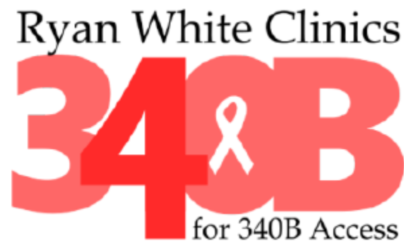


**VIA ELECTRONIC SUBMISSION**

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4–26–05
Attention: CMS-1695-P
7500 Security Boulevard, Baltimore, MD 21244–1850

**Re: File Code CMS–1695–P: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for Potential CMS Innovation**

To Whom It May Concern:

Ryan White Clinics for 340B Access (RWC-340B) is a national organization of 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 Centers for Medicare and Medicaid Services (CMS) on July 31, 2018, revising the Medicare payment rates under the hospital outpatient prospective payment system (OPPS) for calendar year (CY) 2019 (Proposed Rule).[1] RWC-340B opposes the payment cuts described in the Proposed Rule both on procedural grounds and because they conflict with the purpose of the 340B program.

## Background

The 340B program is critically important to Ryan White clinics (RWCs) and their patients, allowing them to stretch their resources to support the full continuum of care that their

---

[1] Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for Potential CMS Innovation, 83 Fed. Reg. 37,046 (July 31, 2018) (CMS–1695–P). https://www.federalregister.gov/documents/2018/07/31/2018-15958/medicare-program-proposed-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical

patients need, from testing, to linkage to care, to medication adherence and viral suppression. Many of these services are not reimbursed by any payer, though these are the services that most directly influence people living with HIV/AIDS to access and remain in care. 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 RWC's access to savings.

The Proposed Rule would reduce the rate that Medicare reimburses for "nonexcepted", off-campus provider based departments of hospitals for separately payable, Part B drugs (other than pass-through drugs and vaccines) acquired under the 340B program from Average Sales Price (ASP) + 6% to ASP – 22.5%.[2] As background, for CY 2018, CMS reduced payment for separately payable, 340B-acquired drugs (other than pass-through drugs and vaccines) furnished in hospital departments paid under OPPS, which does not include nonexcepted clinics.[3] The Proposed Rule would extend the payment reduction to nonexcepted hospital clinics, which are recently opened, off-campus hospital clinics that are more specifically described at 42 U.S.C. § 1395l(t)(21)(B).

**Procedural Flaws**

CMS's attempt to impose a rule change for services payable under the Medicare Physician Fee Schedule through a proposed rule to the OPPS contravenes the notice-and-comment requirements of both the federal Administrative Procedure Act (APA) and the Medicare statute.[4] In the commentary on the Proposal Rule, CMS conceded that payments to nonexcepted clinics are made under the Physician Fee Schedule and not the OPPS. "Under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, however, nonexcepted items and services furnished by nonexepted off-campus PBDs [Provider Based Departments] are no longer covered outpatient department services and therefore not payable under OPPS. This means that nonexcepted off-campus PBDs are not subject to the payment changes finalized in the CY 2018 OPPS/ASC final rule with comment period that apply to hospitals and PBDs paid under the OPPS."[5] The Proposed Rule, however, expressly applies to payments under the OPPS and not to payments under the Medicare Physician Fee Schedule.

A federal agency is required to be clear in its announcement of a proposed rule so that interested parties are on notice of the proposed changes.[6] In the *McLouth Steel Products* case, a federal agency purported to announce a proposed rule under a misleading subheading, which the court determined "would not have altered a reader to the stakes" and did not comply with notice requirements of the APA.[7] In the Proposed Rule, CMS is announcing a payment change not simply under an incorrect heading, but in an entirely incorrect proposed rule. CMS cannot

---

[2] 83 Fed. Reg. at 37,145-46.
[3] *See* 83 Fed. Reg at 37,145.
[4] 5 U.S.C. § 553; 42 U.S.C. § 1395hh; *see also Allina Health Servs. v. Price*, 863 F.3d 937, 944 (D.C. Cir. 2017)(statutory text of Medicare statute expressly requires notice-and-comment rule making).
[5] 83 Fed. Reg. at 37145 (July 31, 2018).
[6] *See McLouth Steel Products Corporation v. Thomas,* 838 F.2d 1317, 1323 (D.C.Cir. 1988). ("An agency may not introduce a proposed rule in this crabwise fashion.")
[7] *Id*.

propose a rule that addresses one payment system (OPPS) when the proposed change affects reimbursement under a completely different payment system (Physician Fee Schedule). The appropriate way of proposing cuts to payments for nonexcepted clinics would have been through the proposed rule related to updates to the Medicare Physician Fee Schedule, which CMS issued only a few days before the Proposed Rule.[8] A party who was interested in whether CMS would be proposing changes to reimbursement for nonexcepted clinics for drugs purchased with 340B discounts, therefore, would logically have looked for those changes in the proposed Physician Fee Schedule rule. Seeing no changes proposed in that rule, the interested party would not be on notice of CMS' proposal to reduce payment for certain 340B-acquired drugs from ASP +6% to ASP -22.5% and would not have a meaningful opportunity to comment.

