Ryan White Clinics for 340B Access

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4–26–05
Attention: CMS-1678-P
7500 Security Boulevard, Baltimore, MD 21244–1850

Re: File Code CMS–1678–P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

To Whom It May Concern:

Ryan White Clinics for 340B Access (RWC-340B) is a coalition 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 20, 2017, setting Medicare payment rates under the hospital outpatient prospective payment system (OPPS) for calendar year (CY) 2018 (Proposed Rule).[1]

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 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 pays 340B hospitals for separately payable Part B drugs under the OPPS from Average Sales Price (ASP) + 6% to ASP – 22.5%. CMS is proposing to redistribute these savings by increasing reimbursement for other OPPS services, but is also accepting comments on whether the savings should be redistributed to certain categories of providers or across "Part B generally".[2]

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[1] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33,558 (July 20, 2017) (CMS–1678–P).

[2] *Id*. at 33,634, 33,712 (July 20, 2017).

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."[3] Congress intended the benefits of the 340B program to accrue to 340B covered entities, not to other providers that do not have the same 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."[4]

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

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

[4] 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.

access to appropriate care.[5] 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.[6] 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 340B hospitals would set a precedent for other forms of discriminatory reimbursement for 340B 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.

Sincerely,

MEMBERS OF RWC-340B

AIDS Center of Queens County
AID Atlanta
AIDS Care Group
AIDS Healthcare Foundation
AIDS Resource Center of Wisconsin
AIDS Taskforce of Greater Cleveland
Alamo Area Resources Center
Big Bend Cares
Cares Community Health
Chattanooga CARES
Community AIDS Network
Conemaugh Health System
Damien Cares
Evergreen Health Services
Fenway Health
Heartland CARES
Hyacinth AIDS Foundation

[5] 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.

[6] *See, e.g., West Virginia Univ. Hospitals Inc. v. Rendell*, 2007 WL 3274409 (M.D. Pa. 2007).

MetroHealth
Northland Cares
Open Door Health Center
Pittsburgh AIDS Task Force
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