

Submitted via Regulations.gov

June 3, 2019

Ms. Seema Verma
Administrator, Centers for Medicare &
Medicaid Services
U.S. Department of Health and Human
Services
P.O. Box 8016
Baltimore, MD 21244-8016
ATTN: CMS-9115-P

Don Rucker, M.D.
National Coordinator for Health Information
Technology
U.S. Department of Health and Human
Services, Mary E. Switzer Building
330 C. Street SW
Washington, DC 20201
ATTN: 21st Century Cures Act:
Interoperability, Information Blocking, and
the ONC Health IT Certification Program
Proposed Rule

RE: Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanges and Health Care Providers

Dear Administrator Verma and Dr. Rucker:

On behalf of the Tribal Technical Advisory Group (“TTAG”) to the Centers for Medicare and Medicaid Services (“CMS” or “the agency”), I write to respond to the proposed rule issued by CMS on March 4, 2019, regarding its joint efforts with the Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) to promote interoperability across the health care continuum. The TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children’s Health Insurance Program, and any other health care programs funded (in whole or part) by CMS. In particular, TTAG focuses on providing policy advice to CMS regarding improving the availability of health care services to American Indians and Alaska Natives (“AI/ANs”) under these federal health care programs, including through providers operating under the health programs of the Indian Health Service (IHS), Tribes, Tribal organizations, and Urban Indian organizations (I/T/Us or Indian health care providers).

Together with the ONC, CMS has issued broad proposed regulations for establishing a nationwide system to improve patient access to health care data, pursuant to section 4001 of the 21st Century Cures Act (Cures Act), Public Law 114-255. The 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.”¹

The National Indian Health Board (NIHB)² previously submitted comments on the ONC’s *Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and Electronic Health Records*.³ The TTAG is disappointed that, despite receiving comments and recommendations from NIHB and Indian Health Service (IHS) Area Tribal health organizations,⁴ neither the CMS nor ONC proposed rules or RFIs acknowledge the potential Tribal impact, or mention Executive Order (E.O.) 13175, which includes specific requirements and provisions for federal agencies to follow in order to meaningfully consult with Tribes on agency actions that have Tribal impact.

Background—Tribal Health Care System

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 (IHCA).⁵ In the IHCA, 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.”⁶ Title V of the IHCA 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 IHS,

¹ ONC, *Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* (Nov. 2018).

² 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. NIHB advises the TTAG through the Medicare, Medicaid and Health Reform Policy Committee (MMPC).

³ National Indian Health Board (Jan. 28, 2019), <https://www.nihb.org/tribalhealthreform/wp-content/uploads/2019/01/NIHB-ONC-HIT-Draft-Strategy-Comment-Letter.pdf>.

⁴ See Alaska Native Tribal Health Consortium (Jan. 28, 2019), https://www.healthit.gov/sites/default/files/webform/reducing_burden_report/anthc-comments-onc-reg_adm_burden---1-28-2019.pdf.

⁵ 25 U.S.C. § 1601 et seq.

⁶ Id. § 1601(1).

thereby empowering Tribes to design and operate health programs that are responsive to community needs. Together, this complex health care system makes up the “I/T/U” 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.⁷ 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.⁸ IHS’s EHR system met 2014 certification requirements set by CMS and ONC, which established standards and other criteria for structured data that EHRs must use. However, IHS will not meet the 2015 certification requirements by the end of Fiscal Year (FY) 2019.⁹ This is just one challenge facing Tribes with respect to the adoption of systems that are capable of advancing the HIT interoperability goals of CMS and ONC.

In addition, IHS faces a uniquely challenging situation because the Veterans Health Administration (VHA) is also in the midst of transitioning to a Commercial Off-the-Shelf (COTS) system that it is acquiring from Cerner Government Services, Inc. (Cerner) under the Electronic Health Record Modernization (EHRM) program. This is problematic because RPMS is based on the current VA Vista architecture. If the VA moves away from Vista, it is not very likely that RPMS will be able to continue to be maintained and updated going forward. As a result, RPMS faces an uncertain future since many Tribes are moving towards COTS-EHRs and the VA’s move to Cerner.

In 2017, the IHS issued a Request for Information (RFI) in an effort to improve interoperability between its EHR and Cerner, as well as the Epic and the eClinicalWorks commercial systems.¹⁰ At that time, IHS reported its inability to adopt a one-size-fits-all commercial system because of the diversity of its facilities. Today, it is still the case that the decentralized nature of the IHS EHR system inhibits efforts to streamline health data exchange between RPMS and other systems. In its RFI, IHS stated, “The challenge of both intra and interoperability becomes enhanced given diversity and individuality of the instances, as well as rising operations and maintenance (O&M) costs that result from ‘one-off’ instantiations and lack of standardized configuration management.”

