This document sets out revisions requested by the CMS Tribal Technical Advisory Group to the I/T/U addendum required for use by Part D plan sponsors beginning Jan. 1, 2011.

I/T/U Revised Addendum

Note: All Part D sponsors will be required to use the attached revised version of the I/T/U Addendum effective January 1, 2011. ~~Existing Part D sponsors will be required to use this version of the I/T/U Addendum for any future re-contracting or new contracting.~~

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 "Part D Plan Sponsor") and _____ (herein "Provider") for administration of Medicare Prescription Drug Benefit program at pharmacies and dispensaries of Provider authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Parts 403, 411, 417, 422 and 423 of Title 42, Code of Federal Regulations. To the extent that any provision of the Part D Plan Sponsor's 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 Part D Plan Sponsor's agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Part D Plan Sponsor" means a nongovernmental entity that is certified under 42 CFR 417.472, 42 CFR Part 423 or 42 CFR Part 422 as meeting the requirements and standards that apply to entities that offer Medicare Part D plans.

(b) The terms "Part D Plan" means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 CFR 423.272, 42 CFR 422.502 or 42 CFR 417.472 and that is offered by a PDP sponsor that has a contract with the Centers for Medicare and Medicaid Services that meets the contract requirements under subpart K of 42 CFR Part 423 or subpart K of 42 CFR Part 422.

(c) The term "Provider" means the Indian Health Service (IHS) and all pharmacies and dispensaries operated by the IHS, or 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 ("IHCIA"), 25 USC §1661.

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

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the IHCIA, 25 USC §1603.

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

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

(j) The term "dispensary" means a clinic where medicine is dispensed by a prescribing provider.

3. Description of Provider.

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

/_/ IHS operated health care facilities located within the geographic area covered by the Provider Agreement, including hospitals, health centers and one or more pharmacies or dispensaries ("IHS Provider"). Where an IHS Provider operates more than one pharmacy or dispensary, all such pharmacies and dispensaries are covered by this Addendum.

/_/ 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 IHCIA.

4. Deductibles; Annual Out-of-Pocket Threshold.

The cost of pharmaceuticals provided at a pharmacy or dispensary of Provider or paid for by the Provider through a referral to a retail pharmacy shall count toward the deductible and the annual out-of-pocket threshold applicable to an IHS beneficiary enrolled in a Part D Plan.

Explanation: This revision reflects the change made to Sec. 1860D-2(b)(4)(C) of the

Social Security Act by Sec. 3314 of the PPACA. It becomes effective Jan. 1, 2011.

5. Persons eligible for services of Provider.

(a) The parties agree that the IHS Provider is limited to serving eligible IHS beneficiaries pursuant to 42 CFR Part 136 and IHCIA section 813(a) and (b) of the IHCIA, 25 USC ~~§1680c (a)~~ § 1680(a) and (b), who are also eligible for Medicare Part D services pursuant to Title XVIII, Part D of the Social Security Act and 42 CFR Part 423. The IHS Provider may provide services to non-IHS eligible persons only under certain circumstances set forth in IHCIA section ~~813(b)~~ 813(c) and in emergencies under section ~~813(c)~~813(d) of the IHCIA.

Explanation: Revisions reflect changes to subsection lettering made in the revised IHCIA Sec. 813 (enacted by Sec. 10221 of the PPACA). Since IHS drafted this paragraph originally and since it applies only to IHS, no attempt was made here to make any changes except to the subsection lettering. If IHS wants to change anything else, it can make its own recommendation.

(b) The parties agree that the persons eligible for services of the Provider who is an Indian tribe or a tribal organization or a Provider who is an urban Indian organization shall be governed by the following authorities:

(1) Title XVIII, Part D of the Social Security Act and 42 CFR Part 423;
(2) IHCIA sections 813~~(a) and Sec. 813(c)~~, 25 USC §1680c ~~(a) and (c)~~;
(3) 42 CFR Part 136; and
(4) The terms of the contract, compact or grant issued to the Provider by the IHS for operation of a health program.

Explanation: Revision is offered to apply the entire Sec. 813 to tribally-operated programs. That IHCIA section was revised, and other changes were made to the IHCIA by Sec. 10221 of the PPACA. At a minimum, subsections (a), (b), (c) and (d) apply to tribally-operated programs. The easier course is to cite to the full Sec. 813.

(c) No clause, term or condition of the Part D Plan Sponsor's 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 Part D Plan that is inconsistent with the authorities identified in subsection (a) or (b).

Explanation: This addition corrects an omission in the current text of paragraph (c).

