



Tribal Technical Advisory Group

to the Centers for Medicare and Medicaid Services



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September 30, 2004

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

RE: Comments on Proposed Rule -- Medicare Part D Permanent Prescription Drug Benefit pursuant to Notice in 69 Federal Register 46632 (August 3, 2004)
File Code CMS-4068-P

Dear Administrator:

On behalf of the Tribal Technical Advisory Group, I hereby submit the attached comments on the proposed rules to implement the Permanent Prescription Drug Benefit under Part D of the Medicare program.

The attached comments address issues related to the impact implementation of the proposed rules will have on American Indian and Alaska Native beneficiaries who are served by pharmacies operated by the Indian Health Service, Indian tribes, tribal organizations or urban Indian organizations (I/T/U pharmacies). As proposed, the rules would have a devastating adverse impact on the revenue collected by the I/T/U pharmacies for their dual eligible Indian patients and must be revised to prevent this outcome. It clearly was not the intent of Congress in enacting the Medicare Modernization Act to reduce revenues to Indian health programs. The United States has a trust responsibility for Indian health, and this responsibility must assure that the Indian health system is not harmed by implementation of Part D.

We urge CMS to make revisions to the Part D regulations pursuant to recommendations set out in these comments.

Sincerely yours,

Valerie Davidson, Chair

Attachment -- Part D Comments

**COMMENTS REGARDING
PROPOSED REGULATIONS TO IMPLEMENT
THE MEDICARE PRESCRIPTION DRUG BENEFIT UNDER
THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT AND
MODERNIZATION ACT OF 2003
as published in
69 Fed. Reg. 46,632 *et seq.* (Aug. 3, 2004)
File Code CMS-4068-P**

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 D's 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" -- conservatively estimated at between \$23 million to \$53 million. Since the loss of revenue to Indian health was **not** Congress's objective in enacting the Part D benefit, the rules must be revised in several respects to protect the Indian health system from what would doubtless be substantial harm.

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 D does not result in inadvertent and unintended harm to that system.

The regulations governing the Part D prescription drug benefit must be revised to achieve the following goals:

- Guarantee that AI/ANs have a meaningful opportunity to access the benefit *through the pharmacies of the Indian health delivery system*;
- Require private prescription drug plan sponsors (PDPs) and Medicare Advantage organizations offering prescription drug coverage (MA-PDs) to reimburse or contract with the pharmacies in the Indian health system -- those operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (collectively referred to as "I/T/Us");
- Order Indian-specific terms that must be included in those contracts to guarantee that I/T/U pharmacies can collect from PDPs, building on the experience gained from the Medicare Prescription Drug Discount Card program; and
- Develop a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. One idea for achieving this protection could be modeled on the "hold harmless" mechanism Congress established for FQHCs in Section 237 of the MMA. A less costly and less administratively cumbersome option is to keep AI/AN dual eligibles under State Medicaid plans for drug coverage, since the federal government has full economic responsibility for them under Medicaid (100% FMAP) and Medicare Part D.

In order to fully comprehend the potential adverse impact Part D 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 D program does not wreak havoc on the Indian health system by reducing the level of pharmacy reimbursements from Medicaid on which the system has come to rely.

Indian Health Care System and Indian Health Disparities

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

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

Health Disparities. AI/ANs have a higher rate of disease and illness than the general population and consequently require more medications and incur higher prescription drug costs than most Americans. An examination of the health status data leads one to conclude that AI/ANs are the "Poster Children" of health disparities. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights³ 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 appropriations to the Indian Health Service. Regardless of the operational form, all Indian health programs are severely underfunded. In a 2003 report⁴, 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-

¹ See, e.g., 25 U.S.C. § 1601.

² 42 U.S.C. § 2001.

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

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

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. Using the Federal Employee Benefit Package as a standard, in a 2002 study mandated by Congress the federal government has found that the Indian Health Service is funded at only 52 percent of the level of need.⁵

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 IHS and tribes to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. When drug coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that reimbursement for drugs for Indian dual eligibles continues without interruption and without reduction.

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.

Pharmacy Services for Dual Eligibles

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 25,963⁶ and 30,544⁷ 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 \$918.⁸ 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 million⁹ and \$53.6 million¹⁰**. 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 rolls for prescription drugs with the inauguration of Medicare Part D in 2006. In their present form,

⁵ Federal Disparity Index Report for 2002, showing an expenditure of \$1,384 per HIS user compared to a benchmark price of \$2,687 per user.

⁶ This number represents 85 percent of the three-year total of active users.

⁷ This is the number of active users, defined as at least one visit in the past three years.

⁸ 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.

⁹ 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.

¹⁰ This higher number uses the 30,544 number of dual eligibles in 2003 and the \$1,756 estimated spending in 2006.

however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements.

Barriers to Part D access of Indian dual eligibles. There are several reasons why the intended conversion of dual eligibles from Medicaid to Medicare could be extremely problematic in the Indian health system:

- Switching payment sources from Medicaid to PDPs under Part D will hurt AI/AN consumers and Indian health providers because most tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. Dual eligibles in those areas will have difficulty accessing the Part D benefit unless they use an Indian health pharmacy admitted to PDP networks.
- Medicaid revenues have been an important source of income for Indian health facilities. **As drug coverage for AI/AN dual eligibles is removed from Medicaid and placed under Medicare, the amount of revenue in jeopardy is estimated to be between \$23.8 million and \$53.6 million.** Reductions in reimbursements for pharmaceuticals cannot be absorbed by raising rates for other services, as Indian patients are served without charge.
- The level of revenue an I/T/U would collect under Part D will very likely be less than it currently collects under Medicaid for dual eligible drug coverage. Therefore a “wrap around” payment from Medicare, consisting of the difference between the PDP/MA-PD contract amount and the amount the I/T/U would have received under Medicaid, must be utilized to “hold harmless” I/T/Us, if an I/T/U contracts with a PDP/MA-PD.
- If private prescription drug plans are not required to contract with I/T/U pharmacies, there will be little incentive for them to do so, as the service population of these pharmacies is comparatively small and the Indian population tends to be sicker. Without network status or payment for off plan services, an I/T/U pharmacy will not be able to collect for drugs dispensed to any AI/AN enrolled in a Part D plan. This would produce three negative results: (1) a loss of revenue to the I/T/U pharmacy; (2) no meaningful opportunity for the enrolled Indian to use his Part D benefit; and (3) a windfall for the PDP who collects premiums from CMS for a dual eligible, but pays no claims.
- Even if private plans are required to contract with I/T/U pharmacies, this command will be meaningless unless the regulations set out terms specifically drafted to address the unique circumstances of the IHS, tribal and urban Indian pharmacies.
- Even if an Indian beneficiary is enrolled in a Part D plan, the I/T/U pharmacy may not know what PDP or MA-PD to bill. Particularly with automatic enrollments, the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delay in accessing the benefit if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. This situation mirrors the disastrous consequences suffered by the I/T/Us when State mandatory Medicaid managed care enrollment programs were implemented.
- If delays in implementation occur, it is not clear how the I/T/U pharmacies will recoup payment for expenditures made during the period between when the AI/AN is switched from Medicaid to Medicare pharmacy benefits and when the I/T/U pharmacy is an established network provider or able to bill for out of network services. Even if the I/T/U pharmacy is allowed to bill for services provided from the beginning of 2006, they may not have the staff to deal with a backlog of billing. Confusion and lack of information could result in not billing for covered services.

The Part D program will also impact AI/AN Medicare beneficiaries who are not dual eligibles and must pay a premium for Part D participation. Since these individuals receive drugs at Indian Health Service and tribal health pharmacies without charge, there is no incentive for them to pay premiums to enroll in a Part D plan. In order to be able to collect reimbursements for drugs dispensed to those patients, CMS must facilitate group payer options for tribes who wish to pay premiums for these beneficiaries in order for their pharmacy to be reimbursed for drugs dispensed.

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 by Section 1860D-4(b)(1)(C)(iv) of the MMA which authorizes him to establish standards to assure access to Part D for I/T/U pharmacies. By this provision, Congress recognized that access for Indian beneficiaries means the ability to utilize that benefit through I/T/U pharmacies.

ACCESS TO COVERED PART D DRUGS
Comments regarding: Section 423.120: Pharmacy Access Standards

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To guarantee access to Part D prescription drug benefits for AI/AN beneficiaries by requiring private drug plans to contract with those pharmacies which serve the majority of this population -- I/T/U pharmacies.

Access Issue, Pages 46655-57: Should CMS use its authority under Section 1860D-4(b)(1)(C)(iv) of the Act (authorizing the Secretary to establish standards to provide access for I/T/U pharmacies to participate in the Part D program) to *require* or *strongly encourage* private drug plan sponsors (PDPs) and MA organizations offering MA-PD plans (MA-PDs) to contract with I/T/U pharmacies?

Comment: In order to realize its goals (as communicated on pages 46655 and 46633 of the Preamble) of ensuring convenient access to covered Part D drugs to plan enrollees and broad participation by Medicare beneficiaries in the new prescription drug benefit under Part D, CMS must use its authority under Section 1860D-4(b)(1)(iv) of the Act to **require** PDPs and MA-PDs to contract with I/T/U pharmacies. Without this requirement the private drug plans will have little or no incentive to contract with I/T/U pharmacies.¹¹ This is true because there is no financial incentive for private plans to contract with I/T/U pharmacies since these pharmacies and the AI/AN beneficiaries they serve are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. If PDPs and MA-PDs are merely “*strongly encouraged*” to contract with I/T/Us¹² they will not do so because of the uniqueness and remoteness of Indian health programs the comparatively small and sicker populations they serve, and the perceived cost and time it may take to enter into individual contracts with each I/T/U pharmacy. CMS acknowledges these concerns on page 46657 of the Preamble.¹³

Failure to include language in the rule requiring private plans to contract with I/T/U pharmacies will have the unintended consequence of *denying* access to the benefit for a majority of AI/AN beneficiaries. This would be contrary to the access requirements of the Act. If I/T/U pharmacies are not included in the PDP or MA-PD network, an estimated 26,000 AI/AN beneficiaries who obtain their drugs from I/T/U pharmacies will be unable to access the Part D drug benefit. CMS acknowledges this fact on page 46657 of the Preamble by stating that I/T/U pharmacies may be the only facilities available to AI/AN beneficiaries and recognizes that **access to I/T/U pharmacies should be preserved** because it “would greatly enhance Part D benefits” for AI/AN enrollees.

Access for I/T/U pharmacies to the Part D program is crucial for preserving current revenues. All AI/ANs dual eligibles will lose their Medicaid drug benefits and are required to enroll in a Part D or Part C plan. Those dual eligible who fail to enroll will be automatically enrolled in a private plan. Regardless of such a beneficiary’s enrollment in the new prescription drug benefit, an AI/AN beneficiary will continue to utilize his/her I/T/U pharmacy. Absent an agreement with the private drug plans, these pharmacies will be unable to collect reimbursement for prescription dispensed to Medicare beneficiaries. In order for I/T/Us to collect reimbursement for prescription drugs provided to dual eligibles **they must be included in the private plan network**.

¹¹ Allowing the private plans to count I/T/U pharmacies toward access standards may provide incentive for private plans to contract with a few I/T/U pharmacies but only where the private plan needs the I/T/U pharmacy to meet the Tricare access standards. It will not be an incentive to contract with all I/T/U pharmacies.

¹² CMS proposes this option in 69 FR at 46657.

¹³ One way to decrease administrative costs while at the same time assuring access for AI/AN beneficiaries who use I/T/U pharmacies is to create special endorsement PDPs and MA-PDs to serve AI/AN beneficiaries similar to the mechanism used in the Temporary Prescription Drug Discount Card Program. This matter is discussed further in our comments regarding §423.120(a)(1).