⁷ 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”).

⁸ 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 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.

⁹ IHS, Dear Tribal Leader Letter (Nov. 19, 2018), https://www.ihs.gov/newsroom/includes/themes/responsive2017/display_objects/documents/2018_Letters/DT_LL_DUIOLL_RPMSCertification_11192018.pdf.

¹⁰ EHR intelligence, Indian Health Service Requests Information for EHR Modernization (Dec. 26, 2017), <https://ehrintelligence.com/news/indian-health-service-requests-information-for-ehr-modernization>.

Although this statement supports and aligns with CMS and ONC’s broad goal to standardize the usability of Health IT, Tribes’ challenges go beyond promoting and achieving interoperability.

Ongoing: Health Information Technology Modernization Research Project¹¹

Tribes have cited the following reasons for converting to an EHR system: gaining additional functionality, access to more EHR interfaces once a transition to EHR has been completed, more efficient care management and referral management, an improved billing system—depending on the EHR system, increase of ability to report to different funding streams, and greater connectivity to local health care providers. Some Tribes reported success, such as the ability to bill more in an EHR system, as compared to RPMS, allowing monthly statements to go out and accounts receivable to be manageable.¹² Such variation is characteristic of the I/T/U and for each Tribe, success depends on services offered and capacity of electronic health systems.

A project that the IHS is undertaking to evaluate its EHR needs—the ability to “create seamless data linkages” as well as “align with universal patient record systems to link off-reservation care systems that serve American Indians and Alaska Natives”—is the Health Information Technology Modernization Research Project.¹³ According to IHS, the project, which began in October 2018 and is set to conclude in September 2019, will produce a report to provide recommendations for how IHS can streamline its HIT infrastructure, applications, and capabilities. Tribes have participated in almost a dozen site visits, and eagerly await the results of the modernization project report. Preliminary findings as of May 2019, demonstrate that the IHS health IT system involves a complex ecosystem of human interactions, workflows, and systems of practice in a clinical environment unique to the 400 sites that constitute the Indian health system.¹⁴ The findings also show that IHS patients require access to their health information, the ability to share these records with their providers, and the tools to understand how this information can be used enable to patients and their families to participate in their own health care.

Consistent Challenges for Tribes

While the Modernization Project’s report will provide a basis for understanding the capabilities of Tribal technological infrastructure, it will not speak directly to many of the proposed requirements in the CMS/ONC rules.

¹¹ President’s budget has \$25M to fund new Indian Health Service EHR, <https://www.healthdatamanagement.com/news/presidents-budget-has-25m-to-fund-new-indian-health-service-ehr>.

¹² In 2012, Cherokee Indian Hospital Authority (CIHA) used an electronic health record (EHR), population management system (PMS), and health information exchange (HIE) to provide care for members of the Eastern Band of Cherokee Nation. According to a study, Cherokee supplemented their base EHR with various interfaces to gain additional functionality, such as access to electronic lab reporting, an electronic oral health record, and a digital imaging system. *See* Cherokee Indian Hospital Authority – Leveraging health IT to provide quality care (June 2012), https://www.healthit.gov/sites/default/files/pdf/CIHA_CaseStudyReport.pdf.

¹³ IHS, HHS OCTO Indian Health Service Health Information Technology Modernization Initiative (IHS HIT MOD), <https://www.ihs.gov/hit/>.

¹⁴ IHS Blog, HHS IHS Health IT Modernization of Electronic Health Records Focuses on Patient Needs (May 23, 2019), <https://www.ihs.gov/newsroom/ihs-blog/may2019/hhs-ihs-health-it-modernization-of-electronic-health-records-focuses-on-patient-needs/>.

