DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Indian Health Service
Rockville, MD 20857

Dr. Lynn Malerba
Chairwoman
Tribal Self-Governance Advisory Committee
c/o Self-Governance Communication and Education
P.O. Box 1734
McAlester, OK 74502

Dear Chairwoman Malerba:

I am responding to your October 15, 2020, letter, which summarizes a number of the key issues and action items discussed during the Tribal Self-Governance Advisory Committee (TSGAC) meeting held virtually, on September 30, 2020. I also would like to thank the TSGAC, Tribes, and Tribal Organizations for providing recommendations during various Tribal Consultations, held in 2020, on the best path forward to address the COVID-19 pandemic in Indian Country.

While we have made progress in treating patients diagnosed with COVID-19 and saving lives, the positivity rates for Tribal members infected with COVID-19 continues to surge in some parts of the nation. Our best days lie just ahead, along with hope and healing, as more COVID-19 therapeutics and vaccines become readily available. I look forward to working with the TSGAC in unity under our new Administration.

1. Commitment to Self-Determination and Self-Governance. In the context of Tribal Consultation, e.g., Special Diabetes Programs for Indians (SDPI) and behavioral health grant funding mechanisms, the TSGAC advises the Agency to: (1) take Tribal comments and recommendations under serious consideration when making final decisions; and (2) carry forward those messages when Congress requests technical assistance, or at the very least, to check back with Tribal Leaders, including the TSGAC for further input before responding.

IHS response: The Indian Health Service (IHS) fully supports Tribal Self-Determination and Self-Governance and remains committed to the principles of improved internal and external communication, and sound management. For example, the IHS has taken its responsibility to comply with Executive Order 13175, seriously, including implementation of a policy on Tribal Consultation, which establishes processes and protocols for regular and meaningful consultation and collaboration with Tribes. On January 26, 2021, President Joseph R. Biden signed a Presidential Memorandum titled, *Tribal Consultation and Strengthening Nation-to-Nation Relationships*, which directs Federal agencies to submit a detailed plan of actions for how they will implement the policies and directives of Executive Order 13175. We look forward to updating you in the near future on our efforts with the Department of Health and Human Services (HHS) to improve our policy on Tribal Consultation and respond to the Presidential Memorandum.

2. The 340B Drug Pricing Program Administered by the Health Resources and Services Administration (HRSA). The TSGAC reiterates an appeal to the IHS to work with TSGAC to advance the following requests within HHS and HRSA: (1) to take enforcement action against pharmaceutical manufacturers violating rebate agreements; (2) that the HHS Office of Inspector General (OIG) investigate the pharmaceutical manufacturers and impose applicable civil and monetary penalties; and (3) that HHS engage in Tribal Consultation to ensure this matter is resolved in a way that protects our Tribal citizens and honors our Government-to-Government relationship.

IHS response: On December 30, 2020, the HHS Office of the General Counsel (OGC) released an advisory opinion concluding that drug manufacturers are required to offer discounts under the 340B Drug Pricing Program (340B Program) on covered outpatient drugs when contract pharmacies are acting as agents of 340B covered entity purchasers.[1] The OGC concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B Program ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients. While this Advisory Opinion sets forth the legal views of the OGC, it is not a final agency action or a final order, and it does not have the force or effect of law. [2] The OGC advisory opinion may be modified or supplemented by the OGC. However, the IHS acknowledges your requests, and we are committed to continuing to work towards a satisfactory resolution of the issues and initiating discussions on the topic with the new leadership.

3. 105(*l*) Leases. The TSGAC expressed appreciation for IHS's commitment, made during the TSGAC September 30, 2020 meeting, to re-convene the budget sub-workgroup sometime in the month of October 2020, which would provide better estimates for future projections and report to the IHS-Tribal Budget Workgroup annually to include in the recommendations to the HHS Secretary. The TSGAC also requests that the IHS move forward on TSGAC's previous request to create a 105(*l*) Lease Policy Tribal and Federal workgroup, similar to the Contract Support Cost Policy Workgroup to develop a guidance policy for 105(l) lease negotiations and calculations.

