January 28, 2019

Office of the National Coordinator for Health Information Technology
Mr. Donald W. Rucker, M.D., National Coordinator for Health IT
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

RE: Comments on Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, November 2018

Dear Dr. Rucker:

On behalf of the National Indian Health Board (NIHB)\(^1\) and the 573 federally recognized Tribal Nations that we serve, I write to submit comments in response to the Office of the National Coordinator for Health Information Technology’s (ONC) draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, November 2018 (Draft Strategy).

NIHB has in the past worked collaboratively with ONC staff to provide expertise as to the types of service sites that Tribes utilize, the geographic challenges American Indians and Alaska Natives (AI/ANs) face, and the inconsistency of information technologies from site to site. These include each site’s bandwidth challenges, staffing, and capacity to utilize Electronic Health Records (EHRs). We have benefitted greatly from previous discussions with ONC staff. Moving forward, ONC and Tribal partnership will be critical to facilitate the long-term success of Health IT in Indian Country.

\(^1\) Established in 1972, the National Indian Health Board (NIHB) is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all American Indians and Alaska Natives (AI/AN). The NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service (IHS) Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with the NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-68, the Indian Self-Determination and Education Assistance Act (ISDEAA), or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.
Pursuant to Section 4001 of the 21st Century Cures Act, Public Law 114-255, the Department of Health and Human Services (HHS) created the ONC Draft Strategy to gather input from stakeholders to improve infrastructure, interoperability, accessibility, and overall utility of health care information. The Draft Strategy represents the Administration’s goal to reduce the regulatory and administrative burden related to the use of EHRs. NIHB appreciates the opportunity to provide comments to be sure that the strategy is inclusive of Tribal needs and concerns.

**Background**

We kindly remind the ONC that the United States has a unique legal and political relationship with Tribal governments established through and confirmed by the United States Constitution, treaties, federal statutes, executive orders, and judicial decisions. Central to this relationship is the Federal Government’s trust responsibility to protect the interests of Indian Tribes and communities, including the provision of health care to American Indians and Alaska Natives. Congress has passed numerous Indian-specific laws to provide for Indian health care, including establishing the Indian health care system and permanently enacting the Indian Health Care Improvement Act (IHCIA).² In the IHCIA, for instance, Congress found that “Federal health services to maintain and improve the health of the Indians are consonant with and required by the Federal Government’s historical and unique legal relationship with, and resulting responsibility to, the American Indian people.”³ Title V of the IHCIA authorized federal funding for urban Indian organizations to provide health services to American Indian/Alaska Natives (AI/ANs), many of whom had been relocated to urban areas by federal relocation programs. Congress also enacted the Indian Self-Determination and Education Assistance Act of 1975 to enable Tribes and Tribal Organizations to directly operate health programs that would otherwise be operated by the Indian Health Service (IHS), thereby empowering Tribes to design and operate health programs that are responsive to community needs. Together, this complex health care system is often referred to as the “I/T/U” (Indian Health Service/Tribal facilities/Urban health programs) system or Indian health system.

Currently, a majority of service delivery sites within the Indian health system utilize the Resource and Patient Management System (RPMS), a health information system which is a comprehensive suite of applications that supports virtually all clinical and business operations at IHS and some Tribal facilities, from patient registration to billing.⁴ However, in recent years, driven largely by the inability of the I/T/U system to keep pace with the technological advances of Commercial Off-the-Shelf (COTS)-EHRs and the inability to achieve sound EHR certification as required by the federal government, more Tribes are choosing to leave the RPMS because IHS has not been able to properly maintain and update the system.⁵ In addition, IHS faces a uniquely challenging

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³ Id. § 1601(1).
⁴ NIHB, Comments on Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified EHR Technology Definition (July 21, 2014), https://www.nihb.org/tribalhealthreform/wp-content/uploads/2014/07/NIHB-Comments-CMS-NPRM-07-21-14.pdf (“74% of our providers use IHS RPMS, 17% use Cerner, 4% use NextGen, 4% do not have EHR yet, and final 1% use other EHR’s.”).
⁵ The scope of RPMS usage varies per Urban Indian Health Programs – some use it for all of their operations, some for registration, E-pharmacy, etc. A survey conducted by the National Council on
situation because the Veterans Health Administration (VHA) is also in the midst of planning to transition to the COTS system. As a result, the future viability of RPMS is at risk, because RPMS is linked to the VHA EHR and regularly receives technical updates and changes as a result of VHA’s work.

