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Thomas J. Engles
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Administrator Engles,

On behalf of the United South and Eastern Tribes Sovereignty Protection Fund (USET SPF), we write to provide the Health Resources and Services Administration (HRSA) with comments regarding the proposal to change the 340B Drug Pricing Program from an upfront discount to a rebate model, and the need for HRSA to exempt Tribal Nations from this change. For nearly 35 years, the Program has operated under a model in which eligible entities can purchase prescription drugs at significantly discounted prices up front. This has allowed Tribal Nations to access and provide life-saving specialty medications for our citizens. A 340B rebate model would create financial, operational, and administrative risks that have not been properly considered by HRSA. At minimum, this will stretch already scarce capacity and resources in the Indian Health System and, at worst, may force Tribal pharmacies to close or force them to limit access to these critical medications, which could create life or death consequences for the patients we serve. USET SPF urges HRSA to fully exempt Tribal Nations from any rebate models within the 340B program and allow us to continue accessing the program in its current form.

USET SPF is a non-profit, inter-tribal organization advocating on behalf of thirty-three (33) federally recognized Tribal Nations from the Northeastern Woodlands to the Everglades and across the Gulf of Mexico.[1] USET SPF is dedicated to promoting, protecting, and advancing the inherent sovereign rights and authorities of Tribal Nations and in assisting its membership in dealing effectively with public policy issues.

[1] USET SPF member Tribal Nations include: Alabama-Coushatta Tribe of Texas (TX), Aroostook Band of Micmac Indians (ME), Catawba Indian Nation (SC), Cayuga Nation (NY), Chickahominy Indian Tribe (VA), Chickahominy Indian Tribe–Eastern Division (VA), Chitimacha Tribe of Louisiana (LA), Coushatta Tribe of Louisiana (LA), Eastern Band of Cherokee Indians (NC), Houlton Band of Maliseet Indians (ME), Jena Band of Choctaw Indians (LA), Mashantucket Pequot Indian Tribe (CT), Mashpee Wampanoag Tribe (MA), Miccosukee Tribe of Indians of Florida (FL), Mississippi Band of Choctaw Indians (MS), Mohegan Tribe of Indians of Connecticut (CT), Monacan Indian Nation (VA), Nansemond Indian Nation (VA), Narragansett Indian Tribe (RI), Oneida Indian Nation (NY), Pamunkey Indian Tribe (VA), Passamaquoddy Tribe at Indian Township (ME), Passamaquoddy Tribe at Pleasant Point (ME), Penobscot Indian Nation (ME), Poarch Band of Creek Indians (AL), Rappahannock Tribe (VA), Saint Regis Mohawk Tribe (NY), Seminole Tribe of Florida (FL), Seneca Nation of Indians (NY), Shinnecock Indian Nation (NY), Tunica-Biloxi Tribe of Louisiana (LA), Upper Mattaponi Indian Tribe (VA) and the Wampanoag Tribe of Gay Head (Aquinnah) (MA).

HRSA Must Honor Federal Trust and Treaty Obligations to Tribal Nations
USET SPF reminds HRSA that, as an arm of the federal government, it is required to uphold federal trust and treaty obligations owed to Tribal Nations. A critical component of trust and treaty obligations is the requirement to provide "all resources necessary" to facilitate the "highest possible health status" for American Indians and Alaskan Natives (AIANs). The 340B program, in its original and current form, is an invaluable resource for Tribal health programs in our efforts to provide quality and robust healthcare to our citizens and communities, and HRSA has an obligation to ensure we maintain access to this resource in a way that works for the Indian Health System. Refusal to grant an exemption from the rebate model for Tribal entities will, at minimum, result in diminished patient access to essential medications and, at worst, will destabilize Tribal health programs and threaten their continued existence, all of which is a violation of federal trust and treaty obligations.

We also remind HRSA that RFIs are not a substitute for formal Tribal consultation. HRSA is required by Executive Order and the Department of Health and Human Services' (HHS) own Tribal Consultation Policy to conduct Tribal consultation on any federal action that may affect programs and services delivered by and to Tribal Nations. The 340B program is a vital resource for Tribal health programs and a change of this magnitude requires consideration through formal Tribal consultation prior to HRSA acting.

