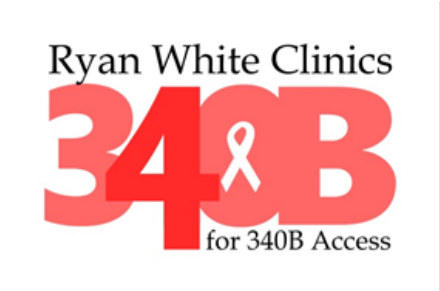

May 22, 2018

Capt. Krista Pedley
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Re: RIN 0906–AB18 - Comments on Notice of Proposed Rulemaking; Further Delay of Effective Date of 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (submitted via Federal eRulemaking Portal: http://regulations.gov)

Ryan White Clinics for 340B Access (RWC-340B) is a coalition of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act and participate as "covered entities" in the federal 340B drug discount program (340B program). RWC-340B appreciates the opportunity to comment on the Notice of Proposed Rulemaking (Proposed Rule) published in the Federal Register by the Health Resources and Services Administration (HRSA) on May 7, 2018, that proposes to further delay the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation's (CMP Rule) effective date from July 1, 2018 to July 1, 2019.[1]

The 340B program is critically important to Ryan White Clinics (RWCs) and their patients, allowing them to stretch their scarce resources to support the full continuum of care that their patients need including testing, linkage to care, and medication adherence. Many of these services are not reimbursed by any payer, though these services directly enable people living with HIV/AIDS to access and remain in care and, most importantly, to become virally suppressed so they cannot transmit the virus to others. RWCs have made great progress in the fight against HIV/AIDS, but that progress is fragile and highly dependent on the continued viability and health of the 340B program and RWCs' access to 340B savings.

RWC-340B strongly urges the United States Department of Health and Human Services (HHS) to implement the regulation beginning July 1, 2018. Any further delay of the rule will adversely affect 340B covered entities, encouraging manufacturer overcharges and

[1] 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 83 Fed. Reg. 20008 (May 7, 2018).

undermining statutory manufacturer integrity provisions, leaving covered entities without any remedies against manufacturer overcharges and no transparency of manufacturer prices. HRSA is required by statute to implement these rules and the statutory deadline for doing so has long passed. Further, HRSA has no lawful justification for a further delay in implementing the CMP Rule.

I. Background

RWC-340B detailed its members' long-standing and widespread problems with manufacturer overcharges and the lack of enforcement in comments dated September 20, 2017, which it submitted jointly with the 340B Coalition to oppose one of the prior delays in implementation of the CMP Rule (attached). To summarize, the HHS Office of the Inspector General (OIG) issued three reports in the mid-2000s examining these issues. In 2003, the OIG reported that sales of eleven drugs by five manufacturers during the one-year period ending September 30, 1999 showed overcharges to covered entities of an estimated $6.1 million.[2] In 2005, the OIG issued a report in which it found that HRSA lacked sufficient enforcement authority against manufacturer overcharges and recommended that HRSA seek authority to establish penalties for violations of ceiling price calculations by manufacturers.[3] In 2006, the OIG issued a report that found that 14 percent of the sampled purchases made by 340B covered entities exceeded the 340B ceiling price.[4] OIG again recommended that HRSA establish penalties for 340B violations by manufacturers, noting "it is important that HRSA have sufficient penalty authority."[5]

In 2010, Congress enacted several important revisions to the 340B statute to address HRSA oversight of manufacturers.[6] As amended, the statute requires HHS to implement certain "improvements in program integrity" for the 340B program.[7] These improvements include a directive to issue regulations for determining manufacturer ceiling prices and for imposing CMPs on manufacturers that "knowingly and intentionally" charge covered entities more than the ceiling price for covered outpatient drugs. The amended statute provides that CMPs "shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act."[8] This statutory deadline passed on September 19, 2010, more than seven and half years ago. If adoption of the regulation is delayed to July 1, 2019, HRSA will have missed its statutory deadline for implementation by almost nine years.