Given the current challenges with RPMS and the evolving health care environment, we suggest that the ONC Draft Strategy, in its final version, designate a section to recommend that Federal agencies commit significant resources toward I/T/U HIT requirements, to allow IHS to either update the current EHR or to initiate a process similar to that of the VHA. Additionally, it is important that the final strategy recognize that RPMS is dependent on an increasingly antiquated broadband infrastructure that is in dire need of upgrade and expansion.

According to the Federal Communication Commission’s (FCC) 2016 Broadband Progress Report, 41% of Americans living on Tribal Lands and 68% of people living in rural Tribal lands lack access to high speed internet, compared to the national average of 10%. Moreover, approximately 75% of IHS sites are located in areas defined by the FCC as “rural.”

Some states with the largest telehealth potential have the lowest rates of broadband adoption on Tribal Lands.

**Lack of Broadband Access on Tribal Lands by State**

*Data is specific to populations living on Tribal Lands*

<table>
<thead>
<tr>
<th>State</th>
<th>People without Broadband</th>
<th>Percentage of Population</th>
<th>State</th>
<th>People without Broadband</th>
<th>Percentage of Population</th>
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<td>Florida</td>
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<td><strong>National Average</strong></td>
<td><strong>33.9 million</strong></td>
<td><strong>10%</strong></td>
<td><strong>All Tribal Lands</strong></td>
<td><strong>1.5 million</strong></td>
<td><strong>41%</strong></td>
</tr>
</tbody>
</table>

*All above data sourced from the Federal Communications Commission’s 2016 Broadband Progress Report-Appendix G*

NIHB urges HHS to revise the Draft Strategy to address the uniqueness of the I/T/U systems and to include the needs of Indian Country. We request that the final strategy integrate Tribal expertise,

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Urban Indian Health (2017-18) found that, of 25 UIHP-respondents, approximately 70% use RPMS and around 10% indicated they have switched to an off the shelf system.

acknowledge infrastructure shortcomings within Indian Country, and propose sustainable solutions to improve interoperability of Health IT across the I/T/U system.

We also set forth detailed responses to specific items in the Draft Strategy. Please see our comments below.

Clinical Documentation

Core Strategies

1. Reduce regulatory burden around documentation requirements for patient visits;
2. Continue to partner with clinical stakeholders to encourage adoption of best practices related to documentation requirements;
3. Leverage health IT to standardize data and processes around ordering services and related prior authorization processes.

Regulatory Burden

Tribal government entities struggle with meeting burdensome requirements imposed by Federal health care IT systems. For example, in order for the Indian health system to demonstrate “meaningful use” (MU) of certified electronic health record technology (CEHRT), the Centers for Medicare and Medicaid Services (CMS) have instituted EHR Incentive Programs which provide financial incentives to eligible professionals (EPs), eligible hospitals (EHs) and critical access hospitals (CAHs). Unfortunately, as NIHB noted in a 2016 letter to CMS, the current paradigm of incentives and penalties did not take into account the many complexities and challenges embedded in the Indian Health System. Some of these challenges include: high provider turnover rate in IHS regions; provider staffing shortages that make it difficult and time-consuming to produce clinical summaries required by MU; lack of technology and equipment due to the extreme expense for I/T/U users of COTS-EHR systems; and Tribal health care providers’ dependence on the IHS RPMS system, and the unforeseen operating delays therein. Other persistent barriers include underfunding, as well as implementation of harmful policies that did not, at inception, account for the unique needs of Indian Country.

Clinical Stakeholders: Tribal Consultation & Trust Responsibility

As outlined by ONC, a core strategy in identifying and alleviating regulatory burden is to continue valuable partnerships with a variety of stakeholders in order to encourage best practices related to documentation requirements. We remind ONC that the public notice and comment procedure is only one mechanism by which Tribes interact with the Federal regulatory system. Our

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8 HHS Indian Health Service, Meaningful Use, https://www.ihs.gov/meaningfuluse/.
participation here, therefore, is not a substitute for the mandated Tribal consultation procedures pursuant to Executive Order 13175. Moreover, the Federal government’s trust responsibility provides the legal justification and moral foundation for Indian specific health policymaking—with the purpose of enhancing American Indian/Alaska Native (AI/AN) access to health care and helping AI/ANs to overcome chronic health disparities.

