NATIONAL ASSOCIATION OF
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Captain Krista Pedley
Director
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Health Resources and Services Administration
5600 Fishers Lane
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Rockville, MD 20857

Re: RIN 0906-AA89
Comments on HRSA Interim Final Rule Further Delaying Effective Date of 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

Dear Capt. Pedley:

The National Association of Community Health Centers (NACHC) is pleased to respond to the Health Resources and Services Administration's (HRSA) Interim Final Rule (IFR) regarding the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties (CMP) Regulation. NACHC is the national membership organization for federally qualified health centers (FQHCs or "health centers"). With over 9,800 sites nationwide, FQHCs provide affordable, comprehensive primary care to over 25 million medically-underserved individuals. Our members include Community Health Centers, Migrant Health Centers, Health Care for the Homeless Grantees, and Public Housing Primary Care Grantees, all of whom who strive to meet the health care needs of the uninsured and underserved.

As HRSA staff, you are likely aware that 340B plays a critical role in enabling health centers to achieve their Congressionally-mandated mission of providing comprehensive primary and preventive care and case management to underserved patients. Health centers are required – by both statute and mission - to reinvest all 340B revenues into activities that are approved under their HRSA/BPHC Scope of Project and advance their charitable goals. Thus, 340B revenues support a wide range of services that meet the needs of health centers' patients and communities; the specific activities vary by health center, as each center's patient-majority board determine what uses are most appropriate for its patients and community.

NACHC is a signatory to the extensive comments about this Interim Final Rule that have been submitted by the 340B Coalition. We are submitting these separate comments to further emphasize our strong concerns about the most recent, and the proposed, delay to the effect date of the CMP provisions. We begin with a summary of our comments, and then discuss each individually.

Summary of NACHC Comments

NACHC is seriously concerned about the most recent delays in implementing the Final Regulation and CMPs and Ceiling Price Calculations, and strongly opposes any further delays, for the following reasons:

- **The effective date for this Final Rule is now delayed more than six-and-a-half years past the statutory deadline set by Congress.**
- **HRSA has already requested and reviewed public comment on this regulation three times, starting six and a half years ago, so it is inappropriate to argue that the agency has had insufficient time to consider public input.**
- **The OIG has found substantial evidence of manufacturers not complying with the law's pricing requirements.**
- **Without this Final Rule in place, neither HRSA nor covered entities have any realistic ability to force manufacturers to abide by the law's pricing requirements.**

For these reasons, NACHC strongly urges HRSA to implement this Final Rule immediately, and definitely not to delay it until October 1, 2017.

Specific NACHC Comments

The effective date for this Final Rule is now more than six-and-a-half years past the statutory deadline set by Congress. In March 2010, Congress gave HHS 180 days to issue regulations on determining manufacturer ceiling prices and imposing CMPs on manufacturers that "knowingly and intentionally" charge covered entities more than the ceiling price for covered outpatient drugs. Thus, the statutory deadline for making this regulation effective was September 19, 2010[1] - six and a half years ago. Any additional efforts to further delay the effective date of this regulation are in direct contradiction to an explicit Congressional mandate.

HRSA has already requested and reviewed public comments on this regulation three times, starting six and a half years ago, so it is inappropriate to argue that the agency has had insufficient time to consider public input. In the IFR, HRSA states that it needs more time to fully consider all key issues involved in the regulation. However, HRSA has already solicited and reviewed public comment on this regulation on three separate occasions, over the course of more than six years, as follows:

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[1] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 825 (2010).

- On September 10, 2019 (the day after the statutory deadline for implementing the regulations), HRSA issued an Advanced NPRM to seeking stakeholder input so for developing this regulation.[2] HRSA spent almost five years considering that input.
- Based on that input, in June 2015 HRSA finally published a notice of proposed rulemaking.[3] The agency received 35 comments totaling 283 pages on the NPRM, from both covered entities and manufacturers. These comments addressed all aspects of the proposed rule, including the calculation of the ceiling price, the penny pricing rule, and the CMP procedures.
- HRSA reopened the comment period on April 19, 2016, on three issues: 1) the penny price policy; 2) estimation of ceiling prices for new drugs; and 3) the definition of "knowing and intentional" for purposes of manufacturer CMPs.[4] This third comment period closed on May 19, 2016, and HHS received 70 comments[5] totaling 385 pages. Again, these comments came from both covered entities as well as manufacturers, and expressed views on all aspects of the three issues for which HRSA sought additional comments.

Given this history, it is implausible to suggest that more study is needed before this regulation can be implemented. Covered entities, manufacturers and organizations representing these stakeholders have all had ample opportunity to comment, and HRSA has spent years considering their input.

The OIG has found substantial evidence of manufacturers not complying with the law's pricing requirements. 340B overcharges have long been a problem. In 2003 and 2005, the Department of Health and Human Services (HHS) Office of Inspector General issued reports showing that covered entities are frequently overcharged for 340B drugs.[6] In 2003 alone, six manufacturers overcharged covered entities by $6.1 million.[7]

Without this Final Rule in place, neither HRSA nor covered entities have any realistic ability to force manufacturers to abide by the law's pricing requirements. In its 2005 report, the OIG stated that "HRSA lacks the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price."[8] In response, it recommended that HRSA be given such authority and mechanisms, and Congress enacted such provisions in 2010, including the directive to develop and implement this regulation. As previously discussed, Congress gave HHS until September 19, 2010[9] to

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[2] *ANPRM*, 75 Fed. Reg. 57,230.
[3] *Proposed Rule*, 80 Fed. Reg. 34,583.
[4] *340B CMP Reopened Rule*, 81 Fed. Reg. 22,960.
[5] *340B CMP Final Rule*, 82 Fed. Reg. at 1,211
[6] Department of Health and Human Services Office of Inspector General (OIG), Pharmaceutical Manufacturers Overcharged 340B-Covered Entities (Mar. 2003); OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program (Oct. 2005).
[7] OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program 17 (Oct. 2005).
[8] *Id.* at ii.
[9] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7102(a), 124 Stat. 119, 825 (2010).

complete this task. As HRSA has now missed that deadline by more than six-and-a-half years, it still lacks any enforcement tools that it can reasonably use to ensure that manufacturers comply with their 340B pricing obligations.

Meanwhile, health centers and covered entities also lack any ability to force manufacturers to abide by the statutory pricing requirements. In 2011, the Supreme Court found in *Astra USA, Inc. v. Santa Clara County* that health centers and other covered entities have no right to sue manufacturers who fail to adhere to these requirements. Thus, without this regulation in effect, there is absolute no mechanism for either HRSA or covered entities to ensure manufacturers to comply with the statute – despite ample evidence of manufacturer non-compliance, which has major financial implications for health centers and other covered entities.

For these reasons, NACHC strongly urges HRSA not to delay this Final Rule any further, and instead to begin enforcing it immediately. If you have any questions, please see the comments submitted by the 340B Coalition, or contact Ms. Colleen Meiman, NACHC's Director of Regulatory Affairs, at 301-296-0158 or cmeiman@nachc.org.

Thank you for your consideration of our comments.

Sincerely,

Colleen P. Meiman, MPPA
Director, Regulatory Affairs
National Association of Community Health Centers

cc: Tonya Bowers
Acting Associate Administrator
Bureau of Primary Health Care
Health Resources and Services Administration

Carrie Cochran
Director
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