6. Applicability of other Federal laws.

Federal laws and regulations affecting a Provider, include but are not limited to the following:

(a) An IHS provider:

(1) The Anti-Deficiency Act 31 U.S.C. § 1341;
(2) The Indian Self Determination and Education Assistance Act ("ISDEAA") ; 25 USC §450 *et seq.;*

(3) The Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§ 2671-2680;
(4) The Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653;
(5) The Federal Privacy Act of 1974 ("Privacy Act"), 5 U.S.C. § 552a, 45 CFR Part 5b;
(6) Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2;
(7) The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45CFR Parts 160 and 164; and
(8) The IHCIA, 25 U.S.C. § 1601 *et seq*.

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

(1) The ISDEAA, 25 USC § 450 *et seq.;*
(2) The IHCIA, 25 USC § 1601, *et seq.;*
(3) The FTCA, 28 USC §§ 2671-2680;
(4) The Privacy Act, 5 USC §552a and regulations at 45 CFR Part 5b; ~~and~~
(5) The HIPAA, and regulations at 45 CFR parts 160 and 164; and
(6) Sec. 206(e)(3) of the IHCIA, 25 USC §1621e(e)(3), regarding recovery from tortfeasors.

Explanation: The revised Sec. 206 added a new subsection (e)(3) modeled on the Federal Medical Care Recovery Act to extend to tribal and urban Indian organization programs the same recovery rights the FMCRA provides to IHS.

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

(1) The IHCIA, 25 USC § 1601, *et seq.;*
(2) The Privacy Act, 5 USC § 552a and regulations at 45 CFR Part 5b;
(3) The HIPAA, and regulations at 45 CFR parts 160 and 164; and
(4) Sec. 206(e)(3) of the IHCIA, 25 USC §1621e(e)(3), regarding recovery from tortfeasors, as made applicable to urban Indian organizations by Sec. 206(i) of the IHCIA.

Explanation: see above.

7. Non-taxable entity.

To the extent the Provider is a non-taxable entity, the Provider shall not be required by a Part D Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

(a) As an IHS provider, FTCA coverage obviates the requirement that IHS carry private malpractice insurance as the United States consents to be sued in place of federal employees for any damages to property or for personal injury or death caused by the negligence or wrongful act or omission of federal employees acting within the scope of their employment. 28 U.S.C. § 2671-2680. Nothing in the Part D Plan Sponsor's Agreement shall be interpreted to authorize or obligate any IHS employee to perform any act outside the scope of his/her employment. The IHS Provider shall not be required to acquire insurance, provide indemnification, or guarantee that the

Plan will be held harmless from liability.

(b) A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain professional liability insurance to the extent such Provider is covered by the Federal Tort Claims Act (FTCA) pursuant to Federal law (Pub.L. 101-512, Title III, §314, as amended by Pub.L. 103-138, Title III, §308 (codified at 25 USC §450 F note); and regulations at 25 CFR Part 900, Subpt. M. To the extent a Provider that is an urban Indian organization is covered by the FTCA pursuant to section 224(g)-(n) of the Public Health Service Act, as amended by the Federally Supported Health Centers Assistance Act, Pub.L. 104-73, (codified at 42 USC §233(g)-(n)) and regulations at 42 CFR Part 6, such Provider shall not be required to obtain or maintain professional liability insurance. Further, nothing in the Part D Plan Sponsor's 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 the Part D Plan Sponsor.

9. Licensure.

(a) States may not regulate the activities of IHS-operated pharmacies nor require that IHS pharmacists be licensed in the State where they are providing services, whether the IHS employee is working at an IHS-operated facility or has been assigned to a pharmacy or dispensary of a tribe, tribal organization or urban Indian organization. The parties agree that during the term of the Part D Plan Sponsor's Agreement, IHS pharmacists shall hold state licenses in accordance with applicable federal law, and that the IHS facilities where the pharmacies and dispensaries are located shall be accredited in accordance with federal statutes and regulations. During the term of the Part D Plan Sponsor's Agreement, the parties agree to use the IHS facility's Drug Enforcement Agency (DEA) number consistent with federal law.

(b) Federal law (Sec. 221 of the IHCIA) provides that a pharmacist employed directly by a Provider that is an Indian tribe or tribal organization is exempt from the licensing requirements of the state in which the tribal health program is located, provided the pharmacist is licensed in any state. Federal law (Sec. 408 of the IHCIA) further provides that a health program operated by an Indian tribe or tribal organization shall be deemed to have met a requirement for a license under state or local law if such program meets all the applicable standards for such licensure, regardless of whether the entity obtains a license or other documentation under such state or local law. The parties agree that these federal laws apply to the Part D Plan Sponsor's Agreement and any addenda thereto. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

Explanation: This paragraph (b) reflects new Sections 221 and 408 added to the IHCIA regarding licensing of health care professionals employed by an Indian tribe or tribal organization provider, and licensing of health programs operated by such entities. It also retains the existing sentence regarding a DEA license.