**Health IT Usability and the User Experience**

Core Strategies
1. Improve usability through better alignment of EHRs with clinical workflow; improve decision making and documentation tools;
2. Promote user interface optimization in health IT that will improve the efficiency, experience, and end user satisfaction;
3. Promote harmonization surrounding clinical content contained in health IT to reduce burden;
4. Improve health IT usability by promoting the importance of implementation decisions for clinician efficiency, satisfaction, and lowered burden.

**Improve Usability**

The ONC Draft Strategy must in its final analysis of clinician burden and clinical workflow include, at minimum, a reference to challenges unique to the I/T/U health care systems when it formulates procedures to implement cross-agency interoperability.

The ONC Draft Strategy emphasizes that interoperability “will not be achieved for users until their experience with electronic health information and technology has been made seamless and effortless, and, as a result, truly interoperable.” The 21st Century Cures Act defines interoperability as “the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user.” For ONC to truly adapt interoperable software to the I/T/U health care systems, there must be a platform that allows Indian Health Service facilities to communicate directly with sister agencies like the Department of Veterans Affairs, HHS, and the Department of the Interior. There have been critical health and safety violations reported to NIHB where IHS systems were slow to integrate user data, either within the I/T/U systems or across agency interfaces.

Furthermore, some I/T/U facilities are situated in geographically remote areas. Indian Health Care Providers (IHCPs) in these areas need robust, scalable, and interoperable Health IT systems and EHRs to improve decision making at the clinical level, thereby delivering more favorable outcomes. Interoperability within the health information arena will enable systems to move beyond the rudimentary tasks of basically recording data into the EHR to a more well-rounded

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approach that encompasses the vital components that comprise the Health IT space. These components could inform a more streamlined approach in relation to the financial, public and population health information sharing, and clinical care for evidence-based decision making.

**Improve Efficiency: Ease clinician burden; effective interaction with EHR interface in busy clinical environment**

NIHB supports ONC’s recommendations as outlined in the draft strategy. However, we urge the ONC to, in its final strategy, make recommendations for improvement of the health information data entry and maintenance systems, and the data submission process, as required by the Indian health care systems – to maintain its accountability to the Federal government. In a 2016 Report to Congress, ONC reported that “as the variety of health IT products increases, health IT comparison tools will become increasingly critical to the provider community in the near future. *Improving comparison tools’ functionality and utility is only one component in ensuring providers have health IT that supports safe, efficient, and effective care.*”

We ask that Tribal governments are included in any analysis of the feasibility of EHR and other health care IT systems to improve health outcomes in Indian Country. Ineffective usability can lead to confusion on the part of the clinician, which could be detrimental to the patient. Challenges associated with usability can result from the design of IT systems, how facilities customize them, unique workflows, user training, and other factors. In terms of usability safety, issues can arise due to confusing interfaces to complete clinical and administrative tasks. Given the more centralized role that EHRs are playing in health care facilities—from ordering procedures to reviewing personal health information (PHI) and retrieving decision support—the burden on each clinician must be addressed.

**EHR Reporting**

Core Strategies
1. Address program reporting and participation burdens by simplifying program requirements and incentivizing new approaches that are both easier and provide better value to clinicians;
2. Leverage health IT functionality to reduce administrative and financial burdens associated with quality and EHR reporting programs;
3. Improve the value and usability of electronic clinical quality measures while decreasing health care provider burden.

**Standardization around IHS clinical intake procedures within EHR to ensure patient safety and seamless delivery of quality health care**

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12 ONC, *Draft Strategy 52.*
The ONC draft identifies a strategy to “promote harmonization surrounding clinical content contained in health IT to reduce burden.”\textsuperscript{14} NIHB has advocated for the standardization of clinical procedures that would reduce wait times to see an emergency department clinician. IHS wait times currently exceed the federally recommended timeframes,\textsuperscript{15} per the U.S. Government Accountability Office’s (GAO) report, “Indian Health Service, Actions Needed to Improve Patient Wait Times” in March of 2016.\textsuperscript{16} Key findings from the GAO Report included IHS’s failure to conduct systematic oversight of the timeliness of primary care provided at its facilities, and the failure to institute standard patient times to account for patient health and hospital flow. Critically, the report found that while some staff measured patient wait times, an aging electronic health record system posed challenges in their ability to share that information. IHS, in turn, launched a Quality Framework that devised strategies to improve the delivery of quality care at IHS facilities and to improve patient safety. Framework objectives include “improving patient wait times for appointments, cycle time during appointments, and emergency department wait times, by reviewing and leveraging best practices from service units and the health care industry.” NIHB and Tribal stakeholders have long known that a lack of standardized procedures is a danger to patients and a burden for well-meaning clinicians. Per the Draft Strategy, NIHB acknowledges that Health IT system revisions must design quality measures that are applicable to individual clinical workflows and to patient care, and at the same time not burden clinicians.\textsuperscript{17}

