N A T I O N A L I N D I A N H E A L T H B O A R D

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January 14, 2004

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

Attention: CMS–4063–IFC

Hand-Delivered:
Room 445-G, Humphrey Building
200 Independence Avenue, SW
Washington DC 20201

Dear Administrator:

The National Indian Health Board appreciates the opportunity to comment on the final interim rule regarding implementation of the discount drug card and transitional assistance being implemented by the Centers for Medicare and Medicaid Services ("CMS") on an extraordinarily foreshortened schedule pursuant to Section 101, subpart 4 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, codified in section 1860D-31 of the Social Security Act.

I. INTRODUCTION

The National Indian Health Board ("NIHB") represents Tribal governments whose Americans Indians and Alaska Natives members receive health care delivered directly by the IHS, as well as those who have accepted the responsibility to operate their own health programs through contracting or compacting with the IHS pursuant to the Indian Self-Determination and Education Assistance Act, as amended.[1] The NIHB Board of Directors consists of representatives from each of the twelve IHS Areas. NIHB also works closely with the third partner in the delivery of health care: the National Council of Urban Indian Health ("NCUIH"), which represents 36 Urban Indian health programs funding in part by the IHS. These three systems – the IHS, Tribes and Tribal Organizations, and Urban Indian Organizations ("I/T/U") – constitute the most important part of the health delivery system for American Indians and Alaska Natives.

NIHB has acquired important knowledge about the impact of managed care on American Indians and Alaska Natives and on the I/T/U providers who serve them. NIHB was instrumental in monitoring, reporting on, and seeking to address the

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1/ Pub. L. 93-638; 25 U.S.C. § 450 *et seq*.

consequences of managed care on American Indians and Alaska Natives and on health services provided directly by the IHS and by Tribes and Tribal Organizations operating IHS programs under contracts and compacts with IHS. In 1995, the NIHB conducted six regional meetings bringing together tribal representatives, urban Indian clinic directors, state Medicaid and public health officials, CMS (previously Health Care Financing Agency ("HCFA")), and IHS to discuss new partnerships in the health care environment. In 1997, the NIHB conducted the study *Tribal Perspectives on Indian Self-Determination and Self-Governance in Health Care Management*,[2] measuring the impact on Tribal health programs as Tribes assume control of their health care system. NIHB produced the report, "Case Studies in Managed Care in Indian Health," sponsored by the Kaiser Family Foundation, later published by the American Public Health Association.[3] In 1998, the NIHB hosted a national meeting, "Indian Health, Medicaid and Managed Care: A Call to Action" to review how nine state Medicaid managed care programs had affected Indian health care providers in those states.[4] An updated study of 10 states was released January 2002.[5] The knowledge gained through these endeavors combined with the direction of Tribal leaders guide the comments made here.

In addition, Tribal leaders, health administrators, and technical consultants from all twelve Indian Health Service ("IHS") Areas have had the opportunity to participate in the review of the Interim Final Rule and development of these comments. Given the very brief comment period and the complexity of the issues, most Tribes and Tribal Organizations are unable to submit individual comments. These comments reflect a consensus among the participants in developing them about the most pressing concerns about the implementation of the drug discount card program and transitional assistance and their impact on American Indians and Alaska Natives and I/T/U providers upon which they rely.

NIHB has specific comments to offer on the proposed Interim Final Rule, but before doing so, we believe that providing some background is instructive. The Centers for Disease Control and Prevention ("CDC") reports that "[d]espite overall declines in morbidity and mortality in the United States in recent years, a persistent gap

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2/ Dixon M, Shelton BL, Roubideaux Y, Mather DT, Smith C. *Tribal Perspectives on Indian Self-Determination and Self-Governance in Health Care Management*, Vol. 4. Denver, CO: National Indian Health Board. 1998.

3/ Dixon, Mim. *Managed Care in American Indian and Alaska Native Communities*. Washington, D.C.: American Public Health Association. 1998.

4/ Dixon, Mim. *Indian Health in Nine State Medicaid Managed Care Programs.* Denver, CO: National Indian Health Board. 1998.

