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September 20, 2017

Captain Krista Pedley
Director
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Health Resources and Services Administration
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Re: Comments on RIN 0906-AB11 - Proposal to Further Delay Effective Date of 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation until July 1, 2018

Dear Capt. Pedley:

The National Association of Community Health Centers (NACHC) is responding to the Health Resources and Services Administration's (HRSA) solicitation for comments on further delaying -- this time until July 1, 2018 -- the effective date of the Final Rule on 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties.

NACHC is the national membership organization for Federally Qualified Health Centers (FQHCs or "health centers"). With over 10,000 sites nationwide, FQHCs provide affordable, comprehensive primary care to over 26 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. Together, it is estimated that health centers account for approximately 7% of all drugs purchased nationally under the 340B program.

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 to underserved patients. Health centers are required – by both statute and mission - to reinvest all 340B savings into activities that are approved under their HRSA/BPHC Scope of Project and advance their charitable goals. Thus, 340B

savings support a wide range of services that meet the needs of health centers' patients and communities. While 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, Attachment A includes some examples of activities that health centers support with 340B savings.

NACHC strongly opposes any further delays to the effective date of this Final Rule, and is a signatory to the extensive comments that are being submitted by the 340B Coalition. We are submitting these separate comments to further emphasize our strong concerns about the most recent proposed delay. We begin with a summary of our comments, and then discuss each individually.

Summary of NACHC Comments

NACHC is strongly opposes the most recent proposal to delay the effective date for the Final Regulation around CMPs and Ceiling Price Calculations -- this time until July 1, 2018 -- for the following reasons:

1. **As clearly stated by the HHS OIG and Congress, drug manufacturers currently operate largely under an "Honor System" when it comes to charging 340B providers the appropriate ceiling price.**

2. **Extensive data demonstrates that the Honor System is <u>not</u> working, as covered entities – particularly smaller ones – are frequently overcharged by drug manufacturers for drugs purchased under 340B.**

3. **The Supreme Court determined in 2011 that covered entities currently have no private right to sue manufacturers over 340B overcharges, pointing instead to Congress' decision to give HRSA enforcement authority through CMPs.**

4. **HRSA's own language in the Federal Register indicates that the agency is aware that some manufacturers are still out of compliance with ceiling price requirements that have been in statute for 25 years, and that they would find being forced to come into compliance to be "disruptive."**

5. **These three factors – extensive data about overcharges, covered entities' and HRSA's current inability to enforce pricing requirements, and HRSA's admission that many manufacturers are still out of compliance – all highlight the need for the Final Rule to go into effect immediately, so statutory requirements that have been in effect for 25 years can finally be enforced.**

6. **Two of the previous delays of the effective date violated the Administrative Procedures Act, and case law – including a decision earlier this year – suggests that such delays would be overturned by the courts.**

7. **It is implausible to state that a "more deliberative process" is needed given that HRSA has already requested and reviewed public comments on this regulation three times, starting six and a half years ago.**

For these reasons, NACHC strongly urges HRSA to implement this Final Rule immediately, and definitely not to delay it until July 1, 2018.

Specific NACHC Comments

1. **As clearly stated by the HHS OIG and Congress, drug manufacturers currently operate largely under the "Honor System" when it comes to charging 340B providers the appropriate ceiling price.**

Although the 340B program has been in existence since 1992 -- without no changes in how ceiling prices are to be calculated – to date there is still no realistic mechanism to require drug manufacturers to comply with the pricing requirements. In short, manufacturers' compliance with the 340B pricing requirements relies almost entirely on the "Honor System" – even though it has been a quarter century since the law was enacted, seven and a half years since after Congress gave HRSA authority to enforce compliance using Civil Monetary Penalties (CMPs), and seven years since Congress indicated that CMPs were to go into effect.

