can be grouped into several categories, only one of which seems likely to have been intended for mandating participation of non-network providers.

First, there are core benefits where *enrollees would typically have provider choices* but might prefer a non-network provider even at increased cost sharing. Provider types in this category would include physicians, hospitals, and drug stores. Without question, the Congress intended that these benefits allow use of in- and out-of-network providers. This legislative choice was not a chimera. Many preferred provider plans in the private sector, such as the Blue Cross Basic plan in the FEHBP, and most HMO plans, limit choices more severely. These models were certainly known to, and rejected by, the Congress.

Second, there are a few benefits that are provided on a contractual basis through a *single provider for all plan enrollees*. These include mail order drugs and nurse hotlines (other examples in some plans would be behavioral management and disease management). These contracts are typically predicated on obtaining **all** of the plan’s business, and the contractual arrangements and bid prices reflect that. It would be impossible to administer a health plan if every mail order drug firm or nurse hotline firm were eligible to participate on the same terms as the firm that signed up for a guaranteed volume of business, and the Congress could not be presumed to have intended to prevent the very kinds of volume discounts on which it relied for obtaining deep discounts on drugs in each plan. Put another way, no second firm could in fact meet the contractual terms and conditions that were designed for one firm, because the first firm would not agree to the same discounts if it were not the exclusive provider. Requiring plans to allow non-network providers for these services would present a Catch-22, since the original sole contractor would not have agree to those terms in the first place. Furthermore, establishing such contracts, integrating provision of those services, and informing enrollees of those services are expensive functions, and a second (or third, or fourth) contract would impose significant expense and inconvenience on plans, thereby increasing cost to the government, to plans, and to enrollees.

Third, there are *ancillary single provider benefits*. These arrangements are for services not normally paid through health insurance, and provide benefits such as gym discounts, eyeglass discounts, and dental discounts. The scope and diversity of these kinds of benefits is staggering. A network called GlobalFit is used by Aetna, Kaiser, CareFirst, and others to provide discounts at a number of gym chains. Some plans offer discounts on massage, acupuncture, and weight control programs. For example, CareFirst gives its enrollees discounts to Weight Watchers. And Cigna provides discounts to health-related magazines. In these arrangements, there is typically no payment by the plan, and no cost sharing by the enrollee. Instead, the enrollee obtains a discount from the retail price he would otherwise have paid. Typically, the plan negotiates an agreed discount with a particular firm or chain, and that firm or its members (who may be franchised rather than owned, or even a provider pool) profit from the larger volume of business that the plan members bring to it rather than to competing providers. These business arrangements cannot survive entry on equal terms by other firms, since their entire economic basis is exclusivity. Indeed, to subject these contracts to free entry would also be to create a Catch-22, since one of the usual contractual provisions is that only one firm or group of firms will obtain the favored arrangement. By definition, this deal cannot be provided simultaneously to additional entrants without altering the expected economic return. Note that this business model is common, and not limited to the world of health insurance. Similar arrangements (e.g., for eyeglass discounts at a particular chain) are often made by affinity organizations.

Although the conference agreement is silent on the rationale for its non-network reimbursement requirement, the Congress cannot have intended to render impossible the normal practices of private health insurance, or to deprive enrollees of otherwise desirable services on favorable terms to enrollees. The sweeping statutory language reflects, instead, the failure of the drafters to consider explicitly the second and third situations described above.

There is no question as to what result HHS should seek on policy grounds—the provision of the widest possible range of inexpensive services to enrollees. The only issue arises as to the rationale for interpreting the unintentionally broad statutory language to prevent a result the Congress could not have intended. I propose several lines of interpretation and explanation below. It may be equally as important to provide preamble examples as to provide regulatory language, and I deal with both.

Preferably, HHS should create a principled distinction between the kinds of benefits reasonably subject to the statutory provision, and the kinds of benefits that would be thwarted if subject to the provision. Using the typology above, the applicability of the statutory provision would be limited to the broad types of benefits for which health plan enrollees normally have multiple provider choices, namely retail providers of hospital, physician, device, and pharmacy services. Core and ancillary benefits normally provided through a single provider for all plan enrollees would be exempted on the grounds that the Congress did not intend to create a Catch-22 situation. Indeed, when a statute is drafted in a way that, read literally, would thwart its reasonable implementation, it is common for regulations to create the kinds of reasonable interpretations that allow a

sensible result. (Elsewhere in your proposed regulations a statutory error in using the word “not” is overridden by you through just this kind of reasoning.)

Another potential line of reasoning is to focus on the statutory terminology that the plan “provides for reimbursement” regardless of whether the benefit is provided in or out of network. The benefits at issue here normally do not involve reimbursable arrangements of the kind referenced by the statute. The statute is clearly aimed at services that are reimbursed for a unit of service, such as a physician visit or drug prescription. It specifically allows for higher enrollee cost sharing for these services, which presupposes a charge for these services. Most of the services at issue here are normally provided “free” to the enrollee and hence would not involve any cost sharing to vary. (Note, however, that although most are “free” to enrollees there is direct plan-to-contractor payment for nurse hotlines. These hotlines might, however, be exempted on the grounds that they are part of the internal operation of the plan, like plan appeal process and benefit payments, and hence not a “covered benefit.” Nor does this approach work for mail order drugs.)

Yet another possibility might be to use the distinction between “basic” and “supplemental” benefits that the statute uses throughout.

