



**VIA ELECTRONIC SUBMISSION**

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Mail Stop C4-26-05  
Attention: CMS-4182-P  
7500 Security Boulevard, Baltimore, MD 21244-1850

**Re: File Code CMS-4182-P: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program**

To Whom It May Concern:

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 Centers for Medicare and Medicaid Services (CMS) on November 28, 2017 to make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our members’ experience participating in the Part C and Part D programs.<sup>1</sup> RWC-340B wishes to make three comments specifically upon CMS’s effort to clarify or modify its interpretations of Medicare Part D requirements as set out in section II. A. 12 of the proposed rule entitled “Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505).”<sup>2</sup> We also want to comment on proposed changes to “negotiated price” requirements as set out in section II. A. 17 of the proposed rule entitled “Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale.”<sup>3</sup> Finally we wish to express our support for establishing stricter quality standards for providing medication therapy management (MTM) as set out in section II. C b. (2) “Medication Therapy Management (MTM) (§§ 422.2420 and 423.2460).”<sup>4</sup>

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<sup>1</sup> Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 82 Fed. Reg. 56,336 (Nov. 28, 2017) (CMS-4182-P).

<sup>2</sup> 82 Fed. Reg. at 56407 - 56411.

<sup>3</sup> 82 Fed. Reg. at 56419 – 56428.

<sup>4</sup> 82 Fed. Reg. at 56458 – 56459.

First, RWC-340B supports CMS's proposed clarification that the "We also support any willing pharmacy" requirements apply to all pharmacy business models. We also support the agency's clarification that Part D Plans may not apply a definition of pharmacy type that excludes pharmacies that meet the standard terms and conditions. Second, RWC-340B urges CMS to further clarify that Part D Plans are prohibited from instituting discriminatory contracting and payment methodologies that single out a subset of similarly situated pharmacies based solely on their participation in the 340B program. Third, because exclusion from Part D pharmacy networks for specialty drugs is especially common and is often associated with manufacturer use of limited distribution networks, we ask that both Part D Plans and manufacturers be prohibited from engaging in such discriminatory practices. Fourth, RWC-340B is concerned that proposed changes to "negotiated price" requirements to reflect more closely pharmacy price concessions could encourage Part D Plans to reduce payment for 340B drugs contrary to the purpose of the 340B program. Lastly, RWC-340B supports CMS's proposal to strengthen the Part D MTM standards for purposes of qualifying MTM services as quality improvement activities (QIA).

***Comment One: RWC-340B supports CMS's proposed clarification that the Part D "any willing pharmacy" requirement applies to all pharmacies***

We agree with the concern expressed by CMS that the development of 'standard' terms and conditions in some cases has had the effect of "circumventing the any willing pharmacy requirements and inappropriately excluding pharmacies from network participation."<sup>5</sup> We further agree with CMS's proposal to clarify or modify its interpretation to better ensure full compliance with the any willing pharmacy requirement. CMS properly identifies standard terms and conditions as a "'floor' of minimum requirements that all similarly situated pharmacies must abide by."<sup>6</sup> Although CMS does permit "Part D Plans to modify some standard terms and condition to encourage participation by particular pharmacies," we agree that CMS should clarify its views further to ensure that such modifications do not discriminate within a class of similarly situated providers. As noted by CMS, the any willing pharmacy provision only permits variation in the standard terms and conditions to accommodate different types of pharmacies "so long as all similarly situated pharmacies were offered the same terms and conditions."<sup>7</sup> We agree that CMS should make clear that Part D plan sponsors may not exclude pharmacies on the basis of not fitting the correct pharmacy type classification and that "similarly situated pharmacies" include "any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type."<sup>8</sup>

***Comment Two: Part D Plans should be prohibited from instituting discriminatory contracting methodologies that single out a subset of similarly situated pharmacies based on the pharmacies' participation in the 340B program***

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<sup>5</sup> 82 Fed. Reg. at 56407.

<sup>6</sup> 82 Fed. Reg. at 56407.

<sup>7</sup> 82 Fed. Reg. at 56408.

<sup>8</sup> 82 Fed. Reg. at 56408.

