Tribal Technical Advisory Group
To the Centers for Medicare & Medicaid Services
c/o National Indian Health Board 910 Pennsylvania Avenue, SE. Washington, DC 20003 (202) 507-4070 (202) 507-4071 fax

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

June 13, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1677-P
P.O. Box 8011
Baltimore, MD. 21244-1850

RE: Medicare Program: Hospital Inpatient Prospective Payment System for Acute Care Hospitals and Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates; Provider Based Status of Indian Health Service and Tribal Facilities and Organizations, etc. Proposed Rule (CMS-1677-P) Comment

Dear Administrator Verma:

On behalf of the Centers for Medicare and Medicaid Services (CMS) Tribal Technical Advisory Group (TTAG), I write to submit comments on the proposed rule with comment period, published in the Federal Register on April 28, 2017, titled “Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices,” (CMS-1677-P) (hereinafter Proposed Rule).

The TTAG advises CMS on Indian health policy issues involving Medicare, Medicaid, the Children’s Health Insurance Program, and any other health care programs funded (in whole or part) by CMS. In particular, TTAG focuses on providing policy advice to CMS regarding improving the availability of health care services to American Indians and Alaska Natives (AI/ANs) under these federal health care programs, including through providers operating under the health programs of the Indian Health Service (IHS), Tribes, Tribal organizations, and Urban Indian organizations (I/T/Us or Indian health care providers). We appreciate the opportunity to submit these comments.

I. Provider-Based Status for Indian Health Service and Tribal Facilities and Organizations

CMS is proposing favorable changes to the provider-based status for Indian Health Service (IHS) and Tribal facilities. The Medicare criteria to be a provider-based facility allows a healthcare entity to be eligible to receive additional Medicare payments for services furnished at the provider-based facility, as well as increased beneficiary coinsurance liability for Medicare beneficiaries.

TTAG appreciates the efforts of CMS to clarify the provider based status of Indian Health Service and Tribal facilities under 42 CFR § 413.65(m). In both the initial regulation finalized in 2000 (68 FR 18507) as well in this proposed rule, CMS has recognized the special and legally recognized relationship between Indian Tribes and the United States Government, the integrated system of care with its foundation in IHS hospitals, and the distinction from private, non-Federal facilities and organizations that serve the general public. Appropriately, CMS developed the provisions of 42 CFR § 413.65(m) under which facilities and organizations operated by the IHS or Tribes meeting the certain criteria would be considered to be "departments of hospitals operated by the IHS or Tribes," and thereby grandfathered from application of the provider-based rules.

Revisions in the Proposed Rule

The proposed rule makes two specific revisions to 42 CFR § 413.65(m). The first is to remove the date limitation in § 413.65(m) that restricted the grandfathering provision to IHS or Tribal facilities and organizations furnishing services on or before April 7, 2000. ***The TTAG agrees with removal of the date limitation.*** The second change in the proposed rule is a technical change to the billing reference in § 413.65(m) by replacing "were billed" with "are billed using the CCN of the main provider and with the consent of the main provider." The intention described in the proposed rule is to make the regulation text more consistent with requirements to comply with all applicable Medicare conditions of participation that apply to the main provider. ***The TTAG also supports this proposed change.***

Further Clarification Recommended in 42 CFR § 413.65(m)

The TTAG recommends specific additional language to further clarify § 413.65(m). In order to qualify to be grandfathered from application of the provider-based rules, an IHS or Tribal facility must meet one of the conditions in § 413.65(m)(1) through (3). These require that facilities and organizations operated by the Indian Health Service or Tribes must either be:

> (1) Owned and operated by the Indian Health Service;
> (2) Owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act (Pub. L. 93-638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes: or
> (3) Owned by the Indian Health Service but leased and operated by the Tribe under the Indian Self-Determination Act (Pub. L. 93-638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes.

The system of hospitals and outpatient facilities is unique to the Indian Health system, and in 1955 became the responsibility of the Indian Health Service. This system was operated

exclusively by the federal government until passage of the Indian Self-Determination Act (ISDA) in 1975 (P.L. 93-638). Congress declared its commitment to the relationship with, and responsibility to, Indian Tribes through "… the establishment of a meaningful Indian self-determination policy which will permit an orderly transition from the Federal domination of programs for, and services to, Indians to effective and meaningful participation by the Indian people in the planning, conduct, and administration of those programs and services." (25 U.S.C. § 450a(b)) With the ISDA, it became the expressed policy of the federal government to support Tribal self-determination.

