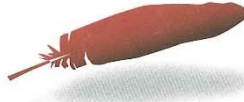


National Indian Health Board



Submitted via e-mail: jmatthews@naic.org

January 12, 2015

Jolie Matthews
National Association of Insurance Commissioners (NAIC),
444 North Capitol Street, N.W.
Washington D.C. 20001-1509

RE: Comments on Health Benefit Plan Network Adequacy Model Act

Dear Jolie Mathews:

This letter is sent on behalf of the National Indian Health Board (NIHB) to comment on the Health Benefit Plan Network Access and Adequacy Model Act issued by NAIC. We appreciate the opportunity to comment on the draft Model Act, particularly since the Centers for Medicare and Medicaid Services (CMS) has indicated in the proposed rule titled, Notice of Benefits and Payment Parameters, CMS-9944-P, that they will look to the to-be-developed NAIC model act prior to revising the Marketplace access standards.¹

Established in 1972, the NIHB is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all American Indians and Alaska Natives (AI/AN). The NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service (IHS) Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with the NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-Determination and Education Assistance Act (ISDEAA), or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.

Thank you for the opportunity to respond to the Notice. We set out our comments and suggestions below.

I. Background

This draft Act includes model language regarding network adequacy in health plans. The Act seeks to:

¹ 79 Fed. Reg. 70726

- A. Establish standards for the creation and maintenance of networks by health carriers; and
- B. Assure the adequacy, accessibility, transparency, and quality of health care services offered under a network plan by:
 - (1) Establishing requirements for written agreements between health carriers offering network plans and participating providers regarding the standards, terms, and provisions under which the participating provider will provide covered benefits to covered persons; and
 - (2) Requiring network plans to have and maintain publicly available access plans consistent with Section 5B of this Act that consist of policies and procedures for assuring the ongoing sufficiency of provider networks.

II. Tribal Concerns

There are 34 states where federally-recognized Tribes are located and many of those Tribes either operate their own health care facilities or have health care provided by IHS. Many of the AI/AN in those states are eligible for Medicaid, Medicare, Children's Health Insurance Program (CHIP), and private insurance plans offered by employers and through the marketplaces/exchanges established by the Affordable Care Act. The network adequacy standards proposed by NAIC are welcome and needed to protect AI/AN consumers, particularly those who live in remote geographic areas and those who have unique cultural and linguistic needs.

In many cases, the primary care providers who are most geographically accessible and culturally appropriate are working in clinics and hospitals operated by Tribes, Tribal Organizations, and IHS. It would make sense for health carriers to include these Indian health providers in their networks; however, there are often barriers to this. The most common barrier is that services provided by the IHS, Tribes and urban Indian clinics are subject to federal regulations that may be different from state regulations and provisions in standard network provider contracts.

In recognition of this, CMS in consultation with Tribes, has developed model addenda for Indian health facilities that may join provider networks for Medicare Part D Plans and Qualified Health Plans offered through the ACA marketplaces. We are attaching copies of these Addenda to this e-mail for your reference and possible inclusion in the Model Act that you are proposing.

One approach that NAIC could take in the revision of the Model Act is to include a section specific to Indian health facilities and providers. The 34 states with federally-recognized Tribes could adopt the section on Indian health providers, while other states may choose to omit it. Another approach would be to amend the wording throughout the agreement to accommodate the

distinctive characteristics of Indian health providers. Of course, the best approach would be to do both.

The federal government has a historic and unique government-to-government relationship with Indian tribes. As a result, Indian Tribes are entitled to special protections and provisions under federal law, including the Indian Health Care Improvement Act (IHCIA), the Indian Self-Determination and Education Assistance Act (ISDEAA), and the Patient Protection and Affordable Care Act (ACA). The Indian health care system includes approximately 44 Indian hospitals (16 of which are tribally operated and of which are accredited) and nearly 570 Indian health centers, clinics, and health stations (of which 83 percent are tribally-operated). When specialized services are not available at these sites, health services are purchased from public and private providers through the IHS-funded Contract Health Services (CHS) program. There are an additional 33 urban programs that offer services ranging from community health to comprehensive primary care.

The remainder of this comment considers specific wording changes that could be made within the proposed document.

III. Definitions

Essential Community Provider.

