



JAN 13 2020

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 22, 2019, letter, which summarizes some of the key issues and recommendations to the Indian Health Service (IHS) discussed at the Tribal Self-Governance Advisory Committee (TSGAC) meeting held in Washington, D.C., on September 30-October 1, 2019.

1. **HHS Operational Division Access to IHS Patient Data:** In the October 22, 2019, letter, the TSGAC reported they continue to be concerned about the access and use of IHS collected-data by a number of HHS operating divisions for research purposes. Consequently, TSGAC requested that the IHS conduct formal Tribal Consultation to establish a data management policy, delineating clear processes and guidelines to govern the use and sharing of IHS-collected data with other HHS operating divisions that may be used for research purposes. Further, TSGAC requested the inclusion of Tribal representation on the IHS Internal Review Board (IRB).

***IHS Response:*** While I am aware of the concerns regarding the protection of patient and Tribal health data as expressed by the TSGAC, the IHS has no immediate plans to conduct Tribal Consultation to develop a data management policy. However, the IHS is committed to assuring that IHS and Tribal data is protected and only used for purposes allowed under Federal law. The IHS has established procedures for the use and disclosure of Protected Health Information (PHI) for research and non-research purposes in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, the Privacy Act, and when applicable, the confidentiality of substance use disorder patient records under 42 CFR Part 2. The IHS data management, related to research requests, is currently governed by policies and procedures detailed in the:

1. IHM, Part 2, Chapter 7, "Health Insurance Portability and Accountability Act Privacy Rule and the Privacy Act," on the IHS Web site at <https://www.ihs.gov/ihm/pc/part-2/chapter-7-health-insurance-portability-and-accountability-act-privacy-rule-and-the-privacy-act/>;
2. IHS Research, Division of Planning, Evaluation, and Research Web site, available at [www.ihs.gov/dper/research/](http://www.ihs.gov/dper/research/); and on
3. IHS Privacy Web site, available at [www.ihs.gov/privacyact/](http://www.ihs.gov/privacyact/).

All research requests, including those from other federal agencies, must be submitted

through the National IRB (or an Area IRB if the request only impacts one IHS Area). Information on procedures for submitting research protocols is available on the IHS Web site at <https://www.ihs.gov/dper/research/hsrp/>. Some data requests are for very limited types of de-identified data (e.g., aggregate data) and in some cases it could be identifiable data (e.g., matching studies to identify racial misclassification or individual patient laboratory data for research studies, with the patients' written consent). The National IRB reviews all research requests based on the merit of the protocol and whether the data is releasable under HIPAA and the Privacy Act. If a research request is approved, the National IRB makes sure appropriate agreements (e.g., Data Use Agreements) are in place to assure that all parties know how the data can be used and when it must be destroyed.

The IHS IRB, commonly referred to as the National IRB, is comprised of 3 non-IHS (Tribal) members, and 6 Federal/IHS staff, for a total of 9 members. The current list of IRB contacts is available on the IHS Web site at <https://www.ihs.gov/dper/research/hsrp/inreviewboards/>.

- 2. IHS Opioid Funding:** In the October 22, 2019, letter, TSGAC reiterated their recommendation to distribute IHS's appropriation of \$10 million dollars to support opioid abuse prevention and treatment through a formula-driven distribution utilizing the Tribal Size Adjustment Formula, rather than distributing the funds through a competitive grants mechanism. TSGAC also requested that the IHS provide a timely decision regarding the method for dispersing these funds, and any further response to the Committee's ideas proposed in their formal comments regarding this issue.

***IHS Response:*** The IHS received \$10 Million in fiscal year (FY) 2019 funding under the Special Behavioral Health Pilot Program (SBHPP) for Indians to be targeted at combatting the opioid epidemic. The conference report creating this program stated that the SBHPP: 1) will award grants for providing services and supporting the development, documentation, and sharing of locally-designed, culturally appropriate prevention, treatment, recovery, and aftercare services for mental health and substance use disorders in American Indian and Alaska Native communities, and 2) shall be developed after Tribal Consultation.