Earlier this month, the OIG testified before a United States Senate committee that, as a result of the delay in the CMP Rule, "the OIG has not received any referrals for enforcement

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[2] Department of Health and Human Services (HHS) Office of Inspector General (OIG), Pharmaceutical Manufacturers Overcharged 340B-Covered Entities at 3 (Mar. 10, 2003), https://oig.hhs.gov/oas/reports/region6/60100060.pdf.
[3] HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program at iv, 22, (Oct. 2005), https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.
[4] HHS OIG, Review of 340B Prices at i, 10 (July 2006), https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.
[5] *Id.* at ii, 20-21.
[6] Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, § 7102, 124 Stat. 823 (2010) (amending Public Health Service Act § 340B(d), 42 U.S.C. § 256b(d)).
[7] 42 U.S.C. § 256b(d).
[8] 42 U.S.C. § 256b (d)(1)(B)(vi)(I).

authority, and we don't anticipate receiving any until the rule is finalized."[9] The problems that the OIG first identified fifteen years ago have not been addressed and HRSA's proposal to delay implementation of the CMP Rule means they will not be addressed for at least another year.

II. Delay Will Encourage Overcharges and Undermine Statutory Manufacturer Integrity Provisions

A. Delay Will Adversely Affect 340B Covered Entities

In the commentary on its proposed rule, HHS states that it does not believe "this delay will adversely affect any of the stakeholders in any meaningful way."[10] This statement ignores not only the extent of overcharges as documented in OIG reports, but also HHS's own statements in the same commentary. The OIG clearly and repeatedly has said that HRSA's failure to penalize manufacturers for ceiling price overcharges severely undermines oversight of the 340B program. In a 2005 report, the OIG noted that, "[e]ven when HRSA attempts action against violators of the 340B Program, its lack of legal authority makes it a challenge to enforce its guidelines….To further illustrate the ineffectiveness of HRSA's current authorities, in 2001, HRSA discovered overcharges based on entities' invoices, but did not pursue the issue further, citing insufficient authority."[11] The OIG also stated in its May 15, 2018 congressional testimony that it found "that 14 percent of all purchases by 340B entities were in fact over the ceiling price…So, we do in fact have evidence that overcharging has taken place."[12]

Moreover, in the same paragraph in which HHS alleges that the delay will not adversely affect stakeholders, it states that "a small number of manufacturers have informed HHS over the last several years that they charge more than $0.01 for a drug with a ceiling price below $0.01" and that it "believes" that a majority of manufacturers follow the "long-standing HHS policy" on penny pricing.[13] These statements are a clear acknowledgement that some manufacturers are NOT following the penny pricing policy. Moreover, HHS's statement that it merely "believes" most manufacturers are following the policy demonstrates that HHS has not attempted to investigate the extent of noncompliance. Rather than implement the CMP Rule, HHS proposes to reward those manufacturers that are flouting ceiling price requirements and the penny pricing policy with another year's free pass.

B. Covered Entities Do Not Have Any Remedy Against Manufacturer Overcharges

HHS asserts that delaying implementation of the CMP Rule "should have no adverse effect given that other more significant remedies are available to entities that believe they have

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[9] Examining Oversight Reports on the 340B Drug Pricing Program, Spoken Testimony of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, Office of the Inspector General Before the United States Senate Committee on Health, Education, Labor and Pensions (May 15, 2018).
[10] 83 Fed. Reg. at 20,009.
[11] HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program at 17 (Oct. 2005), https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.
[12] Examining Oversight Reports on the 340B Drug Pricing Program, Spoken Testimony of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, Office of the Inspector General Before the United States Senate Committee on Health, Education, Labor and Pensions (May 15 2018).
[13] 83 Fed. Reg. at 20,009.

not been provided the full discount that they are entitled to under the program."[14] HHS fails to identify what these "more significant remedies" are and, in fact, there are none. In *Astra, USA, Inc. v. Santa Clara County, Cal.*, the Supreme Court held that 340B covered entities do not have a private right of action against manufacturers for drug pricing overcharges.[15] Because covered entities cannot bring an action against manufacturers for overcharges, they are forced to rely on the government to remedy manufacturer non-compliance. As discussed above, HRSA's ability to enforce ceiling price requirements is hampered without the CMP Rule. In addition, covered entities are not permitted to audit manufacturers, even though manufacturers may audit covered entities for 340B program violations in certain circumstances.

