



Tribal Self-Governance Advisory Committee

January 23 – January 24, 2020



Plymouth Rock to Alcatraz: Triumph of Tribal Self-Governance

2020 Tribal Self-Governance Consultation Conference
April 26 – April 30, 2020
Burlingame, CA



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**INDIAN HEALTH SERVICE TRIBAL SELF-GOVERNANCE ADVISORY COMMITTEE
AND TECHNICAL WORKGROUP QUARTERLY MEETING
Thursday, January 23, 2020 (8:30 am to 5:30 pm)
Friday, January 24, 2020 (8:30 am to 1:30pm)**

Embassy Suites Washington DC - DC Convention Center
900-10th Street NW
Washington, DC 20001
Phone: (202) 739-2001

AGENDA

Thursday, January 23, 2020 (8:30 am to 11:00 am)

Meeting of Tribal Self-Governance Advisory Committee Technical Workgroup

- 8:30 am **Introductions & Opening Remarks**
Terra Branson-Thomas, Director, Planning, Grants & Self-Governance, Muscogee (Creek) Nation, TSGAC Technical Workgroup Tribal Co-Chair
Jennifer Cooper, Director, Office of Tribal Self-Governance, IHS and TSGAC Technical Workgroup Federal Co-Chair
- 8:45 am **Preparation for 2020 Annual Self-Governance Consultation Conference**
Jay Spaan, Executive Director, Self-Governance Communication & Education (SGCE)
- 9:15 am **Technical Workgroup Issues and Concerns**
Facilitated by: Terra Branson-Thomas, TSGAC Tribal Technical Co-Chair
- 10:00 am **Legislative & Judicial Update**
Stacy A. Bohlen, Executive Director, National Indian Health Board
Geoff Strommer, Partner, Hobbs, Strauss, Dean and Walker
- 10:30 am **Tribal Caucus**
Facilitated by: Marilyn "Lynn" Malerba, Chief, Mohegan Tribe, and Chairwoman, Indian Health Service (IHS) Tribal Self-Governance Advisory Committee (TSGAC)
 - Arizona State University Self-Governance Master's Program
 - Special Diabetes Program for Indians Tribal Consultation
 - Medicaid Legislative Initiative
- 11:30 am **Lunch** (Provided)

Thursday, January 23, 2020 (12:30 pm to 5:00 pm)

Meeting of IHS Tribal Self-Governance Advisory Committee (TSGAC)

- 12:30 pm **Meeting Called to Order**
Welcome

Invocation

Roll Call

Introductions – All Participants & Invited Guests

12:45 pm

TSGAC Opening Remarks

*Marilynn “Lynn” Malerba, Chief, Mohegan Tribe, and Chairwoman, IHS TSGAC
RADM Michael D. Weahkee, Principal Deputy Director, IHS*

1:15 pm

TSGAC Committee Business

- Approval of Meeting Summary (September 2019)
- Nomination from Great Plains

1:25 pm

Office of Tribal Self-Governance Update

Jennifer Cooper, Director, Office of Tribal Self-Governance, IHS

1:45 pm

HHS Health Information Technology Modernization Project

Maia Z. Laing, HHS Optimization Team, Office of the Chief Technology Officer, Immediate Office of Secretary, HHS

Mitchell Thornbrugh, Chief Information Officer and Director, Office of Information Technology, IHS

- Summary of final report from the HIT Advisory Committee
- Workgroup next steps

2:30 pm

Indian Health Service Budget Update

Jillian Curtis, Director, Office of Finance & Accounting

Melanie Fourkiller, Policy Analyst, Choctaw Nation

- Fiscal Year 2020 Appropriations
- Fiscal Year 2022 IHS Budget Formulation Process

3:00 pm

Government Accountability Office

Jessica Farb, Director, Health Care Team, Government Accountability Office

Nikki Clowers, Managing Director, Governmental Accountability Office

Anna-Maria Ortiz, Director, Natural Resources & Environment Team, Government Accountability Office

- Affordable Care Act Report
- Indian Health Service (IHS) Funding Allocation and Oversight

4:00 pm

Advancement of Title VI Self-Governance Expansion in HHS

Commissioner Jean Hovland, Deputy Assistant Secretary for Native Americans

Commissioner – Administration for Native Americans

4:30 pm

NIH All of Us Initiative

Dr. Yvette Roubideaux, Vice President for Research and Director of the Policy Research Center, NCAI

Carolyn Hornbuckle, Chief Operations Officer, NIHB

- Tribal Engagement with the NIH All of Us Research Program
- Data Sharing and Management Draft Policy

- Intellectual Property Policy

5:00 pm **Patient Protection and Affordable Care Act (ACA) Implementation Update**
Cyndi Ferguson, Self-Governance Specialist/Policy Analyst, SENSE Inc.
Doneg McDonough, Consultant, TSGAC

5:30 pm **Recess until January 24, 2020**

Friday, January 24, 2020 (8:30 am – 12:00 pm)

Tribal Self-Governance Advisory Committee (TSGAC) and Technical Workgroup with RADM Michael D. Weahkee, Principal Deputy Director, IHS

8:30 am **Welcome and Introductions**
Marilynn “Lynn” Malerba, Chief, Mohegan Tribe, and Chairwoman, TSGAC
RADM Michael D. Weahkee, Principal Deputy Director, IHS

8:45 am **IHS Negotiations Sub-Workgroup**
Sub-Workgroup Representative

9:00 am **HHS Office of Surgeon General Update**

- *VADM Jerome M. Adams, M.D., M.P.H., Surgeon General, HHS Office of the Secretary*

9:30 am **Joint Discussion with IHS Principal Deputy Director**

- Update on VA/IHS MOU

11:45 pm **Closing Remarks**
Marilynn “Lynn” Malerba, Chief, Mohegan Tribe, and Chairwoman, IHS TSGAC
RADM Michael D. Weahkee, Principal Deputy Director, IHS

12:00 pm **Lunch - TSGAC Members’ Executive Session with RADM Weahkee**

1:00 pm **TSGAC Technical Working Session**
Facilitated by: Terra Branson-Thomas, TSGAC Tribal Technical Co-Chair

- Assignments and follow up

IHS TRIBAL SELF-GOVERNANCE ADVISORY COMMITTEE

c/o Self-Governance Communication and Education
 Telephone (918) 302-0252 ~ Facsimile (918) 423-7639 ~ Website: www.tribalsegov.org

TSGAC Membership January 16, 2020

Area	Member	Status	Contact Information
Alaska	Diana Zirul Tribal Council Member Kenaitze Indian Tribe	Primary	alaskadi@pentc.com
	Gerald "Gerry" Moses Senior Director Alaska Native Tribal Health Consortium	Alternate	gmoses@anthc.org
Albuquerque	Richard Aspenwind Governor Pueblo of Taos	Primary	governor@taospueblo.com
	David M. Toledo Governor Pueblo of Jemez	Alternate	Raymond.loretto.dvm@jemezpueblo.org
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	Jennifer Webster Councilwoman Oneida Nation	Alternate	jwebste1@oneidanation.org
Billings	Michael Corcoran Chippewa Cree Tribe	Primary	
	Charmel Gillin Councilmember Confederated Salish & Kootenai Tribes	Alternate	
California	Byron Nelson, Jr Chairman Hoopa Valley Tribe	Primary	cbfdistrict@gmail.com
	Robert Smith Chairman Pala Band of Mission Indians	Alternate	rsmith@palatribe.com
Great Plains	Victoria Ketcheyan Councilwoman Winnebago Tribe of Nebraska	Primary	Confirmation Pending – January 2020
	Danielle Smith CEO Winnebago Healthcare System	Alternate	Confirmation Pending – January 2020

Area	Member	Status	Contact Information
Nashville	Marilynn "Lynn" Malerba* Chief Mohegan Tribe of Connecticut <i>TSGAC Chairwoman</i>	Primary	lmalerba@moheganmail.com
	Casey Cooper CEO Eastern Band of Cherokee Indians Hospital	Alternate	Casey.Cooper@cherokeehospital.org
Navajo	Myron Lizer Vice President Navajo Nation	Primary	myronlizer@navajo.nsn.gov
	Dr. Jill Jim Executive Director Navajo Nation Department of Health	Alternate	Jill.jim@nndoh.org
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	Jacklyn King Secretary Sac and Fox Nation	Alternate	justinwood@sacandfoxnation-nsn.gov
Oklahoma 2	Jefferson Keel Lt. Governor Chickasaw Nation	Primary	lt.gov@chickasaw.net
	Gary Batton Chief Choctaw Nation of Oklahoma (Proxy: Melanie Fourkiller)	Alternate	mfourkiller@choctawnation.com
Phoenix	Joey Whitman Councilman Gila River Indian Community	Primary	joey.whitman@gilariver-nsn.gov
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Portland	W. Ron Allen Tribal Chairman/CEO Jamestown S'Klallam Tribe	Primary	rallen@jamestowntribe.org
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Tucson	Daniel L.A. Preston, III Councilman	Primary	Daniel.preston@tonation-nsn.gov

	Tohono O'odham Nation		
	Anthony J. Francisco, Jr. Councilman Tohono O'odham Nation	Alternate	Anthony.francisco@tonation-nsn.gov

TSGAC Technical Workgroup

Area	Member	Status	Contact Information
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California	John Robbins Hoopa Valley Tribe	Tech Rep	hvtsgjrobbinsjr@gmail.com
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Nashville	Martha Ketcher United South and Eastern Tribes	Tech Rep	mketcher@usetinc.org
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Oklahoma 2	Melissa Gower Chickasaw Nation Division of Health	Tech Rep	Melissa.Gower@chickasaw.net
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Phoenix	Karen Fierro Ak-Chin Indian Community	Tech Rep	KFierro@ak-chin.nsn.us
Portland	Jennifer McLaughlin Jamestown S'Klallam Tribe	Tech Rep	jmclaughlin@jamestowntribe.org

Tucson	Veronica Geronimo Tohono O'odham Nation	Tech Rep	veronica.geronimo@tonation-nsn.gov

Federal Representatives

Area	Member	Status	Contact Information
HQ	Jennifer Cooper OTSG Director	OTSG Rep	jennifer.cooper@ihs.gov
	Jeremy Marshall Policy Analyst	OTSG Rep	jeremy.marshall@ihs.gov
	Tamara Clay Policy Analyst	OTSG Rep	tamara.clay@ihs.gov
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Albuquerque		Area Rep	
Bemidji	Chris Poole Agency Lead Negotiator	Area Rep	chris.poole@ihs.gov
Billings	Michelle Begay Director, Office of Tribal Programs	Area Rep	michelle.begay4@ihs.gov
California	Travis Coleman Contracting Specialist	Area Rep	travis.coleman@ihs.gov
Great Plains	Dan Davis Federal Liaison	Area Rep	daniel.davis@ihs.gov
Nashville	Ashley Metcalf Agency Lead Negotiator	Area Rep	ashley.metcalf@ihs.gov
Navajo	Randall Morgan Director, Office of Self-Determination	Area Rep	randall.morgan@ihs.gov
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Portland	Rena Macy ISDEAA Specialist	Area Rep	Rena.Macy@ihs.gov
Tucson	Mark Bigbey Agency Lead Negotiator	Area Rep	mark.bigbey@ihs.gov

Additional Technical Representatives

Area	Member	Status	Contact Information
DC	C. Juliatt Pittman SENSE Incorporated	SENSE, Inc.	pitt@senseinc.com
	Cyndi Ferguson SENSE Incorporated	SENSE, Inc.	cyndif@senseinc.com
	Doneg McDonough	Health Reform	d.mcdonough@yahoo.com
		NIHB	

TSGAC September 2019 Meeting Summary

Attendance:

Area	Present
Alaska	X
Albuquerque	X
Bemidji	X
Billings	X
California	X
Great Plains	
Nashville	X
Navajo	X
Oklahoma 1	X
Oklahoma 2	X
Phoenix	X
Portland	X
Tucson	

Committee Business:

- A quorum was established.
- Minutes from the July 2019 TSGAC meeting were approved.
- A nomination letter from the Confederated Salish and Kootenai Tribes was presented to the committee that requested Charmel Gillin serve on TSGAC in the alternate for the Billings area. W. Ron Allen made a motion to accept the nomination. The nomination was approved.
- Stewart Ferguson was nominated to continue his role representing TSGAC on ISAC. Motion made by W. Ron Allen and approved by the committee.

Office of Tribal Self-Governance Update

Jennifer Cooper, Director, Office of Tribal Self-Governance, IHS

Director Cooper began with an update on where the IHS Office of Self-Governance is at concerning the end of the fiscal year and what has been accomplished over the past year. Three new self-governance agreements were completed during FY 2019. Work continues creating a succession plan for area lead negotiators (ALNs). There will be an all-feds IDEAA meeting in November, which will be the first time such a meeting has been held in around three years.

Key facts provided by Director Cooper:

- 104 compacts 130 agreements
- 83 fiscal year tribes
- 47 Tribes with calendar year agreements
- Approximately \$3 billion transferred to tribes and tribal organizations

OTSG Priorities:

- Processing Title V payments as soon as possible
- Filling OTSG vacancies
- Finalization of FY 16 – 18 reports for Congress

Director Cooper's presentation is available at <https://www.tribalselfgov.org/tsgac-october-2019-meeting/>.

Patient Protection and Affordable Care Act (ACA) Implementation Update

Cyndi Ferguson, Self-Governance Specialist/Policy Analyst, SENSE Inc.
Doneg McDonough, Consultant, TSGAC

Ms. Ferguson provided an update on efforts made by tribes to implement the ACA. A webinar training is scheduled for November 15 in conjunction with the CMS regarding Medicare payment options for freestanding tribal clinics. They will be sending out a survey to obtain input regarding areas of interest for future trainings to help support efforts to expand implementation of the ACA. Ms. Ferguson opened up the floor for participants to provide suggestions for training topics or areas of interest regarding the ACA.

Key, Comments, Questions, and Responses

A recommendation was made to develop and present material to illustrate how the ACA has impacted tribes and expanded tribal self-governance.

An interest was expressed in exploring ways to utilize the flexibility of ACA and IHCA to include Medicaid and Medicare sponsorship to tribal members that may be residing in other places.

Purchased and referred care information has been anecdotal and we need data to illustrate and articulate the impact of Medicaid expansion.

A recommendation was made to review presentations compiled by the National Advisory Committee on Rural Health and Human Services and the Veterans Rural Health Advisory Committee for guidance in considering reimbursement agreements and other issues.

A suggestion was offered to identify funding streams available for long-term care and perfect an MOU between agencies to transfer money into self-governance for demonstration projects to address the aging population within tribal communities.

Doneg McDonough, Consultant, TSGAC

Mr. McDonough provided an update on Medicaid expansion. Tribes are increasingly recognizing the value of the federal resources coming in from Medicaid expansion. Mr. McDonough was recently contacted by direct service tribes (through Title I) who are interested in sponsorship. He is also witnessing more tribes engaged in sponsorship for their elders under Medicare Parts B and D.

Medicaid expansion facts presented by Mr. McDonough:

- In the 24 states that have expanded Medicaid, there has been a 40% increase in enrollment in Medicaid for AI/ANs.
- Eleven states that have federally recognized tribes have not expanded Medicaid.
- If South Dakota and Oklahoma expanded, 70% of the population of AI/ANs that could be covered would be made eligible.
- There is a 20% increase in enrollment in the marketplace by AI/ANs every year.

Key, Comments, Questions, and Responses

A request for an update on the National Data Warehouse IHS data that the IHCA workgroup recommended for utilization was made.

Legislative Update

Stacy Bohlen, Executive Director, National Indian Health Board

Stacy Bohlen and NIHB staff provided an update on appropriations and few legislative priorities of Indian Country. Two of the twelve appropriations bills that are immediately relevant to the tribes (HHS and Interior) are subject of great concern. Both of the bills passed the House in June. The IHS is funded at \$6.3 billion.

House

Interior

- Hospitals and clinics increased to \$2.24 billion
- \$63 million to help address 105(l) leases
- \$62.9 million for the CHR program

Labor & HHS

- Good Health and Wellness in Indian Country program funded at \$21 million
- Tribal behavioral health grants funded at \$40 million

Senate

The Senate did not begin work on the appropriation bills until September because they did not know how much funding would be available. The budget deal that set the spending levels was not approved until August 1. The Bipartisan Budget Act of 2019 raises defense and non-defense spending caps, raises the debt limit through July 2021, and ends sequestration. The Senate will begin working on finalizing the appropriations bills now that the 302(b) allocations have been determined. Interior allocations were increased by around \$200 million over 2019, the Labor & HHS allocations were increased by roughly \$1.9 billion.

Labor & HHS

- Zeros out Good Health and Wellness program

105(l) leases funding differences between chambers

- **House** - funding increased to around \$63 million.
- **Senate** - funding increased to around \$97 million

Neither proposed funding amount meets the current or projected shortfall. The language on the Senate side is much more detailed. It directs the IHS to work with the DOI and the OMB to then report back to Congress regarding whether or not 105(l) lease contracts should be an appropriated entitlement.

Advance Appropriations Legislation

There are two bills in the House and one in the Senate that would authorize advance appropriations. H.R. 1128 would authorize advance appropriations for both the BIA and IHS (services and contract support costs). H.R. 1135 would provide advance appropriations for the IHS only. The bill on the Senate side (S. 229) is a companion bill (identical) to H.R. 1128.

