To the Centers for Medicare & Medicaid Services

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July 16, 2021

The Honorable Chiquita Brooks-LaSure, Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services P.O. Box 8013 Baltimore, MD 21244–1850

Re: Medicaid "clinic" services: CMS should change its interpretation of the benefit, and no amendment to the statute or regulation is required

Dear Administrator Brooks-LaSure:

On behalf of your Tribal Technical Advisory Group (TTAG), I write to extend our congratulations on your appointment and confirmation as CMS Administrator, and to welcome you to engage with us on a wide range of CMS policies and initiatives that affect tribal health providers and the Indian Health Services beneficiaries we serve. We greatly look forward to meeting with you as soon as your schedule allows, and we hope to see you at our upcoming "face-to-face" quarterly meeting next week, July 21-22.

One issue of pressing concern to TTAG is CMS's 2016 interpretation of the Medicaid "clinic" benefit, which excludes coverage for services furnished by clinic staff outside the "four walls" of the clinic building, except for those furnished to homeless individuals. That interpretation shocked Tribes and States alike: Most State Medicaid programs had a long history of paying tribal clinics for all their offsite services, which are vitally important throughout Indian Country and especially for isolated communities that have no clinic of their own and rely on the services of visiting health care providers.

Since 2016, CMS, the States, and Indian health providers have been hard at work trying to find practicable workarounds to avoid the serious and deleterious consequences of that interpretation. But as we have advised several times, CMS's proposed solution—redesignating tribal clinics as FQHCs—although well-intentioned, has proved costly, time-consuming, overly complicated and impracticable for many States and Indian health providers. Moreover, several States will be unable to implement the solution before CMS's deadline for doing so: October 31, 2021, just over three months from now.

But the flawed workaround and its deadline are completely unnecessary, because CMS's 2016 interpretation was simply wrong. Without any change to the governing statute or regulation, CMS can and should expand its interpretation of the "clinic services" benefit to include offsite services furnished to patients who are not homeless, as explained in the attached paper.

TTAG Letter to CMS Administrator Chiquita Brooks-LaSure Re: Medicaid Clinic Services July 16, 2021

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The TTAG leadership looks forward to working with you to finally resolve this long-running issue, and we would be happy to answer any questions you may have concerning the attached paper or the issues raised in it.

Sincerely,

W. Ron Allen, Chairman Jamestown S'Klallam Tribe

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Tribal Technical Advisory Committee

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

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July 15, 2021

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To: The Honorable Chiquita Brooks-LaSure, Administrator

Centers for Medicare and Medicaid Services (CMS)

From: CMS Tribal Technical Advisory Group (TTAG)

Re: Medicaid "clinic" services: CMS should change its interpretation of the benefit, and no

amendment to the statute or regulation is required

In 2016, CMS issued an interpretation of the Medicaid "clinic" benefit that covers offsite services only if they are furnished to homeless individuals. This interpretation is directly contrary to the plain language of the underlying statute, and the "work-around" presented by CMS to avoid the harsh result of this overly-limited interpretation has proved time-and-resource consuming, extremely burdensome, and impractical for Tribes and States. CMS has the authority to reinterpret the Medicaid "clinic" benefit without any amendment to the relevant statute or regulation so that it covers services that are furnished outside a clinic's "four walls" to all eligible Medicaid beneficiaries, not just to those who are homeless.1 It should do so before October 31, 2021, when its four-walls enforcement grace period is set to expire.

¹ The paper is presented on behalf of the CMS Tribal Technical Advisory Group (TTAG), which has asked CMS to revisit its "four walls" interpretation of the rule. The author is a TTAG Technical Advisor for the Alaska Region.

Briefly stated:

