

# National Indian Health Board



*Submitted via <http://www.regulations.gov>*

December 15, 2015

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3310-FC & CMS-3311-FC  
P.O. Box 8013  
Baltimore, MD 21244-8013

**Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program-  
Stage 3, CMS-3310-FC and CMS-3311-FC**

To Whom It May Concern:

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 and Modifications to Meaningful Use.

Established in 1972, the 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 93-638, 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.<sup>1</sup> 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).

---

<sup>1</sup> The HITECH Act (Title IV of Division B of the ARRA, together with the 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 eligible professionals (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.”<sup>2</sup> 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 recognizes and supports the unique government to government relationship between sovereign Tribal governments and the United States.

---

<sup>2</sup> 25 U.S.C § 1601(1).

The following discussion of the proposed regulations is given from the viewpoint of the 567 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.<sup>3</sup>

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: Regulations/Definitions Across the Medicare Fee-for-Service, Medicare Advantage, and Medicaid Programs:**

The EHR Incentive Program Stage 3 final rule is designed to transition the incentive program to a more simplistic and flexible single stage by removing duplicative reporting requirements in order to improve patient outcomes. The third and final rule specifies the requirements that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under the Medicare EHR Incentive Program. The Indian health care system suffers from constant resource shortages, and is currently underfunded at only 59% of need. Therefore, I/T/Us cannot afford to have funds reduced further by potential downward payment adjustments that will begin for the EHR Incentive Program in 2015. There is a need for Tribal consultation for CMS to address the specific needs of I/T/Us with regards to the EHR Incentive Program Stage 3 final rule.

NIHB is supportive of the accepted provision for the Medicare and Medicaid EHR Incentive Programs to create a single electronic health record (EHR) 2015 reporting period to a 90-day period aligned with the calendar year to assist in achieving a stated goal of Stage 3 to realign and simplify the reporting process such as with 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. In addition, this final rule with comment period establishes the requirements for Stage 3 of the program as optional in 2017 and required for all participants beginning in 2018.<sup>4</sup> This will provide Indian Country with more time to implement stage 3.

The Indian Health System stands to benefit from Meaningful Use (MU), if it can achieve the goals to set out in the definition of MU. 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.

---

<sup>3</sup> Indian Health Service, Disparities, <http://www.ihs.gov/newsroom/factsheets/disparities/> (last visited May 27, 2015)

<sup>4</sup> 80 Fed. Reg. 16,770

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 meaningful use.

Tribal commentators have raised serious concerns regarding possible penalties against Indian Health Service, Tribal Health Clinics, and Urban Indian Clinics (I/T/Us) due to the lack of information technology (IT) infrastructure.

The proposed rule for certified electronic health record technology (CEHRT) health information exchange threshold would not allow for the continued use of paper-based formats for certain objectives and measures in Stage 3. As stated earlier, it should not be mandatory for I/T/Us in Indian Country to discontinue the use of paper-based formats, due to the undue hardship as many of their patients do not have internet access.

In the final rule, CMS should exclude I/T/Us and their patients from the “no paper allowed” patient electronic access to health information doctrine for Stage 3 and reconsider requirements on application-program interfaces (APIs) for Indian Country. I/T/Us would have difficulty meeting the proposed objective that, as required by the proposed rule, 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, as well as have timely access to their full health record, as these providers (and their patients) lack the necessary tools.

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 dramatic underfunding of the Indian Health System (IHS) makes the comprehensive, continuous technical assistance that is necessary to achieve and sustain meaningful use out of reach for almost all IHS providers and clinics. CMS should take into consideration in the final rule that most, if not all of I/T/Us cannot afford to run the security analysis as needed to meet the meaningful use requirements in the proposed rule. The majority of I/T/Us will already qualify for the hardship exceptions that have been articulated for the EHR Incentive Program. For the I/T/Us using the Indian Health Service’s Resource and Patient Management System (RPMS) encounter delays in training and technical assistance, which makes it difficult to meet all of the requirements proposed by this rule. 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. Consequently, running security risk analyses are expensive and beyond the financial means of most, if not all, I/T/Us.

The Electronic Prescribing (eRx) serves as one of eight objectives for MU in 2017 and subsequent years, and the proposed rule would require eligible professionals (EPs) to generate and transmit permissible prescriptions electronically and eligible hospitals and critical access hospitals (CAHs) to generate and transmit permissible discharge prescriptions electronically--requirements that I/T/U would have difficulty meeting because of the rural nature of Indian Country; CMS should exclude I/T/Us from these requirements in the final rule. NIHB strongly agrees with the final rule that

responded to these concerns by exempting any eligible provider who has neither a pharmacy within its practice location nor a pharmacy that accepts electronic prescriptions within 10 miles of the provider's practice location from the requirement that 50% of prescriptions be electronic. The alternate CMS measure instead requires such providers to electronically transmit more than 40% of all permissible prescriptions using CEHRT. "Permissible prescriptions" includes all drugs meeting the current Stage 2 definition as well as controlled substances "where feasible and allowed by law." The final rule should include over-the-counter medicines within the definition of permissible prescriptions.

CMS modified Stage 3 patient engagement thresholds by altering the 5% thresholds for patient action measures to instead require that at least one patient electronically access their health information after seeing an eligible provider. Such flexibility will enable providers to promote health literacy among their patients through the implementation of patient-specific culturally appropriate education. Eligible providers are excluded from patient access to electronic health information requirements if the provider is located in a county where at least 50% of residents do not have 4Mbps of broadband availability.<sup>5</sup> This is an important exception to Stage 3 patient engagement measures as a large number of patients in Indian Country do not have ready access to internet services.

Clinical Decision Support (CDS) was constructed to lead to a positive impact on the quality, safety, and efficiency of care delivery. However, NIHB recommends that CMS exclude I/T/Us from the requirements of the CDS. I/T/Us will have difficulty achieving meaningful use if they must have computerized alerts and reminder 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 would require.

CMS did not consider the specific concerns of I/T/Us with regard to implementation of Computerized Provider Order Entry (CPOE). I/T/Us would have difficulty meeting the proposed objective regarding CPOE for Stage 3, as the proposed rule would require including diagnostic imaging--such as ultrasound, magnetic resonance, and computed tomography in addition to traditional radiology. Medical technologies such as these are scarce in Indian Country due to chronic underfunding. I/T/Us should not be penalized for the federal government's failure to uphold its trust responsibility.

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 rural area without sufficient internet access.<sup>6</sup> CMS should grant I/T/Us in Indian Country a permanent exemption as they fall within that category.

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

---

<sup>5</sup> *Id.* at 16,754

<sup>6</sup> *Id.* at 16,777

delivery of health care services for American Indians and Alaska Natives and look forward to meaningful Tribal Consultation as outlined in the CMS Tribal Consultation Policy.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Lester Secatero', with a long horizontal flourish extending to the right.

Lester Secatero, Chair  
National Indian Health Board

Cc:

Kitty Marx, Director, CMS Division of Tribal Affairs