The ISDA, both authorized and mandated the IHS to transfer operation of programs and services to Tribes and Tribal Organizations pursuant to certain requirements and Tribal request. Over time, the ISDA has been amended by Congress resulting in two mechanisms to transfer programs and services to Tribal operation: a self-determination contract, or a self-governance compact. These agreements are not federal procurement contracts, but are unique to the ISDA. The number of Tribes and Tribal Organizations assuming programs and services from the IHS has steadily grown, and currently approximately one-half of the IHS appropriation is Tribally administered under the ISDA.

One principle of the ISDA is that the amount of funds provided to a Tribe/Tribal Organization entering a contract or compact shall not be less than the "Secretary would have otherwise provided for the operation of the programs or portions thereof for the period covered by the contract, without regard to any organizational level" within the Department of Health and Human Services. (25 U.S.C. § 450j-1(a)(1)) Because the provider-based regulations of CMS determine how Tribal facilities may bill for health services, such status affects the amounts available for operation of the programs that are transferred under a contract or compact. It is clear in the ISDA that Congressional intent was that the same resources available to IHS be also available to Tribes to operate the same programs and services.

The TTAG strongly recommends that the conditions listed in 42 § 413.65(m)(1) through (3) be revised to add an additional condition to include facilities ***owned and operated by a Tribe or Tribal Organization pursuant to a contract or compact under the Indian Self-Determination Act.***

By adding this condition to those listed in § 413.65(m), CMS would ensure that the same provider-based rules that were applied with IHS operation of the program are continued uninterrupted once transferred to Tribal operation.

II. Medicare Part A Payment Reforms

The proposed rule would make certain changes to Medicare Part A payment reforms, including the Hospital Value-based Purchasing Program and the Hospital Inpatient Quality Reporting Program, among others.

Hospital Readmissions Reduction Program

Under the program, payments for discharges from an "applicable hospital" under Section 1886(d) of the Social Security Act are reduced to account for excess levels of hospital readmissions based on a hospital's risk adjusted readmission rate during a 3-year period for certain medical conditions. The proposed period for calculating the FY 2018 readmissions rate is the 3-year period of July 1, 2013 through June 30, 2016. ***TTAG believes that the 3-year time period is too long.*** Hospitals need to use the Hospital Readmission Reduction Rates as data to improve readmissions for their hospitals. ***A 3-year period makes it difficult to work on performance improvement if the data is not reflective of a current period.*** For example, hospitalist and physician turnover is likely during this period making it hard for a hospital to nail down the root cause of the issue. ***TTAG recommends that a one-year period will be better utilized data to a health care system. They can use this data annually and work to implement real change for their hospital.***

Hospital Value-Based Purchasing (VBP) Program

CMS has proposed removing the Patient Safety for Selected Indicators measures 90 (PSI 90) beginning in FY 201Value-Based Purchasing PSI-90 measures for the FY 2019 period due to the difficulty of calculating performance scores with ICD-10 upgrades. ***TTAG supports the removal of the PSI-90 measure.*** PSI-90 measure is a claims-based calculation. ***We also encourage the review of the PSI-90 measure as a whole.*** The data does not provide Tribal hospitals usable data to improve performance. The PSI-90 report has a difficult formula that adjusts itself regardless of measure outcomes. The overall goal for hospitals is to have a score as close to 0 and as far away from 1 as possible. However, a hospital may have no outcomes and have a score close to 1.

Hospital-Acquired Condition (HAC) Reduction

Subsection (d) hospitals under the Social Security Act are required to report data on certain measures in a given fiscal year to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that period. CMS is proposing to refine two previously adopted measures regarding the assessment of ischemic stroke severity and patient communications on pain levels during a hospital stay. ***Although a shorter time period of 1 year is recommended, a 2-year time period is supported. Shortening the time period for this type of data gives hospitals information to make sustainable solutions from.***

