

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 email: Marc.Hartstein@cms.hhs.gov

October 14, 2015

Marc Hartstein
Director, Hospital and Ambulatory Policy Group
Center for Medicare
Centers for Medicaid and Medicare Services
Baltimore, MD 21244-8013

RE: Grandfathered Provider-Based Facility to Grandfathered Tribal FQHCs

I. Introduction.

The Tribal Technical Advisory Group (TTAG)¹ thanks the Centers for Medicare and Medicaid Services (CMS) for participating in our September 30, 2015 teleconference to discuss CMS's Notice of Proposed Rulemaking (Proposed Rule) in which CMS set out significant changes to the requirements for achieving "grandfathered provider-based tribal status" for the purposes of Medicare billing.² We appreciate the opportunity CMS offered on the teleconference to follow up with our specific suggestions for clarifying the Proposed Rule in order to maintain Indian health program reimbursement under CMS's proposed "grandfathered tribal federally-qualified health center (FQHC)" designation, minimize confusion during the implementation of the Proposed Rule, and clarify the rights and responsibilities of the new grandfathered tribal FQHCs.

It is important, however, to reiterate that the Proposed Rule is not necessary and should be withdrawn, as CMS's stated concern with the lack of administrative integration between grandfathered provider-based tribal health programs and the Indian Health Service (IHS) hospitals with which they are affiliated is unfounded. We will not reiterate every argument here, but do discuss this issue briefly in the Section II of this Memorandum.

Should CMS nevertheless move forward with the Proposed Rule, the TTAG has very specific suggestions for improving the Rule, which we offer after considering the information provided by CMS on the September teleconference, as well as CMS's responses to the TTAG's

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.

² 80 Fed. Reg. 41,686 (July 15, 2015).

questions, comments, and previous submissions. We discuss these proposals in Section III of this Memorandum.

II. Reconsider the Interpretation of the Conditions of Participation and 42 C.F.R. § 413.65.

As we have demonstrated in prior correspondence with CMS, existing law (42 C.F.R. § 413.65(m)) already exempts grandfathered provider-based Indian health clinics from the administrative integration provisions of the hospital conditions of participation with which CMS is concerned. Any ambiguity could be easily clarified by minor changes in either the Medicare hospital regulations at 42 C.F.R. Part 482 or the provider-based regulations at 42 C.F.R. § 413.65.³

While we appreciate CMS's effort to work with the TTAG and find solutions for overcoming the potential harm of the new, more limited interpretation of the provider-based exemption for Indian health programs, we respectfully must note that the Proposed Rule misses the mark. While we address partial remedies in Section III of this memorandum, there are impacts that the Grandfathered Tribal FQHC proposal cannot address.

For instance, we have learned that there is at least one IHS clinic billing through a Tribally-operated hospital in reliance on and in accordance with the provider-based grandfather clause at 42 C.F.R. § 413.65(m). Our understanding is that Federal health programs cannot be FQHCs. If this is correct, this clinic will no longer be able to claim provider-based status under the CMS reinterpretation, meaning that the tribal community served by that IHS clinic will be deprived of the revenue that it would have earned as a provider-based clinic. Also, unless further changes are made to the interpretation of the grandfathered tribal FQHC rule, even if a tribe were to later take over the program, it may not be able to benefit either. The effect is a chill on self-determination and self-governance that the provider-based grandfather clause was intended to prevent.

We again urge CMS to confirm that grandfathered provider-based Indian health clinics associated with IHS or Tribal hospitals may continue to bill Medicare accordingly, and that it is not necessary to force such clinics to transition to a new, poorly understood, and lower paying provider type, assuming they are even permitted to do so.

III. Clarifications and Amendments Needed to the Grandfather Tribal FQHC NPRM.

1. Clarification of applicable law.

On our September teleconference, the TTAG expressed concern about the possible application of certain requirements of Section 330 of the Public Health Service Act⁴ to grandfathered tribal FQHCs. The concerns were that certain FQHC requirements might be more

³ We have developed proposed regulatory language to this effect that we attach for your consideration.

⁴ 42 U.S.C. § 254b.

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stringent for grandfathered tribal FQHCs than for grandfathered provider-based clinics, which need only be an IHS directly-operated clinic or a clinic of a tribal provider operating under the ISDEAA. On the call, CMS assured us that Section 330 requirements would not apply to grandfathered tribal FQHCs. We remain concerned.