- As defined by statute, the Medicaid "clinic" benefit does not restrict who may receive offsite services; CMS's narrower interpretation is both unnecessary and contrary to the statute's plain language.
- CMS's regulation defining the clinic benefit is also broad enough to cover offsite services to all Medicaid beneficiaries. States and Tribes understood it that way for decades: States paid tribal clinics for their offsite services to non-homeless beneficiaries and were reimbursed for them by CMS States and tribes were shocked when CMS advised otherwise in 2016. The regulation's plain language, which merely paraphrases the statute, does not establish a general onsite requirement to which services to the homeless is the sole exception.
- CMS can revise its interpretation without amending the regulation because doing so would not "unfair[ly] surprise" regulated parties, upset settled expectations, increase program costs, or otherwise present a hardship to anyone.
- CMS's work-around to the clinic four walls restriction allowing tribal clinics to be redesignated as FQHCs and paid at the same rate as tribal clinics under an appropriate State Plan Amendment is more limited and complex than CMS anticipated when it offered the option in 2016:
 - some States cover fewer services for FQHCs than they do for clinics; unless they align the two benefits, tribal programs will be forced to choose whether to sacrifice offsite services (by continuing their clinic designation) or other vital services (by becoming an FQHC);
 - o changes to State regulations and systems take months to analyze and implement;
 - o the option is unavailable for IHS-operated clinics; and
 - o the Tribal FQHC option has yet to be taken up by at least twelve States with affected Tribal health programs.
- Offsite services are essential in the remote and under-resourced communities served by Tribal health programs and have long been reimbursed by Medicaid programs as clinic services at the IHS All-Inclusive Rate (AIR). States, Tribes, and CMS all want coverage and AIR reimbursement for the services to continue. They should not be forced to spend precious resources jumping through administrative hoops to implement an imperfect Tribal FQHC alternative when CMS could more fully and easily achieve the same objective by reinterpreting the clinic benefit to cover them.
- A broader interpretation of the clinic benefit would better align with the plain language of the statute and regulation, past practices, established expectations, evolving health care policy, and the healthcare needs of American Indian and Alaska Native Medicaid beneficiaries.
- The Tribal FQHC option may benefit some Tribal providers in some States and should be retained, but the Clinic benefit should be more broadly interpreted to include offsite services to all beneficiaries so that the Tribal FQHC option is not required.

Background:

1.1 CMS's surprise announcement and proposed work-around.

In December 2016, CMS advised State Medicaid Officials and Indian health programs that Medicaid's "clinic" benefit covers offsite services only if they are furnished to homeless individuals.²

The announcement came as a shock. Many States had a long history and stated policy of paying Indian and other clinic providers for their offsite services to all Medicaid beneficiaries, and tribal health organizations had designed programs that relied on offsite services to furnish essential care to their remote and under-resourced communities. Neither had understood those services to be covered only for the homeless, and CMS had not previously informed them that offsite services were excluded.

Acknowledging this, CMS offered a work-around that it clearly believed would allow offsite services to continue to be covered and reimbursed as they had been, and that it imagined would be relatively easy to implement: because tribal outpatient programs statutorily qualify as FQHCs and the Medicaid FQHC benefit does not have a "four walls" restriction, tribal clinics could simply ask to be redesignated as FQHCs; States could amend their Medicaid State Plans to pay them at the same IHS AIR that applies to clinics; and CMS would refrain from enforcing the clinic "four walls" rule for the time it judged sufficient to allow this solution to be implemented.

If only it had been that easy.

1.2 The Work-Around's Shortcomings, Complexities, and Delays.

Unfortunately, the Tribal FQHC work-around has proven both less complete and more complex than CMS envisioned.

First, the Tribal FQHC work-around raises a host of unresolved legal and policy questions, and the answers to those questions will likely vary from state to state. For example, may States impose Medicare FQHC requirements on Tribal FQHCs? Which "ambulatory" services are or must be included in the State's FQHC benefit, and at what rate must they be reimbursed? Which tribal practitioners qualify as "clinic" providers who are subject to the four walls restriction, and would their services qualify for payment at the same rate under the FQHC benefit? Are there categories of tribal practitioners who may or must enroll separately from a

² The announcement was formalized in writing on January 18, 2017. CMS, Frequently-Asked Questions (FAQs), Federal Funding for Services "Received Through" an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives (SHO #16-002), January 18, 2017, FAQ # 13 faqs 1-18-17 (medicaid.gov).

clinic or FQHC, and at what rate would they be paid for their offsite services? ³ TTAG representatives and Technical Advisors first posed these and other questions to CMS in March 2017, and they remain unanswered.

It also became clear early on that some States restrict the FQHC benefit in ways that make the Tribal FQHC work-around untenable or ineffective. Although federal Medicaid laws define the FQHC benefit broadly and impose few requirements on Medicaid FQHC providers, States can and have imposed their own requirements and restrictions – in some cases making their FQHC benefit more restrictive than their clinic benefits. ⁴ Alaska Medicaid, for example, has a four-walls restriction for FQHCs but not for clinics, and it requires FQHCs to be enrolled as such in Medicare and to satisfy various Medicare requirements even though federal law does not.⁵ Additionally, Idaho restricts medical FQHC encounters to those visits as defined by Medicare federal regulation.⁶ FQHC encounters. Where a State's FQHC and clinic benefits do not align, States need to determine whether, legally and fiscally, they are willing and able to change their rules to create alignment.⁷ And if they cannot or will not change, Tribal programs are forced to choose which services they will sacrifice: their offsite services (by continuing their clinic designation) or other vital services (by becoming an FQHC).

