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Submitted via: http://www.regulations.gov

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: USET SPF Comments on 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)

Dear Acting Administrator Slavitt,

The United South and Eastern Tribes Sovereignty Protection Fund (USET SPF) is pleased to provide the Centers for Medicare and Medicaid Services (CMS) with the following comments in response to the proposed rule published in the Federal Register on May 9, 2016 entitled "Medicare Program; Merit Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) Inventive Under the Physician Fee Schedule and Criteria for Physician Focused Payment Models." USET SPF regards CMS as a critical element of the federal government's trust responsibility to provide health care services and resources to Tribal Nations. We write to voice several concerns about the proposed rule, as well as seek additional clarification and consultation on the impact the proposed changes to Medicare payments will have on the Indian Health System.

USET SPF is a non-profit, inter-tribal organization representing 26 federally recognized Tribal Nations from Texas across to Florida and up to Maine[1]. Both individually, as well as collectively through USET SPF, our member Tribal Nations work to improve health care services for American Indians. Our member Tribal Nations operate in the Nashville Area of the Indian Health Service (IHS), which contains 36 IHS and Tribal health care facilities. Our citizens receive health care services both directly at IHS facilities, as well as in Tribally-operated facilities operated under contracts with IHS pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), P.L. 93-638.

[1] USET SPF member Tribal Nations include: Alabama-Coushatta Tribe of Texas (TX), Aroostook Band of Micmac Indians (ME), Catawba Indian Nation (SC), Cayuga Nation (NY), Chitimacha Tribe of Louisiana (LA), Coushatta Tribe of Louisiana (LA), Eastern Band of Cherokee Indians (NC), Houlton Band of Maliseet Indians (ME), Jena Band of Choctaw Indians (LA), Mashantucket Pequot Indian Tribe (CT), Mashpee Wampanoag Tribe (MA), Miccosukee Tribe of Indians of Florida (FL), Mississippi Band of Choctaw Indians (MS), Mohegan Tribe of Indians of Connecticut (CT), Narragansett Indian Tribe (RI), Oneida Indian Nation (NY), Passamaquoddy Tribe at Indian Township (ME), Passamaquoddy Tribe at Pleasant Point (ME), Penobscot Indian Nation (ME), Poarch Band of Creek Indians (AL), Saint Regis Mohawk Tribe (NY), Seminole Tribe of Florida (FL), Seneca Nation of Indians (NY), Shinnecock Indian Nation (NY), Tunica-Biloxi Tribe of Louisiana (LA), and the Wampanoag Tribe of Gay Head (Aquinnah) (MA).

Although USET SPF appreciates the opportunity to submit comments on the proposed rule, we are disappointed with the lack of Tribal consultation in the development of the policy. One "All-Tribes" call and the public notice with comment period is not a substitute for Tribal consultation pursuant to the CMS Tribal Consultation Policy and Executive Order 13175. Prior to publication of the proposed rule, the CMS Tribal Technical Advisory Group (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 Tribal Nations throughout all stages of the process when developing a proposed regulation that would impose substantial compliance costs on Tribal Nations.[2] 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.[3]

USET SPF has a number of outstanding questions about the proposed rule and how it will impact IHS and Tribally-operated facilities, and notes that Tribal advocates have made several requests for consultation with CMS prior to publication of the final rule. We reiterate this request, 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 outlined in the proposed rule.

Background

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 spending. Tribally-operated facilities are supportive of increasing coordination of care and extending health care budgets by establishing efficiencies in spending. However, the structure of the proposed rule is incompatible with and over burdensome for the underfunded Indian Health System. 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 System, as a whole, is chronically underfunded and, as a result, often unable to meet those benchmarks. Unlike other health care systems, Indian Health Care Providers (IHCP) cannot pass increased compliance costs on to their customers.

Funded at less than 60% of need, the Indian Health System lacks the necessary resources and manpower to make needed reforms and upgrades, or to meet reporting and technology requirements. Further, Tribally-operated facilities are often forced to prioritize limited funding by rationing medically necessary health services, resulting in a lack of resources for preventive care and other measures that would be expected to improve health outcomes and maximize efficiencies in health care spending. Any CMS payment model which reduces essential resources to the Indian Health System through penalties or any other adjustments in reimbursement will have a long-term negative impact on American Indian/ Alaska Native (AI/AN) patient health outcomes and access to care.