Significantly Higher Upfront Costs Will Severely Impact Tribal Healthcare Access
Imposing a rebate model on 340B program covered entities will increase costs, sometimes exponentially, and an increase in cost this significant has the potential to create disastrous effects for Tribal health and pharmacy programs. Using the 10 drugs included in the original pilot as an example, these medications are estimated to cost 127 to 200,000 times more than the original 340B pricing. As Tribal clinics and pharmacies already operate on razor thin margins, due to chronic federal underfunding, this could have devastating effects on Tribal Nations' and Urban Indian Organizations' (UIOs) ability to provide access to medications our communities rely upon. Under a rebate-only model, Tribal health entities may be forced to delay or deny medications, reduce services, or reallocate limited financial and human resources away from patient care.

This is particularly concerning, as American Indian and Alaskan Native (AI/AN) people suffer disproportionate rates of diabetes, cardiovascular disease, autoimmune conditions, and other chronic diseases, conditions that are treated by the very medications on which HRSA is considering imposing a rebate model. Without access to advance discounts through the 340B pricing, Tribal clinics and pharmacies may be unable to purchase these medications, threatening the health and wellbeing of our communities and worsening health disparities. One medication (Jardiance) included in the original pilot and used to treat Type 2 diabetes, chronic kidney disease, and heart failure is estimated to increase in cost from $141 to nearly $205,000 annually *per patient.* Another medication used to treat autoimmune disorders (Enbrel) could increase in cost from less than a dollar per year to over $73,000 per year, per patient. Given the high rates of these conditions in our communities, Tribal health programs could see their upfront annual drug costs increase by hundreds of thousands or even millions of dollars.

Tribal health programs often do not have space in our budgets to absorb an upfront cost increase of this scale, even if we will eventually receive a rebate. If there are insufficient funds to purchase these medications upfront at the higher cost, Indian Health Care Providers may be forced to delay or deny medications, as even the 10-day timeframe for responding to claims may be too long for Tribal entities to absorb. The very nature of the populations we serve and the financial regulations and structures under which Tribal health programs must operate results in a lack of available funds to cover these costs, as every spare dollar is already required by law to be reinvested in our health programs. Moreover, the actual time period between an entity paying for a drug and receiving a rebate could also be much longer than 10

days because covered entities cannot file for a rebate until the medication is actually dispensed to the patient and the claims data is submitted. Uncertain timelines and potentially indefinite delays in receiving the rebates will only exacerbate the cash-flow issues already presented by a rebate model.

Even if we could manage to cover the increased upfront cost, few to no Tribal programs have the resources to absorb these costs indefinitely, if rebates are denied or significantly delayed. This uncertainty could force Tribal programs to limit access to drugs under the rebate model for fear of being unable to recoup the cost. Uncertainty over the amount needed to cover medication expenses in the absence of a clear price ceiling (as exists under the current 340B model) may also compel Tribal programs to pause or forego critically needed equipment, technology, or facility updates to save funds for future unknown cost increases. These decisions would further limit access to care and services and threaten the health of our citizens.

Tribal Nations already constantly have to deny or defer care to our citizens due to a lack of available funding or resources. A rebate model that creates exponentially higher upfront costs would only exacerbate these resource and cash-flow issues, which in turn could force us to further limit or deny care to our citizens and communities. These medications treat life-threatening conditions that plague our communities thanks to centuries of federal under-investment in the Indian Health System. The federal trust obligation to provide all resources necessary to ensure the highest possible health status for AI/AN people is in direct conflict with the rebate model proposal. The current 340B model that allows Tribal Nations to purchase these medications at the discounted price up front is a critical, life-saving resource in Indian Country. HRSA has an obligation to ensure that this resource is not diminished for Tribal entities.