Even where States and Tribes are able to work through these issues and uncertainties, there are procedural and other hurdles to contend with before a Tribal FQHC option can be implemented, requiring significant time and expense. Most if not all States will need to formally amend their Medicaid regulations and manuals, change their Medicaid claims processing and information management systems, and train their staff and providers on the changes. Tribal clinics making the change to FQHC status will have similar tasks and may need to alter their programs to meet the State's FQHC requirements.

³ TTAG letter to Victoria Wachino, CMCS Director, December 12, 2016, <u>TTAG-Letter-Seeking-5-Year-Grace-Period-or-Transition-to-FQHC.pdf (nihb.org)</u>; see also TTAG letter to the Honorable Seema Verma, CMS Administrator, August 14, 2018, <u>TTAG-July-2018-Face-to-Face-Follow-Up-Letter.pdf (nihb.org)</u>; TTAG letter to Calder Lynch, Deputy Administrator, March 31, 2020, <u>TTAG-letter-Request-extend-clinic-4-walls-grace-period-1-year-3.31.202....pdf (nihb.org)</u>

⁴ It is not always apparent which State Plan services are being covered as "clinic services" that are subject to the four-walls restriction, let alone whether they could be covered by the FQHC benefit. In Alaska, this was unclear for months regarding a number of crucial services including certain dental, behavioral health, community health aide, laboratory, and radiology services.

⁵ After extensive analysis and discussions with Tribal programs and CMS, the State reports it will lift these FQHC requirements and restrictions.

⁶ Idaho has indicated that 42 CFR § 405.2463(2) is a barrier to tribes receiving the encounter rate for vaccine administration furnished by registered nurses because registered nurses are not included in the eligible encounter list for Medicare FQHC programs.

⁷ States must cover the same scope of services for tribal and non-tribal FQHCs, so any change will extend to services that do not qualify for 100% FMAP.

Alaska may be the poster child for these complexities and procedural challenges. There, a State-Tribal workgroup has required more than ten months of bi-weekly meetings, intense mutual effort, and frequent discussions with CMS officials to find ways to align that State's FQHC and clinic benefits. But the process is far from complete, and it is doubtful the required regulation changes can take effect before CMS's enforcement grace period expires on October 31.

Alaska's experience reflects the particular care and Herculean efforts of State and Tribal leaders there to fully evaluate the FQHC work-around and to craft a workable solution. But the challenges and issues they encountered are almost certainly not unique to Alaska, and other States likely face different but equally daunting and complicated issues. Yet at least twelve of 34 affected States have not even begun considering the Tribal FQHC option, and they are quickly running out of time to implement it before CMS's enforcement grace period expires on October 31, 2021. Other States moved swiftly to adopt the necessary State Plan Amendment without fully appreciating all the implications, and are only now recognizing important differences between their clinic and FOHC benefits. Of the states are particular to the particular to the state of the particular to the partic

These complexities, delays, costs, and lost revenues are entirely unnecessary. All CMS needs to do is reinterpret the Medicaid clinic benefit to follow the plain language of the statute: the benefit includes offsite services furnished to all Medicaid beneficiaries, regardless whether they are homeless.¹¹

⁸ While the workgroup has identified a path forward, formal Tribal Consultation has not yet begun and the necessary regulation and State Plan amendments have not yet been drafted.

⁹ CMS's Division of Tribal Affairs reports that there are 34 States with IHS or Tribal facilities potentially impacted by the clinic "four walls" interpretation. Of those, twelve have approved SPAs implementing the Tribal FQHC option and two have SPAs pending CMS approval. Eight more have pre-existing State Plan provisions that may negate the need for the work-around. The remaining twelve have not submitted Tribal FQHCs SPAs or formally engaged with CMS on the option. Some of this delay is likely attributable to the COVID-19 Public Health Emergency, but part of it is due to the complexities involved and the lack of definitive guidance from CMS on key issues.

¹⁰ Tribal FQHCs in California report that they are not being paid for all the same services as when they were enrolled as clinics. In Idaho, both CMS and the State have recently acknowledged that prior to the State Plan Amendment 19-0009 that authorized tribes to designate as FQHC, tribal and IHS clinics were already defined as an FQHC by state regulation, the state plan, and provider handbooks. This ultimately leaves the tribes in Idaho without a choice to designate as FQHC or clinic. Idaho has yet to provide updated guidance to the tribes on FQHC status and implementing SPA 19-0009.