Provider Burden

Tribes request that the agency create guidelines or best practices that include Tribes in developing regulations on the use of EHRs to improve receipt and information exchange of health care data. Interest groups have expressed concerns that it is unclear how a sending provider knows who is connected via a Health Information Exchange.¹⁵ Specifically,

“While we are in strong favor of phasing out faxing, the reality is that most clinicians still rely very heavily on the fax machine. Moving beyond faxing requires removal of systemic barriers. For example, *our rural members report that the Indian Health Services still relies heavily on faxing, which has indirect implications for the providers that must comply with CMS’ rule.* One member noted that their facility is the only tertiary facility in town. Additionally, while their facility has an EHR from large, well-known vendors, they still experience challenges receiving notices about their patients.”¹⁶

Funding

The IHS RPMS EHR system is failing to keep up with the private sector. Tribes do not want investment in HIT improvements to come at the expense of direct care for patients. Unless adequate funding is received, I/T/U facilities will need to request hardship exceptions or extraordinary circumstance exceptions depending on the various quality programs they participate in and report. The IHS has acknowledged that strengthening management of IT means partnering with Tribes. There is a recommendation from the IHS Tribal Budget Formulation Workgroup for the administration to include an Electronic Health Record (EHR) line item in the FY 2021 IHS proposed budget, which will provide an opportunity for the agency to take part in a more direct conversation with Congress on funding Health IT (HIT).¹⁷ An appropriated proposal will go to support HIT and additional resources to conduct planning for an EHR transition. No final purchase decisions have been made, although future requests will include infrastructure, best practices, and supporting the HHS modernization project.¹⁸

Access to broadband and technology

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%.¹⁹ Moreover,

¹⁵ See American Association of Neurologists, <https://healthitsecurity.com/news/aan-tells-cms-interoperability-plan-needs-third-party-app-framework>.

¹⁶ CHIME, <https://chimecentral.org/wp-content/uploads/2019/05/CHIME-letter-to-CMS-and-ONC-on-interop-FINAL.pdf>.

¹⁷ The National Tribal Budget Formulation Workgroup’s Recommendations on the Indian Health Service Fiscal Year 2021 Budget (Apr. 2019), https://www.nihb.org/docs/04242019/307871_NIHB%20IHS%20Budget%20Book_WEB.PDF.

¹⁸ Review of IHS/ISAC meeting (2019).

¹⁹ Federal Communications Commission, 2016 Broadband Progress Report 72-73 (Jan. 29, 2016), <https://docs.fcc.gov/public/attachments/FCC-16-6A1.pdf>.

approximately 75% of IHS sites are located in areas defined by the FCC as “rural.” Lack of reliable Internet access can hinder a Tribe’s ability to access medical portals or electronic health records (EHRs). Thirty-nine percent of rural areas lack reliable access to broadband technologies, hampering the ability of physicians to utilize technology to improve access to care and limiting the use of EHRs. Lack of Internet service can also stifle health literacy and prevent patients from utilizing mobile health technologies, such as applications that support healthy behaviors. A 2012 survey showed that 21% of uninsured persons do not use the Internet, those who are likely to lack health insurance are also likely to not be online, and 59% of uninsured persons did not report seeking health information online. In addition, there is an association between health literacy (the ability to understand basic health care information and use it to make health care decisions) and Internet access and use.²⁰

The vast majority of IHS and Tribal health programs are rural, making access to important Telehealth technologies very important. Yet, many of these sites do not have enough network bandwidth to fully utilize these services.²¹

Tribal Implications of the Proposed Rules

Centers for Medicare and Medicaid Services

In the proposed rule, CMS has identified multiple barriers to interoperability:

1. Lack of a unique patient identifier (UPI). CMS seeks comment on how it can leverage its program authority to provide support to health centers working to improve patient matching.
2. Lack of standardization. Similar to its Blue Button 2.0 approach for Medicare Fee-for-Service (FFS), CMS proposes to require that all Medicare Advantage (MA) organizations, Medicaid managed care plans, CHIP managed care entities, Medicaid state agencies, CHIP agencies that operate FFS systems, and issuers of QHPs in the FFEs, deploy standardized, open APIs to make certain information available to enrollees.
3. Information Blocking. CMS proposes to publicly report the names of clinicians and hospitals who submit a “no” response attestation statements issued by the agency to deter health care providers from engaging in conduct that could be considered information blocking.
4. Lack of Adoption/Use of Certified Health IT among Post-Acute Care (PAC) Providers. CMS has adopted patient assessment data elements as standardized patient or resident assessment data and mapped them to appropriate health IT standards to enable interoperability.
5. Privacy Concerns and HIPAA.

Tribes are concerned or impacted by: API requirements, Dual Eligible Care Coordination, Conditions of Participation for Specialized Providers (Critical Access Hospitals), and Patient Identification.

