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RE: Medicare Provider-Based Status for Indian Health Service and Indian Tribal Health Program Facilities

1. Introduction.

This Memorandum concerns the regulatory history of the Indian-specific grandfather clause of the Medicare “provider-based” regulations. We provide it in response to your request for an explanation of the legal authority under which Indian Health Service (“IHS”) and Tribal facilities (collectively “I/T facilities”) may retain hospital provider-based status, and the hospital retain its Medicare certification, despite the failure to comply with the requirement that the hospital and clinic be governed by the same body.

The Tribal Technical Advisory Group¹ (“TTAG”) appreciates your participation at our February meeting to discuss this issue, as well as your continued efforts to understand the tribal position and find a workable solution. As we discussed at that meeting, this issue is of primary importance for tribal providers. The federal policy of self-determination is founded on the idea that Tribes and tribal organizations do better at providing services for themselves than the federal government does. This is certainly true for health services. But a tribal organization’s ability to take over these programs is dependent on its ability to collect third-party revenue for services provided. If

¹ The TTAG advises the Centers for Medicare and Medicaid Services on Indian health policy issues involving Medicare, Medicaid, the Children’s Health Insurance Program, and any other health care programs funded (in whole or in part) by CMS. In particular, the TTAG focuses on providing policy advice designed to improve the availability of health care services to American Indians and Alaska Natives under these federal health care programs, including through providers operating under the health programs of the Indian Health Service, Indian Tribes, Tribal organizations, and urban Indian organizations.

a tribal organization loses access to third-party revenues the level of services it can provide is significantly reduced, which may cause these organizations to forego contracting at all. TTAG is therefore anxious to resolve this issue and appreciates this opportunity to provide additional information.

2. Discussion.

2.1 Applicable regulations.

There are two sets of conditions of participation at issue in the provider-based context. The first are the standard Medicare hospital conditions of participation (“COPs”) with which all hospitals generally must comply in order to retain their Medicare certification. These are set out in 42 C.F.R. Part 482 and are often referred to as “Part 482.” The second are the COPs for entities who seek provider-based status in relation to a hospital. These are found at 42 C.F.R. § 413.65. These two sets of COPs are similar and in many places directly overlap.

Importantly for our purposes, these regulations provide rules that govern when a facility will qualify for provider-based status. Generally, Part 482 and the provider-based status regulations require integration of the ownership, management, staff and operations between the hospital and the clinic.²

But the provider-based status COPs also contain a grandfather clause relating specifically to I/T facilities, which exempts I/T facilities from the integration requirements. This provides:

(m) Status of Indian Health Service and Tribal facilities and organizations. Facilities and organizations operated by the Indian Health Service or Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if, on or before April 7, 2000, they furnished only services that were billed as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are:

- (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

² See, e.g., 42 C.F.R. § 413.65(e), (h); 42 C.F.R. § 482.54(a).

regulations and policies of the Indian Health Service in consultation with Tribes.³

2.2 The current dispute.

On January 3, 2014, the Southern Ute Indian Tribe's IHS funded clinic, which had been previously treated as provider-based to the Santa Fe Indian Hospital, was informed that CMS had determined that the IHS's Santa Fe hospital would be out of compliance with Part 482 because the hospital and clinic were not eligible for provider-based status, and thus, at risk of losing its certification, if it continued the arrangement. We understand the reason for CMS's decision is that the IHS hospital and the Southern Ute clinic do not meet the management integration requirements.

The TTAG was surprised at CMS's new interpretation of the provider-based rules: to our knowledge, this is the first time in the eighteen years since CMS first proposed the provider-based program that CMS has taken this position. Further, CMS has previously explicitly allowed this sort of arrangement.⁴

In essence, CMS's new position requires I/T facilities that wish to qualify for provider-based status and the hospitals with which they associate with to comply with all portions of the provider-based status and Part 482 regulations. But this interpretation renders the grandfather clause in the provider-based status regulations meaningless. It is also at odds with the purpose of the regulations. As the regulatory history demonstrates, CMS intended to allow I/T facilities to achieve provider-based status, *despite* not being able to comply with portions of the provider-based status and Part 482 regulations. We elaborate below.

3. Analysis.

3.1 The regulatory history demonstrates that CMS intended to allow I/T facilities to qualify for provider-based status in situations where the integration requirements were not met.

³ 42 C.F.R. § 413.65(m).

⁴ See, e.g., Medicare Program; Prospective Payment System for Hospital Outpatient Services, 63 Fed. Reg. 47,552 (Sept. 8, 1998) (proposing provider-based system) [hereinafter "1998 Proposed Rule"]; Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18,434 (Apr. 7, 2000) (establishing I/T grandfather clause to provider-based rules) [hereinafter "2000 Final Rule"]; Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2003 Rates, 67 Fed. Reg. 49,982 (Aug. 1, 2002) (amending provider-based rules and explicitly keeping I/T grandfather clause intact) [hereinafter "2002 Final Rule"].