5/ Kauffman, Jo Ann, Patricia Hansen, Victor Paternoster. *Into the Future: Indian Health, Medicaid, Managed Care & SCHIP*. Denver, CO: National Indian Health Board. Draft Report, December 20, 2001.

in health status remains between American Indians (AIs) and non-Hispanic whites.[6] The same report also notes that "although AIs had a higher prevalence of chronic disease risk factors than other racial/ethnic minority populations, they also were more likely to use preventive services." This accomplishment is attributed to "the commitment of AI communities, tribal corporations, public health authorities, and health-care providers."[7]

When evaluating the impact of any new model of service delivery, maintenance of the culturally competent and sensitive I/T/U system is critically important. Indian health care does not operate simply as an extension of the mainstream health system in America. To the contrary, Federal support has built a system that is designed to serve Indian people. It is important to build upon those programs that Tribes, the IHS and other Indian health providers have started. Although Congress has provided for the right of I/T/U providers to participate in one or more Endorsed Sponsor plans, how this right is implemented will have substantial impact on whether it supports the I/T/U or diminishes it.

The I/T/U health system is only partially funded by direct appropriations. Even when all third party revenue is considered, the I/T/U system is funded at only 52 percent of the amount needed to offer American Indians and Alaska Natives the same level of care provided by the Federal Employee Health Plan.[8] Whenever resources bypass the I/T/U, while a covered American Indian or Alaska Native receives care from an I/T/U, it further impoverishes the I/T/U. This was the experience during the first flush of Medicaid managed care under which States bypassed the I/T/U when enrolling American Indians and Alaska Natives in plans and relieving the plans of any obligation to pay an I/T/U provider that had continued to provide services to the enrolled American Indian or Alaska Native who could not be turned away. CMS must avoid a replication of that experience in the implementation of the Medicare Prescription Drug Transitional Assistance Program.

II. COMMENTS ON PROVISIONS OF THE INTERIM FINAL RULE

§ 403.802. Definition of "Authorized Representative." We believe that the definition of "authorized representative" should be expanded to explicitly state that it includes any individual designated in writing by the beneficiary. The process and requirements for "an authorized representative" as that terms is typically used in the Medicare program generally is so cumbersome as to make it virtually useless, except for the most impaired beneficiaries. But not only the most impaired may want to have help engaging with officials regarding this very new program. Since there is relatively little potential for abuse by an "authorized representative," with regard to the benefits

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6/ CDC. Health Status of American Indians Compared with Other Racial/Ethnic Minority Populations – Selected States, 2001-2002. MMWR 2003;52(47):1148-1152, 1148. (Endnotes deleted.)

7/ *Id*.

8/ IHS. *FY 2003 Indian Health Care Improvement Fund for all Units*. www.ihs.gov/NonmedicalPrograms/LNF/2003/IHCIF2003All.pdf.

under this program, we recommend that the formalities for designating someone who can assist an applicant or enrollee be relaxed.

§ 403.802. Definition of "I/T/U Pharmacy." NIHB recommends retaining this definition, which relies on definitions of "Indian Health Service," "Indian Tribe," "Tribal Organization," and "Urban Indian Organization" found in the Indian Health Care Improvement Act, as amended.[9]

§ 403.806(f). Service Area and Pharmacy Access. In some parts of the United States, the only pharmacy in a rural area, as defined, for the purposes of this Rule, will be an I/T/U pharmacy. In suburban and urban areas, there may be more choice, however, for American Indians and Alaska Natives, the most appropriate provider would be an I/T/U pharmacy. To enhance the likelihood that the Endorsed Sponsors can meet the requirements of this subsection and provide culturally appropriate services to their American Indian and Alaska Native enrollees, Endorsed Sponsors should be required to include in their network any I/T/U pharmacy in the service area that wants to participate, and such participation should be on terms equivalent to those provided for under § 403.816, rather than those generally applicable.