Extraordinary Circumstances Exception (ECE) Policy

The proposed rule would update the Extraordinary Circumstances Exception (ECE) policy to streamline the processing of ECE requests under the hospital-acquired condition (HAC) Reduction Program, Hospital inpatient quality reporting (IQR) Program, Hospital Readmissions Reduction Program, as well as other quality reporting and value-based purchasing programs. ECE requests allow a program to be exempted from program reporting requirements due to an extraordinary circumstance not within a provider's control. ***Currently, there is no ECE policy for IHS or Tribally-operated programs, although tribal programs have requested an exception from CMS in previous fiscal years. TTAG would like to request an ECE specifically for IHS and tribal healthcare programs.***

III. Low-Volume Hospital Payment Adjustment

The proposed rule includes changes to the low-volume hospital payment adjustment for IHS and Tribal hospitals in regards to the calculation of the mileage criterion, which requires that a qualifying low-volume hospital be located at least 25 miles from the nearest subsection (d) hospital. For hospitals to qualify, they must be more than 25 road miles away from another hospital and have less than 200 discharges. Conversely, CMS is proposing additional flexibility to IHS and Tribal hospitals and the populations they serve due to their unique nature. For IHS or Tribal hospitals, proximity would be determined solely on proximity to other IHS and tribal hospitals. The mileage for a non-IHS hospital whose sole disqualifier is in proximity to an IHS or tribal hospital would be determined based on the proximity to other non-IHS hospitals. ***TTAG appreciates and supports the CMS recognition of the uniqueness of IHS and Tribal hospitals and support the proposal for increased flexibility.***

IV. Electronic Health Record (EHR) Incentive Programs

CMS is proposing two changes related to electronic clinical quality measure (eCQM) certification requirements: (1) to require reporting from all eCQMs with EHR technology certification; and (2) to note that certified EHR technology does not need to be recertified each time it is updated to a more recent version of the eCQM specifications.

Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the EHR Incentive Programs

CMS is proposing to modify the CY 2017 electronic CQM reporting policies, but not for eligible hospitals (EHs) and Critical Access Hospitals (CAHs) reporting via attestation. ***TTAG appreciates the attempt to align programs and reduce reporting burdens. However, we feel that it also introduces an additional layer of complexity to have different reporting policies based on the method of reporting. One way to avoid this would be to make the same modifications to all CQM reporting (attestation or electronic).***

Overall, for the Medicare and Medicaid EHR Incentive Programs, we also suggest aligning the CQM reporting period with the EHR Performance Measures reporting period to decrease complexity and confusion. Currently, as proposed, the CQM reporting period in 2017 and 2018 differs from the EHR Performance Measure reporting periods in most cases.

TTAG feels there are a number of providers, particularly those who work in underserved and rural areas within the Indian healthcare system who are exempt from MIPS reporting, but are still participating in the Medicaid EHR Incentive Programs. In these situations, CQM reporting periods that do not align with EHR Performance Measure reporting periods is very confusing.

Clinical Quality Measure Reporting Form and Method for the Medicare EHR Incentive Program in 2018

TTAG is in support of the proposal that an EHR certified for CQMs under the 2015 Edition certification criteria would not need to be recertified each time it is updated to a more recent

version of the CQMs. In addition, TTAG would like to request flexibility in the hardship exemption if unable to meet that timeframe in addition to/besides if a certified EHR technology (CEHRT) was decertified. This will relieve some of the burden of meeting certification requirements and make it easier for vendors to deliver the most updated CQM versions.

Changes to the Medicare and Medicaid EHR Incentive Programs

TTAG is in support of the proposal to modify the EHR reporting period in 2018 for new and returning participations to a 90 day period.

Certification Requirements for 2018

TTAG proposes giving the flexibility to use the 2014 Certification Edition, 2015 Certification Edition, or a combination of the two technologies in 2018 for the EHR Incentive Programs. We appreciate the monitoring and tracking that has been done with ONC to assess adoption and implementation of advancing technology, but we do not feel that penalizing those who are struggling is the best way to encourage and facilitate further upgrades to the 2015 certified technology. It seems beneficial to allow those with 2014 Edition technology to continue to report and move forward in 2018 instead of requiring them to sit out of the program until they are able to upgrade to 2015 Edition technology.

