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January 28, 2019

Don Rucker, MD
Office of the National Coordinator for
Health Information Technology
U.S. Department of Health and Human Services
330 C St SW, Floor 7
Washington, DC 20201

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

Dear Dr. Rucker:

The Alaska Native Tribal Health Consortium (ANTHC) is a statewide tribal health organization that serves all 229 tribes and more than 173,000 Alaska Native and American Indian (AN/AI) individuals in Alaska. ANTHC and Southcentral Foundation co-manage the Alaska Native Medical Center, the tertiary care hospital for all AN/AIs in Alaska. ANTHC also provides a wide range of statewide public health, community health, environmental health and other programs and services for Alaska Native people and their communities.

On behalf of ANTHC, I am writing to provide our comment and recommendations on the Office of National Coordinator for Health Information Technology's (ONC-HIT) draft "Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs," dated November 2018 (hereinafter referred to as the "Draft Strategy").

General Comments

ANTHC supports and recognizes that Federal regulation is largely intended to ensure that healthcare providers are delivering safe, high-quality care, and indeed that some regulation is necessary. However, in recent years, though, clinical staff -- including doctors, nurses and health information technology staff—have been devoting more time to regulatory and specifically—health information compliance. Some of these rules do not improve care, and all of them raise costs, and redirect resources and clinical staff away from patient care. On this note, ANTHC appreciates the ONC-HIT efforts to streamline and reduce the regulatory and administrative burden associated with using health information technology (HIT).

The Draft Strategy is broken down to four broad sections that provide specific strategies related to each section, which include:

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- (1) Clinical Documentation
- (2) Health IT Usability and the User Experience
- (3) Electronic Health Record (EHR) Reporting
- (4) Public Health Reporting

ANTHC supports the inclusion of the sections, and their corresponding strategies, listed in the report. We provide the following comments and recommendations to the Draft Strategy. We provide these comments generally, and do not break them into the individual sections referenced above because they are crosscutting to several of the sections. We defer to ONC-OIT on how to address this into the Draft Strategy.

Measure Alignment Recommendation

ANTHC supports the goal to reduce the effort and time required to meet regulatory reporting requirements for clinicians, hospitals, and health care organizations. As the Draft Report states, “The current design and administration of these programs may impose burden on clinicians in a variety of ways. For instance, regulatory requirements and timelines are often misaligned across programs and subject to frequent updates, which require significant investments from clinicians to ensure annual compliance. Government requirements are often also poorly aligned with the reporting requirements across many of the federal payer programs in which clinicians may participate, thus, requiring additional work on the part of the health care provider.” The issues associated with this statement have been the experience of ANTHC, as well as many Indian health care providers across the United States.

Since FY 2005, we have requested Indian Health Service (IHS) and Health Resource Services Administration (HRSA) to address coordination/interface issues that arise when an IHS funded tribal clinic is also a HRSA funded community health center. The issue of measure alignment has been requested to both IHS and HRSA on many different occasions.

HRSA funded community health centers are required to submit a Uniform Data Set (UDS) report as a condition of receiving the HRSA grant funds. The UDS is a standardized reporting system that provides consistent information about community health centers. The UDS includes data elements about the number and socio-demographic characteristics of people served; types and quantities of services provided; information about the quality of care provided to patients; cost and efficiency data about the delivery of services, and; sources and amounts of health center income. The Government Performance Results Act (GPRA) and GPRA Modernization Act of 2010 (GPRAMA) require IHS programs to measure and report clinical measures that are in turn reported to Congress.

In addition to IHS and HRSA reporting requirements, Indian health programs operated under the Indian Self-Determination and Education Assistance Act (ISDEAA, Pub. Law 93-638) must also meet other data reporting requirements of state and local health agencies. The data reported to these agencies are used for purposes such as clinical outcomes measurement, performance improvement, financial auditing, or to satisfy the requirements of specific programs and funding mechanisms.

Many of the UDS and GPRA clinical measures and reporting requirements are nearly identical except for slight—but crucial—differences in measurement criteria. For example, there are differences in the numerators and denominators that result from varying age-groupings or the number of medical visits

recorded in a year. This results in different outcomes (e.g. women's health, immunizations, depression screening, etc.) that are reported to Congress by the federal agencies and Tribal health programs. This can be confusing for Congress who may not understand the reasons for the variation in health outcomes and could potentially affect resource allocation for addressing health disparities among AN/AI people. In addition to the UDS and GPRA reporting requirements, other reports for local and state agencies are produced as required to demonstrate the effectiveness of funding provided by these programs like chemical dependency treatment, maternal and child health services, or public health services. In order to mitigate the effect of these varying, and in certain instances duplicative requirements, we provide the following recommendations.