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

[3] *Id*. at § 5.6.

Additionally, IHS and Tribal Nations, operating health programs under ISDEAA, are charged with fulfilling the United States' trust responsibility to provide health care services to AI/ANs.[4] The IHS is the primary federal agency tasked with carrying out this responsibility; however, CMS' role in providing health resources to Tribal Nations is essential to AI/AN patients' access to care. Although USET SPF does not question the need for CMS to set global quality-of-care benchmarks in implementing the MIPS and APMs, the Agency cannot abdicate its trust responsibility by failing to account for the unique needs of the Indian Health System and consult with Tribal Nations as it finalizes this rule. Unless the rule is modified to include additional flexibilities and exclusions, the Indian Health System will be unable to meet the benchmarks proposed in the rule and will be unfairly penalized for this. The trust responsibility requires that the federal government assist IHS and Tribally-operated facilities in meeting the highest standards for efficiency and quality of patient care. We encourage CMS to work with IHS and Tribal Nations to establish alternative, non-punitive avenues to meet these benchmarks.

Cost of Compliance and Need for Federal Support to Uphold Trust Responsibility.

While USET SPF recognizes 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 Tribally-operated facilities and IHCPs. 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 System already faces a critical resource gap and many of its facilities have longstanding provider vacancies. If compliance with these new measures is overly costly or onerous, it will harm IHS and Tribally-operated facilities and create additional barriers to meeting the quality standards MACRA seeks to achieve.

In cases where Tribally-operated facilities lack the resources to implement and comply with the proposed rule, they will be forced to divert funding that would otherwise go toward patient care. The result would likely be a decline in access to and quality of care unless the programs or providers receive additional support from CMS or other federal sources. However, under the MIPS, a decline in quality of care would lead to a reduction in reimbursement rates, leaving impacted Tribally-operated facilities in an even worse position to address patient needs and improve quality of care. The Administration should not implement this rule in a manner that exacerbates this problem.

The federal government's trust responsibility requires it to take affirmative steps to improve the health status of AI/ANs, and not to issue unfunded mandates that have the opposite effect. As recent events reveal, many Areas of the Indian Health System already have major difficulties providing a sufficient level of care to their patients, which can be attributed, at least in large part, to the persistent and severe underfunding of the IHS. In fact, IHS health expenditure per capita for patients is just $3,099, which is approximately 61.7% less than health spending for the total U.S population at $8,097 per capita[5]. In the

[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.

[5] Indian Health Service "Year 2015 Profile" December, 2015.

absence of adequate funding for the Indian Health System as a whole and without MACRA compliance dollars, these deep disparities will be further intensified.

USET SPF, therefore, requests that funding be available to assist clinicians in IHS/Tribally-operated facilities serving AI/AN populations to meet the requirements successfully, particularly in the first year. In the absence of funding, the IHS system should be exempted from these requirements pending receipt of such funding. We recently became aware that there is $100 million dollars in funding available to small practices to assist them in complying with the Quality Payment Program under MACRA. CMS must identify and provide similar funding specifically for IHS and Tribally-operated facilities in order to address the unique needs of the Indian Health System and meet its trust responsibility to Tribal Nations.

Need for IHS/Tribal-specific Data

USET SPF requests an evaluation of how these reforms will impact the quality of care for AI/AN Medicare beneficiaries. 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 Composite Performance Score in MIPS Year 1, and the number that will be excluded as Qualified APM Participants (QP). 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 Tribal advocates. If not, we request that this be a sub-category in future studies and estimates so that IHS and Tribal facilities 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 and Tribal providers only on the Physician Compare website. In general, we request that CMS remain cognizant of IHS and IHCPs 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 doesn't appear to account for the unique funding sources and financing mechanisms in the Indian Health System. It is critical that CMS engage in face-to-face consultation with Tribal Nations, so that we can determine how the proposed scoring and payment adjustment system will function with respect to IHS and Tribally-operated facilities.

IHS and Tribally-operated 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, IHCPs employed by IHS or Tribally-operated facilities who bill under the PFS and the Medicare Inpatient Prospective Payment System (IPPS) will be affected, thus impacting the resources entering the Indian Health System. Medicare and IHS are both important components of our health care delivery system, and consultation regarding health care reform initiatives must consider the impact Medicare reform will have on the IHS. CMS must involve IHS and Tribal Nations in the development of the federal policies underlying this proposed rule.

