



Submitted via: www.regulations.gov

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Re: Comments on RIN 0906-AB08, 340B Drug Pricing Program Omnibus Guidance

On behalf of the National Indian Health Board¹, we thank you for the opportunity to comment on the proposed 340B Drug Pricing Program Omnibus Guidance. Our comments are below.

The Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program Omnibus Guidance redefines the required relationship between a provider and a patient in such a way that it will drastically curtail tribal health program access to 340B drug pricing. As proposed, the guidance would: (1) require that the relationship between a patient and a provider be evaluated on a prescription-by-prescription basis; and (2) that the prescription be issued at a tribal facility. This will prohibit tribal health program patients from accessing 340B pricing when they receive outpatient care outside of tribal clinic facilities, such as under valid referral or contractual arrangements or under a tribal health plan provider network. Such a restriction is inconsistent with federal law and undermines the 340B program's purpose of enabling covered entities to increase access to care by maximizing federal dollars.

We request that the proposed guidance be revised to clarify that an individual is a patient for purposes of the 340B program if he or she is an individual that a tribe or tribal organization is authorized to serve under its Indian Self-Determination and Education Assistance Act (ISDEAA) contract, in accordance with requirements in Section 813 of the Indian Health Care Improvement Act (IHCIA).

I. The Proposed Guidance Drastically Curtails Tribal 340B Access

The proposed guidance introduces two new requirements that, when applied together, will significantly curtail access to 340B pricing for tribal health programs. First, whether an

¹ Established in 1972, the NIHB is an inter-Tribal organization that advocates on behalf of Tribal governments for the provision of quality health care to all American Indians and Alaska Natives (AI/ANs). The NIHB is governed by a Board of Directors consisting of a representative from each of the twelve Indian Health Service (IHS) Areas. Each Area Health Board elects a representative to sit on the NIHB Board of Directors. In areas where there is no Area Health Board, Tribal governments choose a representative who communicates policy information and concerns of the Tribes in that area with the NIHB. Whether Tribes operate their entire health care program through contracts or compacts with IHS under Public Law 93-638, the Indian Self-Determination and Education Assistance, or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.

individual is considered a patient for 340B purposes is to be evaluated on a prescription-by-prescription basis. Second, for an individual to be considered a patient the prescription must be issued at a tribal facility by an employee or independent contractor of the tribal facility. This would make prescriptions issued by providers serving tribal health program patients outside of tribal clinic facilities ineligible for 340B pricing, such as prescriptions issued under valid referral or contractual arrangements or under tribal health plan provider networks.

The 340B program requires drug manufactures to provide outpatient drugs to "covered entities" at significantly reduced prices, allowing these entities to stretch their scarce federal dollars. Section 340B(a)(4) of the Public Health Service Act (PHSA) defines a "covered entity" as including a federally qualified health center (FQHC). 42 U.S.C. § 256b(a)(4). For purposes of the 340B program an FQHC is defined as including "an outpatient **health program or facility** operated by a tribe or tribal organization under the Indian Self-Determination and Education Assistance Act ... or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act ... for the provision of primary health services." 42 U.S.C. § 1396d(l)(2)(B)(iv). The use of the conjunctive "or" in the definition of an FQHC for purposes of the 340B program means that it is not just a tribal health program's facility that can be considered a covered entity. Rather, the entire tribal health program can register as the covered entity.

Covered entities are prohibited under section 340B(a)(5)(B) from reselling or transferring a drug to a person who is not a "patient" of the covered entity. 42 U.S.C. § 256b(a)(5)(B). This section does not, however, define patient. The criteria for determining who is a patient of a tribal health program are established under Indian Self-Determination and Education Assistance Act (ISDEAA) agreements and statutes and regulations governing eligibility for Indian health services.

Current HRSA guidance provides that an individual may be considered a patient for 340B purposes so long as: (1) the covered entity has an established relationship with the patient, such that it maintains the patient's health records; (2) the patient receives care from an employee of the covered entity or "under contractual or other arrangements (e.g., referral for consultation)" such that the covered entity maintains responsibility for the care; and (3) the scope of services is consistent with the scope of federal funding or FQHC look-alike status provided to the entity. 61 Fed. Reg. 55157–8 (Oct. 24, 1996).

