Ryan White Clinics

340B for 340B Access

December 17, 2018

BY HAND-DELIVERY

Peter Mucchetti
Chief, Healthcare and Consumer Products Section
Antitrust Division
Department of Justice
450 Fifth Street NW, Suite 4100
Washington, DC 20530
P: 202-307-0001

Re: Proposed Acquisition of Aetna Inc. by CVS Health Corp.— Impact on 340B Safety Net Providers and Their Patients

Dear Mr. Mucchetti:

We write to oppose the proposed acquisition of Aetna Inc. by CVS Health Corporation (CVS) under the terms of the Final Judgment filed with the U.S. District Court in *United States of America v. CVS Health Corporation and Aetna, Inc.*, Civ. Action No. 1:18-cv-02340, because the acquisition would exacerbate current practices by CVS that are detrimental to safety net health care providers that participate in the federal 340B drug discount program and to the patients who they serve. Moreover, the divestiture by Aetna of its individual prescription drug plan business would not ameliorate these anti-competitive practices.

Ryan White Clinics for 340B Access (RWC-340B) is the preeminent national association of HIV/AIDS medical providers receiving support under the Ryan White CARE Act. The CARE Act provides funding for services primarily to poor and/or uninsured people with HIV/AIDS. Ryan White providers are eligible to participate in the federal 340B Drug Discount Program, which enables them to expand and support care. Eligibility for the 340B program is limited to community health centers, Ryan White HIV/AIDS clinics, hemophilia treatment centers, family planning clinics and other federal grantees, hospitals that serve a large number of uninsured and underinsured patients and federally qualified health center "look-alikes." In short, only providers that are committed to serving low-income and vulnerable patient populations may participate in the 340B program. The federal 340B program requires drug manufacturers to provide discounts on the sale of outpatient drugs to these qualified safety net providers and was created to help safety net providers fulfill their mission of serving uninsured, underinsured, and underserved patient populations. Safety net providers rely on the savings generated from the program to help finance their mission of serving low-income patients.

An essential part of covered entity participation in the 340B program is providing drug products to patients. Since 1996, the Health Resources and Services Administration (HRSA), which administers the 340B program, has permitted covered entities to dispense 340B drugs to their patients through both on-site pharmacies operated by the 340B covered entities, as well as through outside pharmacies that contract with the 340B covered entities. While 340B covered entity-owned pharmacies and outside pharmacies both provide pharmacy services, the contract pharmacy program enables 340B qualifying patients to fill prescriptions more conveniently and allows access to 340B pricing for covered entities that do not have their own pharmacies. Indeed, thousands of retail pharmacies, including CVS pharmacies, have entered into contract pharmacy arrangements with 340B covered entities. CVS operates over 9,800 stores in 49 states, the District of Columbia, and elsewhere,[1] many of which are 340B contract pharmacies. According to the 340B program database, CVS is second to only one other pharmacy chain in the total number of contract pharmacy arrangements. Under HRSA's original contract pharmacy guidance in 1996,[2] as well as its expanded guidance in 2010,[3] HRSA made clear that contract pharmacy arrangements are a matter of agency law designed to further Congress's intent of supporting 340B covered entities, not the retail pharmacies under contract with them.

Recently, however, CVS has declared that it will illegally confiscate 340B savings from covered entity-owned pharmacies and will improperly favor "retail" contract pharmacies, including its own CVS pharmacy network—a move that not only runs contrary to the 340B program's intent, but also clearly represents an anti-competitive move that exploits CVS's near-absolute control over its reimbursement rates and membership network. In letters dated November 30, 2018 that CVS issued to many 340B covered entities, including those in California, Florida, and elsewhere, CVS unilaterally altered the terms of its pharmacy enrollment forms, effective in early 2019, to reduce reimbursement rates to any pharmacy that is owned by a 340B covered entity. The letters indicate that "retail" pharmacies—such as CVS pharmacies—will continue to receive a higher reimbursement rate, without further explanation as to why the ownership status of the pharmacy would justify such a distinction. CVS concludes its letter with a stark choice to the 340B covered entities recipients: submit to CVS's arbitrary and illegal decision to advantage its own pharmacies over the 340B covered entities' pharmacies, or terminate enrollment as a provider under CVS commercial networks entirely.