Therefore, it is vital that Section 423.120 be modified to include language requiring PDPs and MA-PDs to contract with I/T/U pharmacies, but required contracting is not enough. The unique status of tribes may become an issue in contract negotiations. The standard PDP/MA-PD contract could prove problematic for I/T/Us as CMS acknowledged in the Preamble on page 46657. In order to assist CMS, PDPs, and MA-PDs in resolving this difficulty, we urge that specific contract provisions, which are contained in the draft language below, be required provisions for agreements between PDPs/MA-PDs and I/T/U pharmacies.¹⁴

The following changes should be made to § 423.120:

Section 423.120 Access to covered Part D drugs.

§423.120 (a) *Assuring pharmacy access.*

Insert the following new paragraph and re-number all subsequent paragraphs:

“(2) *Access to IHS, tribal and urban Indian pharmacies.* In order to meet access standards under Section 1860D-4(b)(1)(C)(iv), a prescription drug plan or MA-PD plan must offer to contract with any I/T/U pharmacy in its plan service areas, and such contract must include the elements set out in §423.120(a)(4).”

§423.120(a)(4) *Pharmacy network contracting requirements.*

Insert the following new subparagraph (iv):

- “(iv) Must incorporate in all contracts entered into with I/T/U pharmacies, within the text of the agreement or as an addendum, provisions that:
- (A) Acknowledge 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) State that the terms of the contract may not change, reduce, expand or alter the eligibility requirements for services at the I/T/U pharmacy as determined by the Medicare Modernization Act of 2003; 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 the tribal or urban Indian organization’s pharmacy by the IHS for operation of a health program.
 - (C) Incorporate federal law and federal regulations applicable to tribes and tribal organizations, including 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) Recognize that I/T/Us are non-taxable entities.
 - (E) State that IHS, tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.
 - (F) State that a PDP may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.
 - (G) Include confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.
 - (H) State that an I/T/U pharmacy is not subject to the PDP formulary.
 - (I) State that the Agreement may not restrict access the I/T/U pharmacy otherwise has to purchase drugs from the Federal Supply Schedule or the Drug Pricing Program of Section 340B of the Public Health Service Act.
 - (J) State that the I/T/U shall not be required to impose co-payments or deductibles on its Indian beneficiaries.
 - (K) Authorize I/T/U pharmacies to establish their own hours of service.”

¹⁴ We submit as Attachment 1 a model tribal addendum prepared by the CMS Tribal Technical Advisory Group to be utilized by tribal and urban Indian pharmacies participating in the Temporary Prescription Drug Discount Card Program.

REGULATIONS MUST PROVIDE A MECHANISM TO ASSURE NO REDUCTION IN REVENUES TO I/T/U PHARMACIES

Comments regarding: §423.120: Access to covered Part D drugs and §423.124: Special rules for access to covered Part D drugs at out-of-network pharmacies

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To include in the regulation a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. We provide four options in our comments to achieve this goal:

- Option 1: *In-Network Status + Wrap-Around Payment.* One mechanism for achieving this protection would be to require PDP to recognize I/T/U pharmacies as in-network providers and for CMS to provide “a wrap-around payment” modeled on the provision Congress established for FQHCs in Section 237 of the MMA. This payment would supplement the difference between the amount paid by the PDP/MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid.
- Option 2: *Out of Network Status + Wrap-Around Payment.* In the event that I/T/U pharmacies are not treated as in-network pharmacies, they should be recognized as out-of-network pharmacies eligible for reimbursement from the private plan under §423.124 and receive a supplemental “wrap around” payment from the federal government which would include any increased differential in cost sharing related to use of out of network pharmacies. This supplemental payment would provide reimbursement for the difference between the out of network plan payment and the amount the I/T/U would have received as an in network provider.
- Option 3: *Special Endorsement PDP/MA-PD Plans.* Specific PDPs could be designated to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Benefit Discount Card program.
- Option 4: *Exemption of AI/AN Dual Eligibles.* Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid. This alternative would allow CMS to avoid the complicated issues of access and revenue loss that we discussed throughout these comments.

Comment: The regulations must contain a provision which protects the level of revenue I/T/U programs receive under the current Medicaid drug coverage for dual eligible individuals. 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. Drug coverage for dual eligibles under Medicaid will cease January 2006, transferring these individuals to the Medicare Part D prescription drug coverage. This change in coverage will disproportionately and negatively impact Indian health facilities if I/T/Us are unable to secure the same level of reimbursement under Medicare as they currently receive under Medicaid for prescription drugs provided to dual eligibles. The MMA and its implementing regulations should not be used as a vehicle to reduce the amount of revenue I/T/U pharmacies currently receive under Medicaid for drug coverage to dual eligible beneficiaries.

As we discussed in the Introductory Statement to these comments we estimate that the Medicaid recovery for **AI/AN dual eligibles drug costs ranges between \$23.8 million¹⁵ and \$53.6 million.¹⁶** 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 rolls when Medicare Part D becomes operative in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements. Even

¹⁵ 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.

¹⁶ This higher number uses the 30,544 number of dual eligibles in 2003 and the \$1,756 estimated spending in 2006.

if PDPs and MA-PDs are required to contract with I/T/U pharmacies, it is very likely that these contracts will not provide the level of reimbursement I/T/Us currently receive under Medicaid.

We propose that one of the four “hold harmless” provision options be included in the regulation to maintain the current level of revenue I/T/U pharmacies receive under Medicaid.

Option 1: In-Network Status with Wrap-Around Payment

While it would be the responsibility of CMS to establish ways to prevent loss of revenue at I/T/U pharmacies, we propose that CMS:

- (a) Require all PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the appropriate rate¹⁷, *and*
- (b) Provide a “wrap around” payment for drug coverage services similar to the special payment rules for medical services provided at federally qualified health centers (FQHCs) contained in Section 237 of the MMA.