V. Accreditation Reporting Requirements for Private Accrediting Organizations

Depending on the type of facility, healthcare entities must demonstrate compliance with conditions of participation (CoPs), conditions for coverage (CfCs), or other conditions of certification to participate in Medicare and Medicaid programs. Healthcare facilities that qualify as "provider entities" under Section 1865 of the Social Security Act—i.e., a healthcare supplier, facility, clinic, agency, laboratory, or provider of services—may also demonstrate compliance with CMS standards through accreditation by a private, national accrediting organization (AO) approved by the Secretary of the Department of Health and Human Services.

The proposed rule would require private AOs to post all final accreditation survey reports and acceptable CoPs for the most recent three years on their company website. According to CMS, the proposal is intended to address concerns regarding disparities in accreditation reports, promote informed patient decision-making processes, and align the public disclosure requirements with those already in place for nursing homes, critical access hospitals (CAHs), and short-term acute care hospitals. ***TTAG requests that CMS consult with IHS, Tribes, and Tribal organizations to create an exemption or modifications for IHS or Tribally-operated facility accreditation reporting standards.***

VI. Request for Information on CMS Flexibilities and Efficiencies

The conditions that must be met for IHS and Tribal facilities to be considered grandfathered from the application of the provider-based rules are found in 42 CFR § 413.65(m), which are the subject of the proposed rule. These conditions are not mirrored in the standard Medicare hospital conditions of participation ("COPs") with which all hospitals generally must comply in order to

retain their Medicare certification. These COPs are set out in 42 C.F.R. Part 482 and are often referred to as "Part 482."

Generally, Part 482 requires integration of the ownership, management, staff and operations between the hospital and the clinic. CMS' recent position has been that IHS or Tribal facilities that wish to qualify for provider-based status and the hospitals with which they associate with must comply with all portions of the Part 482 regulations. But this interpretation renders the grandfather clause in the provider-based status regulations at 42 CFR § 413.65(m) meaningless for some facilities. It is also at odds with the purpose of the regulations.

When CMS first initiated rulemaking on the provider-based regulations in 1998, the proposal did not include any special provisions concerning IHS or Tribal (I/T) facilities. Rather, CMS suggested that all facilities or organizations claiming provider-based status would have to fulfill the same set of proposed provider-based COPs, designed to ensure that any entity seeking provider-based status was an "integral and subordinate part[] of the main provider."[1]

In response, IHS and numerous other parties requested an I/T exception to the provider-based COPs.[2] Commenters pointed out that the requirements of integrated governance between the main and satellite facilities simply would not work in the case of "IHS facilities that are currently operated by Indian tribes under the auspices of Public Law 93–638" or the "[m]any tribes [that] have acquired operations of outpatient facilities and [were] in the process of acquiring the affiliated hospitals." IHS further argued that the provider-based COPs failed to account for "the statutory opportunities for self-determination by the Indian tribes," and ultimately recommended that "the current [I/T] system be 'grandfathered' to meet the definition of provider-based entity."

CMS agreed with these commenters, and ultimately finalized the exception for I/T facilities at 42 CFR § 413.65(m).

This exception for I/T facilities makes sense. The entire purpose of the provider-based COPs is to require near-seamless integration between the ownership, management, staff, and operations of the main and provider-based facilities. But this cannot be achieved when IHS operates the main hospital and a Tribe, under a self-determination contract, operates a clinic, or vice versa. In these cases, the main hospital and the provider-based I/T clinic will have separate governance structures and staffs, and will not be able to demonstrate shared management. Thus, in these situations, the clinic could never satisfy the provider-based COPs. To address this issue, CMS added the grandfather provisions at § 413.65(m) to allow I/T facilities to qualify for provider-based status. To also require these exempted facilities to be closely integrated under the Part 482 regulations in order to qualify for provider-based status would be to effectively read § 413.65(m) completely out of the regulation.

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[1] 1998 Proposed Rule at 47,588. CMS proposed additional requirements for facilities that were not on the same campus as the main provider, operated as a joint venture, sought provider-based status in relation to a hospital, or operated under management contracts. See generally 1998 Proposed Rule at 47,589-94 (codified as amended at 42 C.F.R. § 413.65(e) – (h)).

[2] 2000 Final Rule at 18,507.

