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June 27, 2016

The Honorable Andy Slavitt Acting Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

RE: Medicare Program: Merit-Based Incentive Payment System and Alternative Payment Model Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P) Comment

Dear Acting Administrator Slavitt:

On behalf of the National Indian Health Board (NIHB), I write to submit comments on the proposed rule, published in the Federal Register on May 9, 2016, entitled "Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models."

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/ANs). 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.

We appreciate the opportunity to submit these comments. We note, however, that the public notice and comment period is not a substitute for Tribal consultation pursuant to the CMS Tribal Consultation Policy and Executive Order 13175. The Federal government's trust responsibility provides the legal justification and moral foundation for Indian specific health policymaking—with the objectives of enhancing their access to health care and overcoming the chronic health status disparities of this segment of the American population. It's important to underscore that when Congress passed the Patient Protection and Affordable Care Act (ACA),

Indian specific provisions were included to honor the federal trust responsibility to provide health care to American Indians and Alaska Natives.

NIHB requests that CMS extend the deadline for Tribal comments on the proposed rule until meaningful Tribal consultation can take place. NIHB also requests that the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG) counsel CMS by providing review of the final rule before it is issued. On November 17, 2015, prior to publication of the proposed rule, the TTAG requested Tribal consultation on the development of MIPS policies and coordination with the IHS in its response to a CMS request for information (CMS 3321-NC). Under the CMS Tribal Consultation Policy, CMS is to consult with Tribes throughout all stages of the process when developing a proposed regulation that would impose substantial compliance costs on Indian Tribes. Moreover, CMS shall:

- Encourage Indian Tribes to develop their own policies to achieve program objectives;
- Where possible, defer to Indian Tribes to establish standards; and,
- In determining whether to establish federal standards, consult with Tribal officials as to the need for federal standards and any alternatives that would limit the scope of federal standards or otherwise preserve the prerogatives and authority of Indian Tribes.²

The proposed rule, which would implement the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), would impose federal standards intended to increase coordination of care and efficiencies in health care. The Tribal and Urban Indian health providers appreciate and share these goals, but the structure of the proposed rule is problematic with respect to the IHS, Tribal, and Urban Indian health programs (I/T/Us), for several reasons. The proposed rule, which will have significant compliance costs, is designed to incentivize compliance by penalizing providers that do not meet certain benchmarks through a reduction in reimbursements; however, the Indian health care system as a whole is chronically underfunded, at about 59% of need³, and overburdened and, as a result, often unable to meet those benchmarks. Our programs often lack the resources or manpower to make needed reforms and upgrades, or to meet reporting and technology requirements. Further, our health programs are frequently forced to prioritize limited funding, resulting in a lack of resources for preventive care and other measures that would be expected to improve outcomes and maximize efficiency, but that require an up-front investment. An incentive system that reduces funding to Tribal and Urban Indian health programs that cannot meet benchmarks due to their lack of resources in the first place makes little sense and will have a negative long-term impact.

Indian health care programs are unique. Unlike other health care providers, Tribal health programs cannot pass increased compliance costs on to their customers. Further, Tribal health programs implement the United States' trust responsibility to provide health care services to

¹ Centers for Medicare & Medicaid Services, Tribal Consultation Policy § 5.7 (Dec. 10, 2015).

² *Id.* at § 5.6.

³ NATIONAL TRIBAL BUDGET FORMULATION WORKGROUP'S RECOMMENDATION ON THE INDIAN HEALTH SERVICE FISCAL YEAR 2017 BUDGET, 8 (2015).

AI/ANs.⁴ The IHS is the primary federal agency tasked with carrying out this responsibility; however, the federal trust responsibility extends to every branch of the federal government and to every Executive Department and agency, including CMS. While NIHB does not question the need for CMS to set global quality of care benchmarks in implementing the MIPS and APM, CMS must not abdicate its trust responsibility by failing to account for the unique needs of the Indian Health system as it finalizes this rule. Unless the rule is modified, the Indian Health System will be unable to meet the benchmarks proposed in the rule and will be penalized for it. The trust responsibility requires more than this. It is inappropriate for an agency of the federal government to penalize an IHS, Tribal, or Urban (I/T/U) health program for its inability to meet efficiency and quality of care benchmarks by withholding resources that could be used to help reach those benchmarks. Rather, the trust responsibility requires that the federal government assist IHS, Tribal, and Urban Indian health programs in meeting the highest standards for efficiency and quality of patient care.