One potential remedy in the 340B statute, a mandatory administrative dispute resolution process, was supposed to have been implemented on September 19, 2010 (the same date that HRSA was required to implement the CMP Rule).[16] However, HRSA withdrew the Notice of Proposed Rulemaking to implement the regulation.[17] The existing voluntary dispute resolution process is ineffective because both parties have to agree to the process and as demonstrated by the fact that Congress saw the need to adopt a mandatory dispute resolution process. As discussed below, HRSA has stated that it will not make ceiling price information available to covered entities until the CMP Rule is implemented. Covered entities, therefore, have no meaningful way to know whether they have been overcharged because they do not have access to ceiling price information. In sum, not only are there no "significant" remedies available to covered entities for manufacturer overcharges, there are no remedies of any sort.

The lack of a current remedy for manufacturer overcharges is exacerbated by the fact that HRSA does not plan to implement the CMP Rule retroactively. When HRSA published the CMP Rule, it stated that the rule would not be implemented retroactively because it would be "administratively burdensome and difficult for all stakeholders."[18] The fact that the CMP Rule will not be enforced retroactively, coupled with the lack of remedies for covered entities or current enforcement by HRSA, means that manufacturers will continue to overcharge covered entities with impunity, knowing that they will not be subject to CMPs for doing so.

C. Delay of the CMP Rule Results in Further Delay of Access to Ceiling Prices

Currently, covered entities rely on HRSA for ceiling price information in excess of the ceiling price and to act against manufacturers if the manufacturer charges in excess of the ceiling price. The OIG has confirmed that covered entities cannot independently verify that they receive the correct 340B discount.[19] The OIG recommended that CMS and HRSA work together to

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[14] 83 Fed. Reg. at 20,009.
[15] *Astra USA, Inc. v Santa Clara County, Cal.*, 563 U.S. 110 (2011).
[16] 42 U.S.C. § 256b (d)(3).
[17] See https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AA90.
[18] 82 Fed. Reg. 1210 at 1211 (Jan. 5, 2017).
[19] HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program at iii, 18 (Oct. 2005) https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf; *see also* Examining Oversight Reports on the 340B Drug Pricing Program, Written Testimony of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, Office of the Inspector General Before the United States Senate Committee on Health, Education, Labor and Pensions at 3 and 4 (May 15 2018). https://www.oig.hhs.gov/testimony/docs/2018/maxwell-testimony05152018.pdf

ensure accurate and timely pricing data for the government's official record of 340B ceiling prices.[20]

In 2010, Congress responded to the lack of access to ceiling prices and required HHS to publish a database of ceiling prices that is accessible to covered entities.[21] In HRSA's FY19 budget proposal, however, it stated that it would delay publishing the ceiling price database until after it finalizes the CMP Rule.[22] Therefore, the delay in the CMP Rule is adversely affecting covered entity's access to ceiling price information. As discussed above, without access to ceiling price information, covered entities have to rely on HRSA to confirm any instances in which the covered entity suspects that it was overcharged by a manufacturer, thereby hampering any meaningful enforcement against manufacturers.

D. HHS Has Not Offered Any Meaningful Justification for Further Delay

In its commentary on the proposed rule, HHS states that proposed delay "would allow necessary time to consider more fully the substantial questions of fact, law, and policy identified by the Department during its review of the rule".[23] HHS fails, however, to identify any questions that it has not already been extensively considered or its basis for concluding that further consideration is necessary. Although HHS says it is in the "process of developing new comprehensive policies to address the rising cost of prescription drugs," HHS does not provide any reason to believe that such policies will materially change the CMP Rule.[24]

HHS has already fully considered whether the CMP rule stands on its own, independent of other programmatic regulations:

> HHS does not believe that the issuance of additional guidance is needed in order to implement this final rule. The provisions of this final rule will be effectively implemented independent of other programmatic regulations and guidances. Current policies under the 340B Program provide stakeholders with sufficient guidance regarding programmatic compliance.[25]

The Proposed Rule provides no new information or plausible rationale for changing the conclusion in the quote above. HRSA has received and considered comments on all essential aspects of the CMP Rule.