IHS response: I am pleased to highlight the new, separate, indefinite appropriation included in the fiscal year (FY) 2021 budget for fully funding the costs of 105(*l*) lease cost agreements. This new appropriation protects the funding for health services provided in the IHS's Services appropriation account. The emergent COVID-19 priorities delayed our initial efforts in 2020 to work on 105(*l*) lease cost agreement cost projections and policy. However, building on the successful achievements of the National Tribal Budget Formulation Workgroup's recommendations and the Administration's budget proposal, the IHS will

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[1] The Department of Health and Human Services Office of General Counsel (December 30, 2020). *ADVISORY OPINION 20-06 ON CONTRACT PHARMACIES UNDER THE 340 PROGRAM DECEMBER 30, 2020.* Retrieved from https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf

[2] *Ibid.*

resume efforts to refine cost projections and policy. An updated timeline and process for conducting this work that includes Tribal input and Tribal Consultation is under development.

4. Health Information Technology (HIT) Modernization Project/ Telehealth Capacity. The TSGAC shared their appreciation for the update provided by the IHS during the last TSGAC meeting, including the establishment of a Tribal Advisory Committee for HIT Modernization. However, the TSGAC requests that the IHS continue to actively consult with all Tribes and Tribal Organizations as the IHS advances strategies to implement the HIT Modernization Project, prior to decisions being made, such as on vendor selection, etc.

The TSGAC also reiterated their concerns, as shared in their September 2, 2020, letter to the IHS, regarding the IHS's decision to utilize the $95 million from the CARES Act set-aside to support expansion of telehealth activities for centralized services and shared technology infrastructure. Consequently, the TSGAC recommends that the IHS establish a joint Tribal and Federal workgroup to develop constructive options to bolster and sustain Tribal telehealth capacity.

IHS response: By letter dated December 10, 2020, the IHS informed Tribal Leaders and Urban Indian Organization Leaders of two virtual listening sessions to garner Tribal input on the next steps for health information technology (IT) modernization at the IHS, specifically, requesting Tribes to submit comments and questions regarding the option of full replacement of the Resource Patient Management System (RPMS). The IHS held the listening sessions on December 17, 2020, and January 14, 2021. The comment period closed on January 24, 2021. To date, the IHS continues to review the comments and questions received to determine the next steps for the IHS Health IT Modernization initiative.

Additionally, the IHS acknowledges and will take under consideration your recommendation to establish a joint Tribal and Federal workgroup to address telehealth activities for the IHS. In terms of funds, the IHS continues to deliberate on the use of the $95 million from the CARES Act set-aside to support expansion of telehealth activities for centralized services and shared technology infrastructure. As part of this deliberation, the IHS is evaluating the feasibility of disbursing of a portion of the $95 million based on previously established COVID-19 funding processes and practices to Tribes, Tribal Organizations, and Urban Indian Health Organizations.

5. Provider Relief Fund. The TSGAC expressed concern regarding the formula used by the Administration to generate the set-aside of $500 million for Indian health care providers in the Provider Relief Fund. Subsequently, the TSGAC requests that the IHS support advancing Tribal recommendations to HHS and Congress that any future funding allocations for Indian health care system providers be based on the actual cost to provide care (e.g., the average national health care cost per person is $11,172), rather than the historically underfunded IHS appropriated amounts ($3,943 cost per person).

IHS response: I appreciate the TSGAC's input and the feedback provided by Tribes, Tribal Organizations, and Urban Indian Organizations following HHS's targeted distribution of $500 million from the Provider Relief Fund. I understand your concerns regarding the basis for these funding allocation calculations. The IHS is committed to sharing this feedback with HHS and Congress, and working diligently to support the resources necessary for providing health services across our entire Indian health system.