The issues associated with Indian health programs having to report both GPRA measures required by IHS; and UDS measures required by HRSA have persisted for a very long time. Compound this with the reporting of electronic clinical quality measures (eCQMs) using an EHR, one can see that this causes a tremendous regulatory and administrative burden for Indian health providers. These duplicative reporting requirements are taking valuable resources away from patient care that ultimately can affect quality. Unfortunately, Indian health programs have made very little progress to resolve these concerns.

To address these issues experienced by ANTHC, as well as other Indian health care providers, ANTHC recommends that ONC-HIT include strategic activities to address measure alignment within the Indian health system. Unless this is included, HHS, ONC-HIT, and the individual operating divisions are not likely to address these issues and improve the situation for Indian health programs.

Confidentiality of Substance Use Disorder Patient Records

ANTHC and tribal health providers, especially those that coordinate care for individuals and/or address the behavioral and physical health needs of their patients, frequently report difficulty navigating (federal and state) health information privacy laws and regulations. This creates an issue of equal access where individuals with substance use disorder should have the same access to the benefits of increased care coordination as individuals without substance use disorder.

Patients who are in a substance use disorder treatment program have their records protected by confidentiality provisions under 42 Code of Federal Regulations at Part 2 (42 CFR Part 2). The Part 2 records have a higher standard of protection. The higher standards on permissible uses by health care provisions have created barriers that restrict the use of data between healthcare providers who treat the patients. The part 2 regulations were made in an era when electronic health records were virtually nonexistent. In today's environment, hospitals and providers, and their records heavily rely upon electronic health exchanges and electronic health record systems. The health information on those systems are protected by HIPAA and for federal agencies and some tribal entities the data is also protected by certain provisions of the Federal Privacy Act of 1974 pursuant to the Indian Self-Determination And Education Assistance Act, and the Indian Health Care Improvement Act.

The Part 2 regulations must be changed to create alignment with HIPAA. The purposes of the part 2 regulations are to prevent abuse and discrimination of those patients who wish to seek treatment for their substance use disorders. Part 2 regulations restrict the use of the record data and therein lies the tension of improving health treatment and protections of data. In order to effectively treat substance use disorder, the unreasonable prohibitions on the use of Part 2 records should be changed in order to align those access and use provisions with HIPAA standards. Part 2 records should be treated in the same

fashion as other health records under HIPAA, including the permissible uses for the purposes of treatment, payment, and health care operations. Aligning the Part 2 regulations with HIPAA will provide for seamless coordinated and quality of care by a patient's health care providers.

Recently many individuals and entities have recommended that SAMHSA align Part 2 regulations with HIPAA to broaden the allowable sharing of data for purposes of care coordination and patient safety. Toward this end, SAMHSA has made strides in doing so but there are still obstacles, for example, requiring consent forms to be signed for every disclosure that a patient sees a new treating provider whereas under HIPAA and the Federal Privacy Act have permission and routine uses that are flexible. It should be permissible for healthcare providers and entities to share health information for the purposes of treatment, including the patient records from those persons in a substance use treatment program.

The substance use disorder records and treatments should be held to the same level of privacy as all other health records. There is an issue of equal access where individuals with substance use disorder should have the same access to the benefits of increased care coordination as individuals without substance use disorder. More needs to be done to harmonization of Part 2, HIPAA, and HITECH into a single uniform set of standards applicable for all health information, including substance use disorder treatment and payment. HIPAA is sufficient to protect patient privacy and part 2 is no longer necessary. Since Part 2 also predates the development of EHR and HIEs, and there is pressing need to reconsider these law and rules in light of more recent technological and legal developments. It is clear that healthcare entities are have difficulty in complying with both part 2 and HIPAA as it has unintended and undue administrative burden and management issues across the continuum of patient care.

On behalf of ANTHC, I want to thank you for the opportunity to provide our comments and recommendations. We hope you will address our recommendations into the final report. Please do not hesitate to contact me if you should have any questions at (907) 729-1908, or email gmoses@anthc.org.

Sincerely,



Gerald Moses
Vice President, Intergovernmental Affairs