¹¹ As explained more fully below, the Tribal FQHC option does have some advantages in some States. CMS should retain that option, alongside a more generously interpreted clinic benefit.

2. Legal Analysis.

2.1 The plain language of the statutory definition of "clinic services" includes offsite services furnished to beneficiaries who are not homeless.

Section 1905(a) of the Social Security Act, 42 U.S.C. 1396d(a), identifies the services that States may or must cover under their Medicaid programs. The list of optional services includes, at paragraph (9):

clinic services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, *including* such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

(Emphasis added.) The emphasized word, "including," is key to the offsite services analysis. Clearly, the provision specifically covers offsite services furnished to homeless persons, indicating that Congress was especially focused on ensuring their access to care. But the language also authorizes *all* clinic services furnished by or under the direction of a physician, no matter where located. It does not otherwise restrict coverage to services that are furnished within the clinic facility's four walls or exclude coverage for offsite services to persons who are not homeless. Absolutely nothing in the statute's plain language requires CMS to cover *only* services within the four walls of a clinic, with services to homeless individuals as a limited exception to that rule. The term "including" does not mean "and including only." Yet CMS's new interpretation effectively transforms "including" to "including only" in manner contrary to the plain language of the statute. As discussed below, CMS lacks the authority to adopt any interpretation that contradicts the plain language of the statute.

The term "including" is typically defined to indicate a partial but not exclusive list, and when they interpret statutes, courts afford the term a "presumption of nonexclusivity." ¹²

¹² Include, Black's Law Dictionary (11th ed. 2019); U.S. Bank Nat. Ass'n ex rel. CW Capital Asset Mgmt. LLC v. Vill. at Lakeridge, LLC, 138 S. Ct. 960, 963 (2018) ("Because of the word 'includes' in that section, courts have long viewed its list . . . as non-exhaustive."); Fed. Land Bank of St. Paul v. Bismarck Lumber Co., 314 U.S. 95, 100 (1941) ("[T]he term 'including' is not one of all-embracing definition, but connotes simply an illustrative application of the general principle."); United States v. Helton, 944 F.3d 198, 206 (4th Cir. 2019), as amended (Dec. 4, 2019) ("Because 'include' and its variations are 'more often than not the introductory term for an incomplete list of examples, their use before a list is afforded a presumption of nonexclusively in statutory interpretation." (citation omitted)), cert. denied, 141 S. Ct. 298 (2020); Arizona State Bd. For Charter Sch. v. U.S. Dep't of Educ., 464 F.3d 1003, 1005, 1008 (9th Cir. 2006) (affirming construction of "including' to mean, essentially, 'such as,'" because "[i]n both legal and common usage, the word 'including' is ordinarily defined as a term of illustration, signifying that what follows is an example of the preceding principle"); United States v. Hawley, 919 F.3d 252, 257 (4th Cir. 2019)("When 'include' is utilized in a statute, it is generally improper to conclude that entities not specifically enumerated are excluded" (internal citations omitted)).

Accordingly, CMS's current interpretation is impermissibly constrained because the language "including such services furnished outside the clinic" conveys that other services, not just services to homeless individuals, are also included.

Section 1396d as a whole also compels a non-exclusive interpretation of the benefit. ¹³ A quick review of the entire provision reveals that, when Congress wanted "including" to *not* indicate a partial list, it knew how to do so – by adding the word "only" or the phrase "but not including" after it, for example. In § 1396d(p)(1)(a), the term "qualified medicare beneficiary" is defined to mean an individual "who is entitled to hospital insurance benefits . . . (*including* an individual entitled to such benefits pursuant to an enrollment under section 1395i-2 of this title, *but not including* an individual entitled to such benefits only pursuant to an enrollment under section 1395i-2a of this title)" (Emphasis added.). Describing what chiropractic services States may cover, Section 1396d(g) stipulates that "[i]f the State plan includes provision of chiropractors' services, such services *include only*" (emphasis added)). Section 1396d(h)(1) states that "the term 'inpatient psychiatric hospital services for individuals under age 21' *includes only*" (emphasis added)). Section 1396d(gg)(1) contains this definition of "routine patient costs:" "routine patient costs--(A) *include any* item or service (B) *does not include*" (emphasis added)). ¹⁴

Congress's use of the single word "including" in the clinic provision, when it used the phrases "including only" or "including [x] but not including [y]" in other provisions, is legally significant. "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." Here, given the entirety of Section 1396d, it is evident that, had Congress intended to cover offsite services only for homeless individuals, it would have done so clearly and in the same way it imposed limitations on other services. It could have defined the clinic benefit as: "including such services furnished outside the clinic by clinic personnel only to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address," for example. Or perhaps as: "including such services furnished outside the clinic by clinic personnel to an eligible individual

¹³ "[S]tatutes 'should not be read as a series of unrelated and isolated provisions." *Gonzales v. Oregon*, 546 U.S. 243, 273 (2006). As is clear here, "nothing in the statute evinces a congressional intent to use the word 'including' to mean anything other than its ordinary definition." *City of Los Angeles v. Barr*, 941 F.3d 931, 948 (9th Cir. 2019) (discussing a different statute).