In a report issued in October 2005, Deficiencies in the Oversight of the 340B Drug Pricing Program, the HHS Office of the Inspector General highlighted this major shortcoming, stating that "HRSA lacks the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price." (See Attachment B for additional information on this report.) The OIG then recommended that "HRSA should seek authority to establish [civil monetary] penalties for PHS Act violations." In a hearing held later that year, Stuart Wright, the OIG Deputy Inspector General for Evaluation and Inspections, testified[1] that CMPs were necessary "because the current penalty of kicking manufacturers out of Medicaid and the 340B program is so draconian that it's not likely to be utilized."

Thus, well over a decade ago, the HHS Office of the Inspector General highlighted that HRSA lacks any realistic ability to enforce manufacturer compliance with 340B pricing requirements, essentially relying on an Honor System to ensure compliance. In March 2010, Congress agreed with the OIG's recommendations, giving HRSA the authority to use CMP to enforce compliance, and requiring the regulations promulgating this authority to be published within 180 days.

[1] *Id.* at 20.

Given these clear indications that both the Executive Branch and Congress sought to have this authority implemented at least 7 years ago, it is NACHC's view that the regulation should go into effect immediately, finally putting an end to the current Honor System.

2. Extensive data demonstrates that the Honor System is <u>not</u> working, as covered entities – particularly smaller ones – are frequently overcharged by drug manufacturers.

Extensive data from the HHS Office of the Inspector General, CMS, and health centers all indicate that the Honor System is not an effective mechanism for ensuring that manufacturers comply with 340B pricing requirements.

For example, OIG studies found that:

- 100% of manufacturers investigated overcharged 340B covered entities for every drug that was studied. The OIG estimated these overcharges represented 45% of the amount paid by covered entities during the one-year period studied.
- 68 of the 70 covered entities investigated were overcharged for at least one drug. Of those covered entities, the smaller ones -- such as health centers -- were associated with higher rates of overcharges. (See Attachment B for further information on both OIG reports.)

In addition, over the past 15 years (and as recently as this summer), the federal government (DOJ, on behalf of CMS) has entered into numerous settlements with drug manufacturers based on allegations that they overcharged Medicaid for drugs. Given that the statutory formulas for calculating final Medicaid and 340B prices are virtually identical, manufacturers that overcharge Medicaid are also clearly overcharging 340B covered entities as well.

Finally, NACHC receives frequent complaints from health centers that can tell that they are being overcharged for 340B drugs. (Even without a 340B ceiling price database available, they can tell that they are being overcharged when their prices are substantially out of line with what other 340B providers are being charged, or do not reflect well-known changes in Average Manufacturers Prices.) For example, health centers in Arizona have clear evidence that a specific manufacturer has been overcharging them for a form of insulin. Across just seven Arizona health centers, total overcharges for this one drug between July 1, 2015 and September 1, 2017 came to just under $3 million; total overcharges for all Arizona health centers would be significantly higher. While HRSA/ OPA is well aware of this issue, and both OPA and the health centers have reached out to the manufacturer, they have had no success. Of course, this is not surprising, given that neither HRSA nor the health centers have any ability to compel the manufacturer to abide by the statutory pricing requirements.

Given this extensive evidence of manufacturer non-compliance, as well as the fact that the only way that HRSA can enforce compliance is through implementing the CMP Final Rule, NACHC fails to understand why HRSA continues to delay the implementation of this critical, long-overdue authority.

3. The Supreme Court determined in 2011 that covered entities currently have no private right to sue manufacturers over 340B overcharges, pointing instead to Congress' decision to give HRSA enforcement authority through CMPs.

