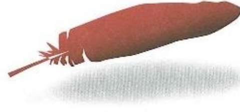
National Indian
Health Board



Submitted via http://www.regulations.gov

May 29, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3310-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3, CMS-3310-P

On behalf of the National Indian Health Board (NIHB), I write to submit comments on the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 proposed rule.

Established in 1972, the NIHB is an inter-Tribal organization that advocated 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 93-638, 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.

Thank you for the opportunity to respond to the Notice. We set out our comments and suggestions below.

I. Background

One of the stated goals of the American Recovery and Reinvestment Act (ARRA), enacted in February 2009, is to increase the "Meaningful Use" of Electronic Health Record (EHR) technology among medical providers.[1] The Centers for Medicare and Medicaid Services (CMS) established an incentive program using ARRA funds to encourage eligible providers and hospitals to adopt and use EHR technology. To achieve Meaningful Use (MU) and receive EHR MU incentives, participating providers and facilities must meet certain criteria established by CMS with the Office of the National Coordinator for Health Information Technology (ONC).

[1] The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA).

The incentives were designed to be released in three stages over several years. Stage 1 MU requirements have been divided into 15 core set objectives and 10 menu set objectives. Stage 2 builds on the requirements of Stage 1, and additionally, focuses on the interoperability and exchange of information between health care settings.

In addition to the incentive program, CMS also has a penalty structure in place for those not meeting MU. These penalties will come in the form of congressionally mandated payment adjustments which will be applied to Medicare eligible professionals who are not meaningful users of Certified Electronic Health Record (EHR) Technology under the Medicare EHR Incentive Programs. These payment adjustments will be applied beginning on January 1, 2015, for Medicare eligible professionals. (Medicaid eligible professionals who can only participate in the Medicaid EHR Incentive Program and do not bill Medicare are not subject to these payment adjustments.)

Payment adjustments are mandated to begin on the first day of the 2015 calendar year, and CMS will apply a prospective determination for payment adjustments. Therefore, Medicare eligible professionals must demonstrate MU prior to the 2015 calendar year in order to avoid the adjustments.

The third and final stage, Stage 3 builds on the first two stages and sets out the requirements that EPs, eligible hospitals, and critical access hospitals (CAHs) must achieve in order to meet MU, qualify for incentive payments and avoid downward payment adjustments. Beginning in 2018, all providers will report on the same definition of MU at the Stage 3 level regardless of their prior participation.

For Stage 3, CMS is proposing to establish a single set of objectives and measures to meet the definition of MU that all providers must report in a calendar year, starting in 2017. In addition, CMS is proposing that beginning in 2017, Medicaid EPs and eligible hospitals demonstrating meaningful use for the first time in the Medicaid EHR Incentive Program, would be required to attest for an EHR reporting period for any continuous 90-day period in the calendar year for purposes of receiving an incentive, as well as avoiding the payment adjustment under the Medicare Program. Finally, the proposed rule describes exceptions for the lack of availability of internet access or barriers to obtain IT infrastructure, a situation found throughout Indian Country.

I. Discussion re: Indian Country

Congress has recognized that "[f]ederal 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."[2] The federal trust responsibility and laws enacted pursuant thereto provide ample authority for the federal agencies of the Executive Department to design, implement and tailor federal programs in a manner that

[2] 25 U.S.C. § 1601(1).

recognizes and supports the unique government to government relationship between sovereign Tribal governments and the United States.

The following discussion of the proposed regulations is given from the viewpoint of the 566 federally recognized Tribes throughout the United States. These Tribes are made up of American Indian/Alaska Natives (AIAN) who reside in some of the most rural locations in Alaska and the lower 48 states. Not only are many Tribes located in rural areas but they are also plagued by high unemployment, extreme poverty, and disparate health outcomes[3].

We agree with many of the provisions of the proposed rule, particularly those that help simplify and align reporting periods (calendar year for EPs and eligible hospitals) as well as the allowance for a 90-day reporting period. We also support the exceptions for the lack of availability of internet access or barriers to obtain IT infrastructure. The rural nature of what is referred to as "Indian Country" not only causes difficulty with IT infrastructure but even the most basic technological needs like access to running water or electricity can be hard to come by.

II. Discussion re: Proposed Regulations, Definitions Across the Medicare Fee-for-Service, Medicare Advantage, and Medicaid Programs

NIHB agrees with the proposal to create a single EHR reporting period aligned to the calendar year. A stated goal of Stage 3 was to realign and simplify the reporting process and we agree this would work with other CMS quality reporting programs such as the Physician Quality Reporting System (PQRS). We further agree that having a single EHR reporting period based on the calendar year allows for a single attestation period.

For Stage 3 of meaningful use, CMS proposes to continue to allow states to specify the means of transmission of the data and otherwise change the public health agency reporting objective. NIHB respectfully requests that IHS, Tribal Health Clinics, Urban Indian Clinics (I/T/Us) be granted the same allowance given the reasons stated above concerning internet access in remote and rural areas. Furthermore, given the government to government relationship enjoyed by federally recognized Tribes the allowance should not be denied nor be up for debate.