Reimbursement as In-network Provider. We request that the regulations require PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the Medicaid rates. This provision would prevent agreements in which the PDP/MA-PD agrees to pay an artificially low rate to the I/T/U pharmacy, with the knowledge that the I/T/U pharmacy will receive supplemental payments from CMS.

Wrap-Around Payment. We also propose that an I/T/U pharmacy which provides Part D drug benefits to AI/AN beneficiaries receive a “wrap-around payment” to supplement the difference between what the I/T/U pharmacy is paid from the private plan and the amount the pharmacy would have received for providing this benefit under Medicaid. This mechanism will allow an I/T/U pharmacy to receive payment from the federal government when the amount paid by the private plan is less than the Medicaid amount.

We suggest that the following provision or ones similar in nature be added to the Part D rules:

Section 423.120(a)(1): *Convenient access to network pharmacies.*

“§423.120(a)(1)(iv). Any PDP or MA-PD plan with one or more I/T/U pharmacies within its service area shall recognize such I/T/U pharmacies as in-network providers for the purpose of paying claims for pharmaceuticals supplied to any American Indian or Alaska Native enrolled in such PDP or MA-PD, regardless of whether the I/T/U pharmacy submitting a claim is a contracted network pharmacy.”

The following language should be inserted into Part 423 at the appropriate place:

§423.____. Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.

“If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid.”

¹⁷ 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.”

Option 2: Out of Network Status with Wrap-Around Payment

In the event that I/T/U pharmacies are not recognized as in-network providers under Option 1, we propose that the regulations recognize these pharmacies as out of network providers under §423.124 and provide a wrap-around payment to supplement the difference between the out of network reimbursement rate and the Medicaid rate.

We suggest that the following sentence be added to Sec. 423.124(a):

Section 423.124(a) ***

“An I/T/U pharmacy that dispenses covered Part D drugs to an American Indian/Alaska Native beneficiary shall be considered an out of network pharmacy for payment of claims.”

Additionally, the following provision should be included in Part 423:

§423.____. Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.

“If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid.”

Option 3: Special Endorsements with Wrap-Around Payment

Designating private plans to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Discount Card program is an alternative that could encourage PDP contracting with I/T/U pharmacies. Specifically identifying the PDP serving AI/AN will help I/T/Us to identify and bill the correct PDP or MA-PD. Additionally, designating specific PDPs and MA-PDs to contract with I/T/U pharmacies would allow an AI/AN beneficiary to easily identify which plan includes his/her I/T/U pharmacy, avoiding the need for the individual to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. Of course, to ensure that I/T/U revenues do not decrease under this option, the wrap-around payment provision discussed above would be necessary. Designation of specific PDPs would also facilitate development of specific I/T/U contract terms.

If CMS is unable to secure private plans to offer the benefit, then it could either subsidize the benefit or provide a “fall back” plan as authorized by Section 1860D-2(b) of the MMA. The Part D proposed regulations depend on the private market to drive the benefit; however, because of the unique characteristics of Indian health programs, private plans may not have incentive or interest in serving a predominately low-income population. Establishing specific PDPs and MA-PDs to serve the AI/AN population is entirely feasible since PDP and MA-PD regions have yet to be established.¹⁸

Option 4: Exemption of AI/AN Dual Eligible Individuals from Part D

We offer an alternative that would allow CMS to avoid the complicated issues of access in Section 423.120, revenue loss to I/T/Us and the “wrap around” mechanism discussed on page 11 of these comments -- **Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid.**

We believe that exempting AI/AN dual eligibles from mandatory enrollment is an efficient and effective alternative for the following reasons:

- Exemption of AI/AN dual eligibles from mandatory enrollment will prevent any loss of revenue to I/T/U pharmacies that will result if drug coverage for dual eligibles is switched from Medicare to Medicaid.

¹⁸ In creating special endorsements for AI/AN CMS could establish:

- A pool of Indian-specific PDP/MA-PD who would serve regions that mirror IHS Areas, or
- Nationwide PDPs/MA-PDs to serve AI/AN in all fifty states

- Exemption of AI/AN dual eligibles will eliminate the barriers dual eligibles, as well as AI/AN basic beneficiaries, will face in accessing the Part D benefit. For example, the MMA strategy to use private plans as a vehicle to provide prescription drug benefits severely restricts access for many AI/ANs because tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks.
- Exemption of AI/AN dual eligibles from mandatory enrollment will eliminate the detrimental impact on reimbursement levels and the increase administrative costs that will occur when the I/T/U pharmacy does not know what PDP or MA-PD to bill. This is particularly true with regard to automatic enrollments because the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delays if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider.

It is important to recognize that exempting AI/AN dual eligibles from mandatory participation in Part D thereby allowing them to continue to receive prescription drug coverage through the State Medicaid Program will have **no budget impact**. This is so because prescription drug coverage costs will be paid by the federal government regardless of whether the benefit is provided under Medicaid at 100% FMAP or Medicare Part D subsidy for dual eligibles.

Exempting AI/AN from enrollment in Part D may be modeled on the existing statutory language exempting AI/AN from enrollment in mandatory Medicaid managed care plans. Section 1932(2)(C) of the Social Security Act, codified at 42 U.S.C. §1396u-2, provides for this exemption in recognition of the many difficulties (similar to the ones we have discussed throughout these comments) facing I/T/Us when dealing with private plans.

I/T/U PHARMACIES AND FEDERAL SUPPLY SCHEDULE (FSS)
Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems

Goal: *To ensure that I/T/U pharmacies that participate in PDP pharmacy networks continue to have the option of purchasing prescription drugs for AI/AN Medicare beneficiaries at Federal Supply Schedule (FSS) prices or at the discounts available under the 340B program.*

Terms and Conditions Issue, Page 46658: CMS notes that the proposed rule does not mandate a single set of terms and conditions for participation in a pharmacy network. CMS seeks comment on whether it should require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks.