If your attorneys cannot agree that the Congress did not intend to nullify the normal panoply of single-contractor benefits offered by private health plans, as articulated above, then a fallback position is to take the approach used under the FEHBP. That program has created a category called “non-FEHB benefits available to plan members.” Under this approach, plans provide benefits that:

“Are neither offered nor guaranteed under the contract with the FEHB Program, but are made available to all enrollees and family members of this Plan. The cost of the benefits described on this page is not included in the FEHB premium and any charge for these services do not count toward any FEHB deductibles, out-of-pocket maximum copay charges, etc. These benefits are not subject to the FEHB disputed claims review procedure.”

This approach is well suited for benefits such as gym, eyeglass, and dental discounts. If applied to MA, plans would be allowed to offer certain services that are not “covered benefits” under the statute. Because these services are not provided as contractual guarantees, the entire panoply of MA requirements is avoided. All that CMS need do to facilitate these arrangements is to allow plan brochures and other informational materials to include information on non-contractual benefits. Since the kinds of benefits involved typically involve no plan payments, but simply discounts for volume, the statutory payment systems are compromised in no way. Unfortunately, this approach will not work for mail order drugs, which are covered benefits.

If your attorneys cannot agree to this entirely reasonable alternative, as endorsed by a sister agency operating a comparable program, then it may be that only one option is left. This option requires little or no change in regulatory text, but the addition of a substantial

preamble explanation in the final rule. You would explain that any plan could avoid the seemingly draconian limitation using the method explicitly endorsed by the Congress. Under this approach, you would explain, plans may charge for out-of-network services on a copayment, coinsurance, or deductible basis, and distinguish between hospital, medical, and drug benefits on the one, and these other services on the other. These amounts, HHS should explain, could be set at levels that would, as a practical matter, prevent non-network firms from applying, or at any rate from obtaining any consequential volume of business, and hence prevent undercutting the discounts that the plan arranged on the basis most favorable to enrollees.

You should specifically address the point that nurse hotlines, and vision and other discount arrangements, need not be, and in the world of private insurance never are, subject to deductibles. However, nothing in the statute precludes plans from establishing a high deductible (perhaps \$500 or more) for using non-network firms, a deductible so high that none would apply. (Hospital and medical services are subject to a unified deductible, and drugs to another deductible, but none of these services except mail order drugs would fall under those deductibles). Thus, these ancillary services could be provided with no deductible using the contractual single firm, and a high deductible if using a “non-network” firm.

The fact that plans have these tools available to solve the problem should not, however, dissuade you from taking the simpler approach of distinguishing between benefits where choice is expected and the use of non-network providers is sometimes very important to enrollee access, and services requiring use of a single provider, directly allowing the use of “one firm only” contracts for the latter.

Another complication arises if these ancillary services were interpreted by CMS to be beneficiary spending subject to the catastrophic limit on out-of-pocket expenditures. Clearly the Congress did not intend that gym fees would count toward this limit.

I trust that you will find these comments helpful in drafting your final rule. Whatever approach(es) you take to dealing with this issue, be sure to discuss specifically the consequences for (a) mail order drugs, (b) nurse hotlines, and (c) myriad discount arrangements, and please provide specific examples of the kinds of cost sharing that would be appropriate to protect these benefits, and implications for the catastrophic limit. For example, would a plan be able to impose a \$500 gym deductible before it allowed a discount for a non-network gym, and exclude beneficiary gym costs from the limit?

Sincerely, W.J. Francis  
Public Policy Network  
703-278-0041

Submitter :  Date & Time:

Organization :

Category :

**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, QDWHs, 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.

Submitter :  Date & Time:

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**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.

Submitter :  Date & Time:

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**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.

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**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 appreciate you allowing me the time to state them. Thanks and take care!

Submitter :  Date & Time:

Organization :

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**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 for 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](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](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.

October 3, 2004

Comments: CMS-4069-P

Submitted by:

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Background--Medicare Prescription Drug, Improvement, and Modernization Act of 2003

As one of five operating Medicaid HIV Special Needs Plans (HIV SNP) established by New York State, New York-Presbyterian System SelectHealth (NYPSSH) supports the proposed establishment of specialized MA plans for the dually insured Medicaid/Medicare HIV/AIDS infected population with the provision of access to required antiretroviral medications and other prescription medications without cost to recipients. The HIV SNP model offers access to HIV Specialists as Primary Care Providers, Psychosocial Case Management, Care Coordination, Treatment Adherence and a full Medicaid benefit package. The Plans have experienced involuntary disenrollments as members become Medicare eligible and would welcome the opportunity to continue to serve these individuals.

NYPSSH recommends the New York State HIV Special Needs Plan Model Contract as a reference for the development of MA Special Needs Plans serving the HIV/AIDS infected community. The full document is described below and can be found online at the web address listed.

New York State  
HIV Special Needs Plan (SNP) Model Contract

This model contract is presented for informational purposes only. It represents the HIV SNP State model contract language as approved in March 2003 by the Centers for Medicare and Medicaid Services (CMS), and may not reflect minor amendments (if any) approved subsequent to March 2003.

This State model contract also does not include any local district-specific provisions that may be included in a SNP's contract with a locality.

<http://www.health.state.ny.us/nysdoh/hiv aids/snps/entirecopy.pdf>

## 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.

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### HIVQUAL PROJECT

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

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## 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.