



Tribal Technical Advisory Group



To the Centers for Medicare & Medicaid Services

c/o National Indian Health Board | 50 F Street NW | Washington, DC 20001 | (202) 507-4070 | (202) 507-4071 fax

September 5, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via regulations.gov

Re: Medicare Part D Addendum

Dear Administrator Brooks-LaSure:

On behalf of the Center for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG), I write to comment on and provide additional revisions to the CMS Medicare Part D Addendum.

TTAG previously submitted two sets of edits for the Addendum. The first set of edits were a series of housekeeping edits to update the Part D Addendum so that it is consistent with the Qualified Health Plan Addendum. The second set of edits accepted all of those housekeeping edits and then added a series of TTAG's substantive policy recommendations to expand the scope of the Addendum to address critically important needs in Indian country.

The TTAG is very disappointed that CMS accepted only the TTAG's housekeeping edits, but not its substantive policy proposals.

The TTAG's housekeeping edits were necessary because CMS had not updated the language of the Part D Addendum since 2005. In the interim, CMS had adapted the Part D Addendum for use with the Qualified Health Plan Addendum. The TTAG's housekeeping edits made the same edits to the document that CMS had already approved when it updated the Part D Addendum language for use with the Qualified Health Plan Addendum. While helpful, these edits do not address the substantive policy concerns that the TTAG requested be addressed with its substantive edits.

The TTAG had two main substantive policy recommendations to make with regard to the Part D Addendum. First, the TTAG requested that the scope of the Addendum be expanded beyond Part D plans so that it applies to other pharmacy plans as well. I/T/U pharmacies are currently encountering all of the issues with other pharmacy plans that led to CMS requiring Part D plans to offer contracts to them using the Indian Part D Addendum. Pharmacy benefit managers, managed care companies, health plan sponsors, and insurance companies are all resisting offers to contract with I/T/U

pharmacies that contain provisions that reflect federal restrictions I/T/U pharmacies operate under, as well as their circumstances. These commercial pharmacy networks are increasingly refusing to reimburse I/T/U pharmacies for otherwise covered services due to I/T/U pharmacies asserting their federal rights and restrictions. That is what these Indian Addenda like the Part D Addendum and QHP Addendum are designed to address – requiring issuers to comply with existing federal laws that apply to I/T/U providers instead of allowing them to try to force I/T/U providers to contract away their federal rights through standard network provider agreements. While some I/T/U providers have the capacity to negotiate with issuers on a case-by-case basis, many do not, and many issuers simply refuse to negotiate any provisions in their standard network provider agreements. The Part D Addendum remedies this for the Part D plans. It needs to be expanded to cover other pharmacy issuers as well.

The TTAG's substantive revisions to the Part D plan would also have required all pharmacy plans to reimburse I/T/U providers at the rates they pay other network providers and not discount reimbursement since an I/T/U exercised its right to repackage pharmaceuticals or access pharmaceuticals using the Federal Supply Schedule or the 340B program. This is an issue with many PBMs now, who are starting to discount reimbursements to I/T/U providers because they acquire pharmaceuticals at discounted rates. This is not allowed under federal law, as Section 206 of the Indian Health Care Improvement Act requires all issuers to pay I/T/U providers at the highest rate they pay other in-network providers.

For reference, we have attached a set of redlines which reflect the substantive changes TTAG previously recommended. The TTAG recognizes that the Part D program office may not have the authority on its own to expand the scope of the Part D Addendum beyond the Part D program. That is why the TTAG is addressing these comments to the Administrator in the hope that its request can be reviewed at a higher level within the Agency with the authority to consider the TTAG's request. If it is not workable for the Part D Addendum to be expanded to cover other issuers, then the TTAG requests that HHS develop a new Addendum that would cover all other issuers.

We appreciate your consideration of the above comments and recommendations and look forward to engaging with your agency further.

Sincerely,

A handwritten signature in black ink that reads "W. Ron Allen". The signature is fluid and cursive, with the first name "W." and last name "Allen" clearly legible.