H.R. 1135 amends section 825 of the Indian Healthcare Improvement Act and would provide advance appropriations for services and facilities; whereas, H.R. 1128 is more of a broader authorization bill for advance appropriations. H.R. 1128 will provide advance appropriations for the IHS services line item and contract support costs, not for facilities. Senator Murkowski introduced a companion bill (S. 2541) to H.R. 1135 and would provide advance appropriations for all three IHS accounts (services, facilities, and contract support costs). S. 2541 has been referred to the Senate Committee on Indian Affairs.

Reforming SDPI Structure

NIHB has approved a formal resolution in the past supporting moving SDPI into contracting and compacting and is currently reviewing and discussing strategies to move forward with efforts.

The legislative & litigation update presentation is available at <https://www.tribalsegov.org/tsgac-october-2019-meeting/>.

IHS Ongoing Tribal Consultation Issues

Tamara James, Acting Director, Division of Behavioral Health, IHS filling in for Darrell LaRoche, Director, Office of Clinical & Preventive Services, IHS

Behavioral Health Consultation

Director James provided an update on the three on-going consultations. The first consultation discussed was the Behavioral Health Funding consultation. Between May and August of 2018, IHS initiated consultation and confer regarding the Behavioral Health Initiative funds. Between October 2018 and March 2019, the DBH met quarterly with the National Tribal Advisory Committee (NTAC) to review and discuss consultation comments. On March 14, the NTAC forwarded recommendations to RADM Weahkee and requested an in-person meeting to consider suggestions. The requested meeting was held on June 17. On August 2, it was decided to extend the deadline for the comment period to October 1. The recommendations will be reviewed and utilized to develop a summary report.

Key, Comments, Questions, and Responses

Q: So, does that mean there will not be a decision until after January?

A: It does not mean that. We expect the summary report to be completed by November, discuss the report throughout November, then share with community members immediately following.

Opioid Grant Consultation

On June 19, a "Dear Tribal Leader" letter was issued regarding consultation sessions for opioid grant funding. Consultations and urban confers were conducted, and the consultation period ended on September 3. DBH has been working to collect and summarize the notes that they have received. The comments received are available on their Adobe Connect sessions that have been recorded.

They are making efforts not to duplicate efforts made by SAMHSA. They expect to have a summary report ready for review within the next couple of weeks. We are aware that these are limited funds available over a limited period of time.

They expect the solicitation of the funding opportunity to be released in the spring of 2020.

Key, Comments, Questions, and Responses

There are so many different grants that it becomes cumbersome. Finding a way of consolidating different funding streams into some manageable fund would be helpful.

There is a lot of pilot program money, but when we find something that is successful, there isn't sufficient funding to sustain the operations of the successful pilot programs.

For anyone who is going to receive the funding, whatever is in their proposal, they should tell you how they are going to measure results.

Only 5% of the funding should go to the national level for the administration of this program.

Community Health Aide Program (CHAP)

Minette C. Galindo, Public Health Advisor, Office of Clinical and Preventive Services, IHS

Christina Peters, Tribal Community Health Provider Project Director, Northwest Portland Area Health Board

Ms. Galindo provided an overview of the larger three goals of the IHS Strategic Plan and how CHAP aligns with those goals. When adequately funded, the CHAP will increase access to care and highlight the quality of management of operations. Ms. Galindo briefly explained the three different provider types and the differences between the community health aide, behavioral health aide, and dental health aide positions. All providers will operate under the supervision of a licensed physician. Minette discussed the possibility of transitioning CHR personnel to CHAP if they are interested in continuing their education and career development.

Consultations were held regarding the expansion of CHAP in 2016. The three biggest concerns gleaned from the consultations were as follows:

- Make sure the program is regional and has regional flexibility
- Do not disrupt Alaska
- Do it in partnership with Tribes

In 2018, the IHS established the CHAP TAG. The CHAP TAG was charged with providing real-time feedback to the IHS regarding the best methods for the CHAP expansion. Outside of Alaska there is no context for how the program would work.

On May 7, IHS initiated a 30-day comment period on the draft policy. A request for a 30-day extension on the comment deadline was submitted on the last day, and the extension was granted. The extended comment period closed on July 8. The CHAP TAG reconvened in September to review the comments received and produce two sets of recommendations (one regarding the policy, and one regarding the future of the group). The IHS is currently awaiting the recommendations. Once the recommendations are received, the necessary changes will be incorporated, and a summary of the recommendations will be published, followed by the issuance of a “Dear Tribal Leader” letter.

Key, Comments, Questions, and Responses

Q: Is there a targeted number for the lower 48?

A: In the FY 2020 budget, there is a \$20 million proposal for the expansion of the CHAP. It would include \$10 million for tribal shares, \$5 million to support the training and \$5 million for management and operations.

Update from the House Committee on Veteran’s Affairs

Sarah Dean, Democratic Professional Staff Member, Subcommittee on Health, House Committee on Veterans’ Affairs

Ms. Dean provided an update on the MISSION Act and efforts to perfect the MOU between the IHS and VA. There will be a hearing before the House Subcommittee at the end of October regarding Native veterans’ access to healthcare – the first of its kind ever. Ms. Dean also wanted to hear concerns and recommendations from meeting attendees about how the federal government could better serve Native American vets.

Key, Comments, Questions, and Responses

One concern shared with Ms. Dean was the lack of reimbursement for PRC by the VA as mandated by statute.

Tribes are still waiting for the implementation of the Mission Act. Coordination of care issues continues to persist.

There is a need for tribal veteran service officers (VSOs).

Indian Health Service Budget Update

*Ann Church, Acting Director, Office of Finance and Accounting, IHS
Melanie Fourkiller, Policy Analyst, Choctaw Nation*

Ms. Church began by providing an update on the continuing resolution (CR) approved by Congress that will fund the government until November 21. The CR included a couple of anomalies for staffing of new facilities and additional funding for SDPI. For the first time, the IHS requested and was approved for an exception apportionment. The purpose of exception apportionment is to authorize special authority for IHS to pay ISDEAA contractors and compactors for the majority of their fiscal year contract and compact amounts. With the new authority, the agency may be able to transfer funds above the level allowed by the CR to ISDEAA contractors and compactors; however, the special authorization only pertains to contractors and compactors who operate on a fiscal year cycle. If the Congress seeks an extension to the CR in November, HHS will seek an apportionment that would also cover contractors and compactors on a calendar cycle.

Congress is making progress on the budget. The Senate mark was not as generous as the House. The House mark was \$6.3 billion, and the Senate mark was \$6 billion. Both retained all of the 2019 funding levels, and they explicitly rejected all of the administration's proposals for program decreases. Both bills include funding for the newly recognized tribes located in the state of Virginia and additional funding for quality and oversight within the IHS. The chambers will still have to conference on differences (e.g. electronic health records modernization, CHAP, and proposed amounts).

Distributions from the IHS Director's Emergency Fund have not been released yet, because they are holding off until they identify if the funds are needed to cover the 105(I) leases. If funds are not required, everyone will be notified, and funds will be distributed following the standard process.

Key, Comments, Questions, and Responses

Q: Where does the funding for the exception apportionment originate from?

A: This is special authority that OMB can provide. We are not impeding the discretion of Congress to set budgetary limits. Essentially, we are saying that Congress has given enough indication of what the funding level is going to be that we have a higher rate of spending authority. So, they are giving us more access to the funding that we would ordinarily have.

Q: Where do you think the conversations regarding making sure that the funding for 105(I) leases are segregated in the budget (similar to CSCs) are going?

A: I think the committees are hearing the tribal recommendation to move in that direction, and they are seeing some parallels in CSCs and how that issue was resolved to ensure full funding. Although, in the marks, in the House and the Senate they have not proposed a separate budget line.

HHS Health Information Technology Modernization Project

*Maia Z. Laing, HHS Optimization Team, Office of the Chief Technology Officer
Mitchell Thornbrugh, Chief Information Officer and Director, IHS*

Ms. Laing provided an overview of the HIT project and a summary of the final report. The RPMS users express frustration with their disjointed user experience, limited functionality across multiple areas of care, lack of training, and under-resourced facilities. The RPMS code cannot be supported over the next decade. Lack of inter- and intra-operability negatively impacts the patient experience. Inadequate reporting functionality negatively impacts both public and population health analytics as well as funding for facilities that rely heavily on grant funding. IHS HIT modernization options include stabilizing the RPMS, renewing the RPMS, selective replacement, or full replacement.

Mr. Thornbrugh reiterated that there are three main documents that will come out of the HIT modernization project. The documents are the legacy assessment, the analysis of alternatives, and the technology roadmap. Those will be sent out with a "Dear Tribal Leader" letter and posted to the relevant websites.

Project Highlights:

- Completed HIMSS Analytics Electronic Medical Record Adoption Model (EMRAM) and Outpatient Electronic Medical Record Adoption Model (O-EMRAM) Pilot Program with 7 IHS sites
- Completed the Legacy Assessment to understand RPMS architecture and a potential path forward for RPMS modernization
- Completed the Data Call / Qualitative Survey
- Completed Site Visits and Listening Sessions – 25 sites visited across 12 IHS areas; 13+ listening sessions have been held with groups including attendees at the TSGAC Annual Conference, Tier 2 Area IT Support, and various IHS groups and Councils
- Completed and submitted the Analysis of Alternatives (AoA) to the HHS Secretary to support the FY2021 budget ask to support IHS HIT modernization efforts
- The Technical Advisory Commission is preparing to make its final recommendations to the project team on considerations for IHS HIT modernization
- Kicked-off the Roadmap workstream; the project team is closely collaborating with IHS and ONC
- Kicked-off the Human-Centered Design workstream to generate User Stories and Journey Maps to understand interactions with HIT and support future modernization efforts
- Community of Practice Whitepaper is being composed to provide support on how to enhance HIT peer support and the training infrastructure throughout the I/T/U

HHS Operational Division Access to IHS Patient Data

Robert Pittman, Deputy Director, Office of Public Health Support, IHS

Mr. Pittman provided an overview of the agreements between IHS and other HHS operational divisions and access to patient data. IHS and urban data are used for the budget process. The data is also used to developing the user population and workload numbers. They also provide aggregate data to HHS and other agencies for a variety of different purposes. Access to the data is determined by HIPAA and the Privacy Act. Those laws determine how IHS can share data.

To access data for research purposes, an entity will submit a research protocol to one of the IRBs. The protocol is then reviewed, modified if needed; subsequently, the data use agreement goes into effect. The National Institute of Health (NIH) is working towards a system where they can get one IRB approval for many sites and different types of sites. IHS does not accept IRB approvals from other organizations. It must be approved by one of the IHS IRBs.

Key, Comments, Questions, and Responses

Q: If an entity requests data from you, is the tribal data sets included in the data submitted to the requestor?

A: It depends on what they are asking for. For instance, if the CDC is asking for public health data, and the tribe is reporting data to the national data warehouse, HIPAA allows us to share that data with the CDC for public health activities.

Q: How often do you have consultations with tribe regarding publications or any type of data that is being released?

A: We don't have a lot of consultations with tribes. We probably need to do that more.

Q: Do you have tribal representation on your IRB?

A: We do not have tribal representation on the National IRB. There is tribal representation on some of the area IRBs.

IHS Tribal Consultation Policy and Process

P. Benjamin Smith, Deputy Director for Intergovernmental Affairs, IHS

Mr. Smith provided an update on consultation efforts. ISDEAA, 25 U.S.C § 5325(i) requires the Secretary to consult with tribes regarding the development of the budget. There are various definitions and interpretations of what constitutes

meaningful consultation. One thing that has been consistent within the HHS and IHS is the policy goal and accomplishment of defining what consultation means. The way that IHS defines it is as follows:

An enhanced form of communication that emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information. Consultation is integral to a deliberative process, which results in effective collaboration and informed decision making with the ultimate goal of reaching consensus on issues.

IHS Circular 2006-01 Tribal Consultation Policy (1/18/06).

Tribal budget consultation and area instruction webinars will be held in September, October, and November. Area report webinars will be held on January 29 and 30, 2020, and the National Tribal Budget Work Session will be held on February 13-14, 2010. More information can be found on the IHS website.

The following consultations were held in 2019:

- IHS Contract Support Costs Policy – Section 6-3.2E(3) – [Indian Health Manual Part 6, Chapter 3](#)
- IHS Sanitation Deficiency System – [A Guide for Reporting Sanitation Deficiencies for American Indian and Alaska Native Homes and Communities](#)
- IHS Purchased/Referred Care Policy – [Indian Health Manual Part 2, Chapter 3](#)
- Draft IHS Strategic Plan – [Fiscal Years 2019-2023](#)
- Proposed Realignment of IHS Headquarters Offices – [Federal Register, Vol. 83, No. 246, December 26, 2018](#)

Joint TSGAC and IHS Principal Deputy Director Discussion

RADM Michael D. Weahkee, Principal Deputy Director, IHS
Benjamin Smith, Deputy Director for Intergovernmental Affairs, IHS
Ann Church, Acting Director of the Office of Finance and Accounting, IHS

• Use of the IHS Director’s Emergency Fund

There has been one request for emergency funds from the Alaska Area and two from the lower forty- eight in this fiscal year. One of the requests has been paid out, and the others are pending review. They are trying to find funding sources for the 105(l) leases and have been looking at every account available to them – including the emergency fund.

The definition of an emergency that they follow is found in the PSFA manual which essentially says “an unexpected occurrence that can’t be for routine administrative activities or construction.”

• Contract Support Cost Policy – outstanding issues for resolution

They have heard multiple requests to pull the CSC workgroup together to work on these lingering issues. Roselyn Tso has been appointed as the director of the Navajo Area of the IHS, but she has agreed to remain involved in this activity. A CSC workgroup meeting will be held; however, the date is to be determined. They need to refill the federal co-chair position and the tribal co-chair position. They have taken an inventory of the tribal leaders who were identified to serve on the workgroup. They have a number of vacancies that need to be filled. They are going to reach out to the area directors for help with filling the vacant positions. The workgroup does not have a charter that details how vacancies will be filled.

• Pharmacy Benefits Management (PBM) Claims Update

The IHS is continuing to work CVS Caremark and Express Scripts; however, contracts will be coming up for renewal soon. They are in the final stages of the “Dear Tribal Leader” letter. It is crucial to continue communicating with the IHS the issues that you are having with pharmacies.

- **105(l) Lease Funding and Consultation Update**

RADM Weahkee stated that they have been telling the appropriations staff, internal stakeholders, the assistant secretary for financial resources, and the OMB that tribes desire a separate indefinite appropriation similar to CSC. Congressional staff is looking for the formation of technical workgroup to project future 105(l) lease-funding needs. Letters were hand-delivered today, asking for individuals to be identified to serve on workgroups.

- **Office of Inspector General Reports and Recommendations**

There are three recently released from the OIG. One of the reports was a retrospective review of the work that the agency did after the Rosebud Hospital emergency department was closed and the effort that went into reopening the department. Another report was focused on quality of care. The third report was focused on health information technology. Many of the recommendations were focused on the inability to recruit and retain staff in rural areas. In addition to working on recruitment efforts, they are working on building headquarters management and capacity and performance science capacity throughout the agency. They are not just focusing on the clinical aspects of care but also the administrative and financial side of operations as well.

They continue to work hard to get off of the GAO high-risk list. They started with fourteen open recommendations, and they are now down to three. They have requested closure for one of the three open recommendations. They have also made strides in filling executive level management positions.

- **IHS Quality Activities**

Jonathan Merrell provided a brief update regarding the Quality, Assurance, and Risk Management Program (QARM) as a new component of the IHS Office of Quality was provided. They are reviewing high-risk issues, clinical issues, business impact, and financial integrity. They are working to put new governance processes and oversight systems in place at the Rockville level. The QARM is probably the most significant of the systems that they are designing.



Cheyenne River
Sioux Tribe

November 21, 2019

Crow Creek
Sioux Tribe

Chief Lynn Malerba
Mohegan Community and Government Center
13 Crow Hill Rd.
Uncasville, CT 06382

Flandreau Santee
Sioux Tribe

Dear Chief Lynn Malerba,

Lower Brule
Sioux Tribe

Nominations for the Tribal Self Governance Advisory Committee (TSGAC) were conducted at the November 5th, 2019 Board of Directors' meeting in Aberdeen, SD. Tribal Leaders from the Great Plains Area selected Victoria Kitcheyan, Councilwoman of the Winnebago Tribe of Nebraska, to serve as the primary delegate for the TSGAC. She is qualified to represent the views and has the authority to act on behalf of the Great Plains tribes. Additionally, Danelle Smith, Chief Executive Officer, Winnebago Comprehensive Healthcare Systems was nominated as the alternate delegate to the TSGAC pending the selection of a tribally elected leader. Likewise, Jerilyn Church, CEO for the GPTCHB, was nominated to serve in role of technical advisor for TSGAC.