NIHB agrees with the proposed rule to eliminate the need for providers to individually report on measures for which providers are already meeting the threshold, otherwise known as "topping out" (care standards that have been widely adopted). This lessens the reporting burden; however, it must be taken into consideration that I/T/Us may not be "topping out" on the most basic measures which if this is the case, calls for flexibility in the way CMS determines if a provider has met MU.

CMS notes that while Stages 1 and 2 allowed the use of paper-based formats for certain objectives and measures, the proposed rule would discontinue this policy for Stage 3. As mentioned before in this comment and will be mentioned again, I/T/Us in Indian Country should be excluded from this proposal due to the lack of internet access for many Tribes.

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[3] Indian Health Service, *Disparities*, http://www.ihs.gov/newsroom/factsheets/disparities/ (last visited May 27, 2015).

Individually identifiable health information protected by the HIPAA Rules is known as "protected health information" and that information in electronic form is known as "electronic protected health information" or "ePHI". The HIPAA Security Rules require covered entities and business associates to conduct a security risk analysis to assess the potential risks to the ePHI they create, receive, maintain, or transmit. The chronic and dramatic underfunding of the Indian Health System makes the comprehensive, continuous technical assistance that is necessary to achieve and sustain MU out of reach for almost all providers and clinics in the Indian Health System. (This picture contrasts with that of many providers in the general population, and certainly those practicing in the medium to large medical systems. Those providers have already demonstrated the ability to access this type of technical assistance.) The fact remains that federal funding is not aligned with federal EHR/MU requirements; the I/T/U system is not well funded; Tribal Shares assigned to the Office of Information Technology (OIT) which are taken by Tribes who desire to use these shares to develop their own systems effectively reduces the support available at the Service Unit, Areas & Headquarters levels. When new technologies are developed by OIT to meet MU by redirecting funding from other agency priorities because there are no dedicated resources assigned to support them, there is no mechanism in place for the Tribes to participate, nor are there Tribal Shares or other funds made available for Tribes to develop something similar. The federal/tribal system is not set up as a business which can upfront costs for IT development which might be recouped later through reimbursements or payments. IHS is dependent on annual appropriations which do not align with costs associated with the new EHR/MU requirements. This is a huge disadvantage for the I/T/U which is already disadvantaged from severe underfunding to meet basic health care needs. Consequently, running security risk analysis is expensive and beyond the financial means of most, if not all, I/T/Us.

Electronic prescribing or "eRx" is one of eight objectives and measures for MU in 2017 and subsequent years. CMS proposes to require EPs to generate and transmit permissible prescriptions electronically and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx). While we agree this may reduce the occurrence of prescription drug-related adverse events and a worthwhile goal, we would maintain that for Indian Country and I/T/Us there are very few, if any, pharmacies within their organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his or her EHR reporting period. This is due to the rural nature of Indian Country and the I/T/Us that operate there. Therefore, a blanket exclusion for all I/T/Us should be granted. The same rationale should be applied in those instances when a hospital issues refills upon discharge for medications the patient was taking when they arrived at the hospital.

Another proposed objective and measure for MU in 2017 concerns Clinical Decision Support (CDS). CDS concerns positive impact on the quality, safety, and efficiency of care delivery. Unfortunately, I/T/Us in Indian Country will have difficulty meeting MU for 2017 if they have to have computerized alerts and reminders for providers and patients; information displays or links; context-aware knowledge retrieval specifications; InfoButtons; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information as the proposed rule suggests. For the aforementioned reasons expressed regarding the lack of electronic

infrastructure, wifi, internet, and adequate hardware, we would ask this objective and measure not apply to I/T/Us and an additional exclusion apply.

The proposed objective and measure regarding Computerized Provider Order Entry (CPOE) is not attainable for the same reasons CDS cannot be attained. Stage 3 requires including diagnostic imaging such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology. Most I/T/Us may have traditional radiology such as x-ray equipment but ultrasound, MRIs, and CT scans are not commonly found in I/T/Us. If they do have the equipment they are more than likely not to have a technician who can operate the machine. NIHB suggests an additional exclusion for Indian Country.

The proposed objective and measure which allows patients to view, download, and transmit their health information to a third party and engage in patient-centered communication for care planning and care coordination plus have timely access to their full health record is a good idea and one that NIHB agrees will result in good health outcomes; however, in Indian Country not only do the I/T/Us not have the necessary tools (wifi, internet, hardware, etc.), but the patients typically have less. Due to financial hardship and poor infrastructure, patients in Indian Country, by and large, cannot meet this objective and measure. An exclusion to the "no paper allowed" doctrine for MU Stage 3 is requested for I/T/Us and patients in Indian Country. Likewise, the application-program interfaces (APIs), which would allow providers to enable new functionalities to support data access and patient exchange must be tempered in light of the previous discussion on electronic needs. Although the API would allow the patient the ability to download or transmit their health information to a third party, Indian Country generally does not have the means or ability to accomplish the download or transmission.