While CMS has repeatedly asserted that it can clarify many of our requested amendments to the grandfathered tribal FQHC proposal in the Preamble to the Final Rule, here, it is the Proposed Rule's Preamble that triggers our confusion. In it, CMS states that grandfathered tribal FQHCs will be subject to "Medicare [FQHC] regulations at part 405, subpart X, and part 491."⁵ One provision of Part 491 is entitled "Basic Requirements" for "Federally Qualified Health Centers." It provides that when:

an entity . . . wishes to participate in the Medicare program, CMS enters into an agreement with an entity when *all of the following* occur. . . .

(i) HRSA approves the entity as meeting the requirements of section 330 of the PHS Act.

(ii) the entity assures CMS that it meets the requirements specified in this subpart [X—Rural Health Clinic and Federally Qualified Health Center Services] and part 491 of this chapter, as described in §405.2434(a).⁶

PHS Act Section 330 requires that "health center[s]" provide a broad spectrum of services (including, among other things, pediatric eye, ear, and dental screenings, preventive dental services, and emergency medical services),⁷ establish a sliding fee scale reducing or waiving medical charges for low-income individuals,⁸ and set their billed charges according to "locally prevailing rates or charges [that are] designed to cover its reasonable costs of operation,"⁹ among other requirements. Section 405.2434(a) requires an FQHC "to maintain compliance with the FQHC requirements set forth in this subpart [X] and part 491. . . ."

Part 491 only makes the possible conflicts worse. Although it expressly recognizes that an FQHC may be "an outpatient health program or facility operated by a tribe or tribal organizations under the [ISDEAA] . . .," it nevertheless imposes very specific staffing, supervision, and licensing requirements that many grandfathered provider-based clinics do not follow and from which they

⁵ Proposed Rule at 41,801.

⁶ 42 C.F.R. § 405.2430(a)(1), (a)(1)(i) and (ii) (emphasis added).

⁷ 42 U.S.C. § 254(b)(1)(A)(i).

⁸ 42 U.S.C. § 254b(k)(3)(G).

⁹ *Id.*

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are exempt under the Indian Health Care Improvement Act (IHCIA) and other federal Indian laws. For example, Part 491 requires that health professionals employed by FQHCs be licensed by the state where the clinic is located, and makes no exception for tribally-operated FQHCs, even though the IHCIA provides that professionals employed by tribal health programs carrying out ISDEAA functions are exempt from such state licensing laws so long as they are licensed in any state.¹⁰

On the teleconference, CMS said that none of these provisions would apply to grandfathered tribal FQHCs, including the specific provisions cited above. While we appreciate the reassurance, in our view the regulatory language is ambiguous, and the applicability of Section 330 is not addressed in the Preamble of the Proposed Rule. Further, the Preamble specifically states that tribal grandfathered FQHCs must comply with all of the Part 491 requirements, and like Part 491 itself, the Preamble does not reference or create any exceptions for tribal clinics operated pursuant to the ISDEAA. We remain concerned that the current and proposed regulations are easily read to require tribal FQHCs to meet all the requirements of Section 330 and Part 491, and the Preamble only reinforces such a reading.¹¹

Thus, the NPRM as currently crafted would impose substantially different requirements than are currently applicable to grandfathered provider-based clinics, many of which would be functionally or legally impossible for tribal clinics to satisfy.¹² CMS should amend the Preamble and expressly amend the requirements for a grandfathered tribal FQHC in the final rule to eliminate this conflict between the plain language in the Proposed Rule and what CMS has stated to be its intent in discussions with the TTAG.

In order to codify CMS's statement of intent, maintain status quo among the grandfather provider-based clinics that will need to become grandfathered tribal FQHCs, and recognize the unique federal laws that apply to tribal health programs (including, we hope, grandfathered tribal FQHCs), we request that CMS include the following provisions either as a standalone regulatory section or as an amendment to 42 C.F.R. § 405.2462:

A grandfathered tribal FQHC, notwithstanding any provision of law or regulation to the contrary:

(1) qualifies automatically for FQHC status under section 2401(b) of this subpart [42 C.F.R. 405.2401(b)] and is not subject to

¹⁰ 25 U.S.C. § 1621t. *Also see*, 25 U.S.C. § 1647a.

¹¹ In addition, the HHS Departmental Appeals Board has stated that with regard to that provision, “[t]here is nothing in the regulations governing FQHCs that suggests that an entity may qualify for FQHC status without first having satisfied these . . . essential prerequisites. Nor do the regulations allow for a waiver of these prerequisites.” *Family Health Servs. of Darke Cnty., Inc.*, DAB CR1862 (2008) (H.H.S. Nov. 14, 2008).