²⁰ Hilary Daniel, BS; Sue S. Bornstein, MD; Gregory C. Kane, MD; Addressing Social Determinants to Improve Patient Care and Promote Health Equity: An American College of Physicians Position Paper (Apr. 17, 2018), <https://annals.org/aim/fullarticle/2678505/addressing-social-determinants-improve-patient-care-promote-health-equity-american>.

²¹ See NIHB, Health IT (May 2017), <https://www.nihb.org/docs/09182017/Health%20IT%20One%20pager.pdf>.

Easy access to health information through a mandatory Application Programming Interface

An Application Programming Interface (API) is a set of commands allowing a seamless user experience. The rule notes:

The lack of a sufficiently mature API functionality technical standard has posed a challenge and impediment to advancing interoperability. In 2015, ONC finalized an API functionality certification criterion in the “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications” Final Rule (2015 Edition final rule) (80 FR 62602). However, while a consensus technical standard specific to the API technical functionality was in development, it had not yet matured enough for inclusion in the 2015 Edition final rule, which does not identify a specific standard for API functionality.

Tribes request an exemption to the required use of APIs as this pertains to the Indian Health Service. There are many issues that would impede the proper implementation of the API criterion that ONC is proposing. First, this is problematic for the I/T/U system since the system is funded at less than 50% of the actual need. The Indian health system also lacks the resources, staff and technology requirements to implement the proposed API criterion.

In addition, the IHS Office of Information Technology (OIT) has stated that not all requirements in the current 2015 Edition Base EHR Certification will have been met for the CY’2019 reporting year and that this requirement will prove burdensome. The agency even provided Tribes recommendations to mitigate the impacts of not being certified in a letter from November of 2018. At the day-to-day operational level, the I/T/U system faces long standing vacancies in relation to support staff and IT staff who would play a pivotal role in this proposal. Educating not only IT support staff on API criterion but also on the EHI propriety component to patients in the I/T/U system is a concern.

The broadband infrastructure in Tribal communities cannot support API standardization at this time. The I/T/U system does not currently have the Health IT infrastructure needed to implement such provisions. Tribes already face many obstacles in maintaining current levels of operation, adding additional burdensome administrative and technical requirements will only exacerbate the challenges.

Conditions of Participation (CoPs) for Specialized Providers

NIHB supports CMS’s proposed expansion of requirements for interoperability within the hospital and Critical Access Hospitals (CAHs) CoPs by focusing on electronic patient event notifications.

Patient Identification

The rule requests comments:

for future consideration on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific UPI does not impede the free flow of information. We also seek comment on how we may leverage our program authority to provide support to those working to improve patient matching.

NIHB supports enhancing data collection and quality, including improving patient matching and proactively monitoring data quality. However, NIHB worries that CMS has simplified the process. The College of Healthcare Information Management Executives (CHIME) reports:

Chief Information Officers report that the clinicians they work with report frustrations with locating patient records and a level of awkwardness that prevents them from using querying features. While a clinician can sometimes get a match depending on the patient matching algorithm, given the lack of a national patient ID solution, this continues to present challenges (as detailed under Section IV below). We would also add that while some of these barriers are related to infrastructure and some to being able to properly and securely identify a patient. Taking into account these concerns, we believe that the number of matches to a medical record stemming from a query on an HIE can provide an inaccurate depiction of interoperability and we caution ONC on over-relying on this as a barometer of interoperability.²²

NIHB supports the adoption of patient matching measures that work in a variety of health care settings, to include interoperability with the Indian health care system.

Office of the National Coordinator for Information Technology

What is the purpose of the Rule?

- To Increase competition and innovation by giving patients and their health care provider's safe and secure access to health information, allowing for more choice in care and treatment.
- Reduce burden and advance Interoperability through the use of United States Core Data for Interoperability (USCDI) standard, new API requirements, and EHI export capabilities for the purposes of switching health IT or to provide patients their electronic health information.
- Promote patient access through a provision requiring that patients can electronically access all of their electronic health information at no cost.

Timeline for Implementation of Rule

The rule proposes to implement the information blocking provisions on the day the rule is finalized. This prospect poses concerns for any organization utilizing health information technology since the ONC proposes a number of exceptions that will require modifications to current business models, accounting methods and significant documentation to ensure compliance with ONC's proposed requirements. Tribes recommend that ONC allow Tribal organizations more time to implement the provisions.

²² Letter to ONC from CHIME, RFI Regarding Assessing Interoperability for MACRA (June 3, 2016).