W. Ron Allen, CMS TTAG Chair
Jamestown S'Klallam Tribe, Chairman/CEO

Attachment(s): CMS TTAG Redlines to 2026 Part D Application – Appendix XVII - I/T/U Contract Addendum

APPENDIX XVII – I/T/U Contract Addendum

Note: All Part D sponsors will be required to use the attached revised version of the I/T/U Addendum.

Indian Health Addendum to Pharmacy Medicare Part D Plan Agreement

1. Purpose and Supersession of this Indian Health Addendum; ~~Supersession~~.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the Pharmacy Agreement ~~(herein “Pharmacy Agreement” by and between _____ (herein “Part D Sponsor”) and _____ (“the herein “Provider”) and _____ (herein “Entity”). for administration of Medicare Prescription Drug Benefit program at pharmacies and dispensaries of the 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 (CFR). To the extent that any provision of the Pharmacy Agreement Part D Sponsor’s standard agreement with network pharmacies, or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supersede all such other provisions.~~

2. Definitions.

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

(a) The term “Entity” means a Part D Plan, Part D Plan Sponsor, pharmacy benefit manager (PBM), a managed care company, a health plan sponsor, an insurance company, a third-party payor, or any company, group or agent that represents or is engaged by those entities than include benefits consisting of prescription drugs, other products and supplies, and pharmacist services provided directly, through insurance or reimbursement, or otherwise and including terms and services paid for a prescription drugs, other products and supplies, and pharmacist services under any hospital or medical service policy or certificate, hospital or medical service plan contract, preferred provider organization agreement, or health maintenance organization contract offered by a health insurance issuer.

(a)(b) _____ The term “Part D Plan Sponsor” means a nongovernmental entity that is certified under 42 CFR § 417.472, 42 CFR Part 422 and 3, or 42 CFR Part 423, as meeting the requirements and standards that apply to entities that offer prescription drug Medicare Part D plans.

(b) _____ (c) _____ The term “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 422.502 or 42 CFR 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the requirements under subpart K of 42 CFR 422 or subpart K of Part 423.

(c) _____ § 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 & Medicaid Services that meets the contract requirements under Subpart K of 42 CFR Part 423 or Subpart K of 42 CFR Part

(d) The term "Indian Health Service" (IHS) 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 U.S.C. § 1661.

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

(f)

The term "Provider" means a ~~n Indian Health Service (IHS)~~ health program or all pharmacies and dispensaries administered by the ~~operated by the~~ IHS, a tribal health program, ~~or an Indian tribe,~~ or tribal organization to which funding is provided pursuant to 25 U.S.C. § 47 (commonly known as the "Buy Indian Act"), or an urban Indian organization that receives funding from the IHS pursuant to Title V of the IHCIA (Pub.L. 94-437) as amended, and is identified by name in Section 1 of this Indian Health Addendum.

(g) The term "Indian" has the meaning given to that term in Sec. 4 (13) of the IHCIA, 25 U.S.C. § 1603(13).

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

(i) "Tribal health program" has the meaning given in the IHCIA Section 4(25), 25 U.S.C. § 1603(25).

(a) _____

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

~~(c) The term "Indian Health Service" (IHS) 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 U.S.C. § 1661.~~

(j) The term "Indian tribe" has the meaning given that term in the IHCIA, Section 4(14), 25 U.S.C. § 1603.

~~(d)~~(k) _____ The term "Tribal organization" has the meaning given in the IHCIA, Section 4(26), 25 U.S.C. § 1603(26).

~~(d)~~ (k) _____ The term "Urban Indian organization" has the meaning in the IHCIA, Section 4(29), 25 U.S.C. § 1603(29).

~~(e)~~(d) _____ The term "Indian" has the meaning given to that term in Sec. 4 of the IHCIA, 25 U.S.C. § 1603.