¹² And, of course, which IHS-directly operated clinics could never satisfy.

the requirements of subpart X of part 405 or part 491 as a condition of qualifying for such status;

(2) is not required to meet, or certify its compliance with or agreement to, any federal requirements for FQHCs or Medicare providers that are inconsistent with, or are made inapplicable by, the Indian Health Care Improvement Act, the Indian Self-Determination and Education Assistance Act, judicial principles of federal Indian law, or the provisions of paragraph (1);

(3) will be paid for services that are provided under the general or indirect supervision of a physician or non-physician practitioner, where that level of supervision would be permitted for services delivered in an outpatient department of a tribal hospital, notwithstanding any FQHC requirement that the services be provided directly by, or under the direct supervision of, a physician or non-physician practitioner.¹³

These provisions are consistent with both CMS's statements of intent and with guiding principles of federal Indian law, and will ensure that grandfathered tribal FQHCs will not be "surprised" down the line with more restrictive requirements than those currently in effect for grandfathered provider-based clinics.

2. G-Codes.

On our September teleconference, CMS indicated that it would authorize grandfathered tribal FQHCs to set their own G-Code billing system charge rates. CMS reasoned that grandfathered tribal FQHCs could set these rates with an eye towards being able to be reimbursed the Medicare outpatient rate established by IHS each year rather than the "lesser of" amount provided in statute. We understand the statutory basis of the "lesser of" requirement and that the G-Codes were established for FQHCs so they too could avoid possible loss of revenue.

The TTAG is concerned that absent additional regulatory clarification,¹⁴ setting billed charges differently for Medicare than for other payors could invite legal challenge and potential

¹³ We would be happy to work with CMS regarding improved ways to express the interests set out in this draft language. The objective is to assure that Indian health programs that are deemed to be FQHCs under paragraph (d) of the definition of "Federally qualified health center" under 42 C.F.R. § 405.2401 are not subject to the limiting conditions in the introduction to that definition ("[FQHC] means an entity that has entered into an agreement with CMS to meet Medicare program requirements under §§ 405.2434") and other provisions of law cited in the Preamble to the NPRM.

¹⁴ We also understand CMS's current view that the language in the Preamble will be sufficient to overcome possible audit challenges later, but given that we had thought the Preamble to 42 C.F.R.

exclusion.¹⁵ We therefore suggest that CMS add the following new subsection (g) to 42 C.F.R. § 405.2462:

(g) A grandfathered tribal FQHC may establish G-code-based charges in any amount, and in its sole discretion, at rates that may exceed the amount charged to patients and other payors for the same or similar services. CMS shall deem such rates to be reasonable and in compliance with federal law.

We believe that this will help assure grandfathered tribal FQHCs that they can design their Medicare charges at levels high enough to assure their actual recovery will be no less than the Medicare outpatient encounter rate established annually by IHS without fear of a potential legal challenge or a future Administration's attempt to apply other provisions of law differently than how this rule was intended to work.

3. Applicability of Alaska Medicare rates.

Medicare outpatient payment rates for grandfathered provider-based clinics (and all other IHS or tribal outpatient hospital programs) are currently set at \$564 for Alaska and \$307 for the lower-48 states.¹⁶ While CMS noted the higher Alaska rates in the Preamble of the Proposed Rule,¹⁷ the actual proposed regulations state that grandfathered tribal FQHCs are will be "paid at the Medicare outpatient per visit rate as set annually by the IHS" or at "the outpatient rate for Medicare as set annually by the IHS for tribal FQHCs that are authorized to bill at this rate." In order to foreclose any confusion as to whether this includes the Alaska adjustment, we suggest that CMS make the following edit in proposed 42 C.F.R. § 405.2462(e)(1)(ii):

(e) * * *

(1) * * *

(ii) 80 percent of the lesser of a grandfathered tribal FQHC's actual charge,

§ 413.65(m) was clear, until it turned out more than a decade later that it was apparently not, we believe that additional safeguards are necessary.

¹⁵ For example, federal law threatens exclusion upon providers who bill Medicare for items or services that are "substantially in excess of such individual's or entity's usual charges (or, in applicable cases, substantially in excess of such individual's or entity's costs)." 42 U.S.C. § 1320a-7.

¹⁶ Indian Health Service, Reimbursement Rates for Calendar Year 2015, 80 Fed. Reg. 18,639 (Apr. 7, 2015).

¹⁷ Proposed Rule at 41,799.

or the outpatient rate for Medicare as set annually by the IHS, including the specific rates for facilities in Alaska.

