National Indian Health Board

Submitted electronically via: *www.regulations.gov*

May 22, 2018

CAPT Krista Pedley
Director, Office of Pharmacy Affairs
Healthcare Systems Bureau
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

RE: 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, RIN 0906-AB18

Dear CAPT Pedley:

On behalf of the National Indian Health Board (NIHB)[1], I write to submit comments in response to the notice of proposed rulemaking regarding the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation. We appreciate that HHS proposes to further delay the effective date of its January 5, 2017 final rule in light of its intention to engage in additional or alternative rulemaking on these issues.

We remind the Health Resources and Services Administration (HRSA) that for the 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

[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 Act (ISDEAA), or continue to also rely on IHS for delivery of some, or even most, of their health care, the NIHB is their advocate.

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.

The 340B program is hugely important to Tribal health programs, which are severely underfunded and face enormous need. Both the 340B and the VA Pharmaceutical Prime Vendor Program (PPV) are the two primary ways that Tribes and Tribal organizations purchase prescription drugs at a volume discount, saving the federal government millions of dollars in drug costs to serve AI/ANs. Additionally, both the 340B and the PPV contract with IHS has either successfully reduced or eliminated both the administrative costs and the time required for Tribal, Federal and Urban facilities to pay different vendors each month.

The number of health sites that utilize the 340B program — currently about 38,000 nationwide— has almost doubled in the past 5 years and over 150 Tribal sites have participated in the program, including 36 urban Indian programs. 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. We remind HRSA that American Indians and Alaska Natives are among the nation's most vulnerable populations, and yet the IHS remains woefully underfunded. IHS is currently funded at around 60% of need,[2] and average per capita spending for IHS patients is only $3,688 compared with $9,523 nationally,[3] therefore access to the 340B program is critically important for AI/ANs and if there are instances where manufacturers are shorting Tribal health programs funds, there must be adequate civil monetary penalties in place to ensure that every monetary amount that is due to the Tribal health program is paid.

We are concerned with any regulatory action that could affect the purposes of the 340B program and reduce the ability of Tribes and Tribal organizations to provide much-needed care to their patients. Therefore, before any final rule is implemented, we request Tribal consultation per Executive Order 13175.

Again, we appreciate that HHS proposes to further delay the effective date of its January 5, 2017 final rule in light of its intention to engage in additional or alternative rulemaking on these issues, however we remind HHS that the rulemaking process is no substitute for Tribal consultation and due to the critical role that the 340B program plays in the Indian healthcare delivery system, we request Tribal consultation before any rule is finalized.

We look forward to continued engagement with you on this program and stand ready to provide any technical assistance or other information that you may need.

Sincerely,

[2] See Indian Health Service, Frequently Asked Questions, https://www.ihs.gov/forpatients/faq/.
[3] Indian Health Service, IHS 2016 Profile, https://www.ihs.gov/newsroom/factsheets/ihsprofile/.

Vinton Hawley, Chair
National Indian Health Board