IHS, Tribal, and Urban Indian (I/T/U) health facilities generally bill at an encounter rate negotiated annually between CMS and the IHS (often referred to as the "OMB rate"), which we understand is not impacted by the changes to the physician fee schedule (PFS) proposed in this proposed rule. However, I/T/U providers bill under the Medicare inpatient prospective payment system (IPPS) and will be impacted. More broadly, Medicare and IHS are both important components of our national health care system and the national conversation on health care reform must consider the impact Medicare reform will have on the IHS. As a result, Tribal and Urban Indian involvement in the development of the federal policies underlying this proposed rule is critical.

NIHB has a number of outstanding questions about the proposed rule and how it will impact I/T/U health programs, and have made several requests for in-person consultations with CMS prior to publication of the final rule. We reiterate that request once again, and urge CMS to engage in in-person Tribal consultation prior to publication of a final rule in addition to its consideration of these comments. This consultation process should be initiated as soon as possible, given the short time frame to implement the MIPS as proposed in the rule.

Cost of Compliance and Need for Federal Support

While we recognize the potential value in the proposed rule's reporting, technology, and care coordination requirements, we are concerned that the cost of compliance may be prohibitive for many Tribal and Urban Indian health providers. For example, in its regulatory impact analysis, CMS acknowledges that the cost for implementation and compliance with the Advancing Care Information and Clinical Practice Improvement Activities performance categories could lead to higher operational expenses for MIPS eligible clinicians. The Indian health care system already faces a critical resource gap and many of its facilities have longstanding provider vacancies. Recruiting and retention has always been a challenge for the

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⁴ See, e.g., 25 U.S.C. § 1601 ("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."); The White House, Memorandum for Heads of Executive Departments and Agencies re: Tribal Consultation (Nov. 5, 2009), https://www.whitehouse.gov/the-press-office/memorandum-Tribal-consultation-signed-president.

Indian health care system, and has reached such a crisis in certain areas like the Great Plains that legislation has been proposed in both the Senate and the House that would give the IHS additional authorities to increase provider payments for recruitment and retention purposes.

The Administration should not implement this rule in a manner that exacerbates this problem. In cases where Tribal and Urban Indian health programs lack the resources to implement and comply with the proposed rule, they would be forced to divert funding that would otherwise go toward health care programs and services or the recruitment of additional providers to address existing vacancies. The result could be a decline in access to and quality of patient care unless the programs or providers receive additional support from CMS or other federal sources. Ironically, of course, under the MIPS a decline in quality of care would lead to a reduction in reimbursement rates, leaving impacted Tribal and Urban Indian health programs in an even worse position to address patient needs and improve quality of care.

The federal government's trust responsibility requires it to take affirmative steps to improve the health status of American Indians and Alaska Natives, and not to issue unfunded mandates that have the opposite effect. NIHB therefore poses the following questions: Will there be funding to assist clinicians in I/T/U health facilities, and other health professionals serving AI/AN populations to meet the requirements successfully, particularly in the first year? If not, will the Indian health care system be exempted from these requirements until they receive such funding? How will HHS support I/T/U health programs through technical assistance, funding, and other means to eliminate any negative impacts of the rule on an already overburdened health care system?

Low-Volume Threshold Exclusion

There are many clinicians in the Indian Health System practicing in Tribal and Urban Indian facilities that bill as a Federally Qualified Health Center (FQHC) or a FQHC "look-alike" to Medicare. NIHB supports the proposal that these alternate payment methodologies are not subject to MIPS adjustments, however, we have difficulty reconciling this idea with the low-volume threshold exclusion that is proposed. We believe that many Eligible Clinicians (EC) may bill less than \$10,000 in Medicare allowable charges, if the allowable charges are specific to the Part B Physician Fee Schedule.