Mandan, Hidatsa
& Arikara Nation
(Three Affiliated
Tribes)

Contact Information for our Great Plains representatives:

Oglala Sioux Tribe

<p>Victoria Kitcheyan, Councilwoman Winnebago Tribe of Nebraska 100 Bluff Street Winnebago, NE 68071 Phone: (402) 878-3135 Fax: (402) 922-3970 Email: tkitcheyan@winnebagotribe.com</p>	<p>Danelle Smith, CEO Winnebago Comprehensive Healthcare System 225 South Bluff Street PO Box HH Winnebago, NE 68071 Phone: (402) 878-2231 Email: danelle.smith@winnebagotribe.com</p>	<p>Ms. Jerilyn Church, MSW CEO, GPTCHB 1770 Rand Road Rapid City SD 57702 Phone: 605.721.1922 Fax: 605.721.1932 Email: Jerilyn.church@gptch.org</p>
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Omaha Tribe
of Nebraska

Ponca Tribe
of Nebraska

Rosebud Sioux Tribe

Sac & Fox Tribe of the
Mississippi Indians in
Iowa/Meskwaiki
Nation

For questions or additional information, please contact Cole Hunter, Executive Coordinator, Great Plains Tribal Chairmen's Health Board at 605-721-1922.

Santee Sioux Tribe
of Nebraska

Sincerely,

Roger Trudell
Chairman, GPTCHB Board of Directors
Chairman, Santee Sioux Tribe of Nebraska

Sisseton-Wahpeton
Tribe of the Lake
Traverse Reservation

Spirit Lake Tribe

cc: Victoria Kitcheyan, Councilwoman, Winnebago Tribe of Nebraska
Danelle Smith, Chief Executive Officer, Winnebago Comprehensive Healthcare System
Jerilyn Church, CEO, GPTCHB

Standing Rock
Sioux Tribe

Trenton Indian
Service Area

Turtle Mountain
Band of Chippewa
Indians

Winnebago Tribe
of Nebraska

Yankton Sioux Tribe

IHS TRIBAL SELF-GOVERNANCE ADVISORY COMMITTEE

c/o Self-Governance Communication and Education

P.O. Box 1734, McAlester, OK 74501

Telephone (918) 302-0252 ~ Facsimile (918) 423-7639 ~ Website: www.Tribalselfgov.org

Sent electronically to denise.turk@ihs.gov

October 22, 2019

RADM Michael D. Weahkee, MBA, MHSA
Assistant Surgeon General, U.S. Public Health Service
Principal Deputy Director
Indian Health Service
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

**RE: Summary of Issues from the Tribal Self-Governance Advisory Committee (TSGAC)
Meeting September 30-October 1, 2019**

Dear RADM Weahkee:

On behalf of the TSGAC, we extend our thanks to you for your active participation in the September 30-October 1 Committee meeting. We appreciate the on-going commitment of you and your senior staff to attend TSGAC meetings and engage in meaningful and respectful dialogue with Tribal leadership on these critically important issues. The following is a summary on some of the key issues and recommendations discussed:

1. HHS Operational Division Access to IHS Patient Data: We appreciated the opportunity to speak with Mr. Robert Pittman, Deputy Director, Office of Public Health Support, during the meeting regarding which HHS operating divisions currently have access to IHS data and to gain a better understanding of how IHS shares this data and for what purpose. However, we remain concerned regarding the use of IHS data for any research purposes (e.g. the National Institute of Health *All of Us* Research Program). Tribal governments have inherent sovereign rights to govern research that occurs with our citizens and on our lands. In some cases, Tribes have established research codes, laws, and oversight processes to govern research to ensure it benefits their respective nations and to reduce risks of harm.

Recommendation/Action: We request that IHS conduct formal consultation with Tribes to establish a data management policy which provides 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. We also request that Tribal representation be included on the IHS Internal Review Board.

2. IHS Opioid Funding: The TSGAC previously provided formal comments to you regarding the distribution on the \$10 million to support opioid abuse prevention and treatment.¹ To reiterate, the TSGAC strongly disagrees that the funding should be dispersed through a competitive grant methodology and recommends a formula-driven distribution through the Tribal Size Adjustment Formula.

Recommendation/Action: We request that IHS provide a timely decision regarding the distribution of these funds and ask that you provide any further response to the ideas proposed by the Committee.

¹ Please see TSGAC letter to RADM Weahkee dated September 3, 2019.

3. **Pharmacy Benefits Manager (PBM):** IHS has not yet provided guidance to Tribes regarding outstanding claims and claim denials. The only recent progress that has been made is with CVS Caremark. We believe that with IHS and Tribes working together, we can improve this process with other PBMs as well.

Recommendation/Action: We ask that you provide a formal response and status update, along with a current timeframe, regarding IHS's role in resolving these outstanding claims.

4. **IHS Tribal Consultation Policy and Process:** The Agency has embarked on numerous Tribal consultations over the past fiscal year on many key issues, including but not limited to, IHS Contract Support Costs Policy, IHS Sanitation Deficiency System, IHS Purchased/Referred Care Policy Draft IHS Strategic Plan (FY 2019-2023), Mechanism to Distribute Behavioral Health and New Behavioral Health Funding to address Opioids. During the most recent TSGAC meeting, we appreciated the presentation by Mr. Ben Smith, Deputy Director for Intergovernmental Affairs, and his succinct summary of the IHS Tribal Consultation and Policy and Process.

Recommendation/Action: As we previously stated in a joint TSGAC/Direct Service Tribal Advisory Committee letter dated 8/10/18, we recommend that IHS establish a formal Federal/Tribal Consultation Workgroup to review the existing IHS consultation policy and provide any recommended changes/updates. We ask the IHS establish a Workgroup charter, timeline, budget and process for identifying Tribal representation.

5. **Identification of TSGAC representatives to serve on the newly-established 105(l) lease sub-group.** The TSGAC appreciates the Agency's action in establishing this technical sub-group workgroup to work with you regarding the expected future costs of 105(l) leases. The following individuals have been officially appointed to serve as the TSGAC representatives on this workgroup:

a. Primary Delegate:
Candice E. Skenandore, Self-Governance Coordinator, Oneida Nation
Phone: (920) 869-4281
Email:
cskena10@oneidanation.org

b. Alternate:
Melanie Fourkiller, Policy Advisor, Choctaw Nation Health Services Authority Choctaw Nation of Oklahoma
Phone: (580) 924-8280
E-mail:
mfourkiller@choctawnation.com

In closing, the TSGAC appreciates our continued partnership and willingness to engage in discussion with the Agency. If you have any questions or would like to discuss these comments in further detail, please contact me at lmalerba@moheganmail.com. Thank you.

Sincerely,



Chief Lynn Malerba, Mohegan Tribe of Connecticut
Chairwoman, IHS TSGAC

cc: Jennifer Cooper, Acting Director, Office of Tribal Self-Governance, IHS
TSGAC Members and Technical Workgroup



IHS TRIBAL SELF-GOVERNANCE ADVISORY COMMITTEE

c/o Self-Governance Communication and Education
P.O. Box 1734, McAlester, OK 74501

Telephone (918) 302-0252 ~ Facsimile (918) 423-7639 ~ Website: www.Tribalselfgov.org

November 15, 2019

The Honorable Julia Brownley
Chairwoman
House Committee on Veterans' Affairs
Subcommittee on Health
B234 Longworth House Office Building
Washington, D.C. 20515

The Honorable Neal Dunn
Ranking Member
House Committee on Veterans' Affairs
Subcommittee on Health
B234 Longworth House Office Building
Washington, D.C. 20515

**Re: House Committee on Veterans' Affairs Subcommittee on Health Oversight Hearing
Entitled "Native Veterans' Access to Healthcare"**

Dear Chairwoman Brownley, Ranking Member Dunn, and Members of the Subcommittee:

On behalf of the National Indian Health Board (NIHB), the National Congress of American Indians (NCAI), the National Council of Urban Indian Health (NCUIH), the Indian Health Service (IHS) Tribal Self-Governance Advisory Committee (TSGAC), and the Alaska Native Health Board (ANHB) – whose organizations collectively serve the sovereign, federally-recognized Tribal Nations and Urban Indian Organizations (UIOs) – we thank you for the opportunity to testify on Wednesday, October 30, 2019, during the House Committee on Veterans Affairs Subcommittee on Health oversight hearing entitled, "Native Veterans' Access to Healthcare".

Compared to their non-Native counterparts, Native Veterans are underrepresented among other Veterans that are able to access Veterans Administration services and benefits. The disproportionate barriers Native Veterans experience neither honors nor respects what they have sacrificed to protect Tribal communities and the United States. Health care for Native Veterans is rightfully owed to them because of the federal government's promise to service members and its treaty obligations and trust responsibility to the Tribal Nations. The demonstration of your commitment to serving the health interests and needs of American Indian and Alaska Native (AI/AN) Veterans is crucial to ensuring that that the federal government upholds its trust responsibility and treaty obligations for healthcare. We thank you for your attention to Native Veteran health disparities, and to assist your work, this letter provides additional information and answers regarding following collective hearing testimony.

Supporting Legislation That Improves Healthcare for Native Veterans

As mentioned during the hearing, there are several ways the Subcommittee can work to improve healthcare delivery to Native Veterans. We urge the Subcommittee to support, and encourage their respective colleagues to support three bills which affirm the federal government's dual responsibilities to Native Veterans. If passed, these bills will greatly expand health services for

American Indian and Alaska Native (AI/AN) Veterans, and therefore, improve the United States Department of Veterans Affairs' (VA) ability to provide quality care:

- H.R. 2791 — The Department of Veterans Affairs Tribal Advisory Committee (VATAC) Act of 2019, to create a Tribal Advisory Committee at VA;
- H.R. 4908 —The Native American Veteran Parity in Access to Care Today Act, to exempt Native veterans from copays when accessing VA services; and
- H.R. 4153 — The Health Care Access for Urban Native Veterans Act, to authorize Urban Indian Organizations (UIOs) and VA to enter into agreements for the sharing of medical services and facilities and other purposes.

Reaffirming the VA's Treaty Obligations and Trust Responsibility

We were encouraged that the purpose of the oversight hearing included an examination of VA's ability to uphold the federal government's trust responsibility and its treaty obligations to Tribal Nations. We respectfully remind the Subcommittee that the treaty and trust relationship applies to every federal agency, including VA. Holding VA accountable for this obligation is a necessary step to improve the health status of Native Veterans who benefit from coordinated care. Moreover, this federal obligation, such as federal fiduciary responsibilities, includes the provision of culturally competent health care which takes into account a Native Veteran's, such as traditions, language barriers, and customs.

Therefore, the following recommendations are being made in the interest of improving the health status of Native Veterans and strengthening the federal government's relationship with the Tribal Nations:

- *Increase Native Veterans' access to culturally competent services:* The VA must increase outreach and education efforts to improve care coordination and improve the healthcare status of Native Veterans. The Tribal Nations have consistently stressed the need for AI/AN toolkits and guides to assist Native Veterans in navigating care access. This work is essential and requires a culturally competent workforce with knowledge and the earned respect of the community to adequately connect a Native Veteran to their services. Further, Native Veterans require assistance with benefits claims and accessing other VA services which could be accomplished through access and support for Tribal Veterans Service Organizations (TVSOs). We urge this Subcommittee to examine ways which ensure Tribal Nations are able to establish TVSOs to assist Native Veterans with the preparation, presentation, and prosecution of benefits claims.
- *Exempt Native Veterans from co-pays, in fulfillment of the trust responsibility:* In recognition of the federal treaty obligations and trust responsibility, VA should eliminate all deductibles and co-pays for Native Veterans. Neither the Native Veteran nor the IHS should be responsible for any co-payments for healthcare services provided to Native Veterans because the services being accessed have been pre-paid by Tribal Nations. Also, neither the IHS nor Tribal Nations charge co-payments or deductibles to AI/AN beneficiaries because of the federal treaty obligations and the Federal trust responsibility to provide for AI/AN healthcare.

- Ensure parity between the VA and appropriations to Indian Country:* In order for the federal government to effectively leverage its resources and successfully coordinate care for Native Veterans, it must also consider funding and additional resource disparities between the departments and agencies expected to collaborate on such efforts, within VA and elsewhere¹. Native Veteran healthcare is particularly vulnerable because the IHS does not receive advance appropriations, is subject to discretionary appropriations, and has been grossly underfunded since its inception and is now at a high point in appropriations with funding 56% of the current level of need. Further, Indian Country is deeply impacted when changes are implemented which fail to recognize the unique challenges of the Indian health system. For example, when VA announced its 2017 decision to replace its open source electronic health record (EHR), the Veterans Health Information Systems and Technology Architecture (VistA) with a commercial off the shelf system, the problems and difficulties in achieving interoperability between VA, the Department of Defense (DoD), and IHS were exacerbated for the Indian health system. As health information technology (IT) at VA advanced, the Indian health system was left behind, despite the fact that IHS relies on VA to provide patchwork updates to its EHR—the Resource Patient Management System (RPMS). The close partnership between the VA and IHS, which greatly contributed to the once ground-breaking and historic development of VA’s legacy system, was overlooked. When VA transitioned towards its new Cerner-based EHR, the development of RPMS improvements was halted and the future of the IHS’ EHR became largely unknown. The current state of Indian health IT has become near dire because VA received appropriations to support their transition towards a new EHR system without any comparative funding for the Indian health system to subsidize this loss. Congress must ensure that the Indian health system is fully integrated across the development and implementation of the VA’s transition to its new EHR. Difficulties in achieving IT interoperability among VA, the DoD, and Indian health facilities pose significant problems for Native Veterans’ care coordination.
- Support meaningful Tribal Consultation and Urban Confer across the VA:* During the hearing, witnesses were asked if they felt assured that IHS and VA would include them in renegotiations of the memorandum of understanding (MOU). The best way to ensure that Native people are at the table is through a meaningful and robust consultation and confer process between Tribal Nations, UIOs, and federal agencies. This cannot be adequately achieved without a strong consultation policy in place at the department and agency levels. We recommend that VA work with Tribal Nations and UIOs to update theirs regularly. Ideally, the proposed VATAC could support updates to VA’s Tribal Consultation and Urban Confer policy and process for Tribal Nations and UIOs. This process must include opportunity for AI/ANs to provide input on a tribal consultation policy further reinforces the sacred government-to-government relationship between Tribes and the federal government. Also, a year ago, GAO Report 19-291 noted shared inadequacies by VA and IHS in measuring progress of their MOU as well as ineffective Tribal Consultation and

¹ Because the IHS system is chronically underfunded, it heavily relies on third party reimbursements from third party payers like VA.

Urban Confer regarding the MOU—we believe that the two are inextricably linked and have provided further information regarding the MOU in the next section.

- *Ensure that Tribes and Tribal health programs are exempt from the establishment and consolidation of VA community care networks (CCNs):* The VA MISSION Act seeks to consolidate VA’s current outside provider programs to eliminate confusion for both the Veterans Health Administration (VHA) and Veterans. The VA MISSION Act indicates which providers will be part of the new CCN, and it does not list Tribal Nation programs, or IHS as a consolidated part of this new network.² We recommend that VA exempt the Tribal Nations and IHS from consolidation to be managed under the third party administrator, like other outside providers. As noted before, Tribal Nations and Tribal organizations have a unique government-to-government relationship with federal departments and agencies. Because of this unique relationship, third-party administrators and administrative services organizations (ASO) often do not correctly complete necessary reimbursements or enrollments accurately. We have seen this time and again in state Medicaid programs across the country which use ASOs and Managed care organizations (MCO). Even when ASO and MCO contracts include provisions requiring them to work with Tribal Nations and IHS and to honor existing agreements, the ASOs and MCOs fail to meet these requirements. Therefore, Tribal agreements and management of these agreements should be maintained by the VA. This approach has the best chance to ensure continued success in future coordination and collaboration.

Improving Coordinated Care

Native Veterans are highly respected throughout Indian Country and deserving of healthcare systems which honor their status as both AI/AN and Veteran. And yet, they are among the least connected and underrepresented among other Veterans who access the services and benefits³. Most of them continue to give more than is required as they wait patiently for a well-coordinated healthcare system that can adequately meet their unique healthcare needs. To date, progress to eliminate barriers for Native Veterans, streamline access to care, and to achieve a coordinated effort by VA and IHS has been slow. In 2010, VA and IHS expanded upon a 2003 MOU to improve the health status of Native Veterans through coordination and resource sharing among VA, IHS, and Tribal Nations. It is our hope that the current iteration of the MOU will eliminate barriers and streamline access to healthcare and services.

In 2012, VA and IHS signed a reimbursement agreement which enabled VA to begin financially compensating IHS (a system that is chronically underfunded) for direct healthcare provided to Native Veterans that are part of VA system. In furtherance of this collaboration, we offer the additional considerations and recommendations that will build upon the federal government’s efforts to coordinate care for the dual users of the VA and IHS systems.

Patient Referrals and Purchase/Referred Care (PRC) Reimbursements

² P.L. 115-182, Section 101(a).

³ Additionally, as a group, they are also more likely to lack health insurance and receive disability benefits. Source: AI/AN Veterans: 2015 ACS Survey, <https://www.va.gov/vetdata/docs/SpecialReports/AIANReport.pdf>.

Native Veterans often require additional services that are not available within the Indian health system. Often, Native Veterans are referred by VA facilities to Tribal and IHS facilities that are eligible to receive reimbursements for providing specialty care. However, VA does not reimburse a referral for services provided by external providers at Tribal health or IHS facilities, through PRC Purchase/Referred Care program. This is overly burdensome, results in duplicative processes that limit access to care for Native Veterans, and wastes federal resources. Additionally, VA should reimburse for services provided by external providers which are paid for by Tribal or IHS facilities through PRC – an IHS program which authorizes Indian healthcare facilities to purchase services from a network of private providers. VA should accept referrals made by the Tribal Nations and IHS, in order to provide the best services to our Native Veterans. Accordingly, we recommend that Congress clarify statutory language under section 405(c) of the Indian Health Care Improvement Act and make explicit the VHA’s requirement to reimburse Tribal Nations and IHS for services under Purchased/Referred Care (PRC).