We note that there is a definition for “Essential community provider” even though it is not used in the draft Model Act:

“Essential community provider” means a provider that serves predominantly low-income, medically underserved individuals, including a provider defined in Section 340B(a)(4) of the PHSA and a tax exempt entity that meets the requirements of that standard except that it does not receive funding under that section.

Drafting Note: The term “essential community provider” is not used in this Act. However, the term is defined in this section to alert states that having a certain number or percentage of essential community providers in a provider network is a requirement that a qualified health plan (QHP) must satisfy in order to be offered on a health insurance exchange under the federal Affordable Care Act (ACA) and implementing regulations.

Indian health providers are listed as essential community providers in the ACA and we think it would be helpful to carriers to have them included in the above definition.

Health Care Professional.

The current definition is:

“Health care professional” means a physician or other health care practitioner licensed, accredited or certified to perform specified health services consistent with state law.

The final phrase—“consistent with state law”—could be problematic for Indian health providers as federal law allows professionals who are licensed in a different state to practice in Tribal and IHS facilities.

Indian health providers.

There are no definitions in the draft document related to Indian health care. We think it would be helpful to add the term “Indian health provider” and define it as a facility or program that is funded in part by the federal government or a federally-recognized Tribe to serve primarily American Indians and Alaska Natives, including the federal Indian Health Service, facilities and programs that are operated by Tribes and Tribal Organizations, and urban Indian clinics (also called “I/T/U”).

IV. Network Adequacy

It is our understanding that Section 5, Part A creates the standard of network adequacy with regard to types of providers. Part B allows carriers to use any reasonable criteria including but not limited to:

- (1) Provider-covered person ratios by specialty;
- (2) Primary care provider-covered person ratios;
- (3) Geographic accessibility;
- (4) Geographic population dispersion;
- (5) Waiting times for visits with participating providers;
- (6) Hours of operation;
- (7) New health care service delivery system options, such as telemedicine or telehealth; and
- (8) The volume of technological and specialty services available to serve the needs of covered persons requiring technologically advanced or specialty care.

In general, we like the criteria of (3) geographic accessibility. However, the concept of (4) geographic population dispersion may be contradictory. For example, if people are living in remote areas, it appears there could be an exception to the geographic accessibility rule. While this may be reasonable under some circumstances due to the economic feasibility for locating health providers in some areas of the country; if Indian health care providers (or other types of providers) are already located in a remote area or areas with low population density, then the carrier should offer a network that includes the providers that are actually available.

Part C addresses the need to provide access to out-of-network providers if the network is inadequate:

C. (1) A health carrier shall have a process to assure that a covered person obtains a covered benefit at an in-network level of benefits from a non-participating provider, or shall make other arrangements acceptable to the commissioner when:

- (a) The health carrier has a sufficient network, but has determined that it does not have a type of participating provider available to provide the covered benefit to the covered person; and
- (b) The health carrier has an insufficient number or type of participating provider available to provide the covered benefit to the covered person.

We recommend that the Model Act specify an additional category for obtaining a covered benefit from an out-of-network provider to specify that the AI/AN consumer can access services from an Indian health provider who is geographically accessible. This provision is already in law and regulations for Medicaid and QHPs.

V. Access Plans

In Section 5, E,(3), the Model Act requires carriers to:

...notify the commissioner of any material change to any existing network plan within fifteen (15) business days after the change occurs. The health carrier shall include in the notice to the commissioner a reasonable timeframe within which it will submit to the commissioner for approval or file with the commissioner, as appropriate, an updated an existing access plan.

We recommend that the Model Act include language to put everyone on notice that there is a government to government relationship between CMS and federally recognized Indian Tribes and under Executive Order 13175, any “material change” to any existing network plan must adhere to the Executive Order. We understand states are not mandated to follow the Executive Order; however, CMS is and any program with their imprimatur should do so likewise. Ultimately, CMS is under an obligation to follow the Executive Order.²

The Model Act requires carriers to submit access plans that describe or contain at least the following:

- (1) The health carrier’s network, including how the use of telemedicine or telehealth or other technology may be used to meet network access standards;
- (2) The health carrier’s procedures for making and authorizing referrals within and outside its network, if applicable;