¹⁴ But see id. § 1396d(a)(5)(A) (definition for "physicians' services" states "whether furnished in the office, the patient's home, a hospital, or a nursing facility, or elsewhere," which could also be interpreted to indicate Congress knew how to specify broader locations if it wanted to).

¹⁵ Kucana v. Holder, 558 U.S. 233, 249 (2010) ((citation omitted)); see also Connell v. Lima Corp., 988 F.3d 1089, 1102 (9th Cir. 2021) ("The word 'includes' shows § 1602(3)(B) is illustrative and a non-exclusive listing The statutory context reinforces this interpretation. Congress could have written a limited definition in the same way it wrote limited definitions elsewhere in § 1602, but did not." (citations omitted)).

who does not reside in a permanent dwelling or does not have a fixed home or mailing address, but not including any other services outside the clinic." But Congress did not do so.

The statute's plain language, then, supports and may well require a broader interpretation of the clinic benefit than CMS has afforded it. As the Supreme Court has "stated time and again," courts "must presume that a legislature says in a statute what it means and means in a statute what it says there." ¹⁶ And where there is a "straightforward statutory command, there is no reason to resort to legislative history." "When the words of a statute are unambiguous, . . . 'judicial inquiry is complete." The words of the statute here are unambiguous, and CMS' overly-restrictive interpretation is wrong.

2.2 The statute's legislative history highlights the broader Congressional purpose CMS should honor.

While there is no need to resort to legislative history when the plain language of a statute is clear, the legislative history of this provision does not indicate any intent of the part of Congress to exclude offsite services for non-homeless people.

To be sure, the legislative history shows that Congress was particularly intent on ensuring coverage for offsite services to homeless persons, just as the statute's own language does. But nothing in the history demonstrates that Congress intended other offsite services to be excluded from the benefit. If anything, the provision's history reveals a pattern of Congress repeatedly being forced to amend the clinic provision to overcome CMS interpretations it deemed too narrow. That history points to the broader public health purposes Congress was trying to achieve, and that CMS should honor now.

The clinic benefit was originally described simply as "clinic services." In 1984, Congress added the language "furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician" in order to override a narrow

¹⁶ Connecticut Nat. Bank v. Germain, 503 U.S. 249, 253-254 (1992).

¹⁷ United States v. Gonzales, 520 U.S. 1, 6 (1997); Ratzlaf v. United States, 510 U.S. 135, 147-48 (1994) (even where there are "contrary indications in the statute's legislative history," the Court "do[es] not resort to legislative history to cloud a statutory text that is clear."). See also, Am. Rivers v. F.E.R.C., 201 F.3d 1186, 1204 (9th Cir. 1999) ("[L]egislative history—no matter how clear—can't override statutory text." (citation omitted).)

¹⁸ Connecticut Nat. Bank, 503 U.S. at 254 (citation omitted).

¹⁹ Social Security Amendments of 1965, Pub. L. No. 89-97, sec. 121, 79 Stat. 286, 351.

²⁰ Deficit Reduction Act of 1984, Pub. L. No. 98-369, sec. 2371, 98 Stat. 494, 1110.

interpretation CMS had imposed on the benefit.²¹ The amendment was made to "provide[] that the clinic need not be administered by a physician."²²

In 1987, Congress added the key language "including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address." ²³ This amendment was again in reaction to an overly limited agency interpretation: "HCFA's interpretation precludes a State that elects to cover clinic services from receiving Federal Medicaid matching funds for services provided by clinic personnel to Medicaid-eligible beneficiaries off the premises of the clinic itself."²⁴

There is no denying that, in this second CMS-course-correcting amendment, Congress was especially focused on the hardship CMS's "four walls" interpretation imposed on homeless people and the States striving to serve them. But like the statute itself, the legislative history uses the term "include," which carries a presumption of non-exclusivity. And there is no language to suggest that Congress wished to include offsite services only for the homeless while excluding them for everyone else. Rather, the legislative history shows that Congress's objective was to eliminate "a major barrier to delivering primary health care services" by allowing States to employ "essential techniques" to address the "pressing unmet health needs" of individuals who have difficulty accessing "mainstream providers:"