§ 403.806(g)(5). Approval by CMS of Information and Outreach Materials Produced by Endorsed Sponsors. NIHB approves of the requirement that information and outreach materials be approved in advance by CMS. However, given the number of plans likely to be endorsed and the short time frame, it appears probable that most of these materials will end up being "deemed approved" under § 403.806(g)(5)(iii) for failure of CMS to have an adequate opportunity to review the materials within the first 30 days after receipt. While this is problematic generally, within the American Indian and Alaska Native community it is especially damaging.

To provide effective information and outreach in the American Indian and Alaska Native community requires a sophisticated understanding of the role of the I/T/U system and the rights of American Indians and Alaska Natives to receive health care without personal expense. It may also require that materials be developed in a variety of languages or that CMS provide resources for translators since for many elders English remains a second language, and among some, it is not spoken at all. We strongly recommend that four changes be made to this part of the final rule.

(1) Information and outreach materials directed at American Indians and Alaska Natives should not be subject to being deemed approved simply by the passage of time.

(2) The requirement that Endorsed Sponsors must disclose to Medicare beneficiaries information regarding any special rules for American Indians

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9/ Pub.L. 94-437, as amended. 25 U.S.C. § 1601 *et seq*.

or Alaska Natives who use I/T/U pharmacies should be stated in the Final Rule, not merely described in the explanatory materials.[10]

(3) CMS should be required to seek the advice of the Tribal Technical Assistance Group ("TTAG") recently approved by CMS regarding the standards for approval of such materials.

(4) CMS should ask the TTAG to form a subcommittee to review and comment on materials upon their submission to ensure that they are culturally sensitive and that they are factually accurate.

Because of the critical role these information and outreach materials will play in the success or failure of the discount drug card and transitional assistance programs, a further initiative would dramatically improve the likelihood of success as the programs affect American Indians and Alaska Natives. CMS should immediately contract, directly or through the IHS, with one or more entities with experience in communication with American Indians and Alaska Natives about health related matters, to develop specialized information and outreach materials to make available to endorsed sponsors. Endorsed sponsors in communities in which there are I/T/Us should be required to consult with the I/T/Us regarding distribution of information and outreach materials.

CMS should make funding available, directly or through IHS, to I/T/Us to engage in providing information about these programs to the individuals they serve. Without these initiatives, the benefits of the Medicare Discount Card and Transitional Assistance programs are likely to be missed by many American Indians and Alaska Natives, exacerbating the under funding of the I/T/U. Full implementation of these programs is the responsibility of CMS and the Endorsed Sponsors. The cost of performing that responsibility in Indian Country should not be shifted to the IHS and Tribes.

We also recommend that all outreach and information materials developed by CMS and the Endorsed Sponsors contain some information about Medicaid eligibility and how to apply for that benefit. Among the applicants for Transitional Assistance, there will undoubtedly be some individuals who also are eligible for Medicaid and who should be encouraged to contact their State Medicaid agency to determine if there may be other benefits to which they are eligible.

§ 403.806(g)(6). Toll-Free Customer Call Center. The interim final rule does not impose any of the requirements for timeliness of response, nor the specific hours of operation that are described in the Preamble Section II.C.7.b.[11] Nor are any standards for training the Call Center operators incorporated in either the Preamble or the Interim Final Rule. We urge that the requirements for timeliness and the specific hours of doing business described in the Preamble be imposed in the Final Rule,

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10/ *See* Preamble Section II.C.7.a(4).

11/ *See* 68 F.R. 69869.

subject to the expanded hours described next. Although the total eligible population of Alaska is small, those Endorsed Sponsors that serve Alaska should be required to staff the Call Center from 8:00 a.m. to 4:30 p.m. Alaska time, just as they are expected to do so in other time zones they may serve. In addition, we recommend that standards for training Call Center operators should be imposed and that Special Endorsed Sponsors of a network including I/T/U pharmacies should be required to ensure that the operators are trained to understand the Indian health care system and the unique rules that apply to enrollees who use I/T/U pharmacies.

We also note that there are no meaningful penalties for failure to meet the objective that 80 percent of all incoming customer calls will be answered within 30 seconds. *Id*. We believe that a failure to be available during normal business hours to respond to questions about the remaining balance of transitional assistance should be grounds for deeming the request for assistance approved. Unless there is a real consequence for failure to meet the standards, the likelihood that they will be met diminishes substantially.