² http://www.cms.gov/Outreach-and-Education/American-Indian-Alaska-Native/AIAN/Downloads/CMSTCP_FINAL_11_17_11.pdf

- (3) The health carrier's process for monitoring and assuring on an ongoing basis the sufficiency of the network to meet the health care needs of populations that enroll in network plans;
- (4) The health carrier's process for making available in consumer-friendly language the criteria it has used to build its provider network, which must be made available through the health carrier's online and in-print provider directories;
- (5) The health carrier's efforts to address the needs of covered persons with limited English proficiency and illiteracy, with diverse cultural and ethnic backgrounds, and with physical and mental disabilities;
- (6) The health carrier's methods for assessing the health care needs of covered persons and their satisfaction with services;
- (7) The health carrier's method of informing covered persons of the plan's services and features, including but not limited to, the plan's grievance procedures, its process for choosing and changing providers, its process for updating its provider directories for each of its network plans, a statement of services offered, including those services offered through the preventative care benefit, if applicable, and its procedures for providing and approving emergency and specialty care;
- (8) The health carrier's system for ensuring the coordination and continuity of care for covered persons referred to specialty physicians, for covered persons using ancillary services, including social services and other community resources, and for ensuring appropriate discharge planning;
- (9) The health carrier's process for enabling covered persons to change primary care professionals;
- (10) The health carrier's proposed plan for providing continuity of care in the event of contract termination between the health carrier and any of its participating providers, or in the event of the health carrier's insolvency or other inability to continue operations. The description shall explain how covered persons will be notified of the contract termination, or the health carrier's insolvency or other cessation of operations, and transferred to other providers in a timely manner; and
- (11) Any other information required by the commissioner to determine compliance with the provisions of this Act.

We think these provide good consumer protections and some are particularly appropriate for AI/AN communities, including items 1, 2, 4, 5, 8, and 9. In addition, in states that have Indian health providers, it would be helpful to specify how plans will coordinate with Indian health facilities for referrals – this could be added to item 2.

We support the concepts of making the access plans and network lists public information. Additionally, we recommend that the Access Plan requires carriers in states that have federally-

recognized Tribes to document their good faith efforts to include Indian health providers in their networks, as further explained in the following section on anti-discrimination provisions.

VI. Anti-discrimination Provisions

We support the principles in Section 6, F(3) that the selection of providers in networks shall not be established in a manner:

- (a) That would allow a health carrier to discriminate against high-risk populations by excluding providers because they are located in geographic areas that contain populations or providers presenting a risk of higher than average claims, losses or health care services utilization;
- (b) That would exclude providers because they treat or specialize in treating populations presenting a risk of higher than average claims, losses or health care services utilization.

In some cases, it could appear that carriers that do not include Indian health providers in their networks are attempting to keep AI/AN out of their plans to reduce the number of people in high risk populations, while carriers may believe that the Insurance Commissioner requires them to adhere to other standards that prohibit them from contracting with Indian health providers. For example, carriers may require minimum liability insurance in their provider contracts, while most Indian health providers are covered by the Federal Tort Claims Act and not required to have liability insurance. Another example is that carriers may require providers in their network to serve the entire population, while Indian health providers may be limited to serving AI/AN. Unless there is an acknowledgement of the federal laws, such as the model Addenda that we have included, carriers may feel that they are required to exclude Indian health providers from their networks. We believe these issues need to be addressed explicitly in the Model Act.

One way that CMS has addressed network adequacy for QHPs in the federally-facilitated marketplace (FFM) is to require that all issuers make a good faith effort to offer provider contracts to all Indian health providers. Evidence of “good faith” would be to include the aforementioned Indian Health Addendum. In addition, “good faith” includes offering payment amounts to providers that are at least equivalent to the amount the plans are required to pay Indian health providers for services provided to enrollees as out-of-network providers under Section 206 of the Indian Health Care Improvement Act (IHCIA).

We strongly recommend that NAIC include these concepts in the Model Act, either in a special Indian health section, or in the section related to anti-discrimination. Furthermore, as we have learned from experience with the FFM, it is necessary for carriers to document and report their efforts and results in offering contracts with the Indian Addendum and payment rates equivalent to IHCIA Section 206 rates. As noted above, we suggest that this be included in the Access Plan requirements.