This HCFA policy interpretation creates particular difficulties for States and clinics that seek to make services available to the Medicaid-eligible homeless. Testimony heard by the Subcommittee on Health and the Environment confirms that a major barrier to delivering primary care services to the homeless population is the reluctance of these individuals to use the services of mainstream providers. However, success has been achieved in making health care available to the homeless by placing physicians, physician assistants, nurse practitioners, nurses, and other personnel directly in shelters, soup kitchens, and similar locations frequented by the homeless, or by placing personnel directly on the streets in mobile vans. HCFA policy effectively prohibits States from reimbursing clinics that use these essential techniques for services rendered to Medicaid-eligible homeless.

Given the pressing unmet health needs of the homeless, the Committee can see no justification for denying a State the option of paying for clinic services delivered offsite to Medicaid-eligible homeless individuals. The Committee amendment therefore clarifies that, for

²¹Specifically, the language was added because "[r]egulations issued by the Department of Health and Human Services limit[ed] coverage of clinic services to situations in which services [we]re furnished under the direction of a physician," and "this physician-direction rule [was] interpreted as requiring that clinic administrators be physicians." H.R. Conf. Rep. No. 98-861, at 1370 (1984).

²² Id.

²³ Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, sec. 4106, 101 Stat. 1330, 1330-147 ("Clarification of Coverage of Clinic Services Furnished To Homeless Outside Facility.").

²⁴ H.R. Rep. No. 100-391, at 523 (1987).

Federal matching purposes, the optional clinic service benefit *includes clinic services furnished outside the clinic* (whether in shelters, soup kitchens, mobile vans, or anywhere else) by clinic personnel (whether physicians, nurses, nurse practitioners, physician assistants, or others) to a Medicaid-eligible homeless individual.²⁵

As Tribal programs have known for decades, and as the COVID-19 pandemic has made others painfully aware, many Medicaid beneficiaries are unable or unwilling to receive primary health care from "mainstream providers," and for some populations and communities — especially geographically remote Native communities — it is essential to offer services where the people are: in their homes, community centers, shelters, schools, mobile vans, or "anywhere else." ²⁶ In clarifying that the clinic benefit "include[s]" offsite services to the homeless, Congress never intended, and certainly never required, that offsite care should be unavailable to others.

CMS's current interpretation is simply wrong. CMS should interpret the clinic benefit broadly and in accordance with the statute's plain language, legislative history, and public health purposes: to include offsite services furnished by clinic personnel to all Medicaid beneficiaries, whether they are homeless or not.²⁷ Doing so would also honor the broad Congressional directive that Medicaid care and services must be provided "in a manner consistent with . . . the best interests of the recipients."²⁸

2.3 A plain reading of CMS's "clinic" regulation also includes offsite services to individuals who are not homeless.

In 1991, CMS amended its regulation defining the "clinic" benefit to reflect the 1987 statutory amendment. Since then, 42 C.F.R. § 440.90 has read as follows:

Clinic services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients:

(a) Services furnished at the clinic by or under the direction of a physician

²⁵ H.R. Rep. No. 100-391, at 523 (1987) (emphasis added).

²⁶ Id.

²⁷ See also *Skubel v. Fuoroli*, 113 F.3d 330 (2d Cir. 1997), in which the reviewing court held that CMS's restriction of "home health services" to those actually furnished in the recipient's home was unreasonable because "[t]here does not appear to be any rational connection between the regulation and the purpose to be served by the statute governing home nursing services. The restriction ignores the consensus among health care professionals that community access is not only possible but desirable for disabled individuals." *Id.* at 336. The court also found "no logical basis to support restricting Medicaid funding to home nursing services provided exclusively at the recipient's place of residence . . . [because] eliminating the in-home restriction will result in no greater cost to the government in administering this Medicaid program." *Id.* at 337.

²⁸ See generally 42 U.S.C. § 1396a(a)(19).

or dentist.

(b) Services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

(Emphasis added.) The regulation follows the statute's lead by using the term "includes" before the reference to offsite services to homeless persons.

Like statutes, regulations that are not ambiguous should be interpreted according to their plain language: other materials and the agency's interpretation become relevant only if the provision is ambiguous.²⁹ And this regulation's language is plain on its face: because the word "includes" is presumed to be non-exclusive, the clinic benefit should be read to include additional services beyond those specifically listed, unless other language in the regulation indicates an exclusive intent. But there is no such other language. To the contrary, the rest of the regulation's language supports the broader reading.