In sum, CMS violated the public notice requirements of the APA and the Medicare statute by announcing the proposed change to payments for separately payable, part B drugs (other than pass-through drugs and vaccines) to nonexcepted clinics through the proposed OPPS rule. The fact that other commenters (including RWC-340B) became aware of the proposed reductions announced in the Proposed Rule does not serve as evidence that CMS' notice was adequate, nor can that fact exonerate CMS from complying with the notice requirements of the APA and Medicare statute.[9]

## **Conflicts with 340B Program**

As RWC-340B explained in response to CMS' proposed rule to reduce payment for 340B-acquired drugs (other than pass-through drugs and vaccines) paid under the OPPS, the proposed cut runs counter to the purpose of the 340B program. Although the cut in reimbursement to 340B hospitals would not affect RWCs directly, RWC-340B opposes the cut because reimbursement that discriminates against any covered entity sets a dangerous precedent for all 340B covered entities and contravenes the purpose of the 340B program. Many RWCs are being asked to agree to this type of discriminatory payment provision by private payors, and the CMS Proposed Rule, if adopted, would embolden these private insurers to try to impose even steeper cuts in reimbursement for 340B drugs.

Importantly, reimbursing 340B drugs at a different rate than non-340B drugs conflicts with the Congressional purpose of the 340B program, which is to enable qualified safety-net providers to stretch their scarce resources so that they may "reach[] more eligible patients" and "provid[e] more comprehensive services."[10] Congress intended the benefits of the 340B program to accrue to 340B covered entities, not to other providers that do not have the same

---

[8] CMS announced CY 2019 proposed revisions to Physician Fee Schedule payments in the July 27, 2018 Federal Register. 83 Fed. Reg. 35,704. In fact, CMS included proposals related to payments to nonexcepted clinics, but those proposals did not include an announcement of any proposed changes to payments for separately payable, Part B drugs (other than pass-through drugs and vaccines).

[9] *See AFL-CIO v. Donovan,* 757 F.2d 330, 339-40 (D.C.Cir.1985) (actual notice cannot be attributed to parties on assumption that they monitor others' comments); *Small Refiner Lead Phase-Down Task Force v. EPA,*705 F.2d 506, 549-50 (D.C.Cir.1983) (same — notice requirement not "an elaborate treasure hunt"). *But see Common Carrier Conference v. United States,* 534 F.2d 981, 982-83 (D.C.Cir.), *cert. denied,* 429 U.S. 921, 97 S.Ct. 317, 50 L.Ed.2d 288 (1976) (finding that "industry was generally on notice").

[10] H.R. Rep. 102-384, 102d Cong., pt. 2, at 12 (2nd Sess. 1992).

safety net mission. CMS's proposal would undermine the purpose of the 340B program by preventing the operation of the 340B statute. Although manufacturers would still have to provide 340B discounts under the Proposed Rule, the discriminatory reimbursement rate would greatly reduce, if not eliminate, the benefit of the discount for 340B hospitals, thereby undermining the purpose of the 340B program.

The 340B program was established to provide additional financial resources to covered entities without increasing the federal budget. The difference between a 340B drug's lower acquisition cost and standard reimbursement represents the very benefit that Congress intended to give covered entities when it established the 340B program. Covered entities use these savings to treat more vulnerable patient populations or to improve services for those populations.

The Health Resources and Services Administration (HRSA), the federal agency that administers the 340B program, views discriminatory reimbursement as a threat to the 340B program. HRSA has expressed concerns that providers would have no reason to participate in the 340B program if insurers take the benefit of 340B savings. HRSA explains that "if covered entities were not able to access resources freed up by the drug discounts when they… bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities."[11]

Discriminatory reimbursement ultimately harms the low income and medically vulnerable patients served by 340B providers. Covered entities use 340B savings in a variety of ways to benefit the vulnerable patients they serve. The Government Accountability Office has found that providers use 340B to offset losses incurred from treating some patients, continue providing existing pharmaceutical and clinical services, lower drug costs for low-income patients and serve more patients, and provide additional services, such as case management, to facilitate access to appropriate care.[12] Reducing reimbursement to 340B covered entities will jeopardize these important programs.

Discriminatory reimbursement also raises issues under the Equal Protection Clause of the Fourteenth Amendment, which prohibits the government from treating similarly situated entities unequally without a rational basis. Case law has recognized that the Equal Protection Clause prohibits the payment of unequal rates to similarly situated providers.[13] The same principle can be applied to forms of discriminatory reimbursement such the one proposed by CMS, which would impose a lower rate on covered outpatient drugs furnished by 340B hospitals simply because of their participation in the 340B program.

CMS's proposal to reduce Medicare payments to off-campus departments of 340B hospitals would set another precedent for other forms of discriminatory reimbursement for 340B

---

[11] HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act* (July 2005), https://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm.
[12] GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, at 17 (Sept. 2011), http://www.gao.gov/products/GAO-11-836.
[13] *See, e.g.*, *West Virginia Univ. Hospitals Inc. v. Rendell*, 2007 WL 3274409 (M.D. Pa. 2007).

drugs that are harmful to RWCs and undermine the purpose of the 340B program. The plain language of the 340B statute and Congress's intent that the 340B program benefit covered entities forbids the type of discriminatory reimbursement proposed by CMS for 340B hospitals. As CMS considers its Proposed Rule, RWC-340B asks it to remain mindful of the example it is setting and the potential long-term impact the rule could have on 340B covered entities and the 340B program.

* * * * *

For the above reasons, RWC-340B opposes the 340B-related payment cuts reflected in the Proposed Rule and asks that they be dropped when the Proposed Rule is finalized.

Sincerely,

**MEMBERS OF RWC-340B**

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*
Equitas Health – *Columbus, Ohio*
Evergreen Health Services – *Buffalo, New York*
Fenway Health – *Boston, Massachusetts*
Foothill AIDS Project – *Claremont, California*
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*