VII. Summary and Conclusion

We appreciate the opportunity to comment on the draft Model Act. Please let us know if you have any questions about our recommendations. We would also like to suggest a follow-up meeting with NIHB or the Tribal Technical Advisory Group to CMS (TTAG) to discuss our concerns. Feel free please contact our Director of Policy and Advocacy, Richard Litsey by e-mail at RLitsey@nihb.org.

Sincerely,



Lester Secatero,
Chair, NIHB

Attachment: Qualified Health Plan Indian Addendum
Qualified Health Plan Indian Addendum Instructions
Medicare Part D Indian Addendum

Cc: Kitty Marx, Director, CMS Division of Tribal Affairs



Model QHP Addendum for Indian Health Care Providers

1. Purpose of Addendum; Supersession.

The purpose of this Addendum for Indian health care providers is to apply special terms and conditions necessitated by federal law and regulations to the network provider agreement by and between _____ (herein "Qualified Health Plan issuer" and/or "QHP issuer") and _____ (herein "Provider"). To the extent that any provision of the Qualified Health Plan issuer's network provider agreement or any other addendum thereto is inconsistent with any provision of this Addendum, the provisions of this Addendum shall supersede all such other provisions.

2. Definitions.

For purposes of the Qualified Health Plan issuer's agreement, any other addendum thereto, and this Addendum, the following terms and definitions shall apply:

- (a) "Contract health services" has the meaning given in the Indian Health Care Improvement Act (IHCIA) Section 4(5), 25 U.S.C. § 1603(5).
- (b) "Indian" has the meaning given in 45 C.F.R. 155.300.
- (c) "Provider" means a health program administered by the Indian Health Service, a tribal health program, an Indian tribe or a 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 Addendum.
- (d) "Indian Health Service or IHS" means the agency of that name within the U.S. Department of Health and Human Services established by the IHCIA Section 601, 25 U.S.C. § 1661.
- (e) "Indian tribe" has the meaning given in the IHCIA Section 4(14), 25 U.S.C. § 1603(14).
- (f) "Qualified Health Plan" (QHP) has the meaning given in Section 1301 of the Affordable Care Act, 42 U.S.C. § 18021.
- (g) "Tribal health program" has the meaning given in the IHCIA Section 4(25), 25 U.S.C. § 1603(25).
- (h) "Tribal organization" has the meaning given in the IHCIA Section 4(26), 25 U.S.C. § 1603(26).
- (i) "Urban Indian organization" has the meaning given in the IHCIA Section 4(29), 25 U.S.C. § 1603(29).

3. Description of Provider.

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

The IHS.

An Indian tribe that operates a health program under a contract or compact to carry out programs, services, functions, and activities (or portions thereof) of the IHS pursuant to the ISDEAA, 25 U.S.C. § 450 et seq.

- /_/ A tribal organization that operates a health program under a contract or compact to carry out programs, services, functions, and activities (or portions thereof) of the IHS pursuant to the ISDEAA, 25 U.S.C. § 450 et seq.
- /_/ A tribe or tribal organization that operates a health program 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 with funds in whole or part provided by IHS under a grant or contract awarded pursuant to Title V of the IHCIA.

4. Persons Eligible for Items and Services from Provider.

- (a) 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 C.F.R. Part 136. 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.
- (b) No term or condition of the QHP issuer’s agreement or any addendum thereto shall be construed to require the Provider to serve individuals who are ineligible under federal law for services from the Provider. The QHP issuer acknowledges that pursuant to 45 C.F.R. 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. Provider acknowledges that the nondiscrimination provisions of federal law may apply.

5. Applicability of Other Federal Laws.

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

(a) The IHS as a Provider:

- (1) Anti-Deficiency Act, 31 U.S.C. § 1341;
- (2) ISDEAA, 25 U.S.C. § 450 et seq.;
- (3) Federal Tort Claims Act (“FTCA”), 28 U.S.C. §§ 2671-2680;
- (4) Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653;
- (5) Federal Privacy Act of 1974 (“Privacy Act”), 5 U.S.C. § 552a, 45 C.F.R. Part 5b;
- (6) Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2;
- (7) Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), 45 C.F.R. Parts 160 and 164; and
- (8) IHCIA, 25 U.S.C. § 1601 et seq.