First, it is notable that the regulation begins by broadly stating what "clinic services means," followed by a list of two services that it "includes." "Means" is an exclusive term, almost the opposite of "includes." When a statute or regulation says what a defined term "means," it is generally understood to mean that the term encompasses everything that falls within the description, nothing less or more, unless other language in the regulation indicates otherwise. And when a definition says what a term "means," followed by a list of what it "includes," it becomes even clearer that the included items are just examples of the term's broader meaning.

Second, the regulation defines "clinic services" to mean those that are furnished "by" – not "at" – a non-hospital facility that is organized and operated to provide medical care to outpatients. The services are thus defined not by where they are provided ("at" a facility), but by whom ("by" an outpatient facility).

Finally, the definition twice uses the word "outpatients," a term that had once been defined to mean patients "at" a medical facility, but that CMS amended in 1987 to mean patients

²⁹ Kisor v. Wilkie, 139 S. Ct. 2400, 2415 (2019) ("First and foremost, a court should not afford <u>Auer</u> deference [to the agency's interpretation of its regulation] unless the regulation is genuinely ambiguous. See Christensen v. Harris County, 529 U.S. 576, 588, 120 S.Ct. 1655, 146 L.Ed.2d 621 (2000); Seminole Rock, 325 U.S. at 414, 65 S.Ct. 1215 (deferring only "if the meaning of the words used is in doubt"). If uncertainty does not exist, there is no plausible reason for deference. The regulation then just means what it means—and the court must give it effect, as the court would any law. Otherwise said, the core theory of Auer deference is that sometimes the law runs out, and policy-laden choice is what is left over. ... But if the law gives an answer—if there is only one reasonable construction of a regulation—then a court has no business deferring to any other reading, no matter how much the agency insists it would make more sense. Deference in that circumstance would "permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation." See Christensen, 529 U.S. at 588, 120 S.Ct. 1655. Auer does not, and indeed could not, go that far."

"of" a medical facility, further signaling that "clinic services" are not limited to those furnished within the facility itself.³⁰

Not only does the regulation's plain language allow States to cover offsite services to persons who are not homeless; CMS has itself interpreted it that way. In 2019, it approved a State Plan Amendment for Alaska that, at CMS's direction, covered "home dialysis training and support services" under the clinic benefit.³¹

2.4 No public health policy supports the four walls restriction.

As far as we are aware, CMS has yet to offer any policy justification for its "four walls" interpretation of the clinic benefit. When CMS officials alerted States and Tribal programs to its narrow interpretation in 2016, they would only say that CMS could not change the interpretation or amend the regulation because it was long-standing and affected other unspecified providers.

Yet CMS recognized the serious hardship this inflicted on Tribal programs and State Medicaid agencies, who had understood the clinic benefit to be broader. While believing then that its options were limited, CMS worked to mitigate the harm by developing the Tribal FQHC option. That action speaks volumes, and it belies the existence of any policy justification to exclude offsite services from the clinic benefit.

Even if there had once been a policy justification behind the four walls restriction, it is impossible to identify one that remains valid today. Over the last two decades, public health policies and the Medicaid program itself have evolved, with a greater emphasis than before on primary, preventive, and integrated health care services, and an increased focus on furnishing services when and where patients can access them. The Covid-19 pandemic highlighted the importance of providing healthcare services in non-traditional settings, and both CMS and Congress are now working to make permanent many of the Medicaid and Medicare flexibilities that were implemented on a temporary basis during the Public Health Emergency. Toward that end, CMS should take the simple step, consistent with this clear public policy trend, to broaden its reading of the existing Medicaid clinic benefit to allow States to cover services furnished offsite by clinic providers to all Medicaid beneficiaries.

³⁰ 52 Fed. Reg. 47934, December 17, 1987. See 56 Fed. Reg. 8832, 8835 (Mar. 1., 1991).

³¹ Alaska Medicaid State Plan, Attached Sheet to Attachment 3.1-A, Page 3.1 (TN No. 19-0004 (August 15, 2019). Before that change, although the State had covered home dialysis and other end-stage renal disease services, they were expressly excluded from the "clinic services" pages of the State's Plan. Beginning in 2012 or earlier, CMS advised the State to remove the exclusionary language and cover the services under the clinic benefit. The State complied in 2019 but, having become aware of the clinic "four walls" restriction through its work on the Tribal FQHC option, it is now working with CMS to amend the State Plan to cover the home dialysis services under a different benefit category.