CMS first initiated the provider-based rulemaking process in 1998.⁵ Although there have been subsequent amendments to the rules (including changing the subsection number of the provision in which the I/T exemption appears),⁶ none of the changes substantively affected the I/T grandfather clause or applied the whole of Part 482 to a grandfathered I/T facility.

When CMS first initiated rulemaking on the provider-based regulations in 1998, the proposal did not include any special provisions concerning I/Ts.⁷ Rather, CMS suggested that “all facilities or organizations”⁸ claiming provider-based status would have to fulfill the same set of proposed provider-based COPs,⁹ designed to ensure that any entity seeking provider-based status was an “integral and subordinate part[] of the main provider.”¹⁰

In response, IHS and numerous other parties requested an I/T exception to the provider-based COPs.¹¹ 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.”¹² IHS further argued that the provider-based COPs failed to account for “the statutory opportunities for self-determination by the Indian tribes,”¹³ and ultimately recommended that “the current [I/T] system be ‘grandfathered’ to meet the definition of provider-based entity.”¹⁴

CMS agreed with these commenters, stating:

The provision of health services to members of Federally recognized Tribes is based on a special and legally recognized relationship

⁵ 1998 Proposed Rule at 47,589-94.

⁶ 2002 Final Rule at 50,118.

⁷ *See generally* 1998 Final Rule, which did not mention I/T facilities at all.

⁸ 42 C.F.R. § 413.65(d).

⁹ *See generally id.*

¹⁰ 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)).

¹¹ 2000 Final Rule at 18,507.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.* (emphasis added).

between Indian tribes and the United States Government. To address this relationship, the IHS has developed an integrated system to provide care that has its foundation in IHS hospitals. Because of these special circumstances, not present in the case of private, non-Federal facilities and organizations that serve patients generally, *we agree that it would not be appropriate to apply the provider-based criteria to IHS facilities or organizations or to most tribal facilities or organizations.*¹⁵

In recognition of this, CMS changed the provider-based COP to provide that it will consider I/T facilities “to be departments of hospitals operated by the Indian Health Service or Tribes” so long as the facility is owned and operated by IHS, or operated by the Tribe under a self-determination agreement.¹⁶

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.¹⁷ Thus, in these situations, the clinic could never satisfy the provider-based COPs. To address this issue, CMS added the grandfather clause to allow I/T facilities to qualify for provider-based status.

The essential point is that, generally, entities *must* be closely integrated to satisfy the provider-based COPs, but the grandfather clause allows certain entities that are not closely integrated to qualify for provider-based status anyway. To ignore this exemption and require these exempted facilities to be closely integrated in order to qualify for provider-based status would be to read section 413.65(m) completely out of the regulation, a result which would violate basic legal canons of statutory construction and fail judicial review.¹⁸

¹⁵ *Id* (emphasis added).

¹⁶ 42 C.F.R. § 413.65(m).

¹⁷ In fact, this exemption was only intended to cover situations in which the hospital and clinic had different government structures, a fact noted by CMS in other correspondence. *See* Letter from Thomas L. Grissom, Director, Center for Medicaid Management, to Marti Mahaffey, Executive Vice President and COO, TrailBlazer Health Enterprises, LLC (Aug. 11, 2003) at 4 (“Section 413.65(m) did not extend provider-based status to any facility owned and operated by a Tribe, if on April 7, 2000 the hospital with which the facility was affiliated was also owned and operated by a Tribe.”).

¹⁸ *See, e.g., Duncan v. Walker*, 533 U.S. 167, 174 (2001) (noting the “cardinal principle of . . . construction” that “no clause, sentence, or word shall be superfluous, void, or insignificant”) (citations and internal quotations omitted).

The Center for Medicare Management (CMM) confirmed this understanding in a Frequently Asked Questions (FAQ) guidance issued in 2003. This guidance was issued to the Medicare Fiscal Intermediary for Indian health billing, with instructions that it be applied “in determining provider-based status” for grandfathered I/T facilities.¹⁹ The FAQ explained how to determine when an I/T facility was eligible for provider-based status based on the grandfather clause. As part of this explanation, it stated at one point:

For example, on April 7, 2000 a particular hospital and a clinic aligned with it may both have been operated by the IHS, but since that date the operational responsibility for the hospital may have been assumed by the Tribe under the Indian Self-Determination Act (Pub.L. 9[3]-638), in accordance with applicable regulations and policies of the IHS in consultation with Tribes. Since section 413 .65(m) would have extended grandfathering to such a facility if this arrangement had been in place on April 7, 2000, a change of this kind would not prevent the clinic from retaining its grandfathered status.²⁰

As this guidance makes clear, the very purpose of the grandfather clause is to allow I/T facilities that do not meet the continuity and integration of management requirements in the provider-based COPs to nonetheless qualify for provider-based status. By recognizing that the clinic would qualify for grandfathered I/T status, CMS recognized that the grandfather exemption allows for certain non-compliance with the provider-based COPs.²¹

3.2 I/T facilities that meet the requirements of the grandfather exemption are similarly exempted from parallel requirements in Part 482.