Comment: As the Preamble recognizes, there are 201 I/T/U pharmacies serving 107,000 elderly and disabled AI/ANs in 27 states (page 46657). These pharmacies currently have access to Federal Supply Schedule (FSS) prices for the prescription drugs they dispense to AI/AN Medicare beneficiaries, or they are covered entities entitled to discounts under the 340B program, 42 U.S.C. 256b, or both. These discounted prices reflect the purchasing leverage of the Federal government and have enabled I/T/U pharmacies to meet the needs of AI/AN beneficiaries, whether or not enrolled in Medicare, in a cost-efficient manner.

We are concerned that PDP sponsors and MA organizations offering an MA-PD plan may require participating pharmacies to purchase drugs through the PDP sponsor or MA organization. This could have the effect of forcing I/T/U pharmacies to choose between participating in Medicare Part D and retaining their current access to FSS prices or 340B discounts, or both. We do not believe Congress intended that I/T/U pharmacies be forced into this choice. We therefore propose that the final rule prohibit PDP sponsors or MA organizations from requiring I/T/U pharmacies to purchase drugs through mechanisms other than FSS or the 340B program. This would not preclude an I/T/U pharmacy that wished to do so from purchasing its drugs through the PDP or MA-PD plan. The option, however, would be that of the I/T/U pharmacy, not the PDP or MA-PD plan.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans should be revised to read as follows (modifications are *italicized*):

“(4) **Pharmacy network contracting requirements.** In establishing its contracted pharmacy network, a PDP sponsor or MA organization offering qualified prescription drug coverage –

- (i) Must contract with any pharmacy that meets the prescription drug plan’s or MA-PD plan’s terms and conditions;
- (ii) May not require a pharmacy to accept insurance risk as a condition of participation in the PDP plan’s or MA-PD plan’s network; *and*
- (iii) *May not require an I/T/U pharmacy to purchase prescription drugs other than through the Federal Supply Schedule or prohibit an I/T/U pharmacy from receiving a discount as a covered entity under section 340B of the Public Health Service Act, 42 U.S.C. 256b.* “

FORMULARY

Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements.

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule.

Goal: *I/T/Us should be exempt from formulary requirements and therefore able to utilize permissible substitutes. This exemption is needed to both accommodate the limited stock carried by many small I/T/U pharmacies and dispensaries and to allow I/T/Us to include in their formulary of drugs for which reimbursement will be paid those drugs available through FSS or 340b.*

Comment: Section 423.120(b)(1) permits PDP and MA-PD plans to develop formularies so long as they meet the requirements of this section. We are concerned that plans that develop such formularies will make stocking the drugs in the formulary a requirement of its contracts with participating pharmacies. Many I/T/U pharmacies are small and cannot stock a full range of drugs, particularly if the condition the drug is used to treat is one beyond the scope of the I/T/U clinic and its providers. When establishing their formularies, I/T/U hospital and clinic pharmacies also consider aspects of treatment that may not be generally important, such as the extent of monitoring of the patient that may be required. Since many patients live far from the I/T/U pharmacy, this is an important therapeutic factor. Another factor in whether the I/T/U pharmacies will stock a particular drug is whether it is available from the Federal Supply Schedule or 340B program, which are the principle sources of drugs purchased by I/T/U pharmacies. *See “I/T/U Pharmacies and Federal Supply Schedule (FSS).”*

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans in Section 423.120(a)(4) should be further revised to add a new paragraph (iv) to read as follows (new language is *italicized*):

(v) May not require an I/T/U pharmacy to provide all the drugs in any formulary that may have been adopted by the PDP or MA-PD.

AI/AN beneficiaries often will have access only to an I/T/U pharmacy due to the remote locations where they live and where the I/T/U pharmacies are located. As noted in the Preamble, in the places where there are concentrations of Alaska Natives and American Indians, the I/T/U pharmacies are often the only pharmacy providers (page 46657). It is unfair to the AI/AN beneficiaries and to I/T/U providers to limit reimbursement or increase co-pays when a beneficiary is prescribed a drug that is not on the PDP or MA-PD formulary when that may be the only drug available from the I/T/U pharmacy that provides the same therapeutic effect as the formulary drug. In such cases, the PDP or MA-PD should be required to reimburse the I/T/U as if the drug were on its formulary in an amount equal to that the PDP or MA-PD would have paid for an equivalent drug on its formulary. In this way, neither the PDP or MA-PD or the I/T/U pharmacy is disadvantaged financially, and the patients are able to maintain access and continuity of care.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add an new paragraph (v) to read as follows (new language is *italicized*):

(vi) *Must provide for reimbursement to I/T/U pharmacies for all covered Part D drugs whether or not they are on the PDP's or MA-PD's formulary at an amount not lower than the reimbursement that would have been made for an equivalent drug on the formulary.*

BENEFITS AND BENEFICIARY PROTECTIONS
Comments on Section 423.100: DEFINITIONS
“Insurance or otherwise” for purposes of “Incurred costs”

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *To ensure that expenditures by I/T/Us on AI/AN beneficiaries (who do not qualify for the cost-sharing subsidy for low-income individuals) on prescription drugs count toward the annual out-of-pocket threshold (\$3,600 in 2006).*

Incurred Cost Issue, Pages 46649-46651: CMS notes that, under the proposed rule, AI/AN Medicare beneficiaries who are not eligible for low-income cost-sharing subsidies may receive drug coverage directly from I/T/U pharmacies or under CHS referrals. While these payments will count toward the AI/AN beneficiary's annual deductible, they will not count as incurred cost toward meeting the out-of-pocket threshold (\$3,600 in 2006). The reason, in brief, is that “incurred costs” are defined by section 1860D-2(b)(4)(C)(ii) of the Social Security Act to exclude payments by “insurance or otherwise.” But this statutory provision does not expressly include the I/T/U programs in this term. Rather, it is CMS, not the law that has defined what is encompassed by the term “insurance or otherwise”. The agency has chosen to include I/T/U health programs as “insurance or otherwise,” -- but has not explained the basis for that decision, nor analyzed the impacts of it on the IHS-funded system and affected Indian Medicare beneficiaries, nor acknowledged that failing to count I/T/U pharmacy contributions toward "incurred costs" would be a windfall to the PDP in which an affected Indian is enrolled. Perhaps CMS recognized that this matter requires additional thought, as it asks for comments on “how ... IHS beneficiaries will achieve maximized participation in Part D benefits.”