~~(f) _____ 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):

/ / The 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 under a, including one or more pharmacies or dispensaries, under a contract or compact with IHS to carry out programs, services, functions, and activities (or portions thereof) of the IHS pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. § 450 *et seq.*~~

~~/ / A tribal organization that operates authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact to carry out programs, services, functions, and activities (or portions thereof) of the with IHS issued pursuant to the ISDEAA, 25 U.S.C. § 450 *et seq.*~~

~~/ / A tribe or tribal organization that operates a health program, including one or more pharmacies or dispensaries, with funding provided in whole or part pursuant to 25 U.S.C. § 47 (commonly known as the Buy Indian Act).~~

~~/ / An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, with funds in whole or part provided by IHS under a grant or contract awarded pursuant to Title V of the IHCA.~~

Where the Provider operates more than one pharmacy or dispensary all such pharmacies and dispensaries are covered by this Addendum.

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

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

5. Persons eligible for services of the Provider.

(a) The parties acknowledge that eligibility for services at the Provider's facilities is determined by federal law, including the IHCA, 25 U.S.C. § 1601 et. seq. and/or 42 CFR Part 136, ~~Subpart B~~. Nothing in this agreement shall be construed to in any way change, reduce, expand, or alter the eligibility requirements for services through the Provider's programs ~~and/or facilities~~.

(b)

No term or condition of the Pharmacy Agreement or any addendum thereto shall be construed to require the Provider to service individuals who are ineligible under federal law for services from the Provider. The ~~Entity Part D Plan Sponsor~~ acknowledges that pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for services from the Provider. The Provider acknowledges that the nondiscrimination provisions of federal law apply.

6. Applicability of other Federal laws.

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

~~(a)~~ a. The IHS as a PAn IHS provider:

~~(1)~~ i. The Anti-Deficiency Act 31 U.S.C. § 1341;

~~(2)~~ ii. The ISDEAA; 25 U.S.C. § 450 et seq.;

~~(3)~~ iii. The Federal Tort Claims Act ("FTCA"), 28 U.S.C. § 2671-2680;

~~(4)~~ iv. The Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653;

~~(5)~~ v. The Federal Privacy Act of 1974 ("Privacy Act"), 5 U.S.C. § 552a, 45 CFR Part 5b;

~~(6)~~ vi. Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR Part 2;

~~(7)~~ vii. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 CFR Parts 160 and 164; and

~~(8)~~ viii. The IHCA, 25 U.S.C. § 1601 et seq.

~~(b)~~ b. An Indian tribe or a Tribal organization that is a Provider:

~~(1)~~ i. The ISDEAA, 25 U.S.C. § 450 et seq.;

~~(2)~~ ii. The IHCA, 25 U.S.C. § 1601, et seq.;

~~(3)~~ iii. The FTCA, 28 U.S.C. §§ 2671-2680;

~~(4)~~ iv. Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653;

~~(4)~~ v. The Privacy Act, 5 U.S.C. § 552a and regulations at 45 CFR Part 5b;

(5) vi. The HIPAA and regulations at 45 CFR Parts 160 and 164; and

~~(6)(4) Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653;~~

(e)c. An Urban Indian organization that is a Provider:

(1)i. The IHCA, 25 U.S.C. § 1601, ~~et seq.~~ (seq. (including without limitation IHCA Section 206(e)(3), 25 U.S.C. § 1621e(e)(3), regarding recovery from ~~terfeaserstortfeasers~~);

(2)ii. The Privacy Act, 5 U.S.C. § 552a and regulations at 45 CFR Part 5b; and

(3)iii. The HIPAA 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 ~~Entity a Part D Plan Sponsor~~ to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

(a) Indian Health Services. The IHS provider is covered by the FTCA, which 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 Pharmacy Agreement or any addendum thereto, 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 Entity Part D Plan Sponsor will be held harmless from liability.