HHS asserts in the Proposed Rule that delaying the CMP Rule would avoid requiring manufacturers "to make targeted and potentially costly changes to pricing systems" that might

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[20] HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program at iii, 21 (Oct. 2005). https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.
[21] 42 U.S.C. § 256b(d)(1)(B)(iii).
[22] HHS Fiscal Year 2019, Health Resources and Services Administration, Justification of Estimates for Appropriations Committee, at page 268. https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy2019.pdf
[23] 83 Fed. Reg. at 20,009.
[24] 83 Fed. Reg. at 20,009.
[25] 82 Fed. Reg. at 1211.

have to be changed subsequently.[26] But, HHS has already stated that the CMP Rule would not impose any new requirements on manufacturers.

> The specific elements required as part of the calculation of the ceiling price are elements that manufacturers are already required to utilize as part of their participation in the 340B Program. HHS expects that these elements would continue to be available. Therefore, calculation of the ceiling price would not result in an economic impact or create additional administrative burden on these businesses.[27]

HHS has already solicited comments four times through the rulemaking process and considered the concerns raised by stakeholders. The comprehensive drug pricing policies that it is developing are not a justification for further delay.

III. Further Delay is Directly Contrary to Law

As thoroughly discussed in RWC-340B's attached comments dated September 20, 2017 and in those of other covered entity organizations, the delays in implementation of the CMP Rule are contrary to the 340B statute and the Administrative Procedure Act. When HRSA issued the CMP Rule with an effective date of March 6, 2017, it had already missed the statutory deadline by six and one-half years. Moreover, it has already delayed implementation of the CMP Rule four times. HHS has not raised any novel issues of law or fact that would justify additional delay. HHS explained one delay by stating that it was following a White House mandate to freeze regulatory action. That freeze, however, "excludes regulations subject to statutory or judicial deadlines."[28] As discussed above, HHS is under a statutory deadline to issue the CMP Rule, so HRSA could have implemented the CMP Rule despite the freeze.

HRSA has delayed implementing any of the manufacturer integrity provisions that were enacted into law more than eight years ago, which include:

(1) implementing "precisely defined standards and methodology for calculation of the ceiling price;"
(2) "comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the secretary;"
(3) "performing spot checks and sales transactions by covered entities" and
(4) "inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies."[29]

The delay in implementing the CMP Rule is only one of the many delays by HRSA in taking action to police manufacturer compliance with the 340B program. HRSA has no reason to continue to flaunt Congressional directives to implement these important measures.

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[26] 83 Fed. Reg. at 20,009.
[27] 82 Fed. Reg. at 1228.
[28] January 20, 2017, Memorandum from the Assistant to the President and Chief of Staff, titled "Regulatory Freeze Pending Review." https://www.whitehouse.gov/the-press-office/2017/01/20/memorandum-heads-executive-departments-and-agencies.
[29] 42 U.S.C. § 256b(d)(1)(B)(i)(I),(II), (III) and (IV).

IV. Additional Rulemaking Should Supplement, Rather Than Modify, the CMP Rule

As RWC-340B stated in its previous comments, if HHS decides to engage in additional rulemaking, HHS should supplement rather than modify the CMP Rule. HRSA has given ample opportunity for comments that permitted HRSA to fully and thoroughly consider stakeholder input.

V. Conclusion

Implementation of the CMP Rule is an essential element of the manufacturer integrity provisions of the 340B program. RWC-340B strongly urges HRSA to implement the CMP Rule on July 1, 2017.

Sincerely,

MEMBERS OF RWC-340B

AIDS Center of Queens County
AID Atlanta
AIDS Care Group
AIDS Healthcare Foundation
AIDS Outreach Center
AIDS Project of the Ozarks
AIDS Resource Center of Wisconsin
AIDS Taskforce of Greater Cleveland
Alamo Area Resources Center
Allies for Health + Wellbeing
Big Bend Cares
CAN Community Health
Cempa Community Care
Christie's Place
Conemaugh Health System
Damien Cares
Equitas Health
Evergreen Health Services
Fenway Health
Foothill AIDS Project
Heartland CARES
Hyacinth AIDS Foundation
Men's Health Foundation
MetroHealth
Northern Nevada HOPES
North Jersey Community Research Initiative

Northland Cares
Nuestra Clinica
One Community Health
Open Door Health Center
Positive Health Clinic
Positively U
Prism Health North Texas
South Carolina HIV/AIDS Council
Southwest CARE Center
Thrive Alabama
Trillium Health
Urban Solutions Inc.
Whole Family Health Center

Attachment