Comment: The effect of CMS's decision to treat I/T/U programs as “insurance or otherwise” is to minimize, not maximize, participation of IHS beneficiaries in Part D benefits. As CMS itself acknowledges, “most IHS beneficiaries would almost never incur costs above the out-of-pocket limit.” (69 FR at 46657). And, as CMS further recognizes, this policy “would likely provide plans with additional cost-savings.” (69 FR at 46657). We do not believe that Congress intended Part D to be administered to minimize participation by AI/AN beneficiaries and to increase revenues for PDP and MA-PD plans at the expense of I/T/U programs. Yet that is precisely the result that the proposed rule achieves.

The proposed rule is not required by the statute. Section 1860D-2(b)(4)(C)(ii) does not expressly prohibit payments by I/T/U programs from being treated as “incurred costs.” By using the phrase “not reimbursed by insurance or otherwise,” Congress intended to give CMS discretion to fashion a sensible definition consistent with federal policy. AI/ANs are not “reimbursed” by their IHS or tribal health care providers or by any insurance. Rather in the case of AI/AN beneficiaries, that federal policy is the trust responsibility of the United States to provide health care to AI/ANs pursuant to laws and treaties. And, as CMS acknowledges in the Preamble at p. 46651, the I.H.S. “fulfills the Secretary's unique relationship to provide health services to AI/ANs based on the government-to-government relationship between the United States and tribes.” In other words, AI/AN Medicare beneficiaries have a different legal standing than other Medicare beneficiaries.

The proposed rule, however, does not recognize this “unique” legal relationship. Instead, the proposed rule would require those AI/ANs who are Medicare beneficiaries but who are not eligible for the low-income subsidy program to pay substantial amounts out of pocket for their Medicare prescription drug coverage in order to meet the out-of-pocket threshold. In this way, the proposed rule violates the federal trust responsibility, under which AI/ANs are entitled to needed health care services, including prescription drugs, at the federal government's expense.

Section 1860D-2(b)(4)(C)(ii) specifies that costs shall be treated as incurred if they are paid “by another person, *such as* a family member, on behalf of the individual.” (*emphasis added*). In the “unique relationship” between the federal government and AI/ANs, the I/T/Us are the functional equivalent of a “family member.” Their mission, on behalf of the federal government, is to pay for prescription drugs and other health care services needed by AI/ANs. In terms of paying for prescription drugs, there is no functional difference between I/T/Us fulfilling their obligations to AI/ANs and family members fulfilling their obligations to one other. Again, there is nothing in the

concept of family members paying incurred costs to suggest that Congress somehow intended that payments by I/T/Us on behalf of AI/ANs not be treated as incurred costs.

In the preamble, CMS explains that contributions made by charities would be considered "incurred costs" and describes in detail the reasons for a desirable objectives achieved by this decision. Many of the considerations recited there apply to the I/T/U system, particularly the outcome that Medicare beneficiaries who are not eligible for the low-income subsidy would be able to qualify sooner for the catastrophic coverage level. In other words, these beneficiaries would have a better opportunity to fully utilize their Part D benefit.

The outcome is just the reverse with regard to an Indian not eligible for subsidy who is served by an I/T/U pharmacy. That Medicare beneficiary would have to pay the same premium for Part D coverage (or have it paid on his behalf by the I/T/U program as CMS suggests at p. 46651), but the benefit received for that premium would be only slightly more than \$1000 -- far lower than that of a non-Indian beneficiary. This is so because this Indian patient would never get out of the "donut hole" and thus would never be able to utilize the catastrophic coverage feature of the Part D benefit.

The proposed rule has the effect of shifting from Medicare Part D and participating private plans to the Indian Health Service, tribes and tribal organizations, and urban Indian programs, the cost of Medicare prescription drug coverage for AI/AN Medicare beneficiaries who are not eligible for cost-sharing subsidies due to low income. This is because the I/T/Us will continue to use their limited appropriated funds to pay the prescription drug costs of these AI/AN beneficiaries – that is the I/T/U mission. As the preamble acknowledges, most of these beneficiaries will never reach the out-of-pocket limit as a result. The I/T/Us will then have to cover the drug costs above the out-of-pocket threshold, absorbing the costs that neither Medicare nor the Part D plans will cover. Given the poor health status of AI/ANs and the demonstrated underfunding of I/T/Us, it is inconceivable that Congress intended that CMS exercise its discretion to achieve this outcome. We therefore urge CMS to make the following revision to the rule:

Section 423.100-“Insurance or otherwise” for purposes of “Incurred Costs”

The definition of “insurance or otherwise” used to define “incurred costs” for purposes of meeting the out-of-pocket threshold should be revised to read as follows (modifications are *italicized*):

“Insurance or otherwise” means a plan (other than a group health plan) or program (*other than a health program operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act , 25 U.S.C. 1603*), that provides, or pays the cost of, medical care..., including any of the following: ...*(7) Any other government-funded program whose principal activity is the direct provision of health care to individuals (other than American Indians or Alaska Natives or urban Indians as those terms are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603).*”

SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL

Comments regarding Section 423.286 Rules regarding premiums.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *Tribes/Tribal Health Programs should be allowed to pay premiums on behalf of AI/AN (Group Payer) for AI/AN beneficiaries. Either rules or administrative policy should allow Tribes to add AI/AN beneficiaries to the group at any time.*

Comment: We urge CMS to include I/T/U and/or tribes as permissible payment options and to remove barriers tribes have encountered in paying Part B premiums for AI/AN under current CMS group payer rules. Without these changes it is unlikely that AI/AN, who are entitled to health care without cost sharing, would elect to pay premiums themselves.