4. Clarification of the billing process during the transition to grandfathered tribal FQHC status.

During the September teleconference and in previous interactions, CMS has repeatedly stated that it is not planning to proactively investigate grandfathered provider-based hospitals and clinics in search of program violations that could trigger the shift to grandfathered tribal FQHC status. CMS also said that the grandfathered tribal FQHC rule will be applied prospectively, meaning that provider-based clinics may continue to bill as provider-based until they officially receive Medicare CMS Certification Number (CCN) as a grandfathered tribal FQHC.

Despite these reassurances, we believe that the Proposed Rule does not adequately inform Indian health clinics about when they must seek to qualify as grandfathered tribal FQHC, nor how they may bill and be paid in the interim. In order to provide proper guidance, we suggest the following edits to the definition of “grandfathered tribal FQHC” at CMS’s proposed 42 C.F.R. § 405.2462(d):

(d) Payment to grandfathered tribal FQHCs.

(1) A “grandfathered tribal FQHC” is a FQHC that:

(i) Is operated by a tribe or tribal organization under the Indian Self-Determination Education and Assistance Act (ISDEAA);

(ii) Was provider-based to an IHS hospital on or before April 7, 2000; and

(iii) Is not operating as a provider based department of an IHS hospital.

(2) A facility that has been operating as a grandfathered provider-based facility under 42 C.F.R. 413.65(m) shall continue to be treated as such, and shall not be required to become a grandfathered tribal FQHC until two years after it is informed in writing by CMS that the facility is no longer clinically or administratively integrated with a hospital operated by the Indian Health Service or a Tribe and it has been provided opportunities to receive technical assistance from CMS regarding the transition to grandfathered tribal FQHC status.

(23) A grandfathered tribal FQHC is paid at the Medicare outpatient per visit rate as set annually by the IHS. A facility that was operating as a grandfathered provider-based facility under 42 C.F.R. 413.65(m) shall remain authorized to do so until it is certified as a grandfathered tribal FQHC by CMS and receives its CMS Certification Number as a grandfathered tribal FQHC.

These amendments clarify that tribal clinics are not required to “self audit” whether they must transition to grandfathered tribal FQHC status and “self-report” to CMS accordingly. Rather, clinics will remain provider-based until affirmatively informed otherwise by CMS, and may continue to bill as provider-based facilities until receiving their CCN.

The transition provisions should also be extended to any clinic that was billing through an IHS hospital under § 413.65(m) prior to a determination by CMS that the hospital did not satisfy the integrated governance conditions of participation. Any payment made through IHS (whether refunded to CMS by IHS or not) and any payment that could be made based on claims that could still be timely filed should be allowed in order to not disadvantage those tribes unfairly.

5. Interpretation of 42 C.F.R. § 413.65(m).

The provider-based tribal grandfather clause at 42 C.F.R. § 413.65(m) states that providers can qualify for grandfathered provider-based status if, and among other things, they billed as hospital outpatient departments “on or before April 7, 2000.” We understand that CMS interprets this requirement as meaning that the facility must have actually been billing as an outpatient department “on” April 7, 2000, and has denied provider-based status to facilities that did bill as hospital outpatient departments (and otherwise satisfy applicable requirements) prior to, but not on, April 7, 2000, thus effectively reading the “or before” clause out of the regulation. CMS also said on the September teleconference that it is retracting its 2003 Frequently Asked Question document in which the agency confirmed that a tribe’s assumption of a hospital or clinic under the ISDEAA would not affect its grandfathered provider-based status.

We believe that this does not accurately reflect the original agency intent behind the provider-based grandfather clause, and has resulted in numerous facilities being disqualified from eligibility for provider-based status. We suggest that CMS amend the provider-based regulation at 42 C.F.R. § 413.65(m), or at the very least clarify in the Preamble of the Final Rule, the following:

(1) A facility will be designated as the department of a hospital operated by the IHS or a Tribe under [insert reference to 42 C.F.R. § 413.65(m)] if it can demonstrate that it satisfied the applicable requirements of that paragraph either on April 7, 2000, or at any point prior to that date.

(2) 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, or the change in status of a hospital or facility from one Tribe or Tribal organization to another, will not cause a loss of status under this subsection if the resulting configuration is one which would have qualified for status under this subsection if it had been in effect either on April 7, 2000, or at any point prior to that date.

(3) A clinic eligible for grandfathered provider-based status under paragraphs (1) or (2) shall be eligible to continue in that status or to be a grandfathered tribal FQHC as provided in §§ 405.4234, as applicable.