§ 403.808(a) and (f). Use of Transitional Assistance Funds. We support the decision to not prorate the amount of transitional assistance available in 2004 and to permit rollover of unused amounts from one year to the next. We agree that education about this new benefit program will be sufficiently complex that it may be difficult for potential enrollees to fully appreciate the benefit and make a decision about whether to enroll and with whom. We do not agree with the justification for imposing the proration requirement in 2005.

The marginal value of the increased numbers of enrolled individuals in negotiating drug discounts[12] do not seem to us a sufficient justification for limiting the benefit available to the poorest participants in the program. We believe that the assumption upon which this decision rests, i.e. that by 2005 "beneficiaries will have ample time to learn about the Medicare drug discount card program[13]" is overly optimistic. We believe that despite the efforts that may be made to provide information and outreach, that most Americans will be as confused about this program as they are about many other aspects of Medicare and that they will not enroll unless a specific and urgent need arises.[14] In such cases, no penalty in the form of prorated, reduced benefits should be imposed.

We note that the difficulties of providing adequate information may be especially present among American Indians and Alaska Natives who generally rely on the health care they receive from I/T/U providers without cost. Communicating to them

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12/ Preamble Section II.A.4.b. 68 F.R. 69846.

13/ *Id*. at 69845-46.

14/ Langwell, Kathryn, *et al*. "American Indian and Alaska Native Eligibility and Enrollment in Medicaid, SCHIP and Medicare: Final Report," pages 36-47. BearingPoint, Inc. and Westat. CMS Contract No. 500-00-0037 (Task 5). December 2003.

the value of this additional coverage will be challenging.[15] No additional barriers to convincing them to enroll should be created. It seems likely that, even though the Part D permanent program will differ from the Discount Drug Card and Transitional Assistance programs, those who enroll to take advantage of the Transitional Assistance are more likely to consider enrolling in the Part D benefit plan.

§ 403.808(e). Co-Insurance. Since American Indians and Alaska Natives who receive services from an I/T/U pharmacy are not subject to copayments,[16] an exception should be made for American Indians and Alaska Natives to the requirement in section 808(e)(1) and (2) that requires a five or ten percent co-pay from the Transitional Assistance enrollee. The I/T/U pharmacy cannot bill an American Indian or Alaska Native beneficiary for the co-pay amount;[17] thus, under the Rule as written the I/T/U pharmacy would have to absorb this expense. Allowing the Transitional Assistance benefit to cover the full charge of a drug dispensed by an I/T/U pharmacy will ultimately benefit all enrollees who use that pharmacy.

§ 403.810(b)(3). Income Eligibility Determination for Transitional Assistance. When calculating whether an American Indian or Alaska Native's income is less than 135 percent of the poverty line, income that derives from Tribal land and other resources currently held in trust status and judgment funds from the Indian Claims Commission and the U.S. Claims Court and from other property held in a protected status should be exempt from consideration when determining eligibility for Transitional Assistance.[18]

§ 403.810(d). Duration of Eligibility Determination. We support the decision to make eligibility determinations effective "for the duration of the individual's enrollment in the Medicare Prescription Drug Discount Card and Transitional Assistance Program." This will eliminate barriers and keep administrative costs down.

§ 403.811(a). Enrollment Process. Once again, we urge that the TTAG be given an opportunity to review and comment on the enrollment materials developed by CMS and Endorsed Sponsors that may be provided to American Indians and Alaska Natives. For all applicants, it is important that the forms be simple, but for American Indian and Alaska Native elders, it is critical that the likely language and cultural barriers be taken into account and addressed in the form design.

We appreciate that the volume of activity and the short time frame for implementation make individualizing materials challenging, however we believe that it is critical that materials addressed to American Indians and Alaska Natives encourage

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15/ *Id*., pages 36, 43-47.

16/ ". . . I/T/U pharmacies . . . are required by law to waive copayments. . . ." Preamble Section II.I. 68 F.R. 69885.

17/ *Id*.