Memorandum of Understanding

As VA and IHS continue modifying their interagency MOU, we urge Congress to ensure that Tribal Nations and UIOs are immediately placed on the MOU leadership team. We believe that renegotiation of the MOU is rooted in the federal treaty obligations and trust responsibility to Tribal Nations, and therefore, this renegotiation should be reflective of government to government relations. It is often communicated to Tribal Nations and UIOs that interagency activities such as renegotiating MOUs are inherent governmental functions. Active participation by representatives of the Tribal Nations and UIOs in the revision of the MOU’s 15 performance measures and other related issues will enable the MOU to truly meet the needs of Native Veterans and safeguard their access to care. Therefore, we urge you to keep the agencies accountable by including Tribal Nations and UIOs on the MOU leadership team. We are also concerned about the process and timeline of measures which track the progress of GAO Report 19-291 recommendations and findings. We ask the Subcommittee to consider the following:

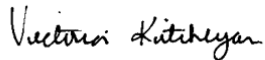
- The VA and IHS should include Tribal Nations and UIOs in MOU renegotiations prior to Tribal Consultation and Urban Confer, to develop the measures for assessing progress toward MOU goals;
- The IHS and VA should identify and present their expected interoperability challenges in supporting the MOU, and consult with Tribal Nations to determine what services will be covered by VA, IHS and DoD;
- Congress should ensure that measures the agencies develop are focused on outcomes rather than counting administrative activities that should already occur as part of routine operations;
- The VA should not impose any additional quality programs upon Tribal Nations or IHS. Sufficient quality requirements already exist and duplicative requirements are burdensome, costly, and unnecessary.
- VA should recognize that the language and intent of the original MOU between the VA and IHS includes UIOs as a part of the MOU; all of the Indian health system, including UIOs, should be able to enter into reimbursement agreements with VA.

Conclusion

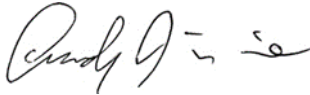
We commend the Subcommittee on its noble pursuit, in fulfillment of the federal treaty obligations and trust responsibility to Tribes, to meet the health care needs of Native Veterans. We greatly appreciate your work to address the many challenges and barriers faced by Native Veterans. We look forward to working with this Subcommittee on a bipartisan basis, and the Administration, to advance federal policies that support those who have served our country and protected our Nations.

Thank you.

Sincerely,



Victoria Kitcheyan, Chair
National Indian Health Board



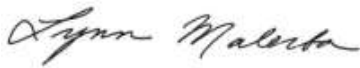
Andrew Jimmie
Chairman, Alaska Native Health Board



Kevin J. Allis, Chief Executive Officer
National Congress of American Indians



Maureen Rosette, Board President
National Council of Urban Indian Health



Chief Lynn Malerba, Mohegan Tribe of Connecticut
Chairwoman, TSGAC

**Testimony of
Chief Mutáwi Mutáhash (Many Hearts), Marilyn “Lynn” Malerba,
On Behalf of the Indian Health Service (IHS)
Tribal Self-Governance Advisory Committee (TSGAC)**

**Submitted to the
U.S. House of Representatives, Committee on
Veterans’ Affairs, Subcommittee on Health Hearing
“Native Veterans’ Access to Healthcare”
October 30, 2019**

Chairwoman Brownley, Ranking Member Dunn, and Members of the Subcommittee,

On behalf of the Indian Health Service (IHS) Tribal Self-Governance Advisory Committee (TSGAC), it is an honor to submit the following formal written testimony on the unique barriers that Native veterans face when seeking access to quality, culturally competent care. Established in 1996, the TSGAC provides information, education advocacy, and policy guidance for the implementation of Self-Governance within the IHS.

Native Veterans have a uniquely special status with the United States. Our American Indian and Alaska Natives have fought alongside the colonial government beginning with the Battle of Bunker Hill, and they have subsequently fought for the United States armed forces in every war and conflict, at higher rates per capita than any other group in the United States.

Treaties between our native governments and the United States included health care for our people. Our Native veterans, as warriors on behalf of this nation are deserving of the best health care we can provide. All veterans, Native and non-Native, alike have sacrificed much for this country and are owed the best health care that we can provide.

The United States Commission on Civil Rights notes in the report titled “Broken Promises: Continuing Federal Funding Shortfall for Native Americans” “the United States expects all nations to live up to their treaty obligations and it should live up to its own.” It specifically recommends that the Federal government should provide steady, equitable and **non-discretionary** funding directly to Tribal nations to support the public safety, health care, education, housing, and economic development of Native Tribes and people.

One way to enhance the funding for the health of our Native veterans was implemented with the Memorandum of Understanding (MOU) between the U.S. Department of Veterans Affairs (VA) and the U.S. Department of Health and Human Services’ (HHS)

Indian Health Service (IHS). In fact, given the inequity of funding for our Native people within the Federal system, the ability to access VA funding for services provided to our Native veterans provides better care for our veterans and provides some relief for a very economically challenged Indian health care system. In 2017, the funding per person per year for an American Indian was \$3,332 while the Veterans Health Administration funding per person was \$8,759.

The TSGAC would specifically like to comment on the effectiveness of this MOU and provide solutions to overcome the systematic health inequities experienced by Native veterans as a means to improve Native veterans' health status and wellbeing.

As reported by the U.S. Government Accountability Office (GAO) in 2019, Federal Indian policy has promoted Tribal self-government—the practical exercise of Indian tribes and nations' inherent sovereign authority—for more than four decades. The Indian Self-Determination and Education Assistance Act of 1975 (ISDEAA), as amended, authorizes Federally recognized tribes to assume the administration of a variety of Federal programs—or portions thereof—that were previously managed by the Indian Health Service. In effect, the Tribes are fulfilling the trust and treaty obligations of the United States through contractual arrangements with the Federal government.

Since enactment of ISDEAA, Tribal nations have demonstrated and proven that a government-to-government relationship based on respect of sovereignty and the inherent right of Tribes to self-govern is an effective and successful approach for both the delivery of services to Tribal communities and to uphold the United States' trust responsibility to Tribal Nations and their citizens.

The VA reports there are 145,000 Native Veterans living in the United States. The VA also reported that Native Veterans have an average life expectancy four years shorter than that of the general U.S. population and are more likely than Veterans of other ethnicities to experience social and economic difficulties that may impact their health or wellness, such as lower income, lower education levels and higher unemployment. Native veterans are eligible to receive health care services from the VA, IHS, and Tribal nations and Tribal organizations that operate under a Self-Governance agreement (referred to as Tribal Health Providers or THPs).

Tribal Nations that elect to administer health programs and services under a Self-Governance agreement to their citizens and communities are effective, in part, because Tribal Nations know the needs of their communities and are in the best position to provide culturally appropriate solutions tailored to address those local needs. Many THPs have significant experience serving veterans in their communities and have

entered into reimbursement agreements with the VA, pursuant to Section 405(c) of the Indian Health Care Improvement Act (IHCIA).¹

As Native veterans return home and seek to access the benefits they are entitled to, healthcare services often fall short to meet their needs. Factors, such as, residing in remote rural communities, poverty, mental health conditions, historical mistrust and a limited number of culturally competent healthcare providers create barriers to care and lead to Native veterans experiencing greater health disparities compared to other veterans. Other social determinants of health impact the overall health of our Native veterans including lack of running water, lack of indoor plumbing, overcrowded housing and in some cases lack of fully functioning kitchen facilities for nutrition.

Further, regulatory barriers exacerbate Native veterans' ability to access care. Restrictions on specialty care, assessment of co-pays, duplicative processes, overly-burdensome administrative requirements and lack of coordination of care delay access to care and have caused irreparable harm to veterans.

Native Veterans reside in rural areas in greater proportions when compared to Veterans of other races—with nearly 40 percent of Native veterans residing in rural areas, often on geographically dispersed reservations or Tribal lands which are often remote, isolated and considered highly rural. THPs are often one of few, if any, health providers in rural areas. As such, THPs are a critical partner for increasing access to quality healthcare to all veterans, both Native and non-Native. IHCIA Section 405(c) provides the authority for Tribes to receive reimbursement for services provided to non-Native veterans but THPs are limited from playing a greater role in providing increased access to healthcare because VA limits the services that IHS can provide to non-Native veterans.

In recent years, the VA and IHS made some progress overcoming these challenges to ensure eligible veterans can access efficient adequate health services in their own communities through THP's. However, the VA limits the types of care that can be provided at IHS and does not cover non-Native veterans who would otherwise routinely receive services through IHS, such as non-Native women pregnant with Native children; even in cases where the IHS or THP is the only facility in close proximity to the veteran. Limiting the services that IHS can provide in turn limits the services that Tribally-administered healthcare programs can provide to their communities.

¹Section 405 (c) of the IHCIA provides that...the Service, Indian tribe, or Tribal organization shall be reimbursed by the Department of Veterans Affairs or the Department of Defense (as the case may be) where services are provided through the Service, an Indian tribe, or a Tribal organization to beneficiaries eligible for services from either such Department, notwithstanding any other provision of law.

Coordination Between VA and IHS

In 2010, VA and IHS expanded upon a 2003 memorandum of understanding (MOU) to improve the health status of American Indian and Alaska Native veterans through coordination and resource sharing among VA, IHS, and Tribal Nations. This 2010 MOU outlined mutual goals for VA and IHS collaboration and coordination of resources and health care services provided to AI/AN veterans. For example, it included provisions for joint contracts and purchasing agreements, sharing staff, ensuring providers in VA and IHS could access the electronic health records of shared patients, and the development of reimbursement policies and mechanisms to support care delivered to AI/AN veterans eligible for care in both systems.

In December 2012, VA and IHS signed a reimbursement agreement that facilitates reimbursement from VA to IHS facilities for the direct care services they provide to eligible Native veterans. VA has established similar reimbursement agreements with individual Tribally administered healthcare programs. The VA and IHS are now in the process of updating the MOU. This process provides a tremendous opportunity for the VA, IHS, and Tribal governments to work collaboratively to identify activities that will help ensure Native Veterans are receiving the quality healthcare services they are owed.

The current MOU between VA and IHS includes the following five primary goals:

1. Increase access to care and services for American Indian and Alaska Native Veterans
2. Promote patient-centered collaboration and communication
3. Improve health-promotion and disease prevention
4. Consult with Tribes at the regional and local levels
5. Ensure appropriate resources are identified and available.

In accordance with these five goals, the MOU contains specific areas in which VA and IHS agreed to collaborate and coordinate on, including:

- Reimbursement: development of payment and reimbursement policies and mechanisms to support care delivered to dually eligible Native veterans.
- Sharing staff: sharing of specialty services, joint credentialing and privileging of health care staff, and arranging for temporary assignment of IHS Public Health Service commissioned officers to VA.
- Staff training: providing systematic training for VA, IHS, THP, and Urban Indian Health Program staff on VA and IHS eligibility requirements to assist them with appropriate referrals for services.
- Information Technology Interoperability: interoperability of systems to facilitate sharing of information on common patients, and establishment of standard mechanisms for VA, IHS, and THP providers to access records for patients receiving care in multiple systems.

We offer the ***following comments and recommendations*** that are related to several of the goals and/or areas of agreed collaboration and coordination:

Patient Referrals

As VA, IHS, and Tribal Nations work to build greater partnerships, we must address issues with regard to coordination of care. Failing to adequately coordinate care is magnified by VA's unwillingness to reimburse referral services. For example, if a Native veteran goes to an IHS or Tribal facility for service and needs a referral, the same patient must then be seen within the VA system before a referral can be secured. This is not an efficient use of Federal funding as it is duplicative, fails to acknowledge similarly credentialed providers and makes care navigation difficult for Native veterans.

Recommendation: The VA should accept referrals made by IHS and THPs in order to provide the best services to our veterans.

Reimbursement of Purchased and Referred Care

Although the MOUs and agreements with VA have demonstrated success in facilitating patient care for veterans, neither the current national agreement nor the Tribal agreements include reimbursement for Purchased and Referred Care (PRC) at IHS or Tribal healthcare facilities. Consequently, veterans are forced to maneuver through a complex healthcare system and an elaborate administrative process.

Veterans often require additional services that are not available at IHS or THPs. In many instances eligible veterans are also eligible for PRC services. The PRC program authorizes Indian Healthcare facilities to purchase services from a network of private providers. IHS and THPs are the payors of last resort, which require that all other sources of obtaining health services must be exhausted prior to receiving care through the PRC program. These services may include primary or specialty care that is not available at an IHS and/or Tribal healthcare facility. Many THPs have existing provider networks to ensure veteran's complex healthcare needs are met.

The VA, however, will not reimburse THPs for their referrals but instead insist that the veteran in need of specialty care return to the VA health system for a VA referral for care. In certain instances, this level of care may be directly available and provided under the current reimbursement agreements and reimbursed by the VA. However, because the mix of direct versus purchased care varies across the Indian health system, some IHS or Tribal health programs may purchase more care from outside providers, which currently is unreimbursed by VA.

This illogical and inconsistent management of care is inefficient, a waste of resources (both time and money) and fails to prioritize the healthcare needs of Native veterans. THPs work hard to provide a seamless health care experience. Lack of coordination of care for specialty care and other medically necessary care paid by PRC creates more

barriers for our veterans. This creates misalignment with the VA's mission for care which strives for improved access to all types of care.

Recommendation: VA should include PRC in the IHS/THP reimbursement agreements to eliminate further rationing of health care provided by IHS and THPs to Native veterans and other eligible veterans and to ensure timely quality healthcare.

Native Veterans Co-Pays

Native veterans who seek health care services at a VA facility are assessed co-payments which is in direct opposition to the Federal trust obligation to provide health care for all American Indians and Alaska Natives. IHS and THPs are the payor of last resort (section 2901(b) of the ACA) whether or not there is a specific agreement in place for reimbursement. Therefore, neither the Native Veteran nor the IHS should be responsible for any co-payments.

Recommendation: The TSGAC recommends the discontinuation of the practice of collecting co-payments from Native Veterans.

Tribal Provider Credentialing

Although stated in the MOU, the VA does not accept provider credentialing from THPs. Tribes that administer their health programs through Self-Governance agreements have the right to choose and operate their own credentialing system or to leverage the credentialing system administered by IHS.

VA acceptance of IHS/THP-credentialed providers facilitates care coordination by allowing IHS/THP primary care providers to refer directly into the VA system for either continued care to be provided in a VA facility, or for care to be purchased through outside providers. This would eliminate the duplicative primary care visit and referral and ensures that the Veteran continues with their primary care provider of choice who coordinates their care and receives all reports and results from other providers. VA has attempted in some local areas to re-credential IHS/THP providers under the VA system, but the length of time required for a provider to proceed through the entire VA credentialing process is not practical or timely.

Recommendation: To ensure care coordination is effective and efficient, VA should accept provider credentialing from IHS/THPs, upon the provider releasing the credentialing package to VA.

Graduate Medical Education (Tribal Medical Residency Programs)

IHS and THPs have significant workforce challenges due, in part, to most facilities being located in rural and/or remote locations. The HHS Health Resources and Services Administration (HRSA) automatically designates IHS, Tribally-operated and Urban Indian Health programs as Health Professionals Shortage Areas (HPSAs) and Medically

Underserved Area and Medically Underserved Population (MUA/MUP) for these reasons. Several THPs currently have Tribal medical residency programs.

TSGAC was very encouraged to review the provisions of the recent VA Mission Act, specifically Section 403 which included a “Pilot Program on Graduate Medical Education and Residency.” This new pilot includes facilities operated by Tribes, Tribal Organizations and IHS as “covered facilities” for purposes of the program and requires such facilities have a priority in placement of residents.

Recommendation: VA should include IHS and Tribes in the planning of the pilot program to ensure that any regulations or policies that may be developed in the future for the pilot work optimally in Indian Country.

Access to Consolidated Mail Order Pharmacy (CMOP)

Currently only those IHS and Tribal Health Programs that use the RPMS system have access to CMOP. This is an important means of improving compliance with prescriptions when those medicines are delivered directly to the Veteran’s homes. This reduces barriers to effective disease management

Recommendation: Information Technology Systems experts from both VA and IHS need to ensure that all systems used by Tribal Health programs are compliant and compatible with the CMOP system.

Quality Measures

The TSGAC is supportive of quality measures that provide for tracking of meaningful outcomes. However, the TSGAC would be very disturbed at the prospect of developing either data reporting requirements that affect reimbursements to IHS/THPs, or that require new collection of data and reporting systems in addition to those already imposed on IHS/THPs. All IHS/THPs receiving reimbursement from VA are required to be accredited by a nationally recognized health accreditation agency, which assures quality standards are being maintained. The VA also conducts quality monitoring, and visits IHS/THP programs regularly for review, even though this is not a requirement of the statute. Finally, all IHS/THPs participating in Medicare and Medicaid must comply with all of their quality and performance programs and reporting, as applicable. The VA itself is not required to comply with this level of accountability to external agencies.

Recommendation:

The IHS and VA should work together and consult with the Tribes to develop evaluation measures for assessing the progress toward MOU goals. Additionally, the VA should not impose any additional quality programs upon IHS/THPs, because it is very burdensome, costly, and unnecessary because there are sufficient quality requirements already in place.