6. Develop Administrative Solutions for Inter-Agency Agreements. The TSGAC requests that the IHS continue to work with Tribes to develop administrative solutions to address and remove barriers and advocate, both internally and through the Intradepartmental Council on Native American Affairs and the White House AI/AN Council, that COVID-19 funding received by HHS be sent to Tribes in non-competitive and formula-driven distributions, with limited administrative burdens (e.g., report frequently).

IHS response: The IHS and our Federal partners continue to work closely with Tribal governments, public health officials, health care providers, researchers, private sector, and the public, to execute a whole-of-government response to the COVID-19 pandemic to protect the health and safety of the American people. As part of this approach, the IHS actively participates in engagements, activities, and Tribal Consultations in coordination and collaboration with other Federal agencies, to address COVID-19 prevention, preparedness, and response in AI/AN communities. The IHS will continue to share Tribal input, including recommendations and concerns, and help educate Federal partners and members of Congress to identify and address the administrative or legislative barriers experienced throughout the pandemic.

7. Budget Formulation Process. The TSGAC reported that the IHS will be pivoting to a virtual format for the upcoming Tribal Budget Formulation meetings. Therefore, the TSGAC requests that the IHS include Tribes in the planning process, as it will need to be reconfigured to accommodate virtual attendance and share other recommendations.

IHS response: The IHS FY 2022 Evaluation and FY 2023 Budget Planning meeting was held on July 17, 2020. During the virtual session, Tribal representatives from the National Tribal Budget Formulation Workgroup and the corresponding technical team discussed how to best execute the FY 2023 National Tribal Budget Formulation Work Session in a virtual setting. For example, the technical team identified key concerns and recommendations, such as, the use of video, ensuring capability for Tribal causes or breakout sessions, distributing meeting materials electronically in advance of the meeting, taking advantage of user-friendly platforms that enable collaboration across a large group, and effectively documenting the discussion and all decisions.

8. VA and IHS MOU – Purchase/Referred Care (PRC) Reimbursement. The TSGAC continues to advocate that the VA should include PRC in IHS/Tribal Health Program (THP) reimbursement agreements to increase access and ensure timely quality health care for AI/AN veterans and other eligible veterans.

IHS response: The IHS and the U.S. Department of Veterans Affairs (VA) Veterans Health Administration (VHA) continue to collaborate on delivering tangible outcomes that increase access to care for AI/AN Veterans. On October 5, 2020, the IHS issued a Tribal Leader Letter to inform Tribes that the IHS and the VA recently amended our national IHS-VA VHA Reimbursement Agreement (Agreement), which affects direct health care services to eligible AI/AN veterans at 74 IHS facilities. The amended Agreement added a new section for the reimbursement of care or services provided by the IHS through a contract established by the IHS (e.g., the PRC Program) for health care provided outside of the facility during the COVID-19 emergency period that meet certain conditions. The IHS will continue to advocate, on behalf of Tribes and Tribal Organizations, for PRC to be expanded to other areas in IHS/THP reimbursement agreements.

The two agencies are also working together to implement a number of recent legislative changes that affect VA reimbursement for PRC. As it was with billing the VA for direct care, there are many details that still need to be discussed internally by both agencies. The IHS and VA intend to have a leadership call when the agencies have had a chance to discuss and make internal assignments. Both agencies realize that reimbursement for the costs of care for eligible veteran patients is a top priority. We are working together to implement additional reimbursement mechanisms for IHS-operated facilities and to identify further opportunities to support implementation across the IHS system. As part of that effort, the VA intends to introduce a Care Coordination program that will allow providers across the IHS system to more easily access the VA referral system. Discussions are ongoing as to how PRC payment will fit into this process.

In FY 2019, the IHS and the VA initiated an in-depth revision of the existing 2010 Memorandum of Understanding with the goal of creating a new MOU that reflects the evolving health care and health information technology landscape. By letter dated December 2, 2020, the IHS and the VHA initiated a joint Tribal Consultation to seek input on a draft revised MOU between the two agencies. The comment period ends March 2, 2021.