18/ *See, eg.* CMS, *State Medicaid Manual*, "Part 3 - Eligibility," Section 3810. (http://www.cms.hhs/manual/45_smm/sm_03_3_3800_3812.asp).

them to seek assistance from their Tribe or an I/T/U provider, in addition to the Endorsed Sponsor, if the applicant has questions or doesn't understand any part of the application or notification process.

§ 403.811(a)(7) and (b)(2). Electing a New Plan. We understand the general justification for limiting disenrollment and reenrollment to the Annual Coordinated Election Period, however we recommend that an additional circumstance be added to (b)(2). An American Indian or Alaska Native who learns after enrollment that the program in which he or she is enrolled does not include in its pharmacy network an I/T/U pharmacy should be allowed to disenroll and reenroll in a plan of a Special Endorsed Sponsor without having to reestablish eligibility. It is highly likely that the full scope of the pharmacies to be included in any Endorsed Sponsor's plan may not be known at the time of the initial enrollments and that the Special Endorsed Sponsor plans will lag behind the others.

In addition, all enrollees who learn that the plan in which they are enrolled does not include a pharmacy within 2 miles if an urban resident, 5 miles if suburban, and 15 miles if rural,[19] should be permitted to disenroll and reenroll in a plan that does provide one or more pharmacies in its network within the applicable pharmacy network access guidelines for distance of enrolled pharmacies from the beneficiary's home. Such disenrollment and reenrollment should be subject to no penalties or limitations. Even when the Endorsed Sponsor achieves the 90 percent benchmark, it is of little use to an enrollee who is one of the 10 percent outside the radius.

§ 403.816(d). Special Endorsed Sponsors. We appreciate the rationale behind trying to identify the best qualified Special Endorsed Sponsors to include I/T/Us in their networks, however we are concerned that this may undermine other important considerations. First, although the Interim Rule does not preclude the Special Endorsed Sponsors including other pharmacies, if only two, or some other small number, are chosen, they are unlikely to have the capacity to seek out other pharmacies in each State to participate in their network. While we strongly support the importance of I/T/U pharmacies being part of networks, if American Indians or Alaska Natives are forced to choose between a network in which only the I/T/U pharmacy is enrolled and one in which other pharmacies are enrolled, they will be likely to choose the latter since they can always exercise their right to use the I/T/U pharmacy without cost. This undermines the I/T/U pharmacy program and ultimately the care that is available to American Indians and Alaska Natives.

Without both types of pharmacies being covered in the same plan, there is also a double hit on the I/T/U program, which may find itself having to use scarce contract health service ("CHS")[20] funds to assist in acquiring a drug that it cannot stock that could have been purchased with the Transitional Assistance, but for the lack of a non-I/T/U enrolled pharmacy that could make the drug available.

19/ *See,* Preamble Section II.C.3; 68 F.R. 69851.

20/ The *IHS Manual* describes the use of CHS funds as those "used to supplement and complement other health care resources available to eligible Indian people." Part 2, Chapter 3, Section 2-3.4.

An alternative that NIHB has advocated consistently with regard to other forms of managed care, is to require any Endorsed Sponsor to make Transitional Assistance payments to any I/T/U pharmacy that provides a covered drug to an enrolled beneficiary without regard to whether the I/T/U pharmacy is part of the Endorsed Sponsor's plan. This has the benefit of assuring that the Transitional Assistance benefits are paid where the services are provided and will encourage all Endorsed Sponsors to enroll I/T/U pharmacies in their networks.

§ 403.816(d)(2). Who May Be Served under the Special Contractual Arrangements. It is essential that the phrase "who are also American Indians/Alaska Natives" be deleted. Under certain circumstances all I/T/Us must service non-American Indians/Alaska Natives.[21] Under other circumstances they may serve non-American Indians/Alaska Natives.[22] In both circumstances, the contractual arrangement between the I/T/U pharmacy and the Endorsed (or Special Endorsed) Sponsor should not vary, except with regard to the cost sharing waiver that applies to American Indians and Alaska Natives and would not apply to those who are not. Both should be covered by the terms of Section 816.