Health Information Exchange

VA belongs to the eHealth Exchange—a national health information exchange—and it reported to GAO in March 2019 that IHS or THPs could join the exchange to access information about common veteran patients. However, IHS reported to GAO that although the agency explored connecting to the eHealth Exchange several years ago, testing and onboarding costs to participate were prohibitive. THPs that GAO spoke with reported being a part of other, more locally-based health information exchanges, but noted that VA was not part of these exchanges.

Recommendation: Local VA health care facilities should work with their local THPs to ensure health information can be exchanged at the local levels through local health information exchanges rather than one national health information exchange.

Tribal Advisory Board

Tribal advisory committees provide an effective forum for Tribes and Federal agencies to work together as government-to-government partners to address policy, legislative, budget, program and service issues and formulate recommended actions. In response to GAO's March 2019 report, VA stated that it will establish a Tribal advisory group that will make recommendations related to care coordination guidance and policies. The VA set a target completion date for establishing this group is spring 2020.

Recommendation: The VA should work in coordination with Tribes to establish a Tribal Advisory Board. Tribal leaders have significant experience serving on Tribal advisory committees/boards at Federal agencies and can provide crucial input on key components and characteristics that make an effective advisory board.

GAO's Review of Coordination Between VA and IHS

The TSGAC fully supports the development of specific, measurable metrics by which to evaluate the progress being made under the MOU. Although there are a number of measures identified in annual reports issued by the IHS and VA, they are largely process measures which report on the number of veterans served, amount of reimbursements, number of trainings or events, etc.

In March 2019, GAO reported that the MOU signed by the VA and IHS lacks sufficient measures for assessing progress towards its goals. Specifically, GAO reported that the agencies established 15 performance measures, but they did not establish targets against which performance could be measured. For example, while the number of shared VA-IHS trainings and webinars is a performance measure, GAO noted that there is no target for the number of shared trainings VA and IHS plan to complete each year. Two of the three recommendations GAO made to the VA and IHS focus on the lack of performance measures and one focuses on the lack of written policy and guidance.

Recommendation: Federal agencies should focus their limited resources on actions that will directly improve the health and wellbeing of Native veterans and should ensure

that measures they develop are focused on outcomes rather than counting administrative activities that should already occur as part of routine operations. Additionally, these outcome measures should be developed and agreed upon jointly.

In closing, VA and IHS have made progress and have demonstrated a willingness to improve quality access to care for Native Veterans. But, as you see in my statements here, there are still significant opportunities for improvement. The TSGAC truly appreciates the opportunity to provide the Subcommittee with these written recommendations. Thank you.

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November 27, 2019

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Director, National Institutes of Health
U.S. Department of Health & Human Services
9000 Rockville Pike
Bethesda, MD 20892

**RE: Comments on Tribal Engagement with the NIH All of Us Research Program;
Data Sharing and Management Draft Policy; and Intellectual Property Policy**

Dear Dr. Collins:

On behalf of the Tribal Self-Governance Advisory Committee (TSGAC), I write to response to the National Institutes of Health's (NIH) "Dear Tribal Leader and Urban Indian Organization Leader" letters regarding the rollout of the *All of Us* Research Program and to provide comments to the Data Sharing and Management and Intellectual Property policies. Established in 1996, the TSGAC provides information, education advocacy and policy guidance for implementation of Self-Governance within the Indian Health Service (IHS).

The TSGAC appreciates NIH's outreach to Tribal leaders and researchers during consultations and listening sessions on these three important initiatives. An ongoing process that provides for meaningful consultation and upholds the sovereignty of each Tribal Nation is of utmost importance to the TSGAC. However, we are greatly disappointed in the lack of transparency, slowness of pace and the overall piecemeal approach with which the agency has adopted Tribal suggestions throughout the consultation periods. While we acknowledge that the NIH in recent months has embargoed the data of individual Tribal members and expanded the timeframes in which it will accept Tribal input on its policies, the agency has done so only upon vigorous Tribal outcry.

The TSGAC looks forward to working with NIH as it finalizes the *All of Us* and policy consultations at the end of the year, and as it gears up for Tribal consultation on the draft of its first ever Tribal Consultation Policy.

Background

Since April of this year, NIH has conducted consultations or listening sessions on three separate programs and policies, as outlined above. We are concerned that NIH, as it continues to gather Tribal input, is failing to adhere to the NIH Guidance on Implementation of the Health and Human Service Department (HHS) Tribal Consultation Policy (TCP) that the agency issued in 2013.¹ NIH created the guidance to facilitate the implementation of the HHS TCP by the more than 25 NIH Institutes and Centers, and the Office of the Director.

¹ NIH THRO, NIH Guidance on Implementation of HHS Tribal Consultation Policy (2013), <https://dpcpsi.nih.gov/thro/policies-and-guidance>

NIH further demonstrated its commitment to Indian Country by forming the Tribal Health Research Office (THRO) in 2015, as provided for in the implementation guidance. Duties of the THRO include coordinating Tribal health research-related activities across NIH; serving as a liaison to and NIH representative on Tribal health-related committees; and coordinating the NIH Tribal Advisory Committee (TAC).

The NIH TAC has advised the agency on the *All of Us* Program during biannual in-person meetings and during monthly phone calls. In addition, the NIH sought the expertise of key TAC members to create the Tribal Collaboration Working Group (TCWG) Report,² which outlines in great detail Tribal concerns about NIH's health research policies, and provides detailed recommendations about how NIH should proceed in interacting with Tribes and gathering Tribal data – with utmost respect and in the most culturally sensitive manner possible. The TCWG Report highlights, in part:

- “Strategies for collaborating with Tribal Nations, clinics, and organizations to enable AI/AN participation in the program;
- Unique considerations, such as Tribal sovereignty, cultural beliefs and traditions, and historical trauma that NIH should be aware of as they seek to engage Tribal populations; and
- Ethical, legal, and social issues that should be considered prior to enrollment of AI/AN individuals.”³

The working group report has proven to be a valuable resource to the TSGAC, the HHS Secretary's Tribal Advisory Committee (STAC), and to Tribal Organizations nationwide, as we seek to educate on the Tribal implications of NIH policies.

Application of the HHS Tribal Consultation Policy

In an era in which Tribes' political status has seen challenges from special interest groups and certain federal government actors, it is more important than ever to emphasize long-established law and policy, including the U.S. Constitution, which make clear Tribes hold political status, are sovereign Nations, and are not racial groups. The Executive branch, like *all* of the federal government has a trust responsibility to Tribes, as well as safeguards for Tribal engagement that we urge NIH, as an executive agency, to follow. The HHS Tribal Consultation Policy (TCP),⁴ calls on the HHS operating staff and divisions, including NIH, to have an accountable process to ensure meaningful and timely input by Indian Tribes in the development of policies that have Tribal implications, to the extent practicable and permitted by law.

In addition, an effective consultation between HHS and Indian Tribes *“requires trust between all parties which is an indispensable element in establishing a good consultative relationship. The [...] extent of consultation will depend on the identified critical event. A*

² NIH THRO, Considerations for Meaningful Collaboration with Tribal Populations (Apr. 4, 2018), https://allofus.nih.gov/sites/default/files/tribal_collab_work_group_rept.pdf

³ NIH, Tribal Consultation and Listening Sessions on the All of Us Research Program (2019), <https://allofus.nih.gov/about/tribal-engagement/national-institutes-health-tribal-consultation-and-listening-sessions-all-us-research-program>

⁴ HHS, Tribal Consultation Policy (2010), <https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf>

critical event may be identified by HHS and/or an Indian Tribe(s).” In practice, this means that once Tribes identify a “critical event,” NIH must communicate clear and explicit information on the means and time frames for Tribal Nations to engage in consultation, to submit comments, and when to expect the agency’s response. As stated in the first paragraph of our letter, it does not appear that NIH adhered to the HHS Tribal Consultation Policy upon distribution of the Dear Tribal Leader letters on the three data initiative; this is because the NIH has through the course of the *All of Us* consultation expanded the timeframe for commenting, yet has not directly responded to Tribes’ requests that the agency provide a final due date.⁵ Deadlines matter to Tribes. Knowing the discussion topic, proper protocols, and comment deadlines allow Tribes to adequately prepare for dialogue with NIH on critically important matters such as DNA research, policy, and protocols.

Additionally, TSGAC respectfully reminds NIH that TAC meetings and regional listening sessions are not substitutes for Tribal consultation. Since NIH has not given Tribes the HHS’s TCP’s proper 30-day notice of consultation timelines and, by extension, discussion topics, the agency has made the unfortunate mistake of conflating consultation sessions and listening sessions. Tribal participants may show up to an *All of Us* consultation, for example, only to discover that NIH will instead informally discuss the draft data management policy, if not multiple policies.

To busy Tribal leaders, this can be confusing at best, and misleading at worst. Tribes are also not clear on the turnaround time for receiving responses to their concerns or whether the agency’s responses will be posted in a public place. NIH’s last-minute schedule changes and vagueness of timelines for accepting Tribal comments in one sense showcases NIH’s flexibility and willingness to collect Tribal viewpoints at all possible venues. At the same time, this approach prevents meaningful Tribal participation and is counterproductive to building trust and consensus with Tribes.

I. All of Us

A pillar of the *All of Us* Research Program is to recruit participants who have been historically underrepresented in the science of precision medicine. It is TSGAC’s understanding that scientific research using *All of Us* participants’ data has not yet begun, although the research database may be open to the public as soon as Winter 2019. At the recent STAC meeting (September 11-12, 2019) in Washington, D.C., representatives from NIH’s THRO assured Tribes that the DNA or biological samples of self-identified American Indians/Alaska Natives (AI/ANs) is embargoed – or, not available to researchers who have completed NIH ethical use training – until the agency concludes its meetings with Tribes at the end of the year.

Tribes are appreciative that NIH has heard and responded to Tribal concerns about the *All of Us* Research Program, but the issues are far from resolved. Specifically, we have the following concerns:

⁵ See United South and Eastern Tribes Sovereignty Protection Fund (USET SPF), Comment Letter to NIH (Aug. 27, 2019), http://www.usetinc.org/wp-content/uploads/2019/09/USET-SPF-Comments-to-NIH_All-of-Us_Draft-Data-Sharing_IP-FINAL-8_29_19.pdf

- **Lack of respect for Tribal data sovereignty.** Data sovereignty involves a Tribe's right to govern the collection, ownership, and application of their own data. Because the parameters of *All of Us* are broad and ambiguous, Tribes feel unsafe and unwilling to partake in the research.
- **Lack of cultural sensitivity training and failure to adhere to data ethics.** Under the *All of Us* program rules, any researcher would have access to data that is shared by volunteers, on the condition that the researcher completes an ethics training, signs a data use agreement, and posts on the NIH website the parameters of their research project. While the research project information would be publicly available, Tribes feel that they should not be put in the position to have to analyze or monitor the scientific community's proposed research projects and the potential impact to Indian Country.

For this reason, Tribes recommend an **Expert Tribal Advisory Committee** to determine the Tribal impact of *All of Us*. The committee would consist of AI/AN scientists and researchers.

- **Lack of clarity in the consultation process.** Tribes are concerned that NIH is conflating Tribal consultation sessions with listening sessions. Additionally, Tribes have reported that the agency has attempted to hold consultation sessions for three different initiatives at once: the *All of Us* program, the Draft Data Sharing and Management Policy, and the Intellectual Property Policy. Holding meetings with Tribes about all three of these very different issues, without notice, makes it impossible for Tribes to adequately prepare for meetings with agency officials and have their voices heard. Furthermore, it does not follow the consultation procedures outlined in the HHS TCP and in Executive Order 13175, "*Consultation and Coordination with Indian Tribal Governments*".
- **Lack of respect for the rights of Tribes regarding research on members living in urban areas.** American Indians and Alaska Native peoples who do not live on Tribal lands should not be viewed or treated as "fair game" for research. Regardless of whether or not Tribal members live on Tribal lands, NIH should respect the data sovereignty rights of Tribes and all self-identified AI/ANs and request consent before moving forward with any use of data.
- **Lack of anonymity.** Although NIH has explained to Tribal leaders some of its procedures for anonymizing data so that the data of individual AI/ANs cannot be matched with the Tribe of origin or to a particular region of the United States, the examples the agency provided were not well thought out and instead instill fear and uncertainty in Tribal Nations.

The TSGAC and member Tribes support advancements in the science of precision medicine that will, over time, serve Tribes and American Indian/Alaska Native people, but we do not support the process that NIH is following to achieve that end. This issue is far from resolved.

II. Data Sharing and Management Policy

The *All of Us* Program and the Data Sharing and Management are very much entwined. The overall sentiment from Indian Country is for NIH to exercise caution in how it approaches these issues with Tribes. TSGAC acknowledges that AI/AN health disparities represent a loss of individual and societal potential that could be reduced through inclusion in research. Unfortunately, AI/AN individuals have been severely underrepresented in clinical trials and often are not included in sufficient numbers in national research studies. The FDA recognized this discrepancy in a recent request for information on draft guidance to broaden the eligibility requirements for clinical trial participants.

The intent of the draft guidance, “Enhancing the Diversity of Clinical Trial Populations: Eligibility Criteria, Enrollment Practices, and Trial Designs,” was to encourage increased diversity in clinical trials by broadening eligibility criteria, so they better reflect underrepresented populations likely to use the drug once approved.⁶ Without mentioning American Indians and Alaska Natives specifically, the FDA guidance observed that some communities may be historically mistrustful of government-sponsored clinical trials. It also recognized this in its *Minorities and Clinical Trials* page.⁷

TSGAC supports federal research initiatives that are meant to improve Tribal health outcomes and elevate the health status of Tribal peoples. However, we highlight FDA’s request for information here, to encourage the THRO to be vigilant of other agency efforts to cultivate AI/AN data and to speak out on behalf of Tribal interests not just within the National Institutes of Health, but across the federal government, where the office finds the opportunity to do so. The TSGAC is prepared to provide technical assistance to support THRO in its government-wide advocacy on behalf of Tribal Nations.

III. Intellectual Property Policy

The Tribal Health Research Office distributed a helpful fact sheet, *Intellectual Property Rights in Biomedical Research*. TSGAC agrees with agency recommendations for Tribes that are provided in the fact sheet:

- Discussions about possible intellectual property (IP) rights should occur with (and within) Tribes before any research begins.
- Tribes must protect their patent rights prior to any kind of public disclosure on invention can occur.
- Tribes should not have substantive discussions/exchanges with any third-parties about unpublished research that could be an invention unless the exchanges are protected by confidentiality obligations.

⁶ See National Health Council, NHC Comment Letter: Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs—Guidance for Industry (Aug. 8, 2019), <https://www.nationalhealthcouncil.org/blog/nhc-comment-letter-enhancing-diversity-clinical-trial-populations-eligibility-criteria>

⁷ See FDA, Racial and Ethnic Minorities in Clinical Trials (current as Aug. 6, 2018), <https://www.fda.gov/consumers/minority-health-and-health-equity/minorities-clinical-trials>

We echo THRO's recommendation that Tribal Nations and communities can develop their own policies that make clear how intellectual property rights are handled. Such policies can specify joint ownership or Tribal ownership and ensure researchers understand any requirements before entering into a research collaboration.

Summary of Tribal Concerns

TSGAC supports the following Tribal recommendations:

- NIH should develop a comprehensive Tribal Consultation Policy that follows the protocols in the HHS Tribal Consultation Policy and includes NIH protocol. NIH should continue to solicit TAC feedback on the draft consultation policy and, when the time is right, publish a notice in the Federal Register and also send an email to TSGAC and our partner Tribal Organizations that gives proper notice of the opening and closing of the comment period for the consultation policy, and describes how to agency will notify Tribes of the responses it receives, and creates a record of the agency's response to each Tribal recommendation.
- NIH should continue the embargo on data that includes self-identified AI/ANs and Tribal members.
- NIH should clarify the rules of consent for participating in *All of Us*. Right now, the process for withdrawing consent, at any point and for any reason, is unclear to Tribes. NIH must continue to address Tribal concerns around broad consent (i.e. how individual Tribes consent to being included in the program) because Tribal members are identifiable due to genetics and Tribal affiliation. Moreover, the agency should be required to seek consent from *all* AI/ANs, not just those living on Tribal lands.
- TSGAC supports the NIH TAC's recommendation that continued Tribal consultation should follow a two-stage approach:
 1. Solicit expert guidance. Since this issue is so complex, the TAC recommends an in-person meeting with technical experts across the 12 IHS areas to do a "deep-dive" into the *All of Us* Research Program and concerns for AI/AN participation; and,
 2. Share meeting results with Tribal leaders to inform ongoing consultation with NIH.

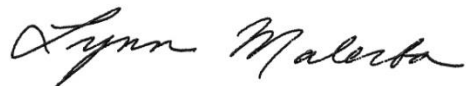
Conclusion

In a recent phone call hosted by the Centers for Medicare and Medicaid Services, the Director of the Tribal Health Research Office, Dr. David Wilson, notified Tribal leaders that his office has provided outlines and guidance to NIH about how to respectfully and effectively engage Tribal Nations in its research initiatives. He said, "Knowledge should not leave [a Tribal] community without benefiting th[at] community." The TSGAC could not agree more and looks forward to the outcome of the consultation and listening sessions.