First, for those not participating in an ACO, NIHB requests clarification on the \$10,000 threshold – does this include the Rural Health Clinic (RHC) All Inclusive Rates (AIR) or FQHC Prospective Payment System (PPS)? We believe the \$10,000 should only be on Part B PFS allowable charges because these other payment methodologies already are alternatives to fee schedules, which is one of the purposes of the MACRA as we understand it.

If the \$10,000 threshold does not include these other payment methodologies, then we believe we have an unintended situation where Eligible Clinicians (EC) at FQHCs, RHCs, and Tribal clinics may easily meet the \$10,000 threshold part of the exclusion, but still are providing care to more than 100 Part B enrolled Medicare beneficiaries. However, these ECs are likely not in the groups of providers that the exclusion strategy is explained to include. They are not typically MIPS eligible clinicians who are treating relatively few beneficiaries, but engaging in

resource intensive specialties, nor are they those ECs treating many beneficiaries with relatively low-priced services. Providers in Tribal clinics are potentially already participating in a form of alternate payment methodology with their Medicare patients when billing like a FQHC and we believe they should be excluded from MIPS for this reason.

NIHB also requests clarification on the low-volume threshold for providers that change positions frequently or work as locums tenans. Will the low-volume threshold be cumulative for these providers throughout the year as they bill under different TINs, or will the threshold be specific to an NPI/TIN combination? We propose that the low-volume threshold be for a specific TIN in which a provider may work. Locums tenans would potentially have a very difficult time avoiding downward payment adjustments through MIPS unless they are at a practice location for a significant amount of time within the reporting period. We do not want Tribal clinics that historically have difficulty retaining staff due to remote geographic location to be consistently penalized by lower reimbursements because they often use short term providers (who are potentially more likely to be receiving downward payment adjustments) to cover their staffing needs.

Need for IHS/Tribal-specific Data

NIHB also notes that there may be a need for an evaluation period to assess the impact of these reforms on quality of care for AI/AN Medicare beneficiaries. For example, we note that the regulatory impact analysis of the proposed rule states that CMS has estimated the number of physicians and other professionals that will be assigned a CPS score in MIPS Year 1, and the number that will be excluded as QPs. Within this estimate, is there a category for clinicians who serve AI/AN Medicare beneficiaries? If so, we request that CMS share that information with NIHB, TTAG, IHS, Tribes, and Urban Indian programs; if not, we request that this be a subcategory in future studies and estimates so that we can evaluate the number of clinicians serving our beneficiaries that are subject to MIPS and the number that qualify as QPs. Likewise, we suggest that CMS provide a category or function for comparing IHS, Tribal, and Urban Indian providers only on the Physician Compare website. In general, we request that CMS remain cognizant of I/T/U health providers as a distinct category when collecting and reporting data so that data can be utilized most effectively to advance our shared goals of efficiency and quality improvement.

Scoring and Payment Adjustments

The scoring formula and payment adjustment process must account for the unique position of Tribal and Urban Indian health care programs in the national health care system. To that end, it is critical that CMS engage in face-to-face consultation with Indian Tribes and Urban Indian health organizations, so that we can determine how the proposed scoring and payment adjustment system will function with respect to I/T/U health programs.

First, CMS must ensure that the scoring system and weighting of performance categories is fair, particularly in the absence of available data for one or more category. For example, some Tribes have been penalized under the Hospital-Acquired Condition (HAC) Reduction Program due to a faulty formula that involved scores in two weighted domains. That formula calculated

the Domain 2 score based on a Standardized Infection Ratio ("SIR") and required that, in the absence of threshold data for the SIR, only the hospital's Domain 1 score could be used to calculate the total score. In one instance, this scoring methodology resulted in a Tribal hospital being subject to a payment reduction because that hospital had a number of predicted infections below the formula threshold and *zero* instances of actual infection, requiring CMS to base 100% of the Tribal hospital's score on Domain 1. This faulty formula effectively punished the Tribal hospital for reaching its goal of zero infection events during the reporting period—an illogical and unfair result. CMS must ensure that the proposed MIPS scoring system will not have similar flaws, especially if there is to be no administrative or judicial review of this methodology or the determination of the MIPS adjustment factor as stated on page 28,279 of the Federal Register publication.⁵

Second, the scoring system may need special rules for IHS, Tribal, and Urban Indian (I/T/U) health programs in order to avoid adverse results. For example, I/T/U health programs should have their own performance threshold that accounts for the government's responsibility to provide quality health care to AI/ANs and the chronic underfunding of our health care systems, and they should be permitted to utilize existing reporting measures (as discussed below). We believe that Tribal consultation on the scoring methodology with respect to I/T/U health providers specifically is necessary prior to adoption of a final rule.