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

- (1) ISDEAA, 25 U.S.C. § 450 et seq.;
- (2) IHCIA, 25 U.S.C. § 1601 et seq.;
- (3) FTCA, 28 U.S.C. §§ 2671-2680;
- (4) Federal Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653;
- (5) Privacy Act, 5 U.S.C. § 552a, 45 C.F.R. Part 5b; and
- (6) HIPAA, 45 C.F.R. Parts 160 and 164.

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

- (1) IHCIA, 25 U.S.C. § 1601 et seq. (including without limitation pursuant to the IHCIA Section 206(e)(3), 25 U.S.C. § 1621e(e)(3), regarding recovery from tortfeasors);
- (2) Privacy Act, 5 U.S.C. § 552a, 45 C.F.R. Part 5b; and
- (3) HIPAA, 45 C.F.R. Parts 160 and 164.

6. Non-Taxable Entity.

To the extent the Provider is a non-taxable entity, the Provider shall not be required by a QHP issuer to collect or remit any federal, state, or local tax.

7. Insurance and Indemnification.

- (a) *Indian Health Service.* The IHS 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 QHP network provider agreement shall be interpreted to authorize or obligate any IHS employee to perform any act outside the scope of his/her employment. The IHS shall not be required to acquire insurance, provide indemnification, or guarantee that the QHP will be held harmless from liability.
- (b) *Indian Tribes and Tribal Organizations.* A Provider which is an Indian tribe, a tribal organization, or employee of a tribe or tribal organization 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 QHP issuer network provider 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 QHP issuer will be held harmless from liability.
- (c) *Urban Indian Organizations.* 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, Public Law 104-73, (codified at 42 U.S.C. § 233(g)-(n)), 42 C.F.R. Part 6, such Provider shall not be required to obtain or maintain professional liability insurance. Nothing in the QHP issuer network provider 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 QHP issuer will be held harmless from liability.

8. Licensure of Health Care Professionals.

- (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 QHP issuer's agreement, IHS health care professionals shall hold state licenses in accordance with applicable federal law, and that IHS facilities shall be accredited in accordance with federal statutes and regulations.

- (b) *Indian tribes and tribal organizations.* Section 221 of the IHCA, 25 U.S.C. § 1621t, exempts a health care professional employed by 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 QHP issuer's agreement and any addenda thereto.
- (c) *Urban Indian organizations.* To the extent that any health care professional of an urban Indian provider is exempt from state regulation, such professional shall be deemed qualified to perform services under the QHP Sponsor's agreement and all addenda thereto, provided such employee is licensed to practice in any state. The parties agree that this federal law applies to the QHP issuer's agreement and any addenda thereto.

9. Licensure of Provider; Eligibility for Payments.

To the extent that the Provider is exempt from state licensing requirements, such Provider shall not be required to hold a state license to receive any payments under the QHP issuer's network provider agreement and any addendum thereto.

10. Dispute Resolution.

In the event of any dispute arising under the QHP issuer's network provider agreement or any addendum thereto, the parties agree to meet and confer in good faith to resolve any such disputes prior to resolution of any disputes through any process identified in the network provider agreement. If the Provider is an IHS provider, 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 provider network agreement, IHS shall not be required to submit any disputes between the parties to binding arbitration.

11. Governing Law.

The QHP issuer's network provider 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 QHP issuer's network provider 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.

12. Medical Quality Assurance Requirements.

To the extent the QHP issuer imposes any medical quality assurance requirements on its network providers, any such requirements applicable to the Provider shall be subject to Section 805 of the IHCA, 25 U.S.C. § 1675.

13. Claims Format.

The QHP issuer 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.

14. Payment of Claims.

The QHP issuer shall pay claims from the Provider in accordance with federal law, including Section 206 of the IHCA (25 U.S.C. §1621e), and 45 C.F.R., Part 156, Subpart E. The QHP issuer shall be deemed compliant with Section 206 to the extent the QHP issuer and Provider mutually agree to the rates or amounts specified in the QHP issuer agreement as payment in full.

15. Hours and Days of Service.

The hours and days of service of the Provider shall be established by the Provider. Though not required prior to the establishment of such service hours, the QHP issuer and the Provider may negotiate and agree on specific hours and days of service. At the request of the QHP issuer, such Provider shall provide written notification of its hours and days of service.

