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December 24, 2014

Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, Hubert H. Humphrey Building, Room 445-G 200 Independence Avenue SW Washington, D.C. 20201

RE: Comments on CMS-1612-FC, Revisions to Payment Under Physician Fee Schedule and Other Revisions to Part B for CY 2015

This letter is sent on behalf of the National Indian Health Board (NIHB) to comment on the Notice of Proposed Rulemaking (Notice) issued by CMS concerning the revisions to payment policies under the Physician Fee Schedule (PFS), Clinical Laboratory Fee Schedule (CLFS), access to identifiable data for the Center for Medicare and Medicaid Innovation Models (CMMI) & other revisions to Part B for CY 2015.<sup>1</sup>

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)

<sup>&</sup>lt;sup>1</sup> 79 Fed. Reg. 67,548 (November 13, 2014).

technology among medical providers.<sup>2</sup> 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). 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 Technology (CEHRT) 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.

# II. Providers in the Indian Health System must be made exempt from CMS penalties for non-compliance with MU or be allowed a 90 day attestation period to meet MU in 2015

The current design of both incentives and penalties did not take into consideration the many complexities and challenges embedded in the Indian Health System (IHS). These challenges include the following but are not limited to:

#### • *High Turnover Rate*

In some of the IHS areas, there is more than a 40% turnover rate of providers over a two year period. Having this level of instability in the system makes it very difficult to put in place systems and sustain them rigorously over time.

#### • Provider Shortages

While many health systems have provider and staff shortfalls, IHS experiences staffing shortfalls to a much greater extent. This situation makes it difficult to add time-consuming additional components, like clinical summaries required under MU, to the provider and staff workflow.

<sup>&</sup>lt;sup>2</sup> The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA).

### • Lack of Technology and Equipment

Many of the providers, clinics and hospitals impacted by the CMS requirements do not have the necessary technology or equipment. Commercial Off-the-Shelf EHR systems are extremely expensive and out of reach for many in the Indian Health System (Indian Health Service, Tribal Health Services, and Urban Services – I/T/U) system.

# • Dependence Upon the IHS Resource and Patient Management System

Those using Indian Health Service's EHR system – Resource and Patient Management System (RPMS) – face other, equally formidable challenges. Those using RPMS depend on the IHS to provide updates and the necessary training to comply with the CMS requirements. As happened this past year, IHS sometimes experiences problems or delays which then have the unintended consequence of preventing Tribal providers and clinics from complying with CMS requirements.

### Underfunding

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.

Stage 2 is underfunded; and for Stage 3 there is no funding; 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.

#### • Policy Barriers

Direct Messaging/Secure email is a requirement; however, specifications that were written by ONC or Health Level-7 (HL7) were written for the private sector and did not accommodate working with the federal health systems. It was discovered too late, that federal policy essentially prevented the federal sites (IHS/VA/DOD) from adoption of Direct Messaging (secure email). These existing federal policies restricted authorities of federal agencies from signing on with the certificate authorities, i.e. Direct Trust, in the case of IHS. This conflict of federal policy, which was not an issue with the private sector, has not yet been resolved for IHS,

let alone all the HIPPA and Security agreements that need to be signed off on by the Tribes. The ONC/HL7 required Direct specifications which were not made to interact or align with federal systems such as the IHS/VA/DOD, need to be resolved.

Time and ability to deploy under the current attestation policy requirement is a real barrier. If not exempted, Tribes would like to see the policy changed from 356 days attestation to 90 days in 2015. There is no feasible way the I/T/U can get the full functions of EHR deployed by the end of December, 2014, especially considering the problems with Personal Health Record (PHR) and Direct Messaging. Tribes & Federal sites are at very high risk of not meeting MU if the 365 days is imposed. To get to this point, there have already been huge business process changes, huge policies issues, huge training issues to large and very remote small sites. For deployment, especially to small sites, there is a pressure for time necessary to push these new technologies and processes out to several hundred sites – the current model is good, but deploying with a very short timeframe is unreasonable to meet the requirement to get 5% of patients using the PHR. If providers cannot get new PHR & Direct mail out due to policies not getting fixed, they will not get performance measure in 2015 to have 5 % of patients using PHR for the full year.