AI/ANs served in an I/T/U will most likely not elect to pay Part D premiums because these patients can access health care through the IHS based on the Federal Government’s obligation to federally recognized Tribes. CMS recognizes this in the Preamble, page 46651, by stating that “the IHS may wish to pay for premiums to eliminate

any barriers to Part D benefits”. It is unlikely that AI/ANs, who are entitled to health care without cost sharing, would elect to pay premiums themselves, therefore, we request that language be included in the regulations recognizing the ability of I/T/Us to pay premiums if they so choose.

WAIVER OF COST SHARING
Comments on Background at 46651 and Section 423.120(a)(4)

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule and Formulary.

Goal. *Assure that I/T/U pharmacies are authorized to waive cost-sharing for AI/AN beneficiaries pursuant to Section 1128B (b)(3)(G) of the Social Security Act, as added by Section 101 of the MMA.*

Comment: As discussed in the Preamble, the AI/AN beneficiaries receive health services under a unique government-to-government relationship between the United States and Tribes (page 46651). Under this relationship most care is provided directly by or through contract health services administered by I/T/U providers who provide the care without cost to the AI/AN beneficiary. The benefit plans provided under Medicare Part D contemplate patients sharing in the cost of the care they are provided. This is antithetical to the relationship between AI/AN beneficiaries and their I/T/U pharmacies.

- The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add a new paragraph (vi) to read as follows (new language is *italicized*):

(vii) *Must authorize I/T/U pharmacies to waive all cost sharing obligations of AI/AN beneficiaries.*

CREDITABLE COVERAGE
Comments Regarding Section 423.56: Procedures to Determine and Document Creditable Status of Prescription Drug Coverage

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *IHS coverage should be deemed “credible coverage” therefore making late enrollment penalties inapplicable to AI/AN beneficiaries.*

Comment: The CMS TTAG strongly supports the decision of CMS to include in the definition of Creditable Prescription Drug Coverage a “medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U)” in the Medicare Prescription Drug Benefit Proposed Rule at § 423.56(a)(9). The Indian Health Service, Tribe or Tribal organizations, or Urban Indian organizations currently provide pharmaceuticals to AI/AN beneficiaries, either through direct care services or IHS Contract Health Services (CHS), at no cost to the beneficiary. For purposes of not being subject to late enrollment penalties, this Proposed Rule will protect those AI/AN beneficiaries who might not initially enroll in Medicare Part D because, for example, they receive their pharmaceuticals from an I/T/U pharmacy but later relocate off reservation and therefore need prescription drug coverage under Medicare Part D.

This definition is consistent with the definition of creditable coverage for purposes of continued health insurance coverage under the Employee Retirement Income Security Act (ERISA). See the Department of Labor regulations at 29 C.F.R. 2590.701-4 (a)(1)(vi). The DOL regulations include the I/T/U programs under their definition to ensure that when AI/AN beneficiaries relocate off reservation, where for example they had coverage from an IHS facility, that coverage counts as creditable coverage for group health plan coverage under the ERISA.

EXCLUDE CERTAIN INDIAN-SPECIFIC INCOME AND RESOURCES
FOR CONSIDERATION OF ELIGIBILITY OF AMERICAN INDIANS AND
ALASKA NATIVES FOR LOW-INCOME SUBSIDIES

Comments regarding Section 423.772: Premiums and Cost Sharing Subsidies for Low-Income Individuals-Definitions

Goal: To exclude from the income and resources tests for determination of an American Indian or Alaska Native (AI/AN) Medicare beneficiary's eligibility for a low-income subsidy under Part D certain income and assets that are excluded from consideration when determining eligibility for Medicaid.

Comment. CMS has recognized that certain Indian-specific income and assets are to be excluded when determining the eligibility of an AI/AN for Medicaid. *See, e.g.,* CMS State Medicaid Manual Part 3 -- Eligibility, §3810. These same exclusions should apply to the determination of whether an AI/AN qualifies for a low-income subsidy under Part D. Since all dual eligibles will be moved from Medicaid to Part D for prescription drug coverage, it is appropriate that the same federally-established exclusions should apply to the affected AI/AN dual eligibles.

In **Sec. 423.772**, the definitions of "income" and "resources" should be revised to exclude income that derives from tribal lands and other resources currently held in trust status, from judgment funds awarded by the Indian Claims Commission and the U.S. Claims Court, and from other property held in a protected status, as specified in the Medicaid Manual. In addition, cultural objects, as specified in the Medicaid Manual, should also be exempted from the definitions of these terms.

ELIGIBILITY AND ENROLLMENT

Comments regarding Section 423.48: Information about Part D.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: *Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to the I/T/U at no cost.*

Comment: Without outreach, education and enrollment assistance from Indian health programs, AI/AN are unlikely to enroll in Medicare Part D or Part C. AI/AN are entitled to receive free health care at I/T/Us and through Contract Health Services, thus they have no incentive to enroll in programs requiring premiums and cost sharing. I/T/Us know who may be eligible for new Medicare programs and how to contact them. AI/ANs trust I/T/U health workers. Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to I/T/U at no cost. As CMS states on Page 46642 of the Preamble, "we would undertake special outreach efforts to disadvantaged and hard-to reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. Materials and information would be made available in languages other than English, where appropriate." In implementing this provision CMS must reach out to AI/AN beneficiaries.

**INDIAN HEALTH ADDENDUM TO
SPECIAL ENDORSED PLAN AGREEMENT**

1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between _____ (herein "Plan" or Plan Sponsor") and _____ (herein "Provider") for administration of Transitional Assistance under the Prescription Drug Discount Card program authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 at pharmacies and dispensaries of Provider. To the extent that any provision of the Special Endorsed Plan Master Agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supercede all such other provisions.