16. Contract Health Service Referral Requirements

The Provider shall comply with coordination of care and referral obligations of the QHP issuer except only in specific circumstances in which such referrals would conflict with federal law or that referral requirements applicable to Contract Health Services would not be met. The Provider will notify the QHP issuer when such circumstances occur.

17. Sovereign Immunity.

Nothing in the QHP issuer’s network provider agreement or in any addendum thereto shall constitute a waiver of federal or tribal sovereign immunity.

18. 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.

APPROVALS

For the Qualified Health Plan Issuer:

For the Provider:

Date _____

Date _____



Overview of the Model QHP Addendum for Indian Health Care Providers

I. Purpose

CMS has developed the attached Model QHP Addendum for Indian health care providers to facilitate the inclusion of Indian Health Service (IHS), tribes and tribal organizations, and urban Indian organization (I/T/U) providers in qualified health plan (QHP) provider networks and help health insurance issuers comply with the QHP certification standards set forth in 45 C.F.R. Part 156. Similar to the standardized contract addendum used in the Medicare Part D program, this Model QHP Addendum has been developed for QHP issuers to use when contracting with I/T/U providers. This Model QHP Addendum is not required, but the U.S. Department of Health and Human Services (HHS) received several comments supporting the development and issuance of a model addendum for this purpose to assist QHP issuers in including I/T/U providers in their networks.

The federal government has a historic and unique government-to-government relationship with Indian tribes. In adhering to QHP certification standards, QHP issuers should reach out to I/T/U providers. A significant portion of American Indians and Alaska Natives (AI/ANs) access care through longstanding relationships with providers in the Indian health system. An important consideration in evaluating network adequacy and essential community provider accessibility will be the extent to which a QHP includes I/T/U providers and whether it can assure that services to AI/ANs will be accessible without unreasonable delay.

It is anticipated that the Model QHP Addendum will assist issuers to meet the QHP certification standards and facilitate acceptance of network contracts by I/T/U providers. We anticipate that offering contracts that include the Model QHP Addendum will provide QHP issuers with an efficient way to establish contract relationships with I/T/U providers, and also ensure that AI/ANs can continue to be served by their Indian provider of choice.

Indian tribes are entitled to special protections and provisions under federal law, which are described further in Section II. The Addendum identifies several specific provisions that have been established in federal law that apply when contracting with I/T/U providers. The use of this Model QHP Addendum benefits both QHP issuers and the I/T/U providers by lowering the perceived barriers to contracting, assuring QHP issuers comply with key federal laws that apply when contracting with I/T/U providers, and minimizing potential disputes. AI/ANs enrolled in QHPs will be better served when I/T/U providers can coordinate their care through the QHP issuer provider network.

II. Background on Indian Health Care

Indian tribes are afforded specific protections and provisions under federal laws, including the Indian Health Care Improvement Act (IHCA), the Indian Self-Determination and Education Assistance Act (ISDEAA), and the Patient Protection and Affordable Care Act (ACA). In order

to carry out its obligation to provide health care to American Indians and Alaska Natives (AI/ANs), the federal government has established a unique health care delivery system through the Indian Health Service (IHS). As part of the Indian health care system, health care services to AI/ANs are provided either directly by the IHS, by tribes or tribal organizations, or by urban Indian programs.

Today the Indian health care system includes 44 Indian hospitals (16 of which are tribally-operated and all of which are accredited) and nearly 570 Indian health centers, clinics, and health stations (of which 83 percent are tribally-operated). When specialized services are not available at these sites, health services are purchased from public and private providers through the IHS-funded Contract Health Services (CHS) program. Additionally, 33 urban programs offer services ranging from community health to comprehensive primary care.

III. Key Provisions in the Addendum

The following is a synopsis of key provisions outlined in the Addendum.

Persons Eligible for Items and Services from an Indian Health Care Provider: This section acknowledges that Indian health programs are generally not available to the public; they are established to serve AI/ANs, as provided in the IHCA. The applicable eligibility rules are generally set out in the IHS regulations at 42 C.F.R. Part 136. The IHCA § 813 (25 U.S.C. §1680c) sets out the circumstances under which certain non-AI/ANs connected with an AI/AN (such as minor children or a spouse) can receive services as beneficiaries. Also, the IHCA § 813 authorizes services to certain other non-AI/ANs if defined requirements are satisfied. Pursuant to 45 C.F.R. 80.3(d), an individual shall not be deemed as subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for services from an Indian health program.