§ 403.816(d)(2). Contractual Arrangements. We support the language actually found in the Interim Final Rule. However, we are very concerned about the related language in the Preamble Section II.I that says:

> special endorsed sponsors must only make a good faith effort to finalize these arrangements [contracts with I/T/U pharmacies] as soon as practicable; we will not require that these arrangements be finalized and approved by us prior to the start of the special endorsed sponsor's commencement of outreach and enrollment activities under its general endorsement, if applicable.[23]

We believe that CMS can dramatically shorten the time it may take to enter into the special arrangements that may be required for contracts with I/T/U pharmacies by providing templates of agreements that contain all the special terms and by expediting additional requests for waivers under Section 816(e)(2). We believe that an applicant for a Special Endorsement who has not yet met all the requirements and

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21/ 25 U.S.C. § 1680c.

22/ *Id*. We believe that the guidance provided in the Preamble Section II.I, 68 F.R. 69885, regarding educating enrollees about possible limits on service by I/T/U pharmacies to non-American Indians and Alaska Natives is useful, when those limits apply, but as with other educational information, the Endorsed Sponsor should be required to ensure that the information is factually correct in the specific context in which it is given. Non-Indians should not be discouraged from enrolling in a Special Endorsed Sponsor plan out of fear that the I/T/Us in their service area won't serve them, if in fact the I/T/U pharmacy does serve non-Indians.

23/ *Id*.

been approved should not be allowed to engage in any targeted outreach to American Indians and Alaska Natives until the Special Endorsement is approved and the targeted outreach materials have been approved. Otherwise, the Sponsor may have very little incentive to actually complete agreements with I/T/U pharmacies.

§ 403.816(d)(3). Special Terms. The special terms and conditions set out in (i) and (ii) should be retained. Some additional terms should be explicitly stated. These include provisions that:

(1) provide that the I/T/U pharmacy need not be licensed by the State provided it meets the applicable standards for licensure;[24]

(2) expressly provide that American Indians and Alaska Natives served by an I/T/U pharmacy are exempt from co-payments;[25]

(3) expressly permitting the I/T/U pharmacy to use Federal Supply Source ("FSS") or 340b source pharmaceuticals when serving Endorsed Sponsor Plan enrollees, subject only to limitations otherwise applicable to the I/T/U;

(4) providing that the I/T/U pharmacy shall not be required to acquire proprietary software or hardware as a condition of participating in the plan; and

(5) providing that the amount of transitional assistance payment to an I/T/U provider for a covered discount card drug provided to an enrollee shall be the I/T/U pharmacy's usual and customary charge for that drug.[26]

Each of these terms expressly stated in the Final Rule and in a template agreement provided to Endorsed Sponsors who may enroll I/T/U pharmacies in their networks will minimize the barriers to inclusion of I/T/U pharmacies.

III. CONCLUSION

NIHB and its members strongly support the decision of the Congress to include special provisions applicable to ensuring that I/T/U pharmacies can participate in the Transitional Assistance Program. We also appreciate the initiative that CMS has taken to try to flesh out the requirements in a way that truly accounts for the unique environment in which I/T/U pharmacies operate and the special, critical role they play in acute and preventive care to American Indians and Alaska Natives. We urge that from

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24/ This will conform these requirements to those applicable to the Medicaid program. *See* 42 C.F.R. § 431.110.

25/ Preamble Section II.I. 68 F.R. 69885.

26/ This recommendation is consistent with the CMS decision to exempt I/T/U pharmacies from having to inform enrollees about any differential between the price of the lowest priced generic drug that is therapeutically equivalent and bioequivalent and the price of the covered discount card drug. 68.F.R. 69682.

here forward CMS will also rely heavily on the expertise available through the TTAG and consult extensively and regularly with the TTAG on all phases of implementation of this Interim Final Rule and other stages of implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

We hope that these comments are helpful and look forward to a continuing dialog regarding implementation.

Respectfully submitted,

H. Sally Smith
NIHB Chairman

cc: Secretary Tommy Thompson
Charles Grim, IHS Director
CMS TTAG Members
Dorothy Dupree, CMS