On June 17, 2019, the IHS Division of Behavioral Health (DBH) held the first face-to-face Tribal Consultation on the SBHPP, during the IHS National Tribal Advisory Committee (NTAC) Meeting in Rockville, Maryland. Following the Consultation at the NTAC meeting, four virtual Consultations and one Urban Confer session were completed between June 17, and July 31, 2019. In addition, written comments were accepted by both e-mail and postal mail through the duration of the Tribal Consultation and Urban Confer process, which ended on September 3, 2019. All SBHPP Tribal Consultation and Urban Confer activities were done in collaboration with the Heroin, Opioid and Pain Efforts Committee, and the IHS Opioid Coordinating Group. The Tribal Consultation and Urban Confer sessions allowed for feedback on priorities, methodologies, and desired outcomes to be used in the selection and award process.

The IHS DBH reviewed the SBHPP feedback and is currently finalizing a report with the findings and recommendations. The IHS expects to issue a Tribal Leader letter with the decision on the programmatic and funding structure of the new SBHPP in the very near future. A funding opportunity for the SBHPP is expected in FY 2020.

- 3. Pharmacy Benefits Manager:** In the October 22, 2019, letter, and a June 12, 2018, letter, the TSGAC reported that the IHS has not provided guidance to Tribes regarding outstanding Pharmacy Benefits Manager (PBM) claims and claim denials. However, TSGAC acknowledged that there has been recent progress with CVS Caremark. TSGAC requested that the IHS provide a formal response and status update, along with a current time frame regarding the IHS's efforts to resolve these outstanding claims.

***IHS Response:*** The IHS will be issuing a Tribal Leader letter that will address the TSGAC recommendations regarding the outstanding PBM claims and claim denials in the near future.

- 4. IHS Tribal Consultation Policy and Process:** The TSGAC recommended in the October 22, 2019 letter, and an August 10, 2018, letter that IHS establish a formal Federal/Tribal Consultation Workgroup to review and provide recommendations to update the existing IHS Tribal Consultation Policy. Additionally, the TSGAC requested that IHS develop a charter, timeline, budget and process for identifying Tribal representation for the Federal/Tribal Consultation Workgroup.

***IHS Response:*** The IHS has no immediate plans to initiate Tribal Consultation on the IHS Tribal Consultation Policy while the HHS Secretary's Tribal Advisory Committee (STAC) is actively engaged in Tribal Consultation policy discussions on the HHS Consultation Policy. Tribal Consultation activities related to the IHS Tribal Consultation Policy will remain on hold while the STAC works to update the HHS Consultation Policy.

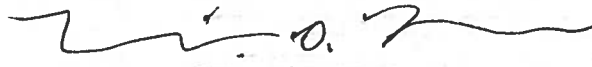
- 5. Identification of TSGAC representatives to serve on the newly-established 105(I) Lease Sub-Workgroup:** The TSGAC shared that they appointed a primary Tribal representative, Candice E. Skenandore, and an alternative Tribal representative, Melanie Fourkiller, to participate in the Federal/Tribal 105(I) Lease Sub-workgroup, a sub-workgroup of the IHS Tribal Budget Formulation Workgroup.

***IHS Response:*** Thank you for officially appointing a primary Tribal representative and an alternative Tribal representative to participate in the Federal/Tribal 105(I) Lease Sub-workgroup, which will operate under the auspices of the IHS National Tribal Budget Formulation Workgroup. Information regarding future meetings of the Federal/Tribal 105(I) Lease Sub-workgroup will be forthcoming. For your awareness, the FY 2022 National Tribal Budget Work Session will be held February 13-14, 2020, in Crystal City, Virginia. We look forward to the dialogue and recommendations of the Sub-workgroup on this pressing issue.

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I hope you find this information 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](mailto:jennifer.cooper@ihs.gov). Thank you for your continued support and partnership as we work towards a shared vision for healthy communities and quality health care systems.

Sincerely,

A handwritten signature in black ink, appearing to read "M. D. Weahkee", with a stylized flourish at the end.

RADM Michael D. Weahkee, MBA, MHSA  
Assistant Surgeon General, U.S. Public Health Service  
Principal Deputy Director