The language clarifying the definition of similarly situated pharmacy is an important step in achieving CMS's goal, although, alone it may be insufficient. The problem identified by CMS of circumvention of the any willing pharmacy provision does not occur in a vacuum and is influenced by the profit motive of Part D Plan sponsors. In addition to the statements that further clarify the meaning of similar situated pharmacies so as to prevent Plans from inappropriately excluding pharmacies based upon definitions of pharmacy type, CMS must clarify that Part D Plans are not permitted to create materially different payment rates for similarly situated pharmacies. Not only are Part D Plans excluding similarly situated pharmacies through inappropriate application of the definition of pharmacy type, but also reaching the same result by establishing payment terms that discriminate in payment rates among similarly situated providers. CMS must make clear that Part D Plans cannot circumvent the requirement all similarly situated pharmacies be offered the same terms and conditions, through by establishing payment methodologies that discriminate based upon criterion independent of a pharmacies capability of complying with standard terms and conditions.

RWC-340B urges CMS to take this opportunity to clarify that whether a pharmacy qualifies as a 340B pharmacy or has access to 340B pricing is not an appropriate basis to justify treating that pharmacy as a different pharmacy type when determining the appropriate standard terms and conditions. Furthermore, CMS should clarify that Part D Plans may not establish standard terms or conditions that apply discriminatory payment rates to pharmacies within a pharmacy type. As noted by CMS, "the Act requires Part D Plan sponsors to permit that participation of 'any pharmacy' that meets the standard terms and conditions."<sup>9</sup> However, historically there have been instances where pharmacy benefit managers and managed care organizations had discriminated against pharmacies with access to 340B prices under the 340B program. RWC-340B urges CMS to further clarify in the preamble that Part D sponsors and Part C Medicare Advantage plans are prohibited from creating terms and conditions that have the effect of discouraging or barring pharmacies with access to 340B pricing from participating in pharmacy networks.

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.

Importantly, the plain language of the 340B statute does not authorize the type of discriminatory reimbursement practices utilized by some Medicare Part D Plans when contracting with safety net providers participating in the 340B program 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

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<sup>9</sup> 82 Fed Reg. at 56408.

they may “reach[] more eligible patients” and “provid[e] more comprehensive services.”<sup>10</sup> 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. Part D Plans that apply lower reimbursement rates for 340B entities undermine the purpose of the 340B program by preventing the operation of the 340B statute.

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.”<sup>11</sup>

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.<sup>12</sup> Reducing reimbursement to 340B covered entities will jeopardize these important programs.

Discriminatory contracting practices 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.<sup>13</sup> The same principle can be applied to forms of discriminatory reimbursement such those used by some Medicare Part D Plans, which would impose a lower rate on covered outpatient drugs furnished by 340B hospitals simply because of their participation in the 340B program.

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<sup>10</sup> H.R. Rep. 102-384, 102d Cong., pt. 2, at 12 (2nd Sess. 1992).

<sup>11</sup> 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>.

<sup>12</sup> 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>.

<sup>13</sup> See, e.g., *West Virginia Univ. Hosps. Inc. v. Rendell*, No. 1:CV-06-0082, 2007 WL 3274409 (M.D. Pa. Nov. 5, 2007).

***Comment Three: RWC-340B supports CMS's efforts to expand access to specialty drugs in the Part C and Part D programs, but asks that such efforts also ensure access to specialty drugs at 340B prices by covered entities and their pharmacies***

In the Proposed Rule, CMS notes that it is “concerned that Part D Plan sponsors might use their standard network contracts in a way that inappropriately limits specialty drugs to certain pharmacies.”<sup>14</sup> CMS expressed similar concerns with respect to Medicare Advantage plans. RWC-340B supports CMS's intent to ensure that barriers are not enacted that may circumvent any willing pharmacy provisions or infringe patient access requirements. CMS should clarify that manufacturers also have an obligation to make specialty drugs available to any pharmacy that meets applicable regulatory and safety requirements. We agree that manufacturers may require a purchaser to meet applicable handling, storage, and preparation requirements to ensure patient safety, but if a 340B provider meets those requirements, the manufacturer should be required to sell the drug at a 340B price to the entity. Even if the 340B provider does not have a specialty pharmacy that meets these requirements, manufacturers should be required to offer the drug to specialty contract pharmacies within the manufacturer's network so that the 340B provider can access the drug through the contract pharmacy.