2. Definitions.

For purposes of the Special Endorsed plan Master Agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Plan Sponsor" means _____ which operates the Prescription Drug Discount Card Plan defined in subsection (b).

(b) The terms "Prescription Drug Discount Card Plan" and "Plan" means a Prescription Drug Discount Card Plan operated by Plan Sponsor that is approved by the Centers for Medicare and Medicaid Services (CMS) pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and holds a special endorsement from CMS to administer the Transitional Assistance feature of the Prescription Drug Discount Card program at pharmacies or dispensaries operated by the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations (hereafter "I/T/U endorsement").

(c) The term "Provider" means an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25 USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.*

A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.*

/ / An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the Indian Health Care Improvement Act.

4. Co-pays, deductibles.

The parties agree that the Provider may waive any co-payments for any Indian who is enrolled in the Plan when such Indian receives services pursuant to the Plan at any pharmacy or dispensary of Provider.

5. Persons eligible for services of Provider.

(a) The parties agree that the persons eligible for services of the Provider under the Special Endorsed Plan Master Agreement and all addenda thereto shall be governed by the following authorities:

- (1) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Part 403 of Title 42, Code of Federal Regulations
- (2) Sec. 813 of the Indian Health Care Improvement Act, 25 USC §1680c
- (3) Part 136 of Title 42, Code of Federal Regulations
- (4) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program, including one or more pharmacies or dispensaries.

(b) No clause, term or condition of the Special Endorsed Plan Master Agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

The parties acknowledge that the following Federal laws and regulations apply to Provider as noted:

(a) A Provider who is an Indian tribe or a tribal organization:

- (1) The Indian Self-Determination and Education Assistance Act, 25 USC §450 *et seq.*;
- (2) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.*;
- (3) The Federal Tort Claims Act, 28 USC §2671-2680;
- (4) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2; and
- (5) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

(b) A Provider who is an urban Indian organization:

- (1) The Indian Health Care Improvement Act, 25 USC §1601, *et seq.*;
- (2) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2;
- (3) The Federal Tort Claims Act, 28 USC §2671-2680 to the extent the urban Indian organization is a Federally Qualified Health Center;
- (4) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

7. Non-taxable entity.

Provider is a non-taxable entity and as such shall not be required by Plan or Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain general liability, professional liability or other insurance, as such Provider is covered by the Federal Tort Claims Act pursuant to Federal law (Pub.L. 101-512, Title III, §314, Nov. 5, 1990, 104 Stat. 1959, as amended by Pub. L. 103-138, Title III, §308, Nov. 11, 1993, 107 Stat. 1416 (codified at 25 USC §450f note); and regulations at 25 CFR Part 900, Subpt. M. A Provider which is an urban Indian organization which holds designation as a Federally Qualified Health Center shall not be required to obtain or maintain general liability, professional liability or other insurance as such Provider is covered by the Federal Tort Claims Act pursuant to such designation. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify Plan or Plan Sponsor.

9. Employee license.

Where a Federal employee is working within the scope of his or her employment and is assigned to a pharmacy or dispensary of Provider, such employee is not subject to regulation of qualifications by the State in which Provider is located, and shall be deemed qualified to provide services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided that such employee is currently licensed to practice pharmacy in any State. To the extent that any State exempts from state regulation a direct employee of Provider, such employee shall be deemed qualified to perform services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements pursuant to 42 CFR §431.110, the Provider shall not be required to hold a State license to receive any payments under the Special Endorsed Plan Master Agreement and any addendum thereto.

11. Re-Enrollment Period.

The Centers for Medicare and Medicaid Services has established as a matter of policy that an enrollee eligible for services from an I/T/U pharmacy shall be permitted to disenroll from a prescription drug discount card plan that does not hold a special I/T/U endorsement and to re-enroll in a plan that has received such endorsement at any time during the life of the Medicare Drug Discount Drug Card Program. Nothing in the Special Endorsed Plan Master Agreement or any other addendum thereto shall be interpreted to impede this right of re-enrollment.

12. Dispute Resolution.

Any dispute arising under the Special Endorsed Plan Master Agreement or any other addendum thereto shall be resolved through negotiation rather than arbitration. The parties agree to meet and confer in good faith to resolve any such disputes.

13. Governing Law.

The Special Endorsed Plan Master Agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between the Special Endorsed Plan Master Agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall subject Provider to State law to any greater extent than State law is already applicable.

14. Pharmacy/Dispensary Participation.

The Special Endorsed Plan Master Agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the Schedule B to this Indian Health Addendum.

15. Acquisition of Pharmaceuticals.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in the Special Endorsed Plan Master Agreement and all addenda thereto require the Provider to acquire drugs from the Plan Sponsor, the Plan or from any other source.

16. Formulary.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's formulary. The Provider is exempt from any provision of the Special Endorsed Plan Master Agreement and all addenda thereto requiring compliance or cooperation with the Plan Sponsor's or Plan's formulary, drug utilization review, generic equivalent substitution, and notification of price differentials.

17. Transitional Assistance Claims.

The Provider may submit claims to the Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim. When the toll-free number is used for non-electronic claims, Plan will verify the balance of an enrollee's Transitional Assistance subsidy remaining as of that time and obligate funds from that subsidy for payment of the Provider's claim at the point of sale. Instructions for filing and adjudicating non-electronic claims are attached as Schedule C.

18. Payment Rate.

Claims from the Provider for Transitional Assistance benefits shall be paid at the same rates as the State Medicaid program fee-for-service in the State where the Provider's pharmacy or dispensary is located, pursuant to Schedule A of this Addendum.

19. Information, Outreach, and Enrollment Materials.

All materials for information, outreach, or enrollment prepared for the Plan shall be supplied by Plan to Provider in paper and electronic format at no cost to the Provider. Provider shall have the right to convert such materials as it deems necessary for language or cultural appropriateness.

20. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Plan, Provider shall provide written notification of its hours of service to the Plan.