In some situations, where the government does not act to protect their rights, impacted parties can seek redress through the courts. However, that is not an option for 340B covered entities that are being overcharged by manufacturers. In 2011, the Supreme Court found in a unanimous decision in *Astra USA, Inc. v. Santa Clara County*[2] that health centers and other covered entities have no right to sue manufacturers who fail to adhere to the law's pricing requirements. However, in that decision, the Court indicated that:

> "Congress did not respond to the reports of lax enforcement by authorizing third-party beneficiary suits. Instead, Congress amended the law to strengthen and formalize HRSA's enforcement authority, to make a new adjudicative framework as the proper remedy for covered entities to complain of over-charging violations, and to provide for judicial review under the Administrative Procedure Act for the HRSA's resolution of over-pricing claims."[3]

Thus, not only has the Executive Branch expressed the need for, and Congress officially given, HRSA the authority to use CMP to enforce 340B pricing requirements; the Supreme Court has also issued a decision pointing to the importance of this authority. In addition, the Supreme Court's ruling made it even clearer that absent HRSA having such authority, manufacturer compliance relies on nothing more than an Honor System.

4. HRSA's own language in the Federal Register indicates that the agency is aware that some manufacturers are still out of compliance with ceiling price requirements that have been in the statute for 25 years, and that they would find being forced to come into compliance to be "disruptive."

In Section II of the NPRM, HRSA states that one of its reasons for proposing the delay the Final Rule's effective date for the fourth time is as follows:

> "Requiring manufacturers to make targeted and potentially costly changes to pricing systems and business procedures in order to

[2] http://www.scotusblog.com/case-files/cases/astra-usa-inc-v-santa-clara-county/

[3] http://www.scotusblog.com/2011/03/opinion-analysis-third-party-beneficiaries-cannot-sue-drug-manufacturers-for-over-charging/

comply with a rule that is under further consideration and for which substantive questions have been raised would be disruptive."

As this regulation makes no changes to the statutory pricing requirements on manufacturers (but simply gives HRSA authority to enforce them), the "targeted and potentially costly changes to pricing systems and business procedures" that the Final Rule would impose on manufacturers can only be those required to come into compliance with the 1992 law. In other words, HRSA is admitting that it knows that manufacturers are out of compliance with the law's 25-year-old pricing requirements, and that they would find having to come into compliance to be "disruptive." While this may be factually correct, it is not a justification for delaying the Final Rule's effective date; to the contrary, it points to the urgent need for effective enforcement mechanisms.

5. These three factors – extensive data about overcharges covered entities' and HRSA's current inability to enforce pricing requirements, and HRSA's admission that many manufacturers are still out of compliance – all highlight the need for the Final Rule to go into effect immediately, so statutory requirements that have been in effect for 25 years can finally be enforced.

6. Two of the previous delays of the effective date violated the Administrative Procedures Act, and case law – including a decision earlier this year – suggests that such delays would be overturned by the courts.

As discussed at length in the comments submitted jointly by the members of the 340B Coalition, the two of the three previous delays of the effective date of the Final Rule – those announced on March 6, 2017 and March 20, 2017 -- violated the Administrative Procedure Act (APA), because HHS did not provide adequate notice and opportunity for comment that is required for such delays. In addition, the agency failed to show "good cause" for making an exception to these APA procedures. While the March 20, 2017 notice claimed that "public health, safety, and welfare could be harmed by allowing the Final Rule to go into effect without a delay," HRSA failed to articulate any actual harm to public health, safety, and welfare that could come from the Final Rule.

In circumstances similar to HHS's delay of the CMP rule, the D.C. Circuit very recently invalidated a federal agency's attempt to delay the compliance date of a properly promulgated regulation.[4] *Clean Air Council v. Pruitt* concerned a final rule issued by the Environmental Protection Agency (EPA) that required certain entities to comply by June 3, 2017.[5] On April 18, 2017, EPA Administrator Scott Pruitt announced a 90-day stay of this compliance date.[6] The D.C. Circuit vacated the stay because EPA did not comply

[4] Clean Air Council v. Pruitt, 862 F.3d 1 (D.C. Cir. 2017).
[5] Clean Air Council, 862 F.3d at 4.
[6] *Id.* at 5.

with APA notice-and-comment rulemaking requirements.[7] With this decision, the D.C. Circuit reconfirmed several bedrock principles of administrative law that prohibit HHS's proposed delay, including that:

- any delay of a regulation's effective date is "tantamount to amending or revoking a rule" and
- to amend or revoke a rule, HHS "must comply with the Administrative Procedure Act (APA), including its requirements for notice and comment."[8]

Please see the full Coalition comments for additional legal analysis and case law around how the previous delays violate the APA and may be overturned by the courts.