This clarification should extend to specialty drugs that are sold through specialty distributors. Some 340B covered entities have been required to purchase all 340B-priced drugs through wholesalers' specialty drug divisions instead of the covered entity's usual wholesaler. This imposes substantial administrative and financial burdens on the 340B provider, which often develop a special relationship with their traditional wholesalers and are able to purchase drugs at a lower price. By mandating purchases through wholesalers' specialty drug divisions, providers not in the 340B program may continue to receive benefits of using their traditional wholesalers, but 340B providers may not. We ask CMS to clarify that a manufacturer must allow 340B covered entities to buy a drug through its 340B wholesale account if it would allow the same entity to purchase the drug through a non-340B wholesale account.

***Comment Four: While RWC-340B supports proposed changes to “negotiated price” requirements, CMS should ensure that such changes do not encourage Part D Plans to reduce reimbursement based on 340B status***

The Proposed Rule discusses at some length CMS's concerns with how Part D Plan sponsors are manipulating a drug's “negotiated price” to the detriment of beneficiaries and the Medicare program.<sup>15</sup> In particular, when manufacturer rebates and pharmacy price concessions are not reflected in a pharmacy's “negotiated price” at the point of sale, beneficiary cost-sharing, which is generally calculated as a percent of the negotiated price, becomes larger, covering a larger share of the actual cost of the drug. CMS is concerned that higher cost-sharing can impede beneficiary access to necessary medications leading to poorer health outcomes and higher medical care costs for beneficiaries and Medicare.<sup>16</sup> While RWC-340B supports these

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<sup>14</sup> 82 Fed. Reg. at 56410.

<sup>15</sup> “17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale,” 82 Fed. Reg. at 56419.

<sup>16</sup> 82 Fed. Reg. at 56420.

proposed changes in general, we urge CMS to expressly clarify that such provisions do not justify lower reimbursement rates on 340B drugs when negotiating with covered entities and their contract pharmacies obtained under the 340B program. As noted above, such discriminatory policies undermine the objectives of the 340B program and violate the anti-discrimination provisions of Medicare Part D.

***Comment Five: RWC-340B applauds CMS's proposal to strengthen Part D standards applicable to MTM***

Part D sponsors are subject to financial and other penalties if the percentage of their revenue used for patient care – referred to in the law as medical loss ratio (MLR) – falls below a statutory threshold of eighty-five percent. Put another way, a sponsor's administrative expenses and profit should not exceed fifteen percent of its net revenue. Quality improvement activities have been formally recognized by CMS as related to patient care for purposes of meeting the eighty-five percent MLR threshold. CMS reports that it has received numerous inquiries seeking clarification whether the costs associated with providing MTM services should be considered QIA.<sup>17</sup> Concerned that Part D Plans lack strong incentives to promote effective MTM programs, CMS has proposed to establish standards that MTM programs must meet in order to qualify as QIA. These standards include improving health quality, meeting defined health outcome benchmarks, being directed to individual enrollees or groups of enrollees and being grounded in evidence-based medicine. CMS hopes these changes “will encourage Part D sponsors to strengthen their MTM programs”, will lead to “higher rates of medication adherence” and will produce “medical spending offsets,” especially for beneficiaries needing individualized disease management for opioid addiction.<sup>18</sup> RWC-340B wholeheartedly agrees that the Medicare Part D MTM requirements should be strengthened so that the full potential of MTM services can be realized for the Medicare population. In particular, RWC-340B recommends that MTM programs be implemented under the supervision of a licensed pharmacist and that the pharmacist be reasonably reimbursed for his or her services.

RWC-340B appreciates the opportunity to submit the above comments. Our members and Executive Committee are available to answer any questions relevant to our comments.

Sincerely,

**MEMBERS OF RWC-340B**

AIDS Center of Queens County  
AID Atlanta  
AIDS Care Group  
AIDS Healthcare Foundation  
AIDS Outreach Center

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<sup>17</sup> 82 Fed. Reg. at 56459.

<sup>18</sup> 82 Fed. Reg. at 56459.

AIDS Resource Center of Wisconsin  
AIDS Taskforce of Greater Cleveland  
Alamo Area Resource Center  
Allies for Health + Wellbeing  
Big Bend Cares  
Chattanooga CARES  
CAN Community Health  
Conemaugh Health System  
Damien Cares  
Equitas Health  
Evergreen Health Services  
Fenway Health  
Foothill AIDS Project  
Heartland CARES, Inc.  
Hyacinth AIDS Foundation  
MetroHealth  
Northern Nevada HOPES  
North Jersey Community Research Initiative  
Northland Cares  
Nuestra Clinica  
One Community Health  
Open Door Health Center of Illinois  
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