



November, 21, 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: RIN 0906–AB19 - Comments on Notice of Proposed Rulemaking; 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 national association 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 Nov 2, 2018, that proposes to change the 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation’s (CMP Rule) effective date from July 1, 2019 to January 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 January 1, 2019. RWC-340B supports the decision to move the implementation date ahead 6 months. 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. 55135 (November 2, 2018).

undermining statutory manufacturer integrity provisions, leaving covered entities without any remedies against manufacturer overcharges and no transparency of manufacturer prices.

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.² 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.³ In 2005, the OIG issued a report titled "Deficiencies in the Oversight of the 340B Drug Pricing Program" in which the OIG recommended that HRSA seek authority to establish penalties for 340B violations.⁴ 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.⁵ OIG again recommended that HRSA establish penalties for 340B violations by manufacturers, noting "it is important that HRSA have sufficient penalty authority."⁶

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.⁷ 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.⁸ **After over 8 years, we urge HRSA to move forward on publishing the database of ceiling prices as soon as possible.** The database will be instrumental in improving program transparency and oversight. We see the tool as invaluable in establishing pricing integrity and stand by ready to assist if needed.

Implementation of the Ceiling Price and CMP Rule include essential elements of the manufacturer integrity provisions of the 340B program. RWC-340B strongly urges HRSA to implement the Ceiling Price and CMP Rule on January 1, 2019.

Sincerely,

MEMBERS OF RWC-340B

² RWC-340B also submitted comments opposing delay of the rule on May 22, 2018 in response to RIN 0906-AB18.

³ 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>.

⁴ HHS OIG, Deficiencies in the Oversight of the 340B Drug Pricing Program iv, 22, (Oct. 2005), <https://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf>.

⁵ HHS OIG, Review of 340B Prices at i, 10 (July 2006), <https://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf>.

⁶ *Id.* at ii, 20-21.

⁷ 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>

⁸ 42 U.S.C. § 256b(d)(1)(B)(iii).

Action Wellness – *Philadelphia, Pennsylvania*
AID Atlanta – *Atlanta, Georgia*
AIDS Care Group – *Philadelphia, Pennsylvania*
AIDS Center of Queens County – *Queens, New York*
AIDS Healthcare Foundation – *Los Angeles, California*
AIDS Outreach Center – *Fort Worth, Texas*
AIDS Project of the Ozarks – *Springfield, Missouri*
AIDS Resource Center of Wisconsin – *Milwaukee, Wisconsin*
AIDS Taskforce of Greater Cleveland – *Cleveland, Ohio*
Alamo Area Resources Center – *San Antonio, Texas*
Allies for Health + Wellbeing – *Pittsburgh, Pennsylvania*
Big Bend Cares – *Tallahassee, Florida*
CAN Community Health – *Sarasota, Florida*
Cempa Community Care – *Chattanooga, Tennessee*
Christie’s Place – *San Diego, California*
Conemaugh Health System – *Johnstown, Pennsylvania*
Damien Cares – *Indianapolis, Indiana*
Equitas Health – *Columbus, Ohio*
Evergreen Health Services – *Buffalo, New York*
Fenway Health – *Boston, Massachusetts*
Foothill AIDS Project – *Claremont, California*
Heartland CARES – *Paducah, Kentucky*
Hyacinth AIDS Foundation – *Elizabeth, New Jersey*
Men’s Health Foundation – *Los Angeles, California*
MetroHealth – *Washington, DC*
North Jersey Community Research Initiative – *Newark, New Jersey*
Northern Nevada HOPES – *Reno, Nevada*
Northland Cares – *Prescott, Arizona*
Nuestra Clinica – *Lancaster, Pennsylvania*
One Community Health – *Sacramento, California*
Open Door Health Center – *Elgin, Illinois*
Positive Health Clinic – *Pittsburgh, Pennsylvania*
Positively U – *Davenport, Florida*
Prism Health North Texas – *Dallas, Texas*
Project Response – *Melbourne, Florida*
South Carolina HIV/AIDS Council – *Columbia, South Carolina*
Southwest CARE Center – *Santa Fe, New Mexico*
Thrive Alabama – *Huntsville, Alabama*
Trillium Health – *Rochester, New York*
Urban Solutions Inc. – *Philadelphia, Pennsylvania*
Whole Family Health Center – *Vero Beach, Florida*