Elsewhere, the provider-based status regulations further require that outpatient clinics comply with the certain regulations found in Part 482.²² And certain of these regulations contain similar integration requirements as the provider-based status regulations. For instance, Part 482 requires that clinics with provider-based status ensure that its providers have clinical privileges at the main hospital.²³ Similarly, Part 482 requires that clinics with provider-based status integrate its

¹⁹ CENTERS FOR MEDICARE AND MEDICAID SERVICES, CENTER FOR MEDICAID MANAGEMENT, FREQUENTLY ASKED QUESTIONS: PROVIDER-BASED STATUS FOR INDIAN HEALTH SERVICE AND TRIBAL FACILITIES 1 (Aug. 11, 2003). To the best of our knowledge, there has been no Tribal consultation subsequent to this letter regarding a change in the application and interpretation of the applicable regulations.

²⁰ *Id.*

²¹ *Cf. id.* at 2 (noting that if a facility no longer satisfies the grandfather clause, it “may qualify for provider-based status only by showing actual compliance with the requirements in section 413.65”).

²² 42 C.F.R. § 413.65(g)(8).

²³ 42 C.F.R. § 413.65(d)(2)(i); 42 C.F.R. § 482.54(c)(4)(i).

outpatient services with the inpatient services of the main hospital.²⁴ At first glance, then, it may appear that an I/T facility must comply with certain management integration requirements in Part 482.

But this interpretation would render the grandfather exemption meaningless. If an I/T facility had to meet all the requirements of Part 482, and some of those are practically identical to the very requirements it had to be exempted from in the provider-based regulations, then Part 482 would have the effect of nullifying the grandfather exemption.

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.²⁵ 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,²⁶ its decision to only incorporate "applicable" provisions of Part 482 must be seen as deliberate.²⁷

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. To find otherwise would be nonsensical. While generally an agency's interpretation of its own regulation is due significant deference, when an agency's interpretation of a regulation is "inconsistent with the regulation," it should be rejected.²⁸ And an interpretation of a regulation that conflicts with an earlier interpretation is due "considerably less deference" than a consistently held agency view.²⁹ Here, the agency's new interpretation is at odds with the

²⁴ 42 C.F.R. § 482.54(a).

²⁵ 1998 Proposed Rule at 47,588 (currently codified as amended at 42 C.F.R. § 413.65(g)(8) (emphasis added)).

²⁶ See, e.g. 42 C.F.R. §§ 413.65(e)(3)(v)(A)-(B) and (g)(1), (4).

²⁷ 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)).

²⁸ *Thomas Jefferson Univ. v. Shalala*, 512 US 504, 512 (1994).

²⁹ *Id.* at 515 (1994) (quoting *INS v. Cardoza-Fonseca*, 480 U. S. 421, 446, n. 30 (1987)).

general regulatory plan to allow I/T facilities to qualify for provider-based status despite not meeting the integration requirements and should therefore be rejected.³⁰

3.3 The grandfather clause applies to all I/T facilities who meet the requirements, regardless of the date that the tribal organization contracted for the program.

Finally, an I/T facility's ability to qualify for the grandfather exemption is not dependent on when the tribal organization contracted to operate the program. Instead, as CMS has already stated in the transmittal memorandum of the 2003 FAQ, the question turns on the type of relationship between the hospital and the clinic. As that memorandum states:

[W]e have concluded that changes in the status of a hospital or facility from IHS to Tribal operation, or vice versa, or the realignment of a facility from one IHS or Tribal hospital to another IHS or Tribal hospital, will not cause a loss of grandfathered status for the facility if the resulting configuration is one which would have qualified for grandfathering under section 413.65(m) if it had been in effect on April 7, 2000.

This memorandum confirms that the relevant question concerning a grandfathered entity's compliance with the provider-based regulations is whether the changed relationship satisfies the substance of the I/T grandfather clause. It is not whether the status change took place before or after the regulatory deadline.³¹

3.4 Hospitals associated with I/T facilities who qualify for provider-based status under the grandfather clause do not lose their right to participate in Medicare.