\textit{Quality Reporting}

In Indian Country, rural hospitals, rural health clinics and other rural providers often face shortages of health care providers, including support staff and IT staff. Therefore, within the Indian health system, clinicians should be spending their time providing patient care and not inundated with satisfying reporting requirements. The Quality Payment Program (QPP) was established under the Medicare Access and Children’s Health Insurance Program Reauthorization Act of 2015 (MACRA) which paves the way to quality care through the Merit-Based Incentive Payment System (MIPS) and advanced Alternative Payment Models (APMs).\textsuperscript{18} The Tribal and Urban Indian health providers appreciate and share these goals, but this is problematic with respect to the I/T/U system for several reasons. First, there are significant compliance costs, and the program is designed to incentivize compliance by penalizing providers that do not meet certain benchmarks through a reduction in reimbursements; however, the Indian health care system as a whole is chronically underfunded, at about 59\% of need, and overburdened and, as a result, often unable to meet those benchmarks. The I/T/U systems often lack the resources or manpower to make needed reforms and upgrades, or to meet reporting and technology requirements. Further, Indian health programs are frequently forced to prioritize limited funding, resulting in a lack of resources for preventive care and other measures that would be expected to improve outcomes and maximize efficiency.

\textsuperscript{14} ONC, \textit{Draft Strategy} 55 (standardize prescription drug information, lab or other procedure orders, and clinical results to avoid burden).
\textsuperscript{15} AHS-2030-09.
\textsuperscript{17} See ONC, \textit{Draft Strategy} 13.
\textsuperscript{18} Indian Health Service, Quality Payment Program, \url{https://www.ihs.gov/qpp/}.
The movement towards value-based care and alternative payment models has created an even greater imperative for health information exchange and interoperability. With that in mind, perhaps ONC can adopt a “collect once, share many” policy and collaborate with other federal agencies to avoid instances where clinicians must report similar measures across a number of different programs. In 2016, NIHB recommended that providers have the flexibility to choose which Clinical Quality Measure (CQM) standard they report based on the scenario they chose to attest to, to demonstrate MU.19 We reiterate that recommendation today.

Financial Burdens

As mentioned previously, the I/T/U system is a woefully underfunded system. Therefore, the cost of compliance poses significant financial burdens on the I/T/U system. The Indian health system already faces a critical resource gap and many facilities across the I/T/U system have had longstanding vacancies, which includes support staff and IT staff. Leveraging Health IT functionality is a way to alleviate these issues in order to avert any duplicative and time consuming reporting requirements for Tribes.

Public Health Reporting

Core Strategies

1. Increase adoption of electronic prescribing of controlled substances (EPCS) and retrieval of medication history from state PDMP through improved integration of health IT into provider workflow;
2. Inventory reporting requirements for federal health care and public health programs that rely on EHR data to reduce collection and reporting burden on clinicians. Focus on harmonizing requirements across federally funded programs that impact a critical mass of health care providers.

An AI/AN individual’s health records may be housed in multiple locations across the I/T/U system – thus interoperability is highly important for patient care of AI/ANs. Any federal-state partnerships to improve interoperability must also include Tribal and Indian Health Service EHR systems into any future assessments or decision-making. Precedent has shown that the strongest partnerships are those with dedicated engagement of the Tribes and their respective Tribal organizations through the meaningful consultation process. Meaningful consultation with Tribes is an effective way for both states and the federal agencies to strengthen their understanding of the unique health needs of Tribal communities, including needs for the development of public health infrastructure. Sustainable public health infrastructure specifically for Tribes and Tribal Organizations ensures that AI/AN communities have the resources they need to promote and achieve optimal health. Public health shortages contribute to lower health outcomes and higher health care costs within Tribal and IHS systems.