7. It is implausible to state that a "more deliberative process" is needed given that HRSA has already requested and reviewed public comments on this regulation three times, starting six and a half years ago.

The NPRM states that a fourth delay is needed "to allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking." 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:

- On September 10, 2010 (the day after the statutory deadline for implementing the regulations), HRSA issued an Advanced NPRM to seeking stakeholder input so for developing this regulation.[9] HRSA spent almost five years considering that input.
- Based on that input, in June 2015 HRSA finally published a notice of proposed rulemaking.[10] 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.[11] This third comment period closed on May 19, 2016, and HHS received 70 comments[12] totaling 385 pages. Again, these comments came from both

[7] *Id.* at 9. The D.C. Circuit also rejected the EPA's alternative arguments that the stay was authorized by the Clean Air Act. *Id.* at 8-14.
[8] *Id.* at 8-9.
[9] *ANPRM*, 75 Fed. Reg. 57,230.
[10] *Proposed Rule*, 80 Fed. Reg. 34,583.
[11] *340B CMP Reopened Rule*, 81 Fed. Reg. 22,960.
[12] *340B CMP Final Rule*, 82 Fed. Reg. at 1,211

covered entities as well as manufacturers, and expressed views on all aspects of the three issues for which HRSA sought additional comments.

In addition, as previously stated, the current Administration has already delayed the effective date of this regulation three time, each time claiming that more time was needed. 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.

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,

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Director, Regulatory Affairs
National Association of Community Health Centers

cc: Jim Macrae
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Attachment A - Examples of how Health Centers use 340B savings to expand services to vulnerable individuals and communities

FQHCs are required by statute[13] to reinvest all 340B savings into activities that advance their mission of providing high-quality, affordable preventive and primary care to medically underserved individuals, regardless of their ability to pay. FQHCs are subject to continuous, individualized oversight by HRSA's Bureau of Primary Health Care (BPHC) to ensure that they comply with this and all other statutory requirements.

Some 340B savings are passed directly to the individual who receives the discounted drug, in the form of a reduced – or zero -- charge for the drug[14]; in many other cases, 340B savings provide services that benefit the FQHCs' patient population more broadly. Examples of 340B-funded activities that benefit the broader FQHC patient population include:

- **Opioid treatment services**, including Medication-Assisted Treatment (MAT).
- **Underwriting sliding fee discounts on non-pharmaceutical services:** FQHCs turn no one away, and discount services to all patients with incomes below 200% FPL.
- **Clinical pharmacy services** such as: Hepatitis C screening and management; diabetes management; anticoagulation management; controlled substance stewardship; home visits for patients by a pharmacist-nurse team within 72 hours of hospital discharge.
- **Care management services** such as: Care Management nurses, health coaches, social workers, case workers and patient resource specialists. Some of these services are provided in the FQHC, while others involve meeting patients in their homes, hospitals or nursing homes.
- **Making home visits** to homebound patients, including those who have recently been discharged from the hospital or a rehab facility, to help avoid readmissions.
- **Expanding access to dental services,** such as mobile dental vans that increase access to preventive services.
- **Helping patients access Patient Assistance Programs:** 340B savings help finance the software and staff needed to help patients access manufacturer Patient Assistance Program medications, allowing them access to expensive drugs they would otherwise go without.
- **Adding evening and weekend hours** so that patients who work during the day do not have to miss work to see the doctor.
- **Supporting community-based support for those with severe mental illness** including supported employment programs and peer support programs to help them re-engage with the community.
- **Facilitating pharmaceutical access for patients in remote areas.** For example, placing drug dispensing machines in very isolated communities; a "drug buggy" that drives around an FQHC's entire 200-mile-wide rural service area each day to deliver pharmaceuticals to patients in remote areas.
- **Establishing Palliative Care programs**.
- **Updating technology and medical equipment.**
- **Supporting provider education programs** to attract and educate providers about working in underserved areas.