However, this apparent contradiction is avoided because outpatient clinics are only required to abide by the main hospital's "applicable Medicare conditions of participation in 42 CFR part 482" in order to qualify for provider-based status.[3] In this provision, CMS did not incorporate Part 482 wholesale, or mandate that hospital outpatient departments comply with "all," "each," or "every" Part 482 requirement: rather, the agency recognized that there would be circumstances in which various provisions of Part 482 might not, for whatever reason, apply to an outpatient department, and so merely mandated that outpatient departments need only comply with the "applicable" provisions of Part 482. Given that CMS did incorporate the entirety of other regulatory provisions as part of the provider-based COPs without using any qualifying language,[4] its decision to only incorporate "applicable" provisions of Part 482 must be seen as deliberate.[5] In the context of I/T facilities, the Part 482 provisions that would inherently prevent an I/T facility from ever achieving provider-based status under the grandfather clause are not "applicable" to a grandfathered I/T.

Similarly, because there is no parallel grandfather exemption in Part 482, we understand CMS has threatened to de-enroll IHS hospitals that are associated with Tribally-operated clinics because they cannot meet the management integration requirements. Despite the fact that there is no similar grandfather clause in Part 482, it is clear that the provider-based exemption for I/T facilities would be meaningless if the associated hospitals did not retain their eligibility to participate in Medicare.

When an agency interprets a regulatory provision in a manner that is inconsistent with the rest of the regulation, such an interpretation must be rejected.[6] ***Accordingly, TTAG requests that CMS recognize that the I/T grandfather clause exempts qualifying facilities from compliance with the management integration requirements of both: (1) the provider-based rules; and, (2) Part 482.*** As long as the grandfather conditions at § 413.65(m) are met, then the I/T facility is by definition considered provider-based in relation to the main hospital, and the hospital may bill CMS for Medicare services without any effect on its Medicare certification. The applicable regulations do not make sense when interpreted in any other manner.

Tribal Grandfather FQHC Status - Annual Cost Report Requirement

One other issue and recommendation regarding CMS flexibilities and efficiencies relates to the implementation of "Grandfathered FQHC" status under Medicare for Tribal clinics. ***TTAG recommends that Tribal Grandfathered FQHCs be excluded from the annual requirement* for *a separate facility cost report given that the cost report is not necessary to set the reimbursement rate.*** Tribal Grandfathered FQHC's are reimbursed under the IHS OMB rate based upon the IHS cost report. Requiring a separate facility cost report is costly for the Tribe and duplicative for the Agency. Rather, only costs that are not included in the calculation of the reimbursement rate such as influenza and pneumococcal vaccines or the costs of Graduate Medical Education need be reported annually on a facility basis.

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[3] 1998 Proposed Rule at 47,588 (currently codified as amended at 42 C.F.R. § 413.65(g)(8) (emphasis added)).
[4] See, e.g. 42 C.F.R. §§ 413.65(e)(3)(v)(A)-(B) and (g)(1), (4).
[5] See, e.g., Keene Corp. v. United States, 508 U.S. 200, 208 (1993) (noting that "where Congress includes particular language in one section of a statute but omits it in another . . . , it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion") (quoting Russello v. United States, 464 U.S. 16, 23 (1983)).
[6] Thomas Jefferson Univ. v. Shalala, 512 US 504, 512 (1994).

Tribal Grandfathered FQHC Status - Date Restriction

TTAG requests that CMS eliminate the date restriction to qualify for Tribal grandfathered FQHC status for the same reasons CMS proposes to eliminate the date restriction for the Tribal provider-based status. Eliminating the date restriction will ensure that --regardless when a Tribal program assumes operation of an IHS clinic that has been provider-based to an IHS hospital -- the clinic will be reimbursed at the same rate as when it was operated directly under IHS; that is, at the OMB rate for most services. This will help ensure a successful transition to tribal operation, and help fulfill ISDA's promise that tribally compacted or contracted programs will receive no less federal financial support than if they had continued under direct IHS operation.

VII. Conclusion

TTAG hopes that CMS, in the spirit of its partnership and shared interest in improving AI/AN access to health care 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. We request that CMS consult with IHS, Tribes, and urban Indian health care programs during the regulatory process. We thank you for this opportunity to provide our comments and recommendations and look forward to further engagement with CMS. Please contact Devin Delrow at ddelrow@TTAG.org or at (202) 507-4072 if there are any additional questions or comments on the issues addressed in these comments.

Sincerely,

W. Ron Allen
Chairman, Tribal Technical Advisory Group

Cc: Kitty Marx, Director, CMS Division of Tribal Affairs