9. VA Graduate Medical Education (GME) Program. The TSGAC requests that the IHS partner with Tribes to advance Tribal efforts to encourage the VA to implement Tribal Consultation to address Tribal concerns (e.g., sporadic funding) regarding the VA Graduate Medical Education Program, authorized by the VA Mission Act, Section 403, "Pilot Program on Graduate Medical Education and Residency."

IHS response: The IHS acknowledges your request, and is committed to working with Tribes and Tribal Organizations on our common objective to see full implementation of the VA Mission Act, Section 403, "Pilot Program on Graduate Medical Education and Residency."

10. Vaccine Distribution. The TSGAC expressed concerns regarding the HHS Tribal Consultation process regarding the COVID-19 vaccine deployment process. Issues of interest included the following: (1) many Tribes received late notice of the Tribal Consultation sessions; (2) sufficient informed data is needed to aid in deployment activities; (3) additional input from Tribal health programs and leaders is necessary to ensure vulnerable communities with limited access to health care, have equal access to future vaccine developments; and (4) Tribal Epidemiology Centers should receive updated information and be part of any public health initiative to deploy vaccines in Tribal communities.

IHS response: We understand the concerns about the timing of communications regarding HHS-initiated Tribal Consultation on COVID-19 Vaccination Planning for Indian Country. Pre-planning efforts, including Tribal Consultation and Urban Confer, have occurred on very short timelines based on the rapid development and dissemination of COVID-19 vaccine information, with limited timeframes for planning and response. The IHS is working closely with the HHS Office of Intergovernmental and External Affairs (IEA) to ensure Tribes receive vaccine-related notifications through routine IHS communication channels. Additionally, the HHS IEA shared written comments received during the Tribal Consultations regarding the COVID-19 Vaccination Planning for Indian Country. All comments were reviewed by the IHS COVID-19 Vaccine Task Force (Task Force) and were used to inform updates to the IHS COVID-19 Pandemic Vaccine Plan, November 2020, as appropriate.

Feedback from the HHS Tribal Consultation sessions and comments on the IHS COVID-19 Pandemic Vaccine Draft Plan included several concerns about the data used to inform vaccination planning efforts. In early October, 2020, the Task Force distributed the IHS COVID-19 Pandemic Vaccine Plan pre-planning tool to IHS Areas. The tool was further distributed for input from IHS, Tribal and Urban Indian (I/T/U) health programs on their vaccination population estimates. These estimates included IHS beneficiaries and non-beneficiaries, such as health care personnel, emergency workers, and others. As stated in the IHS COVID-19 Pandemic Vaccine Plan, November 2020, I/T/U health programs may determine their population estimates with guidance from the Centers for Disease Control and Prevention (CDC), CDC's Advisory Committee on Immunization Practices, and the National Academies of Sciences, Engineering, and Medicine. As such, COVID-19 vaccine population estimates for an I/T/U facility may be different from the IHS user population. IHS will continue to adapt the distribution planning process as new information and Federal guidance evolves and will issue vaccine related updates to Tribes when available.

Regarding updates to TECs and inclusion in any public health initiative to deploy vaccine, the IHS continues to provide COVID-19 updates and several TECs continue to work with their Tribal communities on COVID-19 response by providing public education, Tribal technical assistance, and other support. The IHS expects continued engagement with TECs on COVID-19 related developments.

I trust this information is helpful. If you have any questions, please contact Ms. Jennifer Cooper, Director, Office of Tribal Self-Governance, IHS, by telephone at (301) 443-7821, or by e-mail at jennifer.cooper@ihs.gov. Thank you for your ongoing support and partnership, as we mitigate the COVID-19 pandemic and work towards a shared vision for healthy communities and quality health care systems.

Sincerely,

Elizabeth A. Fowler -S

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Elizabeth A. Fowler
Acting Director