

TRIBAL INDIAN HEALTH ADDENDUM TO MEDICARE PART D 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 "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 Part 423 or 42 CFR Part 422 as meeting the requirements and standards that apply to entities that offer Medicare prescription drug 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 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.

(k) 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):

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. Deductibles.

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 applicable to an IHS beneficiary enrolled in a Part D Plan.

5. Persons eligible for services of Provider.

(a) The parties agree that the persons eligible for services of the Provider 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(a) and Sec. 813(c) of the Indian Health Care Improvement Act, 25 USC §1680c (a) and (c);
- (2) Part 136 of Title 42, Code of Federal Regulations; and
- (3) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program.

(b) 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).

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.

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 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. To the extent a Provider that is an urban Indian organization is covered by the FTCA pursuant to section 224 of the Public Health Service Act (codified as 42 U.S.C. §233), and regulations at 42 C.F.R. Part 6, such Provider 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 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. 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. The parties agree that during the term of the Pharmacy Agreement, such Federal employees will be licensed in accordance with applicable Federal statutes and regulations. To the extent that any direct employee of 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. 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, the Provider shall not be required to hold a State license to receive any payments under the Part D Plan agreement and any addendum thereto.

11. Dispute Resolution.

In the event of any dispute arising under the Participating Pharmacy 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 Pharmacy 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 Provider 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. 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. Point of Sale Processing.

Where the Part D Plan Sponsor's standard pharmacy agreement contains provisions related to drug utilization review and/or generic equivalent substitution and the Provider does not have the reasonable information technology capacity to comply with such, then the provisions shall not apply to the Provider. As specified in §423.132(c)(3) of the final rule, the 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.

18. Information, Outreach, and Enrollment Materials.

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.

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.