For example 2 sites in Alaska are just now going live with the certified 2014 EHR on December 8, 2014, even though it has been certified since August 22, 2014. The time lag to deploy has been a concern for Tribes desiring to meet MU requirements.

The federal government took on a trust responsibility when it made solemn promises to Tribes through treaties. Tribes provided land and delivered peaceful relations, and the federal government made promises of health care, education, and other benefits. The promises of the federal government have been reaffirmed in Supreme Court Cases, Executive Orders, Legislation and regulations. Tribes understandably and correctly demand that the federal government uphold its responsibility to fully deliver the health care promised. Placing penalties on Tribal health dishonors those promises and solemn obligations.

Exemptions will not cause harm to the MU scheme. Exempting I/T/Us from penalties will not result in a degradation of the incentive/penalty scheme. Some I/T/Us will already be exempt from penalties, and the system as a whole provides care to less than 2% of the total, general population. However, penalties will cause great damage to Tribes and AI/AN people. IHS is funded at approximately 56% of its need, with Indian health care receiving the lowest dollar amounts of any of the federally funded health programs. Third party payments to the IHS, Tribal, and Urban clinics and providers have literally been a lifeline to some AI/AN people accessing the system. With penalties of 2% to future projections of up to 5%, the system as a whole takes a tremendous step backwards, with human pain, suffering, and possibly lives, in the balance.

# III. The federal government must make a substantial and sustained investment in Tribal health and the achievement of MU.

The initial investment in assisting IHS providers to achieve MU was very small given the lack of resources, both in technology and technical assistance, in the system. Funding going to the AI/AN Regional Extension Center (REC) had the same requirements of cost sharing as other

RECs despite the gross underfunding of the system as a whole. The complexity of the delivery system, and the steps to achieve coordination and interoperability will require a continued and substantial investment. To achieve MU State 2, the system will be challenged with fostering interoperability between IHS, Tribal facilities, and urban centers. This level of coordination requires more staffing and an improvement in technology that would necessarily include an overlay of technology that will allow systems to speak to each other.

Because each Tribe is a sovereign nation, successful information exchange requires negotiation with each Tribe to ensure Tribal concerns (including HIPAA concerns) are addressed. This will require an investment on the front end, which if done properly, will lead to Tribal buy-in and a successful result, which stands to benefit health delivery, public health surveillance and research. The federal government trust responsibility necessitates this type of investment so that tribes do not fall behind in health delivery and outcomes.

We request a formal review of the level of federal funding needed to address the rapidly emerging digital divide being imposed upon Tribal health systems and to sustain a level playing field for the I/T/U to thrive in a reformed health care delivery environment.

#### IV. Conclusion.

Despite these multi-tiered challenges, the IHS OIT should actually be commended for their ability to meet technical certification requirements for 2014 Certification which was a huge lift for the IHS not dissimilar to what was experienced in private sector. It should be noted, however, this was done at the expense of foregoing other OIT/RPMS development needs and priorities. While purely technical barriers to achieve MU certification requirements at the HQ level were able to be dealt with, the issues have more to do with system-wide technical and workforce capacity deficiencies, federal policy conflicts, and overall lack of sufficient funds necessary to properly deploy the certified 2014 EHR in a timely manner to the hundreds of federal and tribal sites.

For the future, there will be an issue of sustainability if the issue of adequate clinical and technical support is ignored at the Service unit, Area and HQ levels. There has been severe downsizing of staff to perform local ongoing maintenance of lab files, pharm files, medical records files, etc. This is an informatics workforce issue which will need to be addressed in order to support and sustain current investments. Until such time as the technology is developed to move RPMS to a more modernized platform, this level of support must be in place.

Sincerely,

Lester Secatero Chair, NIHB Cc:

Kitty Marx, Director, CMS Division of Tribal Affairs