NIHB seeks clarification and consideration on the proposed sub category of Emergency Preparedness and Response. The proposed rule states that it may measure "...relevant reserve and active duty military MIPS eligible clinician or group activities..." The Indian Health Service Tribal, Urban, and Federal programs often employ officers in the Commissioned Corps of the United States Public Health Service (USPHS). If this sub category moves forward, we request specified language including the USPHS officers in the definition of active duty military MIPS eligible clinicians.

NIHB supports the Advancing Care Information category regarding the meaningful electronic health record (EHR) proposals regarding requirements for the use of certified EHR technology in relation to the selection of objectives and measures under the MIPS advancing care information performance category. This will allow flexibility for providers that had been planning to move towards obtaining 2015 CEHRT as outlined in the 2015 EHR Incentive Programs final rule. We support the concept of group reporting and agree that it will reduce reporting burden. However, we have concerns about the high level of staff turnover experienced in Indian Country and how this may impact the ability to report as a group as well as how to accommodate frequent changes in the group of MIPS Eligible Clinicians.

NIHB supports the Advancing Care Information category reporting requirements method to estimate the proportion of physicians as defined in section 1861(r) who are meaningful EHR users as those physician MIPS eligible clinicians who earn an advancing care information performance category score of at least 75 percent under the proposed scoring methodology for a performance period. We believe that using the other proposed method of defining a meaningful

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⁵ We also agree with other commenters that MIPS eligible clinicians should not be penalized due to data errors outside of their control (see page 28281 of the Federal Register publication).

users as those physician MIPS eligible clinicians who earn an advancing care information performance category score of 50 percent (which would only require the MIPS eligible clinician to earn the advancing care information base score) would result in a much larger number of clinicians meeting this definition and therefore result in the potential reduction of the applicable percentage weight of the advancing care information performance category in the MIPS CPS. We believe this would be detrimental to the goals of increasing patient engagement with health IT and HIE. We believe to drive this adoption forward, the relative importance of increasing performance above the base ACI score is needed.

NIHB disagrees with the Advancing Care Information category removal of the Broadband Access Exclusion as written in the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 Final Rule for the 2 measures that require providers to have broadband access. There are many IHS and Tribal clinics in extremely remote locations that do not have access to broadband and they should not penalized for it.

Utilize Existing Reporting Measures/Systems

As part of the Government Performance and Results Act (GPRA) and the GPRA Modernization Act, the IHS Office of Planning and Evaluation collects and reports clinical performance results annually to HHS and to Congress. The proposed rule provides that quality measures would be selected annually through a call for quality measures process, and that the selection of measures would be based on certain criteria that align with CMS priorities. In selecting those criteria and measures, we ask that you accept the Government Performance Results Act (GPRA) measures that Tribes and Urban Indian health organizations are already required to report, in order to avoid duplication of effort and to lessen the burden on I/T/U health providers. We also ask that when CMS compiles the list of entities qualified to submit data as a QCDR, that CMS accept the IHS RPMS as a qualified entity and that you work with IHS to ensure that the RPMS is capable of meeting MIPS reporting requirements.

IHS/Tribal/Urban Indian Health Programs as Alternative Payment Models

The MACRA and the proposed rule reward participation in APMs. NIHB would like for CMS to explore APMs that are population/provider based, or consider other options for categorizing I/T/U health programs as APMs. As noted below, we have a number of questions about the eligibility of I/T/U health programs for consideration as APMs and believe this topic should be a subject of Tribal consultation prior to adoption of a final rule. We also believe that thresholds should be lowered for APMs targeting eligible clinician populations.

Requests for Clarification

In addition to the general comments outlined above, NIHB requests clarification on the following:

• It appears there may be an error on page 28,204 of the Federal Register publication. In Clinical Topic no. 20, the words Acute Heart Failure are out of place in the UTI episode entry.