**TSGAC Comments on Tribal Engagement with the NIH All of Us Research Program;
Data Sharing and Management Draft Policy; and Intellectual Property Policy
November 27, 2019**

We thank you for the opportunity to provide these comments and recommendations. We stand ready to assist NIH as you move forward. If you have any questions or would like to discuss these comments in further detail, please contact me at lmalerba@moheganmail.com.

Sincerely,



Chief Lynn Malerba, Mohegan Tribe of Connecticut
Chairwoman, IHS TSGAC

cc: Jennifer Cooper, Director, Office of Tribal Self-Governance, IHS
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December 2, 2019

RADM Michael D. Weahkee, MBA, MHSA
Assistant Surgeon General, U.S. Public Health Service
Principal Deputy Director
Indian Health Service
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

RE: Special Diabetes Program for Indians Tribal Consultation

Dear RADM Weahkee:

On behalf of the Indian Health Service (IHS) Tribal Self-Governance Advisory Committee (TSGAC), I write to provide the following comments regarding the funding formula and distribution of the Special Diabetes Program for Indians (SDPI).

As you are aware, TSGAC continues to advocate that funding for health services through granting mechanisms should conclude so that Tribes and IHS Service Units can leverage recurring funds to best serve the needs in tribal communities. Disease-specific and grant-funded programs leave Tribes in the tough position of whether they can and will continue to support a program when federal support concludes. However, we recognize that concluding the granting process for SDPI may not be a short-term option ahead of the next funding cycle and offer responses to the questions identified in your October 2, 2019 Dear Tribal Leader letter.

SDPI Formula Distribution

- a. If SDPI is funded at \$150M, should there be changes in the funding distribution? If so, what changes should be made?***

TSGAC supports continuity of current programs to ensure continued success in program outcomes and continuity of care locally. Therefore, IHS should make every effort to hold current grantee harmless and leave the current distribution procedures for grantees in place.

TSGAC does hope that IHS will reconsider expenses incurred to operate, to oversee, and to manage grantees as it appears these costs are in excess of \$1.5 million dollars under the SDPI Support Grants Management Staff and Grants Management System items. It seems as though IHS has built an unnecessarily heavy administrative structure to fund what has been an uncompetitive and ongoing granting process. IHS and the Tribal Leaders Diabetes Committee (TLDC) should evaluate what the minimum requirements and identify efficiencies for managing this mandatorily funded grant program. Those saving should then transfer to the total grant funding available for grantees.

TSGAC further recommends that TLDC similarly evaluate improvements that have been achieved under the Data Improvements Initiative to determine if funds currently allocated are necessary and serving the larger needs of grant program nationwide. If not, those savings should be allocated to increase the availability of funds for eligible grantees.

b. If the SDPI receives an increase in funding above the current \$150M, how should those funds be utilized?

TSGAC supports utilizing increases in funding to either increase the number of entities receiving funding or the total amount going to grantees. However, TSGAC would not support increasing any funding allocations for SDPI Support or Data Infrastructure Improvement.

SDPI Formula:

a. Should there be changes to the national funding formula?

TSGAC does not recommend changes to the national funding formula at this time.

b. Should more recent user population and diabetes prevalence data be used? If so, how would the resultant changes in the Area funding distribution be addressed?

Though TSGAC does not have a consensus recommendation for changing the formula, the Committee does believe that using updated data to drive distribution is critical to reflect the reality the grantees experience. Therefore, TSGAC supports using the most recent user population and disease prevalence data at the time of grant solicitation and distribution.

In closing, we thank you for seeking input on any future changes. We look forward to continuing this discussion as the decision-making process moves forward. If you have any questions or concerns regarding our recommendations, please contact me at lmalerba@moheganmail.com.

Sincerely,



Chief Lynn Malerba, Mohegan Tribe of Connecticut
Chairwoman, IHS TSGAC

cc: Jennifer Cooper, Director, Office of Tribal Self-Governance, IHS
TSGAC Members and Technical Workgroup
Jay Spaan, Executive Director, Self-Governance Communication and Education

NOV 15 2019

Dear Tribal Leader and Urban Indian Organization Leader:

I am writing to share updates on recent developments associated with modernizing Agency Health Information Technology (Health IT). On November 12, the Department of Health and Human Services (HHS) Office of the Chief Technology Officer released two reports on this topic: “Strategic Options for the Modernization of the Indian Health Service Health Information Technology Final Report” and “Strategic Options for the Modernization of the Indian Health Service Health Information Technology Roadmap Executive Summary.”

The reports provide a roadmap to support improved clinical and non-clinical operations in health care facilities throughout the IHS, Tribes, Tribal Organizations, and Urban Indian Organizations. Taken together, the findings identify key improvement opportunities, related work initiatives for implementing Health IT, along with estimated timelines and performance indicators. For your convenience, I have enclosed a copy of the reports for your information. The HHS Health IT Modernization Project documents will also be available on the IHS Web site at <https://www.ihs.gov/>.

To continue engaging Tribes and Urban Indian Organizations on this topic, the IHS will be hosting three webinars on the HHS Health IT Modernization Project documents. Please call in and join us on any of the following dates:

Health IT Modernization Project Webinars

- November 20, 2019, at 3:00 p.m. – 4:30 p.m. (Eastern Time)
- December 3, 2019, at 1:00 p.m. – 2:30 p.m. (Eastern Time)
- December 4, 2019, at 3:00 p.m. – 4:30 p.m. (Eastern Time)

ADOBE CONNECT: <https://ihs.cosocloud.com/rpi5fjirhh0y/> ROOM PASSCODE: ihs123
WEBINAR DIAL-IN NUMBER: (800) 832-0736 PARTICIPANT PASSCODE: 3014886

We will also continue to keep Tribal Consultation and Urban Confer open on Health IT Modernization to receive your input. If you have any questions about the webinars, or comments on the HHS reports, please contact Mr. Randall Hughes, Tribal Liaison, Office of Information Technology, IHS, by telephone at (301) 348-3402 or by e-mail at randall.hughes@ihs.gov.

Sincerely,

/Michael D. Weahkee/

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

Enclosures

Strategic Options for the Modernization of the Indian Health Service Health Information Technology

Roadmap

Executive Summary

October 2019



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1.0 Purpose of Roadmap

The IHS HIT Modernization Project Roadmap provides guidance to the Department of Health and Human Services (HHS) and the Indian Health Service (IHS) in their efforts to modernize the IHS health information technology (HIT) system. The Roadmap is an overarching plan to support improved clinical and non-clinical operations across IHS, Tribal, and Urban (I/T/U) healthcare facilities through HIT. It identifies key improvement opportunities, related work initiatives for implementing such opportunities, and estimated timelines and performance indicators.

The Roadmap is derived from a synthesis of best practices in HIT Modernization efforts as well as findings and recommendations from the current Modernization Project work. The Roadmap is a technology-agnostic strategic and decision-support tool, designed to guide the overarching modernization strategy, whether it be upgrade of the existing HIT system, selection of a commercial-off-the-shelf (COTS) product, or a hybrid of the two. The Roadmap is aligned with IHS' goals and strategic plan.

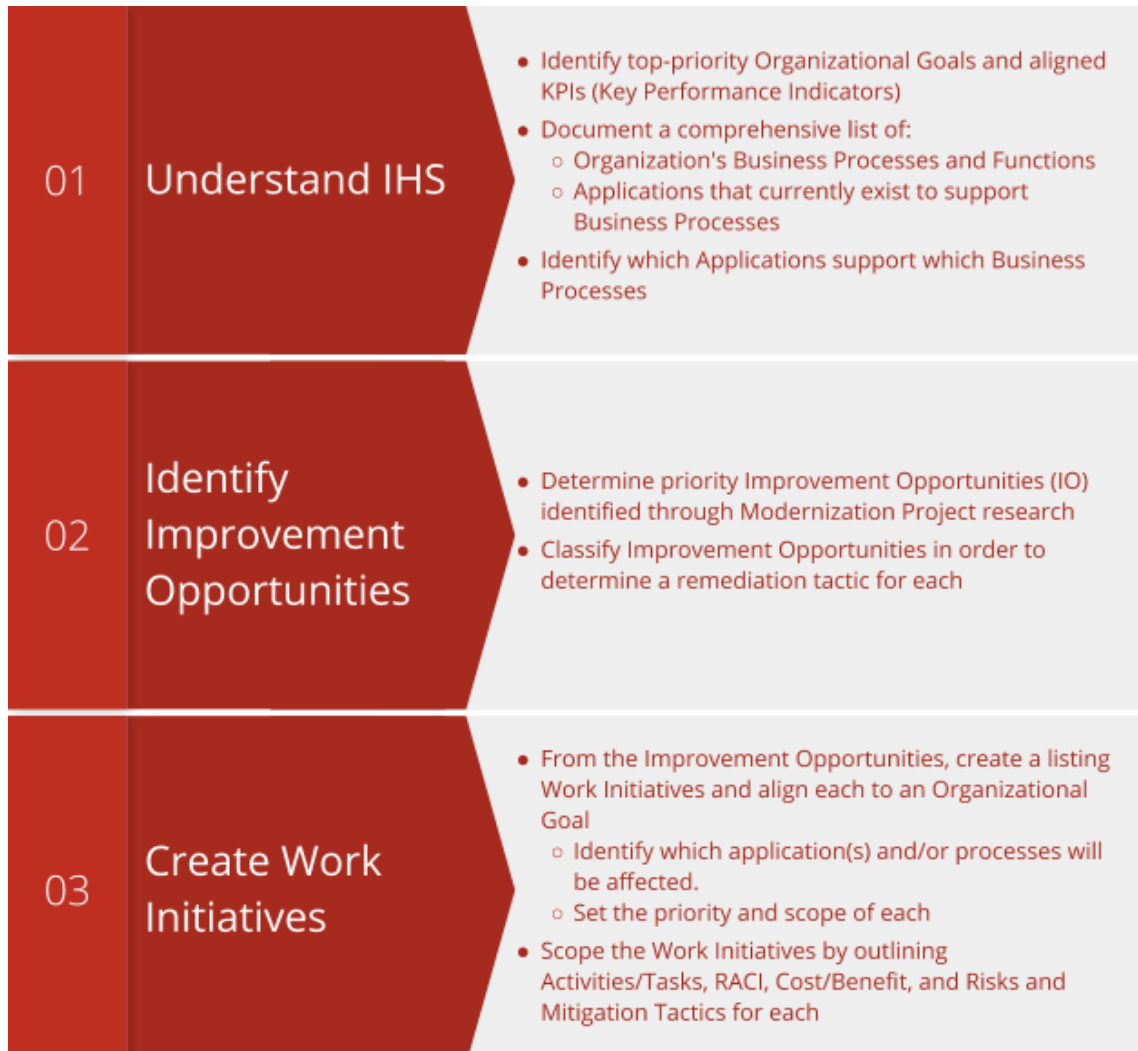
The Roadmap team made up of tribal, federal and private industry stakeholders recommends that the IHS incorporate a human-centered design approach when using the tool, as well as an iterative methodology to maintaining and revising the Roadmap. The human-centered design approach, a cornerstone of the Modernization Project, places people at the center of the process when fulfilling critical requirements.



2.0 Roadmap Tool Development

The Roadmap team efforts have produced an Enterprise Architecture Roadmap Tool that can guide the IHS towards HIT Modernization. This tool was constructed using the following steps:

Figure 2.0-1 Steps to Roadmap Development





3.0 Goals of Roadmap: Moving IHS towards HIT Modernization

The Roadmap includes four key domains. These domains are defined as follows:

Figure 3.0-1 Four Key Roadmap Domains

Four Key Roadmap Domains for IHS HIT Modernization		
<p>Modernization Planning and Execution <i>Strategic Design and Action to Achieve HIT Modernization</i></p>	<ol style="list-style-type: none"> 1. Establish governance, Program Management Office (PMO), and communication plan 2. Select and acquire HIT solution 3. Execute and Implement 	<ul style="list-style-type: none"> • Planning and execution are long, complex processes • Execution requires interaction with the Data Exchange and Infrastructure domains
<p>RPMS Stabilization and Early Wins <i>Develop and Deploy Key Improvements to RPMS</i></p>	<p>Address immediate end user requirements to adequately support business needs and provide adequate care to the population served by IHS</p>	<ul style="list-style-type: none"> • Short-term stabilization must occur regardless of HIT system(s) chosen • Achieves "Early Wins" via immediate intervention and ongoing modernization
<p>Data Exchange <i>Address Inter- and Intra-Operability Requirements</i></p>	<p>Develop data exchange capability and provide a secure personal health record (PHR) electronic application vitally important to fluid populations</p>	<ul style="list-style-type: none"> • Delivers a universal healthcare requirement • Essential to AI/AN populations
<p>Infrastructure <i>Improve Technology to Support Current Needs and Future HIT</i></p>	<p>Make required updates to the hardware, software, networks, data centers, and equipment used to develop, test, operate, monitor, and manage technology services.</p>	<ul style="list-style-type: none"> • Assess current infrastructure state at I/T/U facilities • Improve infrastructure to meet baseline requirements for selected HIT system(s)



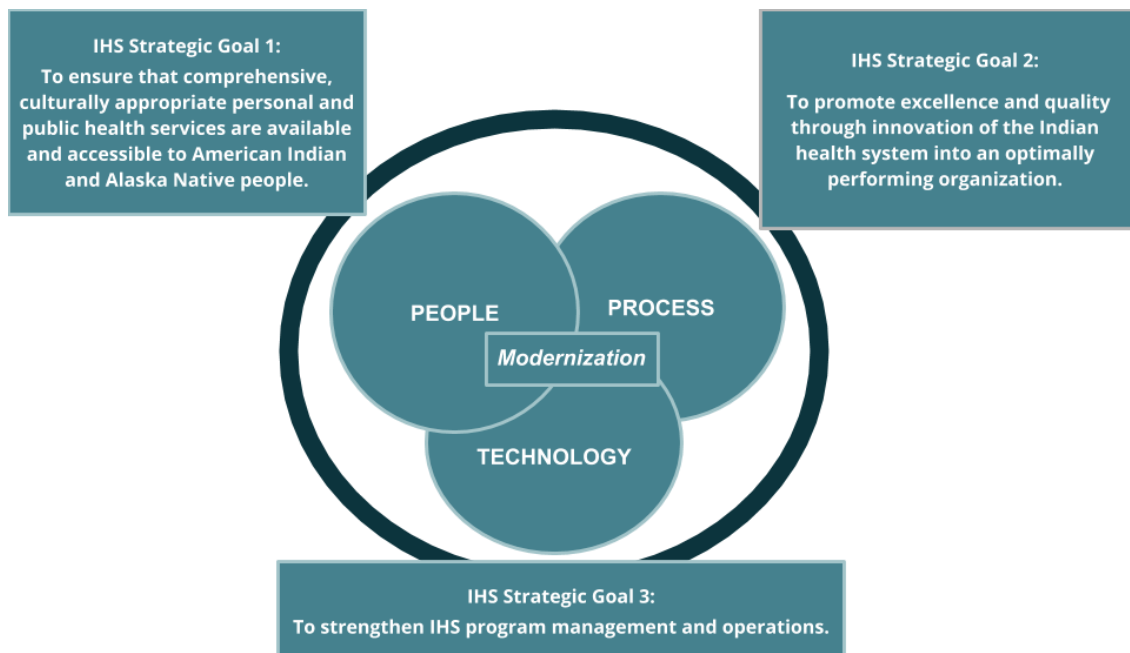
4.0 Objectives, Activities, Milestones, and Stakeholders

Each domain is comprised of multiple objectives, activities, and milestones that contribute toward the success of each respective domain and of the entire HIT modernization effort.

4.1 Key Performance Indicators

The IHS organizational goals from the Strategic Plan FY 2019-2023³ that were selected for inclusion in this Roadmap are displayed in the graphic below. In conjunction with the IHS HIT Modernization project framework, the Roadmap was created with a people, process, and technology paradigm.

Figure 4.1-1 IHS Strategic Goals with a People, Process, and Technology Paradigm





Indian Health Service HIT Modernization Project

Key performance indicators (KPIs) are consistent with the IHS' organizational goals and drive the Roadmap strategy. Each KPI is mapped to one or more organizational goal and is addressed in one or more Roadmap domain.