Administrative and Operational Burdens Created by a Rebate Model

Beyond the simple cost of the medications, a 340B rebate model would also create significant administrative and operational challenges for Indian Health Care Providers that could further threaten our ability to operate and provide care to our communities. It is important to understand that due chronic federal underfunding, Tribal health providers operate with extremely limited capacity and resources—financial, human, and technological. Indian Health Care Providers across the country deal with significant workforce shortages of 25-30%, and these rates may be as high as 50% in some areas. This means that clinics and pharmacies often lack not only physicians and nurses, but administrative and billing staff that are necessary for continued operations. Additionally, severe underinvestment in Tribal health technology and systems means that entities also often lack the tools needed to comply with changing requirements.

Imposing a rebate model on the 340B program would require entities to create new IT systems and workflows to create and track rebates and claims, which will require dedicated human and technical resources. This will require Tribal health programs to either hire additional staff or pull existing staff away from their current duties to keep up with the significantly increased paperwork and processes required to access these medications and recoup rebates. As Tribal programs are already understaffed and routinely struggle to hire new staff due to the rurality of our communities and limited financial resources, it is likely that some Tribal entities will be unable to muster the capacity and resource necessary to support a rebate model. As a result, Tribal entities may be forced to limit patient access to care simply because we do not have the staff to execute and track rebate claims.

In addition, a rebate model will create increased compliance, audit and legal burdens for Tribal health programs. The ability to purchase these medications outright at the discounted price means that Tribal programs avoid the legal and administrative processes involved in filing and executing rebates with multiple private manufacturers (as well as the training required to educate employees on these processes and requirements). Considering the chronic workforce and capacity issues Tribal health programs face, this increased workload combined with the administrative burdens associated with operating health programs

subject to federal compliance standards could become unsustainable for Tribal health programs. Additionally, some entities may decide that the increased administrative burden and audit responsibilities outweigh the benefits of purchasing these medications.

Therefore, Tribal Nations are requesting that HRSA issue an exemption to Tribal entities from the 340B rebate model pilot and maintain current practices to ensure that Tribal Nations are not forced to choose between providing critical healthcare services for our people and maintaining compliance with burdensome administrative requirements.

Tribal Entities Must Retain Recourse Avenues Through the Federal Government for Rebate Denials
The proposal to shift the 340B program to a rebate model undermines federal trust and treaty obligations by shifting responsibility and authority over the program to private entities that do not share in the unique political relationship between Tribal Nations and the federal government. Under the present 340B model, Tribal covered entities can seek recourse through the federal government when manufacturers inappropriately overcharge for medications, just as manufacturers can seek recourse via audits through HRSA when 340B providers act inappropriately. Conversely, the proposed rebate model would provide manufacturers with wide discretion to deny rebate claims and would force covered entities to challenge denials with the drug companies themselves, not the federal government. The proposed model also would not impose any consequences on manufacturers that inappropriately delay or deny rebates. Given the financial and resource challenges we have outlined, Tribal entities do not have the resources necessary to challenge large private companies over these rebates.

More importantly, the 340B program is a resource Tribal programs employ to provide healthcare to our communities, and the federal government has a responsibility to provide "all resources necessary" to support the provision of this healthcare, which we are owed. Allowing private entities nearly unchecked discretion to deny or delay rebate claims for any number of reasons – as the RFI does not specify parameters for denials or impose consequences for manufacturer misconduct – could inappropriately diminish this resource for Tribal entities. Under any 340B model, Tribal entities must retain the authority to seek recourse through the federal government, and that requires the federal government to retain the authority to compel manufacturers to comply with federal requirements.

Conclusion
USET SPF respectfully requests that HRSA exempt Tribal 340B providers from the rebate model to avoid severe and lasting negative impacts on the Indian Health System. Without an exemption, AI/AN patients will lose access to life-saving medications, and the very existence of Tribal health programs may be threatened. The Department of Health and Human Services is well aware of the resource challenges faced by Tribal health programs that would make a rebate program unworkable, as well as the persistent and disproportionate health issues present in Indian Country that necessitate access to these medications. We therefore urge the Department to uphold the federal trust and treaty obligations to provide for AI/AN healthcare by exempting Tribal entities from the rebate model. Should you have any questions or require further information, please contact Ms. Liz Malerba, USET SPF Director of Policy and Legislative Affairs, at LMalerba@usetinc.org or 615-838-5906.

Sincerely,

Kirk Francis
President

Kitcki A. Carroll
Executive Director