Providers should note that 45 C.F.R. 80.3(d) is not an exemption from civil rights obligations generally. It simply clarifies that certain types of exclusions are not considered discrimination under Title VI of the Civil Rights Act of 1964. Providers may be subject to applicable federal nondiscrimination statutes.

Applicability of Other Federal Law: This section describes several federal laws that apply variously when contracting with I/T/U providers.

- *Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. § 450 et seq.* This law directs HHS at the request of an Indian tribe, to enter into a contract or compact with a tribe, a tribal organization, or an inter-tribal consortium to operate federal health programs for AI/ANs with the funds the IHS would have otherwise used to carry out the program directly. Through this law, many Indian tribes and tribal organizations have taken over direct operation of health programs from the IHS.
- *Federal Tort Claims Act (FTCA), 28 U.S.C. §§ 2671-2680.* Congress generally extended the FTCA to cover Indian tribes and tribal organizations operating federal programs pursuant to contracts or compacts under the ISDEAA, 25 U.S.C. § 450f. Urban Indian organization health providers who acquire Federally Qualified Health Center status under Section 224 of the Public Health Service Act can acquire FTCA coverage. Since a claim under the FTCA is

the exclusive remedy for actions against Indian health care providers that are covered by the FTCA, those entities are not required to obtain separate professional liability insurance.

- *Federal Medical Care Recovery Act (FMCRA)*, 42 U.S.C. §§ 2651-2653. This law authorizes federal agencies, including the IHS, to recover from a tortfeasor (or an insurer of a tortfeasor) the reasonable value of health services furnished to a tortfeasor's victim. The right of recovery under the FMCRA extends to Indian tribes and tribal organizations operating ISDEAA contracts and compacts. 25 U.S.C. § 1621.
- *Federal Privacy Act*, 5 U.S.C. § 552a, 45 C.F.R. Part 5b. This law and its regulations apply to the IHS, and may apply Indian tribes, tribal organizations, and urban Indian organizations that operate federally-funded health care programs. The Privacy Act governs the use and disclosure of personally identifiable information about individuals that is maintained in a federal system of records. While the Privacy Act generally applies to federal records maintained by a government contractor, patient records of a Tribal health program are not considered federal records for the purposes of chapter 5 of title 5 of the United States Code (including the Privacy Act and the Freedom of Information Act - see 25 U.S.C. § 4501).
- *Confidentiality of Alcohol and Drug Abuse Patient Records*, 42 C.F.R. Part 2. These regulations restrict disclosure and use of drug abuse patient records that are maintained in connection with the performance of any federally assisted alcohol or drug abuse program. The restrictions would apply to any such records maintained by the IHS, an Indian tribe, tribal organization, or urban Indian organization.
- *Health Insurance Portability and Accountability Act (HIPAA)*, (45 C.F.R. Parts 160 and 164). These regulations restrict access to and disclosure of protected health information maintained by covered entities, including covered health care providers operated by the IHS, Indian tribes, tribal organizations, and urban Indian organizations.
- *Indian Health Care Improvement Act (IHCIA)*, 25 U.S.C. § 1601 et seq. This law provides the comprehensive statutory framework for delivery of health care services to AI/ANs. It applies to all Indian health providers operating ISDEAA contracts and compacts from the Secretary of the HHS; and urban Indian organizations that receive grants from IHS under Title V of the IHCIA. Specific provisions of the IHCIA that would impact contracts between Indian health care providers and QHPs issuers are cited in various provisions of the Addendum.

Insurance and Indemnification: IHS, tribes and tribal organization providers are generally covered by the FTCA. Some urban Indian organizations are also covered under FTCA. Since a claim under the FTCA is the exclusive remedy for actions against FTCA covered I/T/U providers, those entities are not required to obtain professional liability insurance.