Table 4.1-1 KPI Crosswalk with Organizational Goals and Roadmap Domains

Org Goal	Key Performance Indicator (KPI)	Modernization Planning and Execution	RPMS Stabilization and Early Wins	Data Exchange	Infrastructure
2	KPI-001: Improved health status for AI/AN people receiving care from IHS	✓	✓	✓	
2	KPI-002: All IHS facilities will achieve and maintain recognition as Patient Centered Medical Homes	✓		✓	
1	KPI-003: Improved access to services for AI/AN people seeking care from IHS	✓		✓	✓
1, 3	KPI-004: Improved patient engagement through electronic access to health information	✓		✓	
3	KPI-005: Improved interoperability and sharing of patient information within the organization, across the I/T/U and with private and government partners (e.g. VA)	✓		✓	
2	KPI-006: Improved quality of care provided by IHS, as demonstrated by government and industry benchmarks	✓			
3	KPI-007: Improved organizational maturity in use of information technology systems in service of the IHS mission	✓			✓
3	KPI-008: All sites successfully complete and regularly update a Security Risk Analysis	✓	✓		
3	KPI-009: Improved ability for IHS to provide services in a sustainable way through cost recovery	✓			
3	KPI-010: Provider satisfaction with HIT usability.	✓	✓	✓	✓

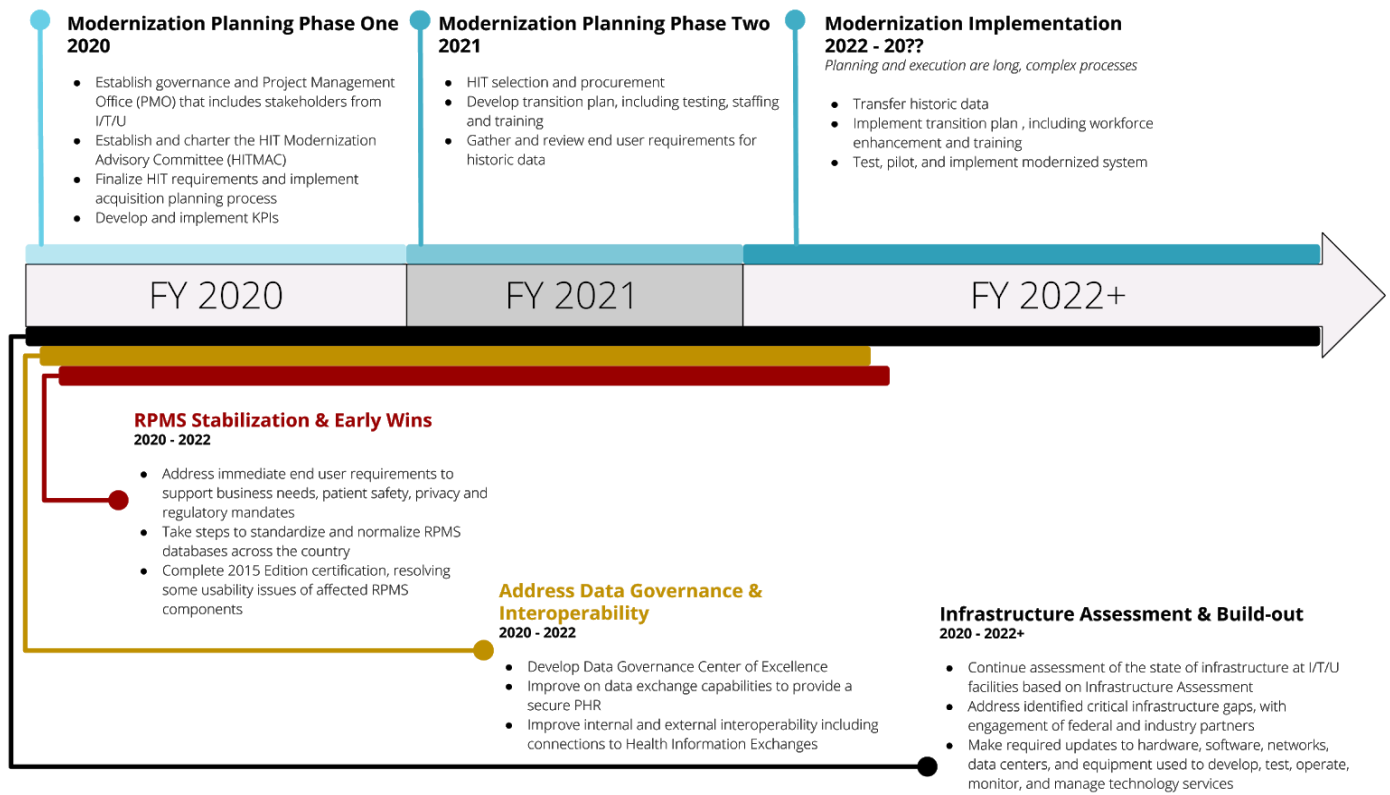


Indian Health Service HIT Modernization Project

4.2 Work Initiatives

The Roadmap leverages IHS processes, supporting applications, and improvement opportunities to generate work initiatives (WIs), which are specific actions required to achieve IHS HIT modernization. A high-level program plan is displayed in Figure 4.2-1.

Figure 4.2-1 High Level Program Plan and Timeline





Indian Health Service HIT Modernization Project

4.3 Stakeholders

Each Work Initiative will be assigned one or more suggested key individuals or groups to be responsible, accountable, consulted, or informed about the effort. The Roadmap displays each stakeholder's proposed involvement and role in each Work Initiative. The HIT Modernization Program will need to engage with these stakeholders as it moves toward modernization. The list below presents some of the proposed stakeholder roles that should ideally be engaged in this program.

Table 4.3-1 Proposed Stakeholder Roles

IHS Leadership	IHS Boards and Committees	I/T/U Representation
<ul style="list-style-type: none"> ● IHS Director ● IHS Chief Medical Officer (CMO) ● IHS Chief Information Officer (CIO) ● IHS Chief Technology Officer (CTO) ● IHS Enterprise Architecture (EA) ● IHS Chief Information Security Officer (CISO) ● IHS Chief Health Informatics Officer (CHIO) ● IHS Chief Medical Informatics Officer (CMIO) ● IHS Privacy Officer 	<ul style="list-style-type: none"> ● IHS Clinical Governance Boards ● IHS Technical Governance Boards ● Information Systems Advisory Committee (ISAC) 	<ul style="list-style-type: none"> ● I/T/U Field ● Tribes / Urban Programs
Federal Partners		Project Management Office (PMO) and Modernization Team
<ul style="list-style-type: none"> ● HHS Chief Information Officer (CIO) ● HHS Chief Technology Officer (CTO) ● HHS Chief Information Security Officer (CISO) ● HHS Customer Experience Lead ● HHS Chief Privacy Officer (CPO) ● Other federal partners including: <ul style="list-style-type: none"> ○ Veterans Affairs (VA) ○ Department of Defense (DoD) ○ Office of the National Coordinator (ONC) ○ Centers for Medicare & Medicaid Services (CMS) 		<ul style="list-style-type: none"> ● External Advisory Board ● Steering Committee ● PMO Exec Director ● PMO Program Manager ● PMO Staff



5.0 Next Steps

The Roadmap will evolve to meet the HIT Modernization Program needs. The Roadmap is a launching point for IHS HIT modernization. The Roadmap is to be referenced and updated on a regular basis as information is gained and funding is acquired.

To facilitate growth and evolution of the Roadmap, ownership by the Department of Health and Human Services (HHS) is required. HHS should initially adapt the model to IHS needs as appropriate. It should later oversee the execution of Roadmap steps, ensuring a coordinated and comprehensive approach to HIT modernization.

Broad-based clinical and technical leadership commitment is essential to implementation and success of this endeavor. Leadership must fully understand and commit to the Roadmap to ensure a successful modernization effort. Once leadership commitment is secured, communication to the I/T/U of the Roadmap's next steps is crucial to generate buy-in and further coordinate the modernization effort. Transparency and responsiveness to I/T/U concerns are key for preparing for modernization of a health enterprise as large as IHS. The modernization effort belongs to them as well as to IHS and HHS.

The Roadmap outlines immediate steps that should be taken to set the modernization effort into motion.

Table 5.0-1 Roadmap Next Steps

Domain	Next Steps
Modernization Planning and Execution	<ul style="list-style-type: none">● Reassess the organization of HIT governance processes within the agency● Fill critical vacancies within IHS's Office of Information Technology● Establish and charter the HIT Modernization Advisory Committee (HITMAC)● Execute an acquisition for expert Program Management Office support
RPMS Stabilization and Early Wins	<ul style="list-style-type: none">● Take steps to standardize and normalize RPMS databases across the country● Complete 2015 Edition certification, resolving usability issues of affected RPMS components to the extent possible
Data Exchange	<ul style="list-style-type: none">● Improve Internal and External Interoperability, including connections to Health Information Exchanges serving appropriate states and federal agencies
Infrastructure	<ul style="list-style-type: none">● Address identified critical infrastructure gaps, engaging federal and industry partners



6.0 Risks, Constraints, and Mitigations

6.1 Risks and Mitigations

Several key risks warrant consideration and mitigation when using the Roadmap:

Risks	Proposed Mitigations
<p>Operating Model Integration: If the Improvement Opportunities identified and related Work Initiatives are not integrated into IHS' operating model, then the modernization program may fail due to an unclear vision or deficient execution.</p>	<p>The HIT Modernization team will brief Executive leadership and senior staff on key elements of the Roadmap, including identified improvement opportunities, proposed work initiatives to remediate cited deficiencies, attendant risks, and interdependencies. Such briefings shall be iterative and interactive.</p>
<p>Executive Sponsorship: If IHS' executive leadership, senior staff, and domain and subject matter experts are not fully engaged and involved in the review, adoption, and evolution of the Roadmap, then the modernization program may fail due to a lack of executive sponsorship, buy-in and resistance to change.</p>	<p>Executive leadership and senior staff will be engaged in the review and refinement of key elements of the Roadmap, focusing on the identification of improvement opportunities, proposed work initiatives to remediate cited deficiencies, attendant risks, and interdependencies. Such interactions shall be iterative, and last for a period spanning hand-off of the Roadmap to ensure IHS' buy-in, adoption, and ownership.</p>
<p>Cost and Time Estimates: If the cost, project interdependencies, and inherent risks of IHS' HIT modernization program are underestimated or understated, then the scope, delivery time, and quality of deliverables will be negatively impacted.</p>	<p>Conduct a comprehensive cost analysis, accounting for the full scope, schedule, and resource requirements of modernization. Verify and validate core requirements for infrastructure upgrades and data cleansing, normalization, standardization, migration, and post-migration validation.</p>
<p>Requirements Management: If the requirements elicitation process for modernization is deficient or fails to capture, verify, and validate critical system requirements and their interdependencies, then the scope, cost, and schedule of the modernization program may be understated and the resultant quality of program outcomes severely impacted.</p>	<p>As a critical work initiative of IHS' HIT modernization program's roadmap, IHS must review and refine existing requirements elicitation practices into a formal Requirements Management process.</p>
<p>Service Maturity and Governance: If IHS is deficient in IT service maturity or critical internal controls and governance practices, processes, and SOPs to guide and enable modernization, then the modernization program will be impeded and unnecessarily protracted due to avoidable delays and rework that will increase costs.</p>	<p>As foundational work initiatives of IHS' HIT modernization program's roadmap, IHS must enhance existing IT service delivery, internal controls, and governance practices into repeatable, verifiable processes.</p>



Indian Health Service HIT Modernization Project

6.2 Known Constraints and Mitigations

The following known constraints and mitigations are presented for review:

Constraints	Proposed Mitigations
Critical and unique system capabilities currently implemented in the Resource and Patient Management System (RPMS) persist to the replacement HIT solution or ecosystem	IHS must provide HIT systems that are attractive to the I/T/U programs through support for integrated, multidisciplinary care (behavioral health, dental, etc.) as well as population health and individual patient care. Requirements and resultant capabilities and functionality related to traditional medicine, AI/AN population health, etc. must persist in the replacement HIT solution.
Funding and staffing levels	Noted as a foregoing operational issue but not assessed in detail; as such, this report assumes that funding to improve infrastructure, to recruit, train, and retain local and national support staff, and to address development and implementation costs for new or updated systems will be available.
Lack of organizational readiness for change	Through an enterprise-wide organizational change management initiative, IHS shall plan and execute the required strategic and operational changes required for success of the Modernization program.
Site-specific infrastructure constraints related to limited bandwidth, poor cellular signal, degraded or inadequate telephony and wide area network (WAN) infrastructure, etc.	As a primary and critical initial step in IHS HIT Modernization program, IHS must conduct a comprehensive infrastructure analysis and subsequent infrastructure build-out to remediate critical infrastructure deficiencies. Moreover, infrastructure constraints that are too costly to mitigate will proactively inform and influence the selection, architecture, design, and topology of the new HIT solution in order to achieve cost-efficiencies and optimal system quality.
Interoperability requirements	<p>The replacement HIT solution or ecosystem must be intrinsically interoperable and must support data sharing, both within and external to the I/T/U. The following recommendations will assist in meeting interoperability goals:</p> <ul style="list-style-type: none"> ● Conduct a gap analysis to identify and prioritize interoperability deficiencies in IHS' HIT ecosystem ● Define IHS' interoperability strategy and communicate it broadly to stakeholders ● Ensure interoperability needs are surfaced through the Requirements Management (RM) and Enterprise Architecture (EA) artifacts ● Partner with the Acquisition Planning and Procurement (AP&P) office to integrate interoperability needs into acquisition planning ● Adhere to open standards in the design and implementation of interoperable systems ● Ensure strict security and privacy of data and information shared across interoperable systems to drive wide-scale adoption ● Utilize efficient, cost-effective infrastructure to achieve interoperability across distributed and external systems ● Implement non-intrusive, value-added data governance practices



Indian Health Service HIT Modernization Project

Regulatory compliance	Through an improved requirements management process, value-oriented lightweight enterprise architecture (EA) practice, and outcome-driven governance, the replacement HIT solution or ecosystem will meet or exceed regulatory requirements, including the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid (CMS) certification requirements and other regulatory constraints, such as Clinical Laboratory Improvement Amendments (CLIA).
Security, confidentiality, patient privacy	Through ongoing and augmented security practices, IHS shall identify, validate, and prioritize external and internal security vulnerabilities and threats through a security risk assessment (SRA). The results of this assessment will lead to improvements in data security, confidentiality, and privacy, thereby driving increased compliance and patient satisfaction.
Support for legacy systems/subsystems/ components	Any approach that retains legacy systems/subsystems/components must plan for ongoing operations and maintenance (O&M) or replacement of VistA-derived packages. Moreover, there are associated cost and resource implications as well as related risks.



References

1. Info-Tech Research Group [Internet]. London (ON): Info-Tech Research Group (Health and Human Services); 2009 Sep 12 [cited 2019 July 25]. Available from: <https://www.infotech.com/>.
2. Gartner Special Reports: providing actionable insights into major trends [Internet]. Stamford (CT): Gartner; 2019 [cited 2019 Aug 22]. Available from: <https://www.gartner.com/en/products/special-reports>.
3. IHS Strategic Plan FY 2019-2023 [Internet]. Rockville (MD): Indian Health Services; 2019 [cited 2019 July 9]. Available from: <https://www.ihs.gov/strategicplan/ihs-strategic-plan-fy-2019-2023/>.



Health Care Reform in Indian Country

Self-Governance Communication & Education

Self-Governance Tribes Striving Towards Excellence in Health Care

Summary from Survey of Self-Governance Tribes December 9, 2019

TSGAC gathered information through a survey on preferred priority topics and methods for training/technical assistance on the ACA/IHCIA project. The following summarizes the information received.

Part A - Tribal Preferences/Priorities on Topics

In response to an open-ended question on the TSGAC survey, the following topics were submitted by respondents under the Survey:

ACA/IHCIA Related	Other IHS Topics (Not specifically ACA)
<ul style="list-style-type: none"> ○ Federally Qualified Health Centers: consideration for Tribal clinics to bill under Medicaid and/or Medicare FQHC status; payment rates; range of services 	<ul style="list-style-type: none"> ○ General statistics on Tribes
<ul style="list-style-type: none"> ○ Medicare Part B billing options 	<ul style="list-style-type: none"> ○ CHAP and DHAT programs
<ul style="list-style-type: none"> ○ Best practices in Medicaid (and other Third party) billing processes 	<ul style="list-style-type: none"> ○ Clinic construction: funding; joint ventures
<ul style="list-style-type: none"> ○ Tribal Sponsorship (Marketplace and Medicare) 	<ul style="list-style-type: none"> ○ Opioid use: Data, treatment, billing
<ul style="list-style-type: none"> ○ Establishing contacts with health plans 	<ul style="list-style-type: none"> ○ 105(l) leases
<ul style="list-style-type: none"> ○ Methodologies for identifying / predicting high-cost cases for potential Sponsorship 	<ul style="list-style-type: none"> ○ Collecting Contract Support Costs (CSC)
<ul style="list-style-type: none"> ○ Medicare vs. Marketplace coverage; options 	<ul style="list-style-type: none"> ○ Advanced appropriations
<ul style="list-style-type: none"> ○ Best practices in PRC management, including use of Medicare-like rates 	<ul style="list-style-type: none"> ○ SDPI
<ul style="list-style-type: none"> ○ Authorities provided under the Indian Health Care Improvement Act, and status of these authorities ○ 	
<ul style="list-style-type: none"> ○ Opportunities with 100% FMAP (for “received through” services) 	
<ul style="list-style-type: none"> ○ Tools on extracting data from RPMS and GPRA 	

○ Alternative resource compliance	
○ Survey of Medicaid programs: covered services; ITU payment ○ Number of encounter payments allowed, per patient, per day, for Tribal clinics	
○ Payment for outpatient prescription drugs (OPDs), including # of encounters and treatment of high-cost cases	
○ Best practices with Patient Registration	
○ Medicaid Indian managed care entities	

For the items in the table above under the left column “ACA / IHCA Related”, TSGAC technical advisors will review to determine: (1) steps needed to gather additional information; and, (2) the mode of delivery of the information. The responses from respondents shown in Part B below will guide decisions on the mode of delivery of the information, including potential use of small group Webinars to provide technical assistance to Tribal representatives.