Many Tribal health systems lack the necessary resources to implement public health programs and policies that lead to higher rates of disease prevention and create stronger, healthier communities. Specifically, many Tribes are still building their capabilities to: conduct robust disease surveillance and tracking of disease morbidity and mortality; develop, implement, and evaluate public health programs; expand health services to cover preventative care such as screening, testing, and health education initiatives; investigate and respond to environmental health hazards such as lead poisoning, air quality concerns, and water safety issues; and, implement and strengthen natural disaster and disease preparedness measures.

Tribes also require technical and capacity building assistance to comply with the demands of running complex health care delivery systems such as the adoption of electronic prescribing of controlled substances at Tribal and IHS health care facilities. In many instances, there is a lack of broadband access and limited EHR interoperability can impede the uptake of electronic prescribing in these Tribal communities which are experiencing devastating consequences of the opioid crisis.

If HHS continues to work towards harmonizing reporting requirements across federally funded programs by requiring the same or similar EHR data from health care providers, special considerations or accommodations for Tribal health care delivery systems will be necessary. Separate reporting standards may need to be established for Tribal health systems, as they do not operate under the same structure as state or federal systems. Currently, reporting systems are lengthy and burdensome. Some Tribes have provided an estimate to NIHB, a burden of 45 minutes per patient to comply with reporting requirements – this takes away from their ability to provide patient care. The current Public Health reporting requirements are highly challenging for many Tribes, given their limited staffing conditions so any type of administrative burden is immediately impacting both the provider and patient.

Systematic improvements are also needed in Public Health reporting to improve interoperability and health data access between I/T/U and non-I/T/U EHR systems, and ensure that Public Health surveillance systems and disease registries are matching their records with IHS registries. By strengthening interoperability between these systems, the quality of public health data would fundamentally increase. Regarding mortality data, which is the backbone of public health, registry matching could help reduce rates of racial misclassification. Too often, racial misclassifications have resulted in the underestimation of mortality and other health disparities among AI/ANs.

Also, many Tribes that are working to comply with reporting requirements are under deep financial constraints to fund their already underfunded systems. Tribes have remained behind States and other localities in their ability to establish foundational public health capabilities, as a result of being largely left behind during the nation’s development of its public health infrastructure. Additionally, chronic underfunding of the Indian health system forces many Tribes to focus limited resources on immediate health risks as opposed to investing in upstream and preventative health services. Tribes do not receive contract support costs (CSCs) for grants from federal agencies like SAMHSA and CDC that require reporting public health data. And for some eligible grantees, the reporting and administrative burdens are too great for eligible applicants to apply for public health funding.
Any additional guidance provided by HHS about HIPAA privacy requirements and federal confidentiality requirements governing substance use disorder health information in order to better facilitate electronic exchange of health information for patient care should also consider how such changes will be implemented throughout the Indian health system. It is important that input from IHS, Tribes and Tribal Epidemiology Centers (TECs) is included. According to many TECs, behavioral health data is partitioned off within the IHS National Data Warehouse and is not included within the Epi DataMart. This means TECs cannot access anonymized, disaggregated data for analysis of population-level data trends. Although TECs are classified as public health authorities under the legislative authority of the Indian Health Care Improvement Act (IHCIA), many TECs face significant barriers in accessing Public Health data from state or local health departments who often erroneously cite HIPAA laws when refusing to share data with TECs.

**Conclusion**

As NIHB has previously stated, NIHB believes the future of improved health status for our American Indian/Alaska Native populations is reliant on advances in health care delivery made possible through information technology advancement. The ONC Draft Strategy must promote policies and programs that reduce the regulatory burden on Tribes to record and report health care information. The final strategy should identify mechanisms to: promote interoperability between HHS and I/T/U IT systems; prevent duplicate reporting from Tribes across multiple health care interfaces; improve broadband access on the reservations. The final strategy must contain a plan to create infrastructure for the Tribal health reporting systems and not neglect Tribal challenges in obtaining funding. Ample funding must be awarded to Tribes to enhance Tribal health care reporting systems.

Tribes must also play a role as key partners in enhancing Tribal health reporting systems and merit being at the forefront of technological developments through this ONC Strategy. NIHB appreciates the opportunity to consult on the ONC Draft Strategy. We are prepared to provide technical assistance and answer any questions that you may have. We look forward to ongoing discussions. Please contact NIHB’s Director of Policy, Devin Delrow, at ddelrow@nihb.org or at 202-507-4072 for any questions.

Sincerely,

Victoria Kitcheyan, Acting Chairperson National Indian Health Board