Tribal Data Sovereignty

We kindly remind ONC that Tribes are independent, sovereign nations. Data supports and strengthens Tribal sovereignty and Tribes are finding new and appropriate ways to manage Tribally maintained data. Federally recognized Tribes are thus learning to protect and control Tribal data in ways that are consistent with Tribal values, objectives, and laws. Tribal data includes health IT. A Tribal leader has said, “Tribal data are perhaps the most valuable tools of self-determination because they drive Tribal nation-building by tribes for tribes.”²³

Data governance and security need to be maintained. Contractors may be used to do a specific study in a controlled way that is safe. IT professionals should be enablers, not gate-keepers of data. Perhaps a SQL driven environment is a path. Indian Country is on a journey towards analytics and Tribal Health IT departments desire to work together and towards a mature environment that is ready during modernization.

Updates to the 2015 Edition Certification Criteria

For hospitals or clinicians that participate in any of the various quality or incentive payment programs sponsored by the Centers for Medicare & Medicaid Services (CMS), the 2018 calendar year is the last reporting period for which eligible hospitals, critical access hospitals, and eligible clinicians (also referred to as eligible professionals) can use 2014-certified Health IT to qualify for incentives or avoid payment adjustments associated with these programs.

In regards to the certification criteria and standards specified in the 2015 Edition Health Information Technology (Health IT) published by ONC,²⁴ IHS has already stated that it will not have met all certification requirements to meet the reporting deadline for the 2019 calendar year. In the rule, ONC proposes to adopt a revised 2015 Edition Certification Criteria. Since IHS will not meet the 2015 criteria by the end of FY 2019, IHS cannot now adapt to a completely revised system. Tribes thus request a hardship exemption and extraordinary circumstance exceptions depending on the various quality programs they participate in and report.

Transparency of Price Information

Some Tribes already list the prices of the health services they provide. For example, Tuba City Regional Healthcare Corporation (TCRHCC) publishes its top 25 charges pursuant to AZ state law (HB 2045) from its chargemaster. TCRHCC also posts these charges to comply with the annual

²³Article, http://www.fedbar.org/Resources_1/Federal-Lawyer-Magazine/2018/April/Data-Sovereignty.aspx?FT=.pdf; https://www.healthit.gov/sites/default/files/pdf/CIHA_CaseStudyReport.pdf

²⁴ 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Final Rule, 80 FR 62601, October 16, 2015.

2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Corrections and Clarifications – December 11, 2015.

IPPS rule and Federal law (§1886(d)(4)) of Social Security Act). Alaska Native Medical Center (ANMC) in Anchorage, AK is another I/T/U facility that lists their chargemaster.²⁵

We encourage CMS/ONC to continue the national dialogue on price transparency as many providers struggle with how to effectively improve price transparency with consumers. Many state legislatures and local municipalities have also taken up the concerns about price transparency with consumers. However it is critically important to note that beneficiaries of the Indian health system do not have to pay for care that they receive from IHS, Tribal, and urban Indian health programs. Since IHS and Tribal hospitals do not charge its patients for services it would be extremely difficult for Indian health providers to develop fee for service schedules that private hospitals maintain in the course of their day to day operations.

For these reasons, it would not be appropriate to require Indian health providers to comply with the price transparency requirements discussed above. It would also be very confusing to beneficiaries of the Indian health system to see such information since they are accustomed to not pay for services when they go to an IHS or Tribally-operated hospital. We recommend that the proposed rule exempt Indian health providers from any of the price transparency requirements in this or future rulemakings.

Health IT and Opioid Use Disorder Prevention and Treatment RFI

ONC requests public comment on how their existing program requirements and the proposals in the rule may support use cases related to opioid use disorder (OUD) prevention and treatment.

ONC and SAMHSA previously collaborated on the development of the Consent2Share application that addressed the privacy protections of patients with substance use disorders (SUDS) who are covered under 42 C.F.R. Part 2. In this rule, ONC is proposing to implement a standardized approach to APIs to facilitate the exchange of health information between providers and patients. The proposed criterion at (§ 170.315(g)(10)) is meant to offer additional flexibility and lessen the burden on the exchange of Electronic Health Information (EHI) through APIs. Additionally, ONC also proposes to adopt § 170.315(g)(11) in the updated version of the 2015 Edition certification. This subsection is meant to support data segmentation and consent management through APIs in accordance with the Consent2Share application.