CMS must also 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 Tribal Nations 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.[6] We believe that Tribal consultation on the scoring methodology with respect to IHCP, specifically, is necessary prior to adoption of a final rule.

Alignment with Existing Reporting Measures/Systems

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. The scoring system may need special rules for IHS and Tribally-operated facilities or recognize existing reporting measures in order to avoid adverse results. In selecting those criteria and measures, we ask that you accept measures that Tribal Nations are already reporting, in order to avoid duplication of effort and to lessen the burden on IHCPs. We also ask that when CMS compiles the list of entities qualified to submit data asQualified Clinical Data Registry Reporting, that CMS accept the IHS Resource and Patient Management System (RPMS) as a qualified entity and that it works with IHS to ensure that the RPMS is capable of meeting MIPS reporting requirements.

IHS/Tribally operated facilities as Alternative Payment Models

The MACRA and the proposed rule reward participation in APMs. We would like for CMS to explore APMs that are population/provider based, or consider other options for categorizing IHS and Tribally-operated facilities as APMs. As noted below, we have a number of questions about the eligibility of IHS and Tribally-operated facilities 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/Miscellaneous Comments

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

- It is unclear if Clinical Decision Support (CDS) objective is being removed. On page 28,220 of the Federal Register publication, CMS noted that the objective would not be required for reporting the Advancing Care Information Performance Category. However, on page 28,227, a CDS Interventions Measure is identified and must be related to high priority health conditions.
- 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 28,232-33 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

[6] We also agree with other commenters that MIPS eligible clinicians should not be penalized due to data errors outside of their control (see page 28,281 of the Federal Register publication).

Model. Only one specialty code is listed for Nurse Practitioner, 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?

- 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 working collaboratively with the IHS and Tribal Nations in identifying what provider list is most accurate for utilization in this section.
- 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 the same time period as other health record requirements.

Need for Tribal Consultation

As stated throughout these comments, the need for true and meaningful Tribal consultation is imperative prior to this rule being finalized. There are many outstanding questions about how the proposed rule will impact the Indian Health System and IHCPs while at the same time, upholding the federal government's trust responsibility to provide healthcare to AI/AN people. USET SPF formally requests a face-to-face consultation session so that Tribal Nations may gain a better understanding of the proposed rule and provide meaningful feedback to CMS. While many of our section specific questions and concerns are identified above, USET Tribal Nations still have a number of additional questions on how MACRA effects the Indian Health System and IHCPs, some of which are outlined below:

- What if an IHS/Tribally-operated facility is lacking in their EHR capability to report and produce according to the policy?
- What impacts to the current way IHS/Tribally-operated 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 IHS/Tribally-operated facilities qualify for payment adjustments under the highest MIPS performance exceptional performance?
- How do individual IHCPs quality as QPs?
- How would IHS/Tribally-operated facilities be considered with respect to eligibility as an alternative payment entity?
- How will CMS help IHS/Tribally-operated facilities identify ways to build on existing quality improvement initiatives that could help them to qualify as an APM?
- How would the financial risk requirement for APM impact IHS/Tribally-operated facilities and how could IHS/Tribally-operated facilities meet this requirement? What would those financial risks be for an IHS/Tribally-operated facilities? Were the unique relationship of the federal government and Tribal Nations including the federal trust responsibility considered with respect to this requirement?

Conclusion

While USET SPF appreciates the opportunity provide proposed feedback on this important policy, we reiterate the need for meaningful Tribal consultation on all policy changes that impact the Indian Health System. The CMS Tribal consultation policy notes that the agency will, "conduct Tribal consultation regarding CMS' policies and actions that have Tribal implications." MACRA and any future CMS health delivery and payment reform initiatives most certainly have a major impact on the way IHS and Tribally-

operated facilities deliver care. We look forward to ongoing dialogue and consultation on ways to ensure CMS policies have the dual focus of working well within the Indian Health System and upholding the federal government's trust responsibility to Tribal Nations.

Should you have any questions or require additional information, please do not hesitate to contact Ms. Liz Malerba, USET SPF Director of Policy and Legislative Affairs, at (202) 624-3550 or by e-mail at lmalerba@usetinc.org.

Sincerely,

Brian Patterson
President

Kitcki A. Carroll
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CC: USET member Tribes
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"Because there is strength in Unity"