As noted above, some of the requirements of Part 482 mirror the requirements of the provider-based COPs.³² While the grandfather exemption to the provider-based status regulations allows

³⁰ See also *King v. Burwell*, 576 U.S. ___, No. 14-114 at *21 (“A fair reading of legislation demands a fair understanding of the legislative plan.”); see also *id.* at *15 (discussing statutory interpretation and stating that “[a] provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme . . . because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law”) (quoting *United Sav. Assn. of Tex. v. Timbers of Inwood Forest Asscs., Ltd.*, 484 U. S. 365, 371 (1988))).

³¹ Further, although the provider-based COPs require non-grandfathered I/T facilities to report status changes to CMS that would affect provider-based eligibility, 42 C.F.R. § 413.65(c), (j), (l), there is no such requirement in the grandfather clause. Establishing disparate treatment within the same regulation is considered deliberate. See, e.g., *United Transp. Union v. BNSF Ry. Co.*, 710 F.3d 915, 928 (9th Cir. 2013).

³² See *supra* at 7-8.

I/T facilities that cannot meet those requirements to qualify for provider-based status anyway, there is no similar grandfather exemption in Part 482. Because of this, we understand CMS has now threatened to de-enroll IHS hospitals that are associated with tribally-run clinics because they cannot meet the management integration requirements.

However, despite the fact that there is no parallel 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. There is no use for an I/T facility to worry about whether it qualifies for provider-based status if the associated hospital is barred, *because of its association with the facility*, from participating in the very program that the facility wishes to qualify for.

Further, the Part 482 requirement that “[o]utpatient services must be appropriately organized and integrated with inpatient services” was adopted in 1986, well before the grandfather clause was added to the provider-based status regulations.³³ Thus, CMS was fully aware of this general requirement in Part 482 when it enacted the grandfather clause in the provider-based status regulations and apparently saw no contradiction in the two regulations.

And indeed, for the last eighteen years, CMS has continued to license IHS hospitals that associate with tribally-run clinics. The very purpose of the grandfather clause, as evidenced by the legislative history quoted above, was to ensure that the tribal clinics could bill Medicare. And when CMS issued guidance in 2003, it again assumed that the hospitals would continue to be eligible to participate in Medicare.

As noted above, 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.³⁴ And although an agency’s interpretation is generally due significant deference, the deference afforded to agency interpretations that change over time is significantly less.³⁵ These rules are equally applicable to Part 482. Up until now, the Agency has consistently allowed IHS hospitals to participate in Medicare that associate with tribally-run clinics. Further, interpreting Part 482 to require decertification of the main hospital in these situations is inconsistent with the regulatory plan to allow I/T facilities to qualify for provider-based status.

³³ Medicare and Medicaid Programs; Conditions of Participation for Hospitals, 51 Fed. Reg. 22,010-01 (June 17, 1986) (Final Rule adopting 42 C.F.R. § 482.54(a)). Other provisions regarding integration appear later. *See* Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II, 79 Fed. Reg. 27106-01 (May 12, 2014) (Final Rule adopting 42 C.F.R. § 482.54(c)(4)(i)).

³⁴ *Thomas Jefferson Univ. v. Shalala*, 512 US 504, 512 (1994).

³⁵ *Id.* at 515.

2. Conclusion.

For eighteen years, CMS recognized that the I/T grandfather clause exempts qualifying facilities from compliance with the management integration requirements of both (1) the provider-based COPs and (2) Part 482. Rather, the only relevant issue when determining whether a grandfathered I/T facility retains its provider-based status is whether the facility's current relationship with either an IHS or Tribal hospital satisfies the terms of the grandfather clause. If so, 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 at the all-inclusive rate without any effect on its Medicare certification. The applicable regulations do not make sense when interpreted in any other manner.

We appreciate the opportunity to continue our dialogue with CMS on these important matters. In the event that CMS has any ongoing concerns, the TTAG requests the formation of a Tribal-CMS provider-based status workgroup, as well as nationwide Tribal consultation concerning CMS's interpretation of the applicable requirements. It is extremely important that Tribes be given an opportunity to review and comment on what would be a sharp change in CMS policy with potentially serious consequences for IHS and Tribes that provide clinical services in conjunction with a hospital.³⁶

Please do not hesitate to contact us with any comments or further questions, or if we can provide you with any additional information.

Sincerely,



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Chairman, Tribal Technical Advisory Group

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³⁶ The TTAG previously addressed the lack of consultation on this matter in letters dated December 1, 2011 and January 14, 2015. Although the current transmittal is a technical memorandum, we incorporate by reference both our requests for consultation and our disappointment at CMS's lack of transparency in its reinterpretation of the provider-based regulations up to this point.

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