Licensure of Health Care Professionals: Section 221 of the IHCIA, 25 U.S.C. § 1621t, permits an Indian tribe or tribal organization to employ a health care professional who is subject to licensure if that individual is licensed in any state. Employees of the IHS obtain their "licensed in any state" status through other federal law.

Medical Quality Assurance Requirements: Section 805 of the IHCA, 25 U.S.C. § 1675, facilitates internal medical program quality reviews; shields participants in those reviews; and restricts disclosure of medical quality assurance records, subject to the exceptions in 25 U.S.C. 1675(d), which provides that medical quality assurance records created by or for I/T/U providers may not be disclosed to any person or entity. These disclosure limitations are also applicable to anyone to whom the I/T/U provider discloses such medical quality assurance records under the authority of 25 U.S.C. 1675(d). Although restrictive, we expect these limitations will have limited applicability to QHPs because there will be few, if any circumstances, where such records may be disclosed to a QHP under the law.

Claims Format: Section 206(h) of the IHCA, 25 U.S.C. § 1621e(h) is applicable to issuers when processing claims from an I/T/U provider. Section 206(h) of IHCA states that a health insurance issuer may not deny a claim submitted by the IHS, an Indian tribe or tribal organization based on the format on which the claim is submitted if the format complies with the Medicare claims format requirements.

Payment of Claims: Federal laws, including Section 206(a) and (i) of the IHCA, 25 U.S.C. § 1621e(a) and (i) and Title 45 Code of Federal Regulation, Part 156, Subpart E¹, are applicable to health insurance issuers when paying claims from I/T/U providers. Section 206(a) and (i) of IHCA provide that the IHS, an Indian tribe, tribal organization, and urban Indian organization have a right to recover the reasonable charges billed, or, if higher, the highest amount an insurance carrier would pay to other providers. However, this paragraph also notes if the issuer and I/T/U Provider mutually agree to rates or amounts specified in the QHP agreement as payment in full, the QHP issuer is deemed to be compliant with Section 206 of IHCA.

Contract Health Service Referral Requirements: In some instances, I/T/U providers may be subject to referral requirements under the contract health services program. For example, IHS may have existing contractual arrangements that require IHS to refer to specific providers and suppliers; or IHS may be prohibited from referring to a provider that has been excluded from Federal Health Care Programs, as defined in § 1128 of the Social Security Act. We believe these circumstances will be rare, but to the extent that they occur, the I/T/U provider may not be able to adhere to QHP issuer referral requirements to use in-network providers. This section acknowledges the potential for conflicting requirements, and that I/T/U providers may be prevented from following QHP issuer referral requirements in such instances. This section affirms that the I/T/U provider will otherwise comply with in network coordination of care and referral requirements.

IV. Database of Indian Providers

To assist issuers in identifying I/T/U providers in their service areas, please use the attached link to obtain a database of I/T/U provider locations, developed with the assistance of the Indian Health Service: <http://cciio.cms.gov/programs/exchanges/qhp.html>.

¹ Title 45 Code of Federal Regulation, Part 156, Subpart E describes rules for the elimination of cost sharing for EHB, for Indians at or below 300% of the Federal Poverty Level, and for no cost sharing for Indians receiving an item or service that is an EHB furnished by the Indian Health Service, an Indian Tribe, Tribal Organization or Urban Indian Organization, or through referral under contract health services. 78 Fed. Reg. 15410, 15535-39 (Mar. 11, 2013).

APPENDIX XIV – 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.

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 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 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 supersede 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.

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 section 813(a) and (b) of the IHCIA, 25 USC §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(c) and in emergencies under section 813(d) of the IHCIA.

(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, 25 USC §1680c;
- (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.

(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).

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"), 45 CFR 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;

- (5) The HIPAA and regulations at 45 CFR parts 160 and 164; and
- (6) Sec. 206(e)(3) of the IH CIA, 25 USC § 1624e(e)(3), regarding recovery from tortfeasors.

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

- (1) The IH CIA, 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 IH CIA, 25 USC §1621e(e)(3), regarding recovery from tortfeasors, as made applicable to urban Indian organizations by Sec. 206(i) of the IH CIA.

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 the 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 IHCA) 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 IHCA) 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.

(c) To the extent that any directly hired employee of an 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 IHCA) 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.

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 Provider Identifier (NPI) number.

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.

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.

(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