In the Patient Electronic Access to Health Information objective, "provides access" is defined as a situation where the patient has all the tools they need in order to gain access to their health information including any necessary instructions or user identification information. As stated previously, a large number of patients in Indian Country do not have access to the internet or the required hardware. We support the exclusion that states that any clinic located in a county that does not have 50% or more of their housing units with 4Mbps broadband availability and where a significant section of the patient population does not have access to broadband internet. [4]

Regarding the objective entitled "Coordination of Care through Patient Engagement", we reiterate our previous discussion on the lack of infrastructure in Indian Country and agree that counties that do not have 50% or more of its housing units with 4Mbps broadband availability can be found in Indian Country and therefore I/T/Us should be excluded.

The purpose of the objective entitled "Transitions of Care," is to ensure a summary of care record is transmitted or captured electronically and incorporated into the EHR for patients seeking care among different providers in the care continuum, and to encourage reconciliation of health information for the patient. This objective promotes interoperable systems and supports the use of CEHRT to share information. There is still some concern over the summary of care measure based on the current status of health information exchange and the ability to partner

[4] 80 Fed. Reg. 16,754 (March 30, 2015).

with other organizations at this time. A more practical approach would be to allow for a demonstration of the capability of a facility and consider implementation of rates in the future.

We note that the Office of the National Coordinator for Health Information Technology's (ONC) 2015 Edition proposed rule includes a criterion for capturing the unique device identifier for implantable medical devices. Such surgical procedures are not performed by I/T/Us but are referred under the Purchased Referred Care program of the Indian Health Service. Consequently, this objective of the proposed rule has no relevance in Indian Country. The exclusions regarding patient encounters in a county that does not have 50% or more of its housing units with 4mbps broadband availability is relevant and raised as an exclusion for I/T/Us and Indian Country in general.

The last objective, "Public Health and Clinical Data Registry Reporting," focuses on the importance of the ongoing lines of communication that should exist between providers and public health agencies (PHAs) or between providers and clinical data registries (CDRs). There is concern regarding the new requirement on bidirectional immunization exchange. This functionality was not part of the EHR certification experience nor does it have comprehensive ability for the state to participate in this service, and will require additional development for vendors that has not been anticipated in the current year. Regarding the exclusions listed in the discussion for a public health agency that is not capable of receiving electronic syndromic surveillance data, we would reiterate I/T/Us are not capable of sending the required electronic syndromic surveillance data due to the aforementioned lack of infrastructure.

III. Discussion re: Provisions of the Proposed Regulations, Certified EHR Technology (CEHRT) Requirements

We support Secretary in seeking to avoid redundant or duplicative reporting and aligning certain aspects of the reporting clinical quality measures (CQMs) component of MU under the Medicare EHR Incentive Program and Physician Quality Reporting System (PQRS) for EPs. We also support the avoidance of redundant or duplicative reporting of CQM reporting requirements for the Medicare and Medicaid EHR Incentive Program for eligible hospitals and CAHs in the Inpatient Prospective Payment System (IPPS). In addition, NIHB agrees that the CQM reporting period for EPs, eligible hospitals, and CAHs should be on a calendar year and a continuous 90-day reporting period that is the same 90-day period as the EHR Reporting Period.

The attestation exception in certain circumstances where electronic reporting is not feasible, should apply to I/T/Us for 2017 and 2018.[5] The certification issue is outside the control of the providers due to extreme financial need and the inadequate infrastructure. CMS has given states the option of how electronic reporting of CQMs occur. Tribes should be given the same option due to their government to government relationship with the federal government.

Regarding EHR reporting in 2017 and subsequent years, we agree with the proposal that for CQM reporting in 2018 and subsequent years, providers participating in the Medicare program must electronically report, <u>where feasible</u> (emphasis added) and that attestation to CQMs would no longer be an option except in circumstances where electronic reporting <u>is not feasible</u>

[5] *Id.* at 16,770.

(emphasis added).[6] Consequently, for I/T/Us in Indian Country where electronic reporting is not feasible an alternative process must be allowed.

The HITECH Act requires reductions in payments to EPs, eligible hospitals, and CAHs that are not meaningful users of certified EHR technology. The Secretary may on a case-by-case basis exempt an EP who is not a meaningful user for the reporting period if it would result in a significant hardship, such as in the case of an EP who practices in a <u>rural area without sufficient internet access</u> (emphasis added).[7] This exception is subject to an annual renewal and may not be granted for more than 5 years. We contend that given the fact Indian Country health care is underfunded by 56%, I/T/Us should be given a permanent exception to the reporting rules. The hardship exceptions were enumerated in the Stage 2 final rule and Indian Country meets the majority, if not all, of the types of hardships listed. The same rationale stated in the above paragraph applies to the reduced update to the IPPS standardized amount for eligible hospitals and the adjustment for cost periods for CAHs.

We agree with many of the provisions of the proposed rule and support the exceptions detailed above. Thank you for the opportunity to respond to this proposed rule. We look forward to working with you to ensure that these proposed objectives and measures do not harm the delivery of health care services for American Indians and Alaska Natives.

Sincerely,

Lester Secatero, Chair
National Indian Health Board

Cc:

Kitty Marx, Director, CMS Division of Tribal Affairs

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[6] *Id.* at 16,773.
[7] *Id.* at 16,777.