2.5 CMS can revise its interpretation of the clinic services regulation without amending it.

It is of course permissible for CMS to change its interpretation of the clinic services benefit. An agency "is not estopped from changing a view [it] believes to have been grounded upon a mistaken legal interpretation," and must be "given ample latitude to 'adapt [its] rules and policies to the demands of changing circumstances," so long as the agency justifies its "change of interpretation with a 'reasoned analysis." 33

The Administrative Procedure Act expressly allows agencies to adopt "interpretive rules" without formal notice-and-comment rulemaking.³⁴ Even so, agencies must sometimes take formal action if they wish to change a regulation's interpretation. Formal action is required if "there is only one reasonable construction of a regulation" and the agency's new and contrary interpretation would "disrupt[] expectations" and "creates an unfair surprise" to regulated parties.³⁵

But those factors do not apply here. In this case, while CMS's 2018 FAQs on the issue assert that it had long interpreted the clinic benefit to exclude offsite services except to homeless persons, CMS has not identified any formal agency interpretation to that effect. As discussed above, that is not what the regulation's plain language says, and CMS in fact has a long history of reimbursing States for such offsite services There is "only one reasonable construction" of the regulation, and it allows coverage of offsite services to all beneficiaries. Interpreting the regulation that way would not "unfair[ly] surprise" regulated parties or "disrupt [their] expectations." To the contrary, what was surprising and disruptive to States and Tribal providers alike was CMS's 2016 announcement that offsite services are generally excluded from the clinic benefit, notwithstanding the absence of any exclusionary language in the statute or regulation and a long history of States paying Tribal clinics for the services and CMS reimbursing States for them. Nor would changing the interpretation create a hardship on State Medicaid agencies by increasing program costs: the Tribal FQHC option was designed to allow offsite services to

³² Good Samaritan Hospital v. Shalala, 508 U.S. 402, 417 (993)(an agency "is not estopped from changing a view [it] believes to have been grounded in a mistaken legal interpretation."

³³ Rust v. Sullivan, 500 U.S. 173, 187 (1991) (alteration in original) (citations omitted).

³⁴ 5 U.S.C. 551(13).

³⁵ Kisor v.Wilkie, 139 S. Ct. 2400, 2415 (Where there "is only one reasonable construction of a regulation," simply deferring to the agency's new interpretation "would 'permit the agency, under the guise of interpreting a regulation, to create *de facto* a new regulation."; *Id.* at 2417-18 ("[A] court may not defer to a new [agency] interpretation [of a regulation] . . . that creates 'unfair surprise' to regulated parties. That disruption of expectations may occur when an agency substitutes one view of a rule for another. We have therefore only rarely given *Auer* deference to an agency construction 'conflict[ing] with a prior' one." (citations omitted)); see also *Long Island Care at Home, Ltd. V. Coke*, 551 U.S. 158, 170-71 (2007) ("as long as interpretive changes create no unfair surprise . . . the change in interpretation alone presents no separate ground for disregarding the Department's present interpretation").

continue to be paid at the same rate that applies to clinic services, making a revised interpretation of the clinic benefit cost-neutral.

By adopting a broader interpretation of the clinic benefit, CMS would simply restore the pre-2017 status quo. That reading would be consistent with the language of the regulation and statute; align the benefit with how it had been understood for decades by States and Tribes; honor once-settled expectations; cause no "unfair surprise" or increased program costs; and spare States and Tribal programs the significant expense, uncertainty, and disruption that are involved in evaluating, developing, and implementing a Tribal FQHC alternative. CMS should embrace the interpretation required by the statute, and need not amend its regulation to do so.

2.6 The Tribal FQHC option should be retained alongside the reinterpreted clinic benefit.

Although the clinic services regulation should be read to cover offsite services more broadly, the Tribal FQHC option should also be continued in order to avoid disrupting any newer expectations that option may have established. The Tribal FQHC option does not work for everyone, but for some services and in some States, it very likely expands coverage and improves reimbursement. For example, the FQHC benefit includes services of psychologists and clinical social workers, which States do not universally cover under their clinic benefit. Further, services furnished under the mandatory FQHC benefit may be better protected from State budget cuts than those furnished under the optional clinic benefit. Accordingly, the Tribal FQHC option should continue to be available to States and Tribes interested in retaining or adopting it.

3. CONCLUSION.

For all these reasons, without any change to the governing statute or regulation, CMS can and should expand its interpretation of the "clinic services" benefit to include offsite services furnished to patients who are not homeless. TTAG encourages it to do so immediately, while also retaining the Tribal FQHC option. If CMS determines that it must formally amend its regulation to make the change, TTAG urges CMS to extend the "four walls" enforcement grace period accordingly so that offsite services can continue to be furnished and reimbursed without interruption.

Respectfully submitted,

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