- It also appears that the radius reference point for the North Dakota reference on page 28,212 of the Federal Register publication is in error. The radius reference point is listed as 25,000 miles.
- We request further clarification on scoring for eligible clinicians participating in MIPS APMs (discussed at page 28,234 of the Federal Register publication).
- On page 28,228 of the Federal Register publication, under the heading "Request/Accept Patient Care Record Measure," please define what "incorporated" means "where an electronic summary of care record received is incorporated by the clinician into the certified EHR technology."
- What are the decision-making process and criteria when CMS is considering an application for reweighting the Advancing Care Information performance category to zero (as discussed on pages 28,232-28,233 of the Federal Register publication)?
- On page 28,296 of the Federal Register publication, certain specialty codes are listed for reference in determining whether an APM has a primary care focus in order to qualify as a Medical Home Model. Only one specialty code is listed for Nurse Practitioners, however, there are different certifications for Nurse Practitioners. Does this code include all Nurse Practitioners or does this list need to be edited to include codes for Family Nurse Practitioners, Geriatric Nurse Practitioners, Adult Nurse Practitioners, and others?

Miscellaneous Comments

NIHB offers the following additional comments on miscellaneous provisions of the proposed rule:

- On page 28,277 of the Federal Register publication, CMS seeks comments on means to be used to notify or contact MIPS eligible clinicians and groups when their performance feedback is available. We propose utilizing an I/T/U health provider list serve.
- CMS proposes that an entity must retain all data submitted to CMS for MIPS for a minimum of 10 years. In our view, this amount of time is excessive. We recommend using a lesser time period similar to other health record requirements.

Need for Tribal Consultation

Finally, we have a number of outstanding questions about how the proposed rule will impact I/T/U health providers and uphold the federal government's trust responsibility to provide healthcare to AI/AN people. We request meaningful face-to-face consultation in order to gain a better understanding of the proposed rule and provide meaningful feedback before CMS adopts a final rule. While we have many questions and believe a two-way dialogue is necessary, some of our questions include the following:

• How will the proposed rule uniquely impact I/T/U health providers and are there any differences in how the rule would be applied to those providers or in how payments will be determined?

- What if an I/T/U health facility is lacking in their EHR capability to report and produce according to the policy?
- What impacts to the current way I/T/U health facilities are paid by Medicare, whether for inpatient or outpatient services, could we expect with the revisions to the Medicare IPPS structure currently?
- How can I/T/U health programs qualify for payment adjustments under the highest MIPS performance measure?
- How do individual I/T/U health providers qualify as QPs?
- How would I/T/U health facilities be considered with respect to eligibility as an alternative payment entity? What are I/T/U health programs already doing that could help them to qualify as an APM?
- How would the financial risk requirement for APMs impact I/T/U health programs and how could I/T/U health programs meet this requirement? What would those financial risks be for an I/T/U health program? Were the unique relationship of the federal government and Tribes and the federal trust responsibility considered with respect to this requirement?
- What would the benefits be to I/T/U health programs in being considered an APM?
- Can Tribal and Urban Indian providers participate in Medical Home Models as expanded under section 1115A(c) of the Social Security Act?
- How are Medicare providers in I/T/U hospitals impacted by this proposed rule?

NIHB hopes that CMS, in the spirit of its partnership and shared interest in improving American Indian and Alaska Native (AI/AN) access to its resources and services, will work with the Indian Health Service, Tribes, and Urban Indian health care providers to prevent harm to the Indian health care delivery system. Until further Tribal consultation can be conducted and all of our concerns/questions addressed, we respectfully request CMS to delay the finalization of this rule and continue to leave the proposed rulemaking process open. We thank you for this opportunity to provide our comments and recommendations and look forward to further engagement with CMS on this important proposed rule. Please contact NIHB's Director of Federal Relations, Devin Delrow at ddelrow@nihb.org or at (202) 507-4072 if there are any additional questions or comments on the issues addressed in these comments.

Sincerely,

Lester Secatero

Chairman, National Indian Health Board

Cc: Kitty Marx, Director, CMS Division of Tribal Affairs Mary Smith, Principal Deputy Direct, Indian Health Service