In addition, the TSGAC presented four potential areas for TSGAC training and requested respondents to rank them. These four topics were generated from discussions among TSGAC quarterly meeting participants in October 2019. The summary results of survey participant responses are as follows:

TSGAC SURVEY: LISTED POTENTIAL RESEARCH TOPICS							
<i>Table A1. We have identified four potential areas for TSGAC training. Please check those that you and / or your staff are likely to participate in. (Please rank with 1 being highest ranking.)</i>							
Topic 1: Benefits of ACA Relative to PRC Program				Topic 2: Impact of ACA on Adequacy of CHEF Funding			
Rank	# of Responses	%	1st or 2nd	Rank	# of Responses	%	1st or 2nd
1	17	53%	69%	1	9	28%	59%
2	5	16%		2	10	31%	
3	6	19%		3	8	25%	
4	3	9%		4	4	13%	
No response	1	3%		No response	1	3%	
Total	32	100%		Total	32	100%	
RANKING: #1 (high interest)				RANKING: #3 (strong interest)			

ACA = Affordable Care Act
PRC = Purchased/Referred Care

CHEF = Catastrophic Health Emergency Fund

Suggested Follow-up:

- Topics #1 and #2 above both will require data from IHS in order for the ACA Project Team to further research. Should this be further pursued with IHS?

TSGAC SURVEY: LISTED POTENTIAL RESEARCH TOPICS							
<i>Table A2. We have identified four potential areas for TSGAC training. Please check those that you and / or your staff are likely to participate in. (Please rank with 1 being highest ranking.)</i>							
Topic 3: Medicaid OPD: Impact of Encounter Rate				Topic 4: Rural Hospital Closures: Impact on Access for AI/ANs			
Rank	# of Responses	%	1st or 2nd	Rank	# of Responses	%	1st or 2nd
1	12	38%	66%	1	7	22%	34%
2	9	28%		2	4	13%	
3	5	16%		3	6	19%	
4	4	13%		4	14	44%	
No response	2	6%		No response	1	3%	
Total	32	100%		Total	32	100%	
RANKING: #2 (high interest)				RANKING: #4 (modest interest)			

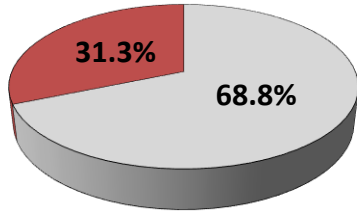
OPD = Outpatient prescription drugs

Suggested Follow-up:

- Topic #3 is a preferred topic and will require some additional research. Following this research and findings, the TSGAC brief on the topic will be updated and a small targeted Tribal only training will be scheduled.
- Topic 4: Rural hospital closures: Impact on AI/AN access to care was ranked significantly lower, with only 34% of respondents indicating a ranking of “1” or “2” and is not a priority at this time.

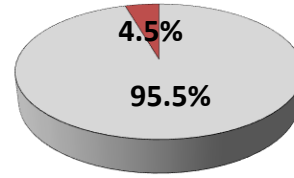
Part B - Tribal Preferences for Training and Technical Assistance

Have you participated in any of the ACA/IHCIA Webinars and Trainings hosted by the TSGAC?



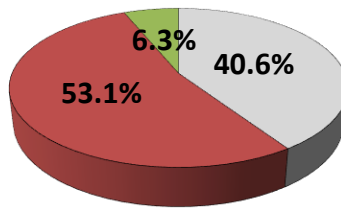
□ Yes ■ No

If answering "yes" , have you shared information with others in your Tribe/Tribal organization?



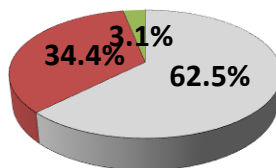
□ Yes ■ No

Have you or staff accessed ACA/IHCIA recorded Webinars and Trainings hosted by the TSGAC on the TSGAC Website?



□ Yes ■ No ■ No response

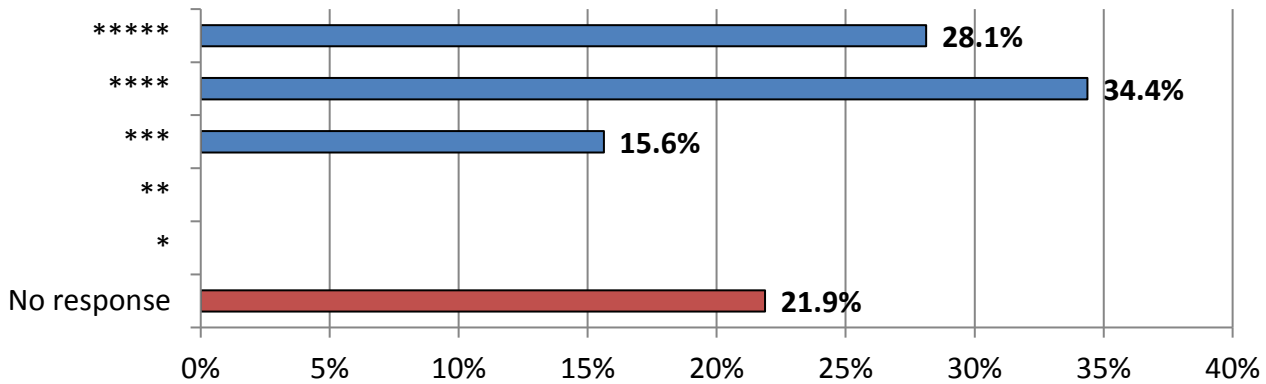
Have you or staff accessed TSGAC briefs on the ACA/IHCIA (either through broadcasts to Tribes or on the TSGAC Website)?



□ Yes ■ No ■ No response

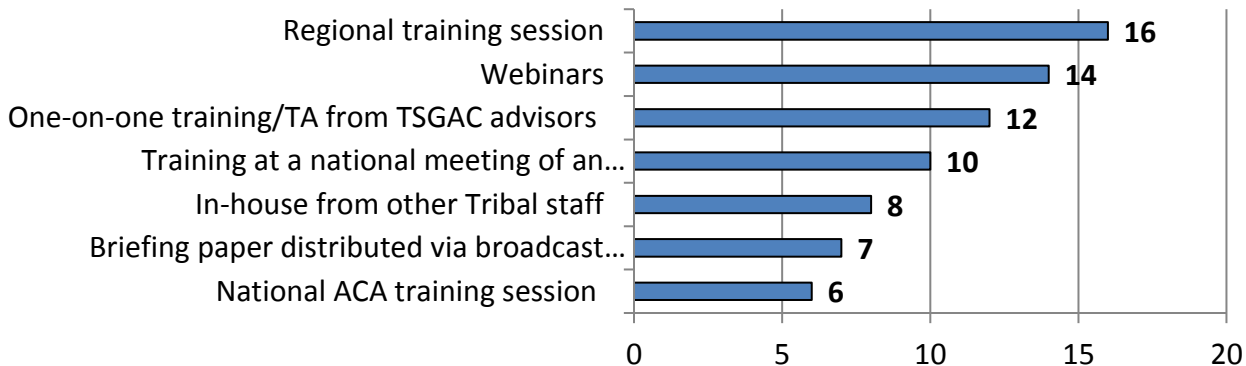
On a scale of 1 to 5 stars, how would you rate the Webinars and/or Trainings hosted by the TSGAC?

(* = not helpful; ***** = very helpful)



What are the preferred ways for your staff to receive Training and Technical Assistance on the ACA/IHCIA?

(ranked by respondents as top or second choice)



How can the TSGAC improve (a) the relevance of the information and/or (b) access to information on the ACA/IHCIA on the TSGAC Website?

- ✓ Avoid information overload
- ✓ Provide more information on regional trainings
- ✓ Provide more local contacts
- ✓ Use 1-page informational graphics
- ✓ Provide link to Website for Title I Tribes

Q9. In general, how can the ACA/IHCIA Outreach and Education Project provide better service to you?

- ✓ Offer 101 workshops
- ✓ Provide more training (particularly regional training)

Why GAO Did This Study

IHS provides care to American Indians and Alaska Natives through a system of health care facilities. The Patient Protection and Affordable Care Act (PPACA) provided states with the option to expand their Medicaid programs, and created new coverage options beginning in 2014, including for American Indians and Alaska Natives. GAO was asked to review how PPACA has affected health care coverage and services for American Indians and Alaska Natives. In this report, GAO describes (1) trends in health insurance coverage and third-party collections at federally operated and tribally operated facilities from fiscal years 2013 through 2018, and (2) the effects of any changes in coverage and collections on these facilities.

To address these objectives, GAO analyzed IHS data on coverage, third-party collections, and PRC. GAO interviewed IHS officials from headquarters and all 12 area offices, as well as from 17 facilities selected to include a mix of federally operated and tribally operated hospitals and health centers in states that both had and had not expanded their Medicaid programs as of September 2018. GAO interviewed officials from 11 federally operated IHS facilities and 6 tribally operated facilities.

GAO provided a draft of this report to the Secretary of Health and Human Services for comment. The Department did not have any comments on the draft report.

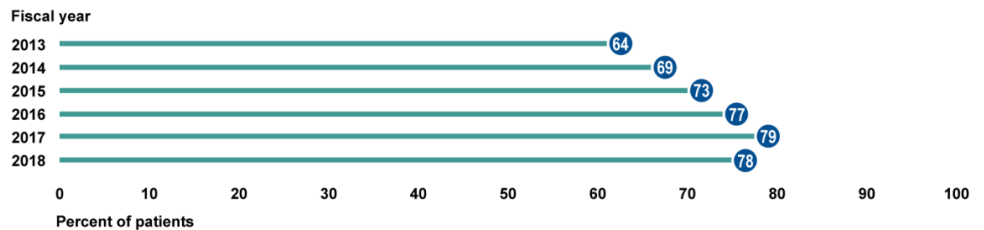
INDIAN HEALTH SERVICE

Facilities Reported Expanding Services Following Increases in Health Insurance Coverage and Collections

What GAO Found

GAO's analysis of Indian Health Service (IHS) data shows that from fiscal years 2013 through 2018, the percent of patients at federally operated IHS hospitals and health centers that reported having health insurance coverage increased an average of 14 percentage points. While all federally operated IHS facilities reported coverage increases, the magnitude of these changes differed by facility, with those located in states that expanded access to Medicaid experiencing the largest increases. Federally operated IHS facilities' third-party collections—that is, payments for enrollees' medical care from public programs such as Medicaid and Medicare, or from private insurers—totaled \$1.07 billion in fiscal year 2018, increasing 51 percent from fiscal year 2013. Although exact figures were not available, tribally operated facilities, which include hospitals and health centers not run by IHS, also experienced increases in coverage and collections over this period, according to officials from selected facilities and national tribal organizations.

Average Percent of Patients at Federally Operated IHS Facilities Reporting Health Insurance Coverage, Fiscal Years 2013 through 2018



Source: GAO analysis of Indian Health Service (IHS) data. | GAO-19-612

Note: Data represent patients' self-reported coverage information at each of the 73 federally operated IHS hospitals and health centers, averaged across the facilities, and do not reflect coverage through the Department of Veterans Affairs.

Increases in health insurance coverage and third-party collections helped federally operated and tribally operated facilities continue their operations and expand the services offered, according to officials from 17 selected facilities. These officials told GAO that their facilities have been increasingly relying on third-party collections to pay for ongoing operations including staff payroll and facility maintenance. Officials at most facilities with increases in third-party collections also stated that they expanded their onsite services, including increasing the volume or scope of services offered by, for example, adding new providers or purchasing medical equipment. Increased coverage and collections also allowed for an expansion in the complexity of services provided offsite through the Purchased/Referred Care (PRC) program, which enables patients to obtain needed care from private providers if the patients meet certain requirements and funding is available. According to IHS and facility officials, increases in coverage have allowed some patients to access care offsite using their coverage, and an expansion of onsite services has reduced the need for some patients to access PRC. Officials GAO interviewed from federally operated and tribally operated facilities stated that facilities' expansion of onsite and offsite services has led to enhancements in patients' access to care in some instances.



Indian Health Service Press Release

December 20, 2019
FOR IMMEDIATE RELEASE
 Contact: (301) 443-3593, newsroom@ihs.gov

IHS Cooperative Agreements Promote Tribal Self-Governance

Today, the Indian Health Service announced the recipients for the Fiscal Year 2020 Tribal Self-Governance Planning and Negotiation Cooperative Agreements administered by the [Office of Tribal Self-Governance](#).

“These cooperative awards highlight the commitment of the Indian Health Service to tribal self-governance,” said IHS Acting Director Rear Adm. Michael D. Weahkee. “The partnership between IHS and the tribes and tribal organizations we serve is critical to our success in providing access to quality health care for American Indians and Alaska Natives.”

These annual IHS cooperative agreement awards support tribes and tribal organizations with the planning and preparation necessary to assume responsibility for providing health care to their tribal members through the Tribal Self-Governance Program. Eight recipients received awards ranging from \$48,000 to \$120,000. The total amount of awards for 2019 is \$802,000.

Planning Cooperative Agreement

The Planning Cooperative Agreement assists tribes with the planning phase of the self-governance program, which includes legal and budgetary research, internal tribal government planning, and organization preparation relating to the administration of health care programs. This year’s awardees include the following:

Tribes/Tribal Organization	City	State	Amount Awarded
Pawnee Nation of Oklahoma	Pawnee	OK	\$120,000
Wichita and Affiliated Tribes	Anadarko	OK	\$120,000
Rosebud Sioux Tribe	Rosebud	SD	\$120,000
Muscogee (Creek) Nation Hospital and Clinics	Okmulgee	OK	\$113,100
San Carlos Apache Tribe	San Carlos	AZ	\$120,000
Catawba Indian Nation	Rock Hill	SC	\$113,142

Negotiation Cooperative Agreement

The Negotiation Cooperative Agreement assists tribes to defray the costs related to preparing for and conducting self-governance program negotiations. Negotiations provide an opportunity

for the tribal and federal negotiation teams to work together in good faith to enhance each self-governance agreement. This year's awardees include the following:

Tribe/Tribal Organization	City	State	Amount Awarded
Round Valley Indian Health Center, Inc.	Covelo	CA	\$48,000
Hopland Band of Pomo Indians	Hopland	CA	\$48,000

The IHS Tribal Self-Governance Program is an expression of the nation-to-nation relationship between the U.S. and the tribes. Strong federal-tribal partnerships are critical to the program's success. Through the program, tribes have the option to assume IHS program funds and manage them to best fit the needs of their tribal communities.

The IHS Office of Tribal Self-Governance serves as the primary liaison for tribes participating in the Tribal Self-Governance Program. The office develops and oversees the implementation of tribal self-governance legislation and authorities within the IHS. They also provide information, technical assistance, and policy coordination in support of IHS self-governance activities, with input from IHS staff and workgroups, tribes and tribal organizations, and the [IHS Tribal Self-Governance Advisory Committee](#).

The IHS, an agency in the [U.S. Department of Health and Human Services](#), provides a comprehensive health service delivery system for approximately 2.6 million American Indians and Alaska Natives. Follow the agency via social media on [Facebook](#) and [Twitter](#).

###

Guiding Principles for Indian Health Service Tribal Self-Governance Negotiations

In order for negotiations to be successful, each participant must make a commitment to achieving shared goals at the outset of the process. Representatives from the Indian Health Service (IHS), Tribes and Tribal Organizations jointly developed the following Guiding Principles. The purpose of the Guiding Principles is to create a set of shared principles that negotiation participants exercise throughout the negotiation process. These guiding principles do not alter, or expand, any statutory or regulatory requirements or remedies. This list is not intended to be exhaustive. Additional principles or unique practices may be jointly agreed to and observed depending on negotiation participant needs, IHS Area capacity, and specific Tribal distinction.

Government-to-Government Relationship – Consistent with the Indian Self-Determination and Education Assistance Act, negotiations are built on the Government-to-Government relationship between the federal government and the Tribe and Tribal organization.

Respect for All Participants & Process – All Tribal and IHS representatives will be prepared and ready to participate in the negotiations through the designated lead Tribal Negotiator or the IHS Agency Lead Negotiator. General framework to guide the process will be jointly agreed upon. Either side may call for a caucus as needed to address issues that may arise during the negotiations.

Access to Information – All parties will disseminate, to the greatest extent practicable, requested information that is necessary for decision making in a timely manner. The lead Tribal Negotiator and the Agency Lead Negotiator will communicate as needed to ensure that documents are tracked and shared with the appropriate parties within the timeframes that are identified during the negotiations.

Communication and Commitment – All parties will communicate in an open and transparent manner and will actively listen and attempt to understand each side's position. Commitments to fulfill any requests for additional information or follow up items will be provided in a timely manner, to the greatest extent practicable. Each party will make a good faith effort to honor, within his or her authority, all agreements made during the negotiations.

Collaboration – To the fullest extent possible, the Tribe or Tribal Organization and IHS will work toward a collaborative approach and propose solutions and/or language that will meet the interests of both parties, when possible.



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/; and on
3. IHS Privacy Web site, available at 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.

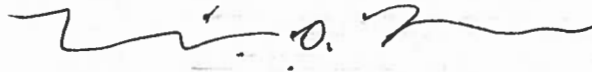
- 5. Identification of TSGAC representatives to serve on the newly-established 105(I) Lease Sub-Workgroup:** The TSGAC shared that they appointed a primary Tribal representative, Candice E. Skenandore, and an alternative Tribal representative, Melanie Fourkiller, to participate in the Federal/Tribal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

Page 4 – Dr. Lynn Malerba

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. 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



www.tribalsef.gov.org