~~(b)~~(c) To the extent that any directly hired employee of an ~~tribal or~~ urban Indian Provider is exempt from State regulation, such employee shall be deemed qualified to perform services under the Part D Plan Sponsor's agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. Federal law (Sec. 408 of the IHCIA) provides that a health

program operated by an urban Indian organization shall be deemed to have met a requirement for a license under state or local law if such program meets all the applicable standards for such licensure, regardless of whether the entity obtains a license or other documentation under such state or local law. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

Explanation: This subsection (c) applies to providers who are urban Indian organizations. The new sentence reflects the application of new Sec. 408 of the IHCIA to urban Indian organizations.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements, the Provider shall not be required to hold a State license to receive any payments under the Part D Plan Sponsor's agreement and any addendum thereto.

11. Dispute Resolution.

a. For IHS Provider. In the event of any dispute arising under the Participating Part D Plan Sponsor's Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. The laws of the United States shall apply to any problem or dispute hereunder that cannot be resolved by and between the parties in good faith. Notwithstanding any provision in the Part D Plan Sponsor's Agreement or any addendum thereto to the contrary, IHS shall not be required to submit any disputes between the parties to binding arbitration.

b. For Tribal and Urban Providers. In the event of any dispute arising under the Participating Part D Plan Sponsor's Agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes. Any dispute hereunder that cannot be resolved by and between the parties in good faith shall be submitted to the dispute resolution procedure pursuant to the Participating Part D Plan Sponsor's Agreement.

12. Governing Law.

The Part D Plan Sponsor's 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 such agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Part D Plan Sponsor's agreement or any addendum thereto shall subject an Indian tribe, tribal organization, or urban Indian organization to State law to any greater extent than State law is already applicable.

13. Pharmacy/Dispensary Participation.

The Part D Plan Sponsor's agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the attached Schedule -------- to this Indian Health Addendum. A pharmacy is required to use a National Council for Prescription Drug Programs (NCPDP) provider number for reimbursement. To the extent a dispensary does not have a NCPDP provider number, it is required to use an NCPDP Alternate Site Enumeration Program

(ASEP) number for reimbursement.

14. Acquisition of Pharmaceuticals.

Nothing in the Part D Plan Sponsor's 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 such agreement and all addenda thereto require the Provider to acquire drugs from the Part D Plan Sponsor or from any other source.

15. Drug Utilization Review/Generic Equivalent Substitution.

Where the Provider lacks the capacity to comply with the information technology requirements for drug utilization review and/or generic equivalent substitution set forth in the Part D Plan Sponsor's agreement, the Provider and Part D Plan Sponsor agree that the Provider shall comply with the Part D Plan Sponsor's drug utilization review and/or generic equivalent substitution policies and procedures through an alternative method. Nothing in this paragraph shall be interpreted as waiving the applicability of the drug utilization review and/or generic equivalent substitution policies and procedures adopted by Part D sponsor in accordance with 42 C.F.R.§§ 423.153(b) and (c), as approved by CMS, to covered Part D drugs dispensed by the Provider to enrollees in the Part D Plan[s]. As specified at 42 C.F.R. §423.132(c)(3), the requirements related to notification of price differentials is waived for the Provider .

16. Claims.

The Provider may submit claims to the Part D 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.

17. Payment Rate.

~~Claims from the provider shall be paid at rates that are reasonable and appropriate.~~ Pursuant to Sec. 206 of the IHCIA (made applicable to the IHS, Indian tribes and tribal organizations in Sec. 206(a), and to urban Indian organizations in Sec. 206(i)), the Part D. Plan Sponsor is required to pay the Provider the reasonable charges billed by the Provider, or, if higher, the highest amount the Part D Plan Sponsor would pay for services furnished by providers other than government entities.

Explanation: Paragraph 17 is updated to reflect the directive of revised Sec. 206 of the IHCIA.

18. Information, Outreach, and Enrollment Materials.

(a) All materials for information, outreach, or enrollment prepared for the Part D Plan shall be supplied by the Part D Plan Sponsor to Provider in paper and electronic format at no cost to the Provider.

(a)

(b) All marketing or informational material listing a provider as a pharmacy must refer to

the special eligibility requirements necessary for service to be provided, consistent with the eligibility requirements as described in this Indian health addendum in paragraphs 5(a) for IHS providers and 5(b) for tribal and urban providers.

19. Hours of Service.

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

20. Endorsement

An endorsement of a non-Federal entity, event, product, service, or enterprise may be neither stated nor implied by the IHS provider or IHS employees in their official capacities and titles. Such agency names and positions may not be used to suggest official endorsement or preferential treatment of any non-Federal entity under this agreement.

21. Sovereign Immunity

Nothing in the Part D Plan Sponsor's Agreement or in any addendum thereto shall constitute a waiver of federal or tribal sovereign immunity.

Signature of Authorized Representative

Printed Name of Authorized Representative

Title of Authorized Representative