November 19, 2018

Krista Pedley, Pharm.D, MS
Captain, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

***RE: Notice of Proposed Rulemaking;* effective date change: RIN 0906-AB19 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; *(Vol. 83, No. 213, Nov. 2, 2018)***

Dear Captain Pedley:

On behalf of our 130-member hospitals and health systems, including 62 340B hospitals that participate in the 340B Drug Pricing Program, the North Carolina Healthcare Association (NCHA) appreciates the opportunity to comment on the Health Resources & Services Administration's (HRSA) proposed rule that would make January 1, 2019 the effective date for implementing the final regulations regarding the 340B Drug Pricing Program ceiling price and drug manufacturers' civil monetary penalties (CMPs) for violations of the ceiling price.

The Health Resources and Services Administration (HRSA) originally released the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties final rule on January 5, 2017. The final rule implements a provision of the Accordable Care Act (ACA) that required U. S. Department of Health & Human Services (HHS) to publish the methods for calculating 340B ceiling prices and imposes civil penalties (not to exceed $5,000 per instance) on manufacturers that intentionally charge a 340B covered entity more than the ceiling price established under the procedures of the 340B program. The rule specifies how drug manufacturers must calculate 340B ceiling prices, codifies the current policy on penny pricing, describes how manufacturers should estimate ceiling prices for new drugs, and gives the Office of Inspector General responsibility for imposing 340B civil monetary penalties on manufacturers. NCHA supports these much-needed provisions.

Since January 2017, the implementation date for the final regulation has been delayed five times. This much-needed legislation was mandated by Congress and is based, in part, on the U. S. Department of Health and Human Services Office of Inspector General's reports showing that pharmaceutical manufacturers have overcharged providers in the 340B Drug Pricing Program. Access to the 340B ceiling prices is critical if covered entities are to prove that the drug manufacturer overcharged for the drug. NCHA and its members support increased 340B Drug Pricing Program transparency and we believe that these rules on ceiling prices and civil monetary penalties are an appropriate first-step in holding drug manufacturers accountable in the 340B program. Hospitals and other covered entities comply with significant 340B program requirements, and we feel strongly that the 340B program would be greatly enhanced by applying similar oversight to the drug manufacturers. Thus, we are pleased that HRSA has

proposed to make January 1, 2019 the compliance effective date for the final rule on 340B drug ceiling prices and civil monetary penalties (CMPs) for drug manufacturers that intentionally overcharge 340B providers. The repeated and lengthy previous delays in making the final rule effective have significantly prejudiced our hospitals and, by extension, our low-income patients whom Congress intended to benefit from the 340B program. **We urge HRSA to publish the final rule in time to implement the January 1, 2019 deadline.**

**Implementation of the ceiling price methodology and the "penny pricing policy" directly addresses longstanding problems identified with the accuracy of required drug discounts and resulting overcharges that 340B providers continue to experience.** The ceiling price, the maximum per-unit price that can be charged to 340B providers for outpatient drugs, is key to the discounts made available under the 340B program. As HHS's Office of Inspector General (OIG) has found, many drug companies fail to accurately provide the required discounts. In its July 2006 report, OIG found that in one month, 14 percent of total purchases made by 70 sampled 340B providers exceeded the 340B ceiling prices, resulting in total overpayments of $3.9 million for the sample of 340B hospitals studied.

In addition, "penny pricing policy," an exception to the ceiling price methodology, discourages manufacturers from raising prices faster than inflation. This inflation penalty applies when the calculation of the drug discount results in a ceiling price of zero and entails imputing a ceiling price of $0.01 for the relevant drug product. The policy, although in place for many years, has not been applied consistently by drug manufacturers and, as the OIG report demonstrates, the largest overpayments by 340B hospitals have resulted from inappropriate handling of ceiling prices that should have been discounted because of the inflation penalty. The OIG report found that manufacturers overcharged for more than half of the drugs subject to the penny pricing policy with incorrect charges ranging "anywhere from $1.65 to $1,931 per purchase over the ceiling price."

Promptly enforcing these final rule provisions is valuable in bringing drug manufacturers into compliance and ensuring that 340B providers are able to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services" as Congress intended. It also is entirely consistent with the Administration's stated goal of addressing the issue of the rising costs of prescription drugs.

**The final rule's CMPs are an important, additional tool to help 340B providers in enforcing the requirements of the 340B statute, as both Congress and the OIG concluded.** Congress specifically added the CMPs to the law to "improve . . . compliance by manufacturers," and to "prevent overcharges and other violations of the discounted pricing requirements." 42 U.S.C. § 256b(d)(1)(A). The threat of CMPs will deter drug manufacturers from charging too much for covered drugs. Making the final rule's CMPs' provision effective would protect 340B providers from manufacturers overcharging and ensure they have savings from properly calculated discounts to devote to helping their low-income patients.

**Congress also determined that making ceiling prices available to 340B providers would assist them in detecting violations of the 340B law, and we urge HRSA to publish the ceiling price website as soon as possible after January 1, 2019.** Prompt publication of the website would give 340B providers access to the data needed to determine if they are being overcharged and allow them to bring such discrepancies in drug ceiling prices promptly to HRSA's attention.

Thank you for your consideration of our comments. If you have any questions, please contact me (slawyer@ncha.org, 919–677-4229), Ronnie Cook, Finance and Managed Care Consultant (rcook@ncha.org, 919-677-4225) or Mike Vicario, Vice President of Regulatory Affairs (mvicario@ncha.org, 919-677-4233).

Sincerely,

Stephen J. Lawler
President
North Carolina Healthcare Association