Under the proposed guidance, however, the relationship between the individual and the covered facility is no longer the focus of the determination of whether a person is a patient for 340B purposes. Rather, the location at which care is received becomes the primary determinant despite the fact that tribal **health programs or facilities** may be the 340B covered entity and therefore 340B pricing should extend to prescriptions even when they are not made at the tribal clinic facility. Tribal health programs frequently operate under contractual or other arrangements with outside providers or maintain provider networks to deliver care to their patients. The preamble to the proposed rule, however, states that "[i]f a patient is referred from the covered entity for care at an outside provider and receives a prescription from that provider, the drug in question will not be eligible for a 340B discount at that covered entity." 80 Fed. Reg. at 52306–07.

The proposed guidance will drastically curtail access to 340B pricing for tribal health programs. Many tribal health programs have limited in-house access to specialty care, relying on referrals or other contractual arrangements. Additionally, many tribes establish provider networks to deliver care to their patients. The structure of tribal health programs and who is considered a patient under these programs is determined by ISDEAA agreements and the statutes and regulations governing eligibility for Indian health services. HRSA lacks the authority to dictate to tribes and tribal organizations how they should structure their health programs by issuing guidance limiting 340B access to certain types of arrangements.

II. The Proposed Guidance Should Clarify Standards Applicable to Tribal Health Programs

HRSA's proposed guidance acknowledges that eligibility for the 340B program is determined by a tribe or tribal organization's ISDEAA contract. The preamble to the proposed guidance includes the following explanation of the requirement that an individual's health care is consistent with the scope of a federal grant, project, designation or contract:

With respect to Indian Tribes or Tribal Organizations whose 340B Program eligibility arises solely from the Indian Self-Determination and Education Assistance Act, Public Law 93-638 (ISDEAA), use of 340B drugs is limited to those individuals that the tribe or tribal organization is authorized to serve under its ISDEAA contract, in accordance with requirements in Section 813 of the Indian Health Care Improvement Act.

80 Fed. Reg. at 52307.

We recommend that this language, as revised below, be incorporated into the guidance itself and should apply as an exception to all six of the requirements for 340B eligibility listed in the proposed guidance. We recommend that the following language be inserted as a new paragraph (3) in Part C (b), which details several exceptions:

(3) Tribal Health Programs. With respect to Indian Tribes or Tribal Organizations whose 340B Program eligibility arises from the Indian Self-Determination and Education Assistance Act, Public Law 93-638 (ISDEAA), use of 340B is authorized for all individuals that the tribe or tribal organization is authorized to serve under its ISDEAA contract or compact. The criteria in subsection (a) of this Part shall not apply to such tribal health programs for determining which individuals are patients for purposes of 340B eligibility.

This exception would ensure that tribal health programs—not just specific facilities—maintain the ability to issue prescriptions that are eligible for 340B drug pricing.

III. HRSA Should Clarify That The Guidance is Non-Binding

We also request that HRSA clarify that its proposed guidance is non-binding. The U.S. District Court for the District of Columbia has determined that the Secretary of Health and Human

Services lacks the authority to issue legally binding regulations governing the 340B program except in three limited circumstances: (1) establishing an administrative dispute process between covered entities and manufacturers; (2) defining a standard methodology for calculating ceiling prices; and (3) imposing civil and monetary penalties. *Pharm. Research and Mfg. v. HHS*, 43 F.Supp.3d 28 (D.D.C. 2014). We request that HRSA clarify that the guidance is agency policy rather than a legally binding regulation.

IV. Conclusion

The intent of the 340B program is "to permit covered entities 'to stretch Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" 80 Fed. Reg. at 52300. The 340B program has been hugely important to tribal health programs, which are severely underfunded and faced with enormous need. We are concerned that the proposed guidance will undermine the purposes of the 340B program and reduce the ability of tribes and tribal organizations to provide much-needed care to their patients. Tribes have previously raised these concerns with HRSA and requested tribal consultation.² The proposed guidance, however, has not adequately addressed tribal concerns and threatens significant harm to tribal health programs and their patients.

Thank you for considering these comments. Please do not hesitate to contact us for further information.

Sincerely,



Lester Secatero, Chair
The National Indian Health Board

² See Letter from Indian Health Service Tribal Self-Governance Advisory Committee to Administrator Mary Wakefield (Aug. 25, 2014), available at http://www.npaihb.org/policy/issue/09052014_tsgac_letter_to_mary_k_wakefield_request_for_tribal_consultation.