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

December 20, 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 to: Chiquita.Brooks-LaSure@cms.hhs.gov

Re: CMS Compliance: Paperwork Reduction Act

Dear Administrator Brooks-LaSure:

On behalf of the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG), I write to comment on the Paperwork Reduction Act of 1995 (PRA) and the requirements of this statute on Tribal health providers participating in the Medicare Part D program. During our recent Face-to-Face meeting, the Center for Medicare, Medicare Drug Benefit and C & D Data Group provided feedback on the Agency's obligations to comply with the PRA as part of the work the Agency does on its Medicare Part D contracts. After a follow up call on December 9th, we have a better understanding of the complexity of compliance with the PRA and we write to share a proposal we believe will bring our request addendum into compliance with the PRA. The TTAG previously submitted comments on substantive matters relating to the Tribal Indian Health Addendum, but this correspondence is focused on compliance with the PRA in the context of our original proposal as presented in the previous correspondences.

We propose that CMS combine our proposed Tribal Indian Health Addendum to Medicare Part D Plans into the existing Indian Health Service's (IHS) Part D Addendum. We believe such a proposal complies with the PRA by simplifying the paperwork requirements for such Medicare Part D Plan Issuer agreements. Further, this will reduce the administrative burden of CMS and the Part D Plan Issuers, which is a key objective of the PRA.

The Tribal Indian Health Addendum and the existing IHS Addendum collect substantially similar information, enforce the same statutory requirements of Medicare Part D Plans to engage with IHS and Tribal health providers, and both were designed to facilitate the relationship between Part D Plan Sponsors and Providers. The added burden that is created by utilizing numerous versions of a form that achieves a common goal is one that is unnecessary and inhibits the federal government from complying with the PRA. Combining the addenda provides an opportunity for CMS to more closely adhere to the PRA by lessening the burden of maintaining two addenda that collect substantially similar information. Combining the addenda will lessen

the burden of CMS in maintaining and updating its addenda in the future and it lessens the physical burden of maintaining and handling two different forms.

There are some edits that will need to be made to bring the current IHS Addendum into acceptable form to recognize the statutory recognition and authority applicable to Tribes, and to that end we have attached a set of redlines which reflect the additions we believe will be necessary to utilize a single IHS/Tribal Addendum. Our TTAG leadership looks forward to working collaboratively with the agency as we continue to advance the health and well-being of American Indian and Alaska Native people.

Sincerely,

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

Attachment: Tribal PRA Edits to Appendix XVII I-T-U Contract Addendum – 7.16.24

Cc: Kitty Marx, Director, CMS Division of Tribal Affairs
Vanessa Duran, Director, Medicare Drug Benefit and C&D Data Group
Mark Newsom, Deputy Director, Medicare Drug Benefit and C&D Data Group
Arianne Spaccarelli, Health Insurance Specialist, Center for Medicare

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 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 (herein "Pharmacy Agreement" by and between ___ (herein "Part D Sponsor") and _____ (herein "Provider") 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 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 "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 Dplans.

(b) 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 § 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 422.

(c) The term "Provider" means an Indian Health Service (IHS) health program or all pharmacies and dispensaries 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.

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

(e) 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.

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

given in the IHCIA, Section 4(26), 25 U.S.C. § 1603(26).

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

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

(i) 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 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 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 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 IHCIA.

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 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.

5. Persons eligible for services of Provider.

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

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 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) An IHS provider:

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

(2) The ISDEAA; 25 U.S.C. § 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"), 45 CFR Parts 160 and 164; and

(8) The IHCIA, 25 U.S.C. § 1601 *et seq*.

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

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

(2) The IHCIA, 25 U.S.C. § 1601, *et seq.;*

(3) The FTCA, 28 U.S.C. §§ 2671-2680;

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

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

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

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

(1) The IHCIA, 25 U.S.C. § 1601, *et seq.* (including without limitation IHCIA Section 206(e)(3), 25 U.S.C. § 1621e(e)(3), regarding recovery from tortfeasors);

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

(3) 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 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 Part D Plan Sponsor will be held harmless from liability.

(b) Indian Tribes and Tribal Organizations. To the extent a Provider 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. 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 Part D Plan Sponsor will be held harmless from liability.

(c) Urban Indian Organizations. To the extent a Provider that is an urban Indian organization 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 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 IHCIA, 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 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. Provider eligibility for payments.

Pursuant to 25 U.S.C.§1647a, the IHS 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.

~~**a. 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.

~~**b. 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 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 State law to any greater extent than state law is already applicable.

13. Acquisition of Pharmaceuticals.

Nothing in the Pharmacy 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.

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. 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.

16. Payment Rate.

As required by 25 U.S.C. § 1621e and 45 C.F.R. Part 156, Subpart E, the Part D Plan Sponsor shall pay the reasonable charges billed by the Provider, or, if higher, the highest amount the Part D Plan Sponsor would pay any non-governmental provider for such services.

17. Information, Outreach, and EnrollmentMaterials.

(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.

(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. 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 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.

Signature of Authorized Representative	Printed Name of Authorized Representative
Title of Authorized Representative	