~~(b) Indian Tribes and Tribal Organizations. To the extent a Provider which that is an Indian tribe, a tribal organization, or employee of a tribe or tribal organization is covered by the 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 U.S.C. § 450f)); and regulations at 25 CFR Part 900, Subpart M; 25 U.S.C. § 458aaa-15(a), and 42 CFR § 137.220, such Provider shall not be required to obtain or maintain professional liability insurance to the extent such Provider is covered by the FTCA pursuant to federal Law (Public Law 101-512, Title III, § 314, as amended by Public Law 103-138, Title III, § 308 (codified at 25 U.S.C. § 450f note); and 25 C.F.R. Part 900, Subpart M; 25 U.S.C. § 458aaa-15(a); and 42 C.F.R. § 137.220).~~ Nothing in the Pharmacy Agreement or any addendum thereto shall be interpreted to authorize or obligate such Provider or any employee of such Provider to operate outside of the scope of employment of such employee. Such Provider shall not be required to acquire insurance, provide indemnification, or guarantee that the Entity Part D Plan Sponsor will be held harmless from liability.

(e)d. Urban Indian Organizations. To the extent a Provider that is an urban Indian

organization ~~is covered by the FTCA pursuant to~~ ~~or employee of 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, Public Law 104-73, (codified at 42 U.S.C. § 233(g)-(n)), 42 CFR. Part 6, such Provider shall not be required to obtain or maintain professional liability insurance. Nothing in the Pharmacy Agreement or any addendum thereto shall be interpreted to authorize or obligate such Provider or any employee of such Provider to operate outside of the scope of employment of such employee. Such Provider shall not be required to acquire insurance, provide indemnification, or guarantee that the ~~Entity Part D Plan Sponsor~~ will be held harmless from liability.

9. Licensure.

(a) Indian Health Service. States may not regulate the activities of IHS-operated health care programs nor require that IHS health care professionals 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 health care program of a tribe, tribal organization, or urban Indian organization. The parties agree that during the term of the Pharmacy Agreement, IHS pharmacists shall hold state licenses in accordance with applicable federal law, and that the IHS facilities shall be accredited in accordance with federal statutes and regulations. During the term of the Pharmacy Agreement, the parties agree to use the IHS facility's Drug Enforcement Agency (DEA) number consistent with federal law.

(b) Indian tribes and tribal organizations. Section 221 of the IHCA, 25 U.S.C. §1621t, exempts a health care professional employed ~~directly by a Provider that is~~ an Indian tribe or tribal organization from the licensing requirements of the state in which such tribe or organization performs services, provided the health care professional is licensed in any state. The parties agree that these federal laws apply to the Pharmacy Agreement and any addenda thereto. ~~The parties agree to use the IHS facility's DEA number consistent with federal law.~~

(c) Urban Indian organizations. To the extent that any health care professional ~~that is directly hired employee~~ of an urban Indian organization provider is exempt from ~~s~~State regulation, such professional shall be deemed qualified to perform services under the Pharmacy Agreement and all addenda thereto, provided such employee is licensed to practice in any State. The parties agree to use the IHS facility's DEA number consistent with federal law.

10. Licensure of Provider; Provider eEligibility for Payments.

Pursuant to 25 U.S.C. §1647a, ~~the IHS, tribal health programs, and as a Provider and Indian tribes, tribal organizations and~~ urban Indian organizations ~~that are Providers~~ are not required to hold a state license to receive any payments under the Pharmacy Agreement and any addendum thereto.

11. Dispute Resolution.

~~For IHS Provider.~~ In the event of any dispute arising under the Pharmacy

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~~ prior to resolution of any disputes through any process identified in the Pharmacy Agreement. 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 Pharmacy Agreement or any addendum thereto to the contrary, ~~the~~ Provider shall not be required to submit any disputes between the parties to binding arbitration.

a. ~~**For Tribal and Urban Providers.** In the event of any dispute arising under the 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 Pharmacy Agreement.~~

12. Governing Law.

The Pharmacy 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 Pharmacy Agreement ~~such agreement~~ and all addenda thereto and Federal law, Federal law shall prevail.