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[13] Section (e)(5)(D) of Section 330 of the Public Health Service Act.

[14] The statute requires FQHCs to charge individuals with incomes below 100% of the Federal Poverty Level no more than a nominal fee for services; individuals between 101% - 200% FPL must be charged on a sliding fee scale.

Attachment B

Evidence of Manufacturer Overcharges Identified by the HHS Office of the Inspector General

As discussed in our comments, three reports conducted by the HHS Office of the Inspector General in the last decade found that:

- Drug manufacturers operate under an "Honor System" to charge 340B providers appropriately, as there is no realistic means to enforce the statutory pricing requirements.
- Under this Honor System:
    - One report found that 100% of manufacturers failed to charge appropriately for 100% of the drugs examined, and that these overcharges represented 45% of the total amount that covered entities paid for 340B drugs.
    - A second report found that 68 of 70 covered entities were overcharged by manufacturers, with smaller entities (such as health centers) generally being subject to larger overcharges.

These three reports are discussed below.

- March 2003. OIG Report A-06-01-0006. Pharmaceutical Manufacturers Overcharged 340B-Covered Entities This study reviewed sales of eleven prescription drugs by five manufacturers during the one-year period ending September 30, 1999 to determine whether the manufacturers overcharged 340B covered entities. The OIG determined that ***100% of manufacturers overcharged 340B covered entities for all eleven drugs***. The OIG estimated ***these overcharges, which totaled $6.1 million, represented 45% of the amount paid by covered entities during the one-year period***.

- October 2005. OIG Report OEI O5-02-00072. Deficiencies in the Oversight of the 340B Drug Pricing Program This report found that HRSA often lacked the appropriate data and systems to determine what the 340B price should be, and to ensure that 340B providers were not overcharged. In other words, ***manufacturers were operating under an "Honor System" to charge 340B providers appropriately and -- as found in the previous OIG report – 100% of them were failing to charge appropriately for 100% of the drugs examined.*** The OIG recommended that the Centers for Medicare and Medicaid Services (CMS) and HRSA work together to ensure accurate and timely pricing data for the government's official record of 340B ceiling prices. The OIG determined that HRSA should establish detailed standards for calculating 340B ceiling prices, including specifying package sizes and a conversion factor for negative ceiling prices. The OIG viewed HRSA's limited options for enforcing manufacturer compliance as significant shortcomings in the 340B program. Thus, the OIG

recommended that HRSA seek authority to establish penalties for 340B violations.

- July 2006. OIG Report OEI-05-02-00073. Review of 340B Prices This report found that ***68 of the 70 covered entities investigated were overcharged for at least one drug***. Of those covered entities, the smaller ones (such as ***health centers) were associated with higher rates of overpayments.***

In response to these OIG reports, the House Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce held a hearing in 2005 on oversight and administration of the 340B program.[15] Stuart Wright, the OIG Deputy Inspector General for Evaluation and Inspections, testified that "HRSA should seek legislative authority to impose civil monetary penalties for situations of noncompliance."[16] Mr. Wright stated that CMPs were necessary "because the current penalty of kicking manufacturers out of Medicaid and the 340B program is so draconian that it's not likely to be utilized."[17]

[15] Oversight and Administration of The 340B Drug Discount Program: Improving Efficiency and Transparency: Hearing Before the H. Subcommittee on Oversight and Investigations of the Comm. on Energy and Commerce, 109th Cong. (Dec. 15, 2005).
[16] *Id.* at 20.
[17] *Id.*