The rule states:

We seek public comment on how the existing 2015 Edition certification criteria as well as proposals within this proposed rule for revised or new criteria support OUD prevention and treatment. Specifically, we seek comment on certification criteria previously adopted in the 2015 Edition that can support clinical priorities, advance interoperability for OUD (including care coordination and the effective use of health IT for the treatment and prevention of OUD). In this proposed rule, we

²⁵ Pricing Transparency at Tuba City Regional Health Care Corporation (TCRHCC), <http://tchealth.org/pdfdownload/Pricing%20Transparency%20at%20TCRHCC.pdf>; Alaska Native Medical Center, Pricing Transparency, <https://anmc.org/pricing-transparency/>.

summarize some of these 2015 Edition certification criteria identified and indicate how they support care coordination, the prevention of OUD and overdose, and the detection of opioid misuse, abuse, and diversion.

The “electronic prescribing” criterion (§ 170.315(b)(3)) provides a way to write and transmit prescription information electronically. This criterion facilitates appropriate opioid prescribing by simplifying the review of prescription information during follow-up visits or transitions to other clinicians, by allowing prescribers to communicate prescription-related messages to pharmacies electronically and by capturing and transmitting medication histories that are shared with PDMPs. In this proposed rule, we propose to update the existing electronic prescribing certification criterion as described in section IV.B.2 of this proposed rule.

We seek comment on how these criteria and what additional 2015 Edition certification criteria may be considered a clinical and interoperability priority for supporting OUD treatment and prevention. We also seek comment on the value of developing a potential future nonbinding informational guide or resource to provide useful information for OUD providers and sites of service related to specific clinical priorities and use cases of focus.

We are proposing new API functionality through the adoption of a new API certification criterion (§ 170.315(g)(10)), which serves to implement the Cures Act requirement to permit health information to be accessed, exchanged, and used from APIs without special effort. This criterion would enable efficient exchange of health information using modern internet technologies and thus enable collaborative, patient-driven, integrated care for individuals recovering from OUD.

As mentioned previously, there is a lack of adequate broadband infrastructure needed to enhance interoperability in the Indian health system. For example, Tribes have previously articulated the challenges associated with the uptake of electronic prescribing of controlled substances which acts as a barrier in addressing the effects of the opioid epidemic. Tribal health providers, especially those involved in care coordination for their patients have difficulty navigating state and federal health information privacy laws and regulations. Tribes have stated that alignment between 42 CFR Part 2 and HIPAA needs to occur in order improve care coordination and the quality of care.

The current opioid epidemic represents one of the most pressing public health crises affecting Tribal communities. While this epidemic is affecting many communities throughout America, it has disproportionately impacted Tribes and has further strained the limited public health and healthcare resources available to Tribes. The federal government must take concrete action to ensure Indian Country has the tools it needs to address opioid abuse and heal Tribal communities. This includes allowing ample time for Tribes and Tribal public health practitioners to respond to ONC’s RFI related to opioid use. Due to the devastation that opioid addiction has caused to many Tribal communities, we respectfully request a separate rulemaking and Tribal consultation on the opioid-related RFI.

Conclusion

As CMS and ONC work to finalize and implement the regulations to promote interoperability of Health IT systems, it is imperative that the ONC consult with Tribes and include specific, meaningful, and achievable goals and indicators specific to increasing Health IT interoperability within Tribal communities. The Tribal I/T/U system and its technology have a broader need that has been discussed from staffing and infrastructure by staff working on the IHS Modernization Project, or even in this letter. Promoting interoperability between Tribal EHRs and non-IHS providers must be addressed from the organizational structure, rather than as a personnel or solely a systems fix. Moreover, a comprehensive federal modernization approach cannot be achieved unless it adequately address the needs of patients and providers dependent on the I/T/U system.

The TTAG and the Tribes stand ready to work with HHS, as well as other engaged federal partners, to build the IT capacity to allow for seamless delivery of treatment and care. Through this letter, we seek to remind the ONC of the unique needs of Tribes promote prevention and advocate for the delivery of high quality treatment and care services to AI/AN peoples.

We thank you for this opportunity to provide our comments on the interoperability proposed rule. We look forward to further engagement with CMS and ONC on leveraging IT resources to raise the health status of all AI/ANs to the highest levels. Should you have any questions regarding the TTAG's comments, or for more information, please contact NIHB's Director of Policy, Devin Delrow, at ddelrow@nihb.org.

Sincerely,

A handwritten signature in black ink that reads "W. Ron Allen". The signature is written in a cursive, flowing style.

W. Ron Allen, Chair
Tribal Technical Advisory Group