6. Additional training and tribal consultation is necessary.

In addition to our suggestions above, if CMS ultimately does decide to move forward with finalizing the Proposed Rule, significant technical training and tribal consultation is necessary to ensure that tribes can properly transition to grandfathered tribal FQHC status. For example, and among other things, CMS must:

- Provide tribes with a detailed crosswalk comparing the differences (to the extent they may exist) between (1) the specific covered services for a tribal hospital outpatient department and a grandfathered tribal FQHC; (2) provider supervision requirements between the two provider types; and (3) any other compliance or conditions of participation requirements between the two provider types.
- Provide technical assistance for tribes concerning the specifics of the FQHC billing process.
- Consult with the TTAG and affected tribes concerning facilities that CMS has already informed no longer qualify for grandfathered provider-based status but for which it has set billing or FQHC designation requirements that are more stringent than those in the Proposed Rule.

CMS should consult with the TTAG on an ongoing basis concerning the specific needs of the tribal community as implementation of the Proposed Rule and actual transition to grandfathered tribal FQHC status move forward.

IV. Conclusion.

While we appreciate CMS's ongoing dialogue with the TTAG concerning the Proposed Rule, we believe that it is ultimately a solution to a problem that does not exist: existing law authorizes grandfathered provider-based tribal facilities to bill Medicare notwithstanding their lack of administrative integration with an associated IHS hospital, and by clear implication this means that affiliated hospitals are also in compliance with certification and other relevant requirements; even if it did not, CMS could easily implement a regulatory clarification that would be far simpler and more beneficial than creating an entirely new provider type. The TTAG requests that CMS withdraw the Proposed Rule and authorize grandfathered provider-based tribal clinics to continue billing accordingly.

If CMS does decide to implement the new grandfathered tribal FQHC status, it must clarify numerous provisions of the Proposed Rule relating to billing and other issues. Absent these

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amendments, and comprehensive tribal consultation and technical assistance, we anticipate significant tribal difficulties during the transition to grandfathered tribal FQHC status.

Thank you for the opportunity to discuss these important issues. Please do not hesitate to contact us with any comments or further questions, or if we can provide you with any additional information.

Sincerely,



W. Ron Allen,
Tribal Chairman and CEO, Jamestown S'Klallam Tribe
Chairman, Tribal Technical Advisory Group

cc: Kitty Marx, Director, Centers for Medicare and Medicaid Services, Tribal Affairs
Group

Attachment:

- 1) Tribal Amendment to 42 CFR 413.65

TRIBAL DRAFT as of September 30, 2015

Clarifying that a Hospitals' Medicare certification is not jeopardized by its association with a grandfathered provider-based facility, and that grandfathered status is not lost when a hospital or clinic moves from IHS to tribal operation, or vice versa.

The grandfathered tribal FQHC proposal responds to CMS's concern that an IHS (or possibly Tribal) hospital associated with a grandfathered tribal or IHS provider-based clinic risks its Medicare certification, because it is not clinically or administratively integrated with the clinic.

The FQHC proposal would not be needed if CMS instead clarifies that there is no such jeopardy to the hospital's Medicare certification. CMS has full authority to do so. Although we do not think a regulation is required, adopting one would help allay concerns, now and in the future.

We recommend the following revisions to 42 C.F.R. 413.65(m). The proposed changes would also confirm that grandfathered status is not lost when a hospital or clinic moves from IHS to tribal operation, or vice-versa.

(Language we recommend adding is underlined; language to be deleted is struck-through and placed in brackets.)

42 C.F.R. 413.65(m) Status of Indian Health Service and Tribal facilities and organizations --

(1) 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)~~(i) Owned and operated by the Indian Health Service;
- ~~(2)~~(ii) 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)~~(iii) 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.

(2) A facility will be designated as the department of a hospital operated by the IHS or a Tribe under paragraph (1) of this subsection if it can demonstrate that it satisfied the applicable requirements of that paragraph either on April 7, 2000, or at any point prior to that date.

(3) 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, or the change in status of a hospital or facility from one Tribe or Tribal organization to another, will not cause a loss of status under this subsection if the

TRIBAL DRAFT as of September 30, 2015

Clarifying that a Hospitals' Medicare certification is not jeopardized by its association with a grandfathered provider-based facility, and that grandfathered status is not lost when a hospital or clinic moves from IHS to tribal operation, or vice versa.

resulting configuration is one which would have qualified for status under this subsection if it had been in effect on or before April 7, 2000.

(4) No hospital shall be considered non-compliant with Parts 413 or 482 of this subchapter by virtue of its association with a facility or organization that is designated as a department of the hospital under this subsection, nor by the lack of clinical or administrative integration between the designated facility or organization and the hospital.