Nothing in the Pharmacy Agreement or any addendum thereto shall subject an Indian tribe, tribal organization, or urban Indian organization to sState law to any greater extent than state law is already applicable.

13. Pharmacy/Dispensary Participation.

The Pharmacy Agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider. Where pharmacies are required to use National Council for Prescription Drug Program (NCPDP) provider number for reimbursement, dispensaries will use NCPDP Alternate Site Enumeration Program (ASEP) numbering for reimbursement.

~~13.14.~~ Acquisition and Repackaging of Pharmaceuticals.

Nothing in the Pharmacy Agreement and all addenda thereto shall require the Provider to acquire ~~affect the Provider's acquisition of~~ pharmaceuticals from the Entity or from any other source, ~~prohibit Provider from repackaging acquired pharmaceuticals into smaller quantities, or reduce or deny the amount to be paid to the Provider for pharmaceuticals it repackages or acquires from any source.~~ Without limitation, Provider may acquire, repackage, dispense, and administer pharmaceuticals it acquires from any source, including the ~~including the~~ Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act, without affecting the amount Provider is paid under the agreements and addenda. Provider's right to payment shall not be denied or reduced for substituting a medically-equivalent or chemically-equivalent drug for any drug included on Entity's formulary.

~~-. 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 and Dispensing by Mail.

- (a) Where the Pharmacy Agreement contains provisions related to drug utilization review and/or generic requirement 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 42 C.F.R. § 423.132(c)(3), the notification of price differentials is waived for the Provider.
- (b) The Provider may dispense and distribute pharmaceuticals by mail or other delivery methods, including from Pyxis machines accessed by appropriate health care professionals, and shall be paid at the same rate as if they had been dispensed or distributed in person.

14. — 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 Pharmacy 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 CFR §§ 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 CFR § 423.132(c)(3), the requirements related to notification of price differentials is waived for the Provider.~~

15.16. Claims.

The Provider may submit claims to the Entity 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, the Provider shall submit a confirmation paper claim.

The Entity shall process claims from the Provider in accordance with Section 206(h) of the IHCA, 25 U.S.C. § 1621e(h), which does not permit an issuer to deny a claim submitted by a Provider based on the format in which submitted if the format used complies with that required for submission of claims under Title XVIII of the Social Security Act or recognized under Section 1175 of such Act.

If the Entity has a separate Provider agreement or claims process for “specialty drugs” or any other class of drugs, it shall allow the Provider an opportunity to enter into such an agreement or to utilize the claims process.

16.17. Payment Rate.

As required by 25 U.S.C. § 1621e and 45 C.F.R. Part 156, Subpart E, the Entity Part D Plan Sponsor shall pay the reasonable charges billed by the Provider, or, if higher, the highest amount Entity the Part D Plan Sponsor would pay any non-governmental provider (whether in-Network or out-of-network) for such services. Provider's right to payment may not be reduced below these amounts, hindered, or prevented for any reason, including but not limited to as the result of any Direct or Indirect Remuneration or other fees, the Provider's

exercise of its federal right to acquire pharmaceuticals using the Federal Supply Schedule or the Drug Pricing Program of Section 340B of the Public Health Service Act or other source or wholesaler, the Provider's failure to meet quality measures imposed by Entity, or the Provider's acquisition of pharmaceuticals, including repackaged or bulk pharmaceuticals.

17.18. Information, Outreach, and Enrollment Materials.

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

~~(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 paragraph 5.~~

18.19. Hours of Service.

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

19. — Endorsement

~~An endorsement of a non-Federal entity, event, product, service, or enterprise may be neither stated nor implied by the Provider or the Provider's 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.~~

20. Sovereign Immunity

Nothing in the Pharmacy Agreement or in any addendum thereto shall constitute a waiver of federal or tribal sovereign immunity.

21. Ethics Language

An endorsement of a non-Federal entity, event, product, service, or enterprise may be neither stated nor implied by Provider or Provider 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.

Signature of Authorized Representative
Representative

Printed Name of Authorized

Title of Authorized Representative