The U.S. Supreme Court has repeatedly warned that anti-competitive predatory pricing or price squeezing violating Section 2 of the Sherman Act may occur when a vertically-integrated entity like CVS, both (1) has a duty to deal with erstwhile competitors, and (2) engages in price (in this case, reimbursement) discrimination to disadvantage its competitors.[4] CVS, as a regulated insurer with significant market power, has a duty to deal with 340B covered entity

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[1] CVS Health, *CVS Health At a Glance*, https://cvshealth.com/about/facts-and-company-information (last visited Dec. 13, 2018).
[2] 61 Fed. Reg. 43,549, 43,552, 43,555 (Aug. 23, 1996).
[3] 75 Fed. Reg. 10,272 (Mar. 5, 2010).
[4] *See Pacific Bell Tel. Co. v. linkLine Comms., Inc.*, 555 U.S. 438, 448 (2009); *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222–24 (1993); *United States v. Grinnell Corp.*, 384 U.S. 563, 576 (1966).

health care providers.[5] Its brash move to disadvantage 340B covered entity-owned pharmacies in favor of its own for-profit commercial pharmacies is plainly anti-competitive. Were this matter brought to the Antitrust Division's attention separate from this proposed acquisition, the Division would have independent cause to take action against CVS to block its anti-competitive conduct. In the present circumstances, CVS's actions provide the basis to oppose an acquisition that would provide CVS with even greater market power and concentration.

The legislative history of the 340B statute states that the purpose of the legislation is to enable qualified providers to stretch their scarce resources so that they may "reach more patients" and furnish "more comprehensive services."[6] Nothing in the 340B statute or its legislative history suggests that the program was intended to benefit for-profit private insurers, pharmacy benefit managers, or their vertically-owned private pharmacies. Passing the benefit of 340B discounts to these for-profit entities through reduced reimbursement rates thwarts the purpose of the program. HRSA shares our concerns about this threat to the 340B program and its eligible providers. According to HRSA, the 340B program provides additional financial resources to covered entities without increasing the federal budget by lowering drug acquisition costs while maintaining the providers' revenue from health insurance reimbursements.[7] The difference between a 340B drug's lower acquisition cost and standard non-340B reimbursement represents the very benefit that Congress intended to give covered entities when it established the 340B program. 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."[8]

A significant loss of 340B savings might force covered entities to reduce dramatically the valuable services they provide to their low-income patients, such as deeply discounted

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[5] Indeed, CVS's anticompetitive behavior in the retail pharmacy market is precisely the type of concern raised by previous commenters as a potential consequence of this merger. See Letter of March 26, 2018 to Makan Delrahim from Diana L. Moss of American Antitrust Institute at 8, available at https://www.antitrustinstitute.org/wp-content/uploads/2018/09/CVS-Aetna_AAI-Letter_3.26.18.pdf ("CVS-Aetna could also exercise its enhanced bargaining leverage post-merger with retail pharmacies, particularly independents. By virtue of their smaller size and lack of bargaining power, independent pharmacies are already susceptible to exclusionary conduct. With enhanced bargaining leverage post-merger, CVS could, for example: (1) drive down dispensing fees and delay reimbursement and (2) cherry-pick the most profitable prescriptions and enforce complex 'take-it-or-leave-it' contracts with independents. The risk of foreclosure for rival retail pharmacies is bolstered by CVS's past conduct, which includes persistent allegations of anticompetitive abuses designed to steer consumers away from its drug store rivals. Such exclusionary behavior has harmed consumers by eliminating an important source of choice, which is particularly important for seniors under Medicare Part D.") (footnotes omitted).

[6] H.R. Rep. 102-384, pt.2, at 12 (1992).

[7] Health Res. and Servs. Admin., Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act (2005), http://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm.

[8] *Id.*

prescriptions and medication therapy management.[9] Approximately 63% of individuals served by the Ryan White program live at or below 100% of the federal poverty level.[10] In addition, 73.3% of individuals in the Ryan White program are racial minorities.[11] Ryan White clinics rely on 340B drug discounts to be able to provide uncompensated, comprehensive services to these patients. Without the discounts and the additional services that they afford, patients could fall out of care and no longer be virally suppressed. Not only would that be an unfortunate outcome for the patient, but it increases the possibility that the patient will spread the HIV/AIDS infection to additional individuals, leading to higher costs for insurers and the health industry in general.

Moreover, while lower 340B reimbursement to 340B covered entity-owned pharmacies might result in lower costs for health plans and their enrollees, there is no guarantee that the company would not simply pocket the savings, leaving no benefit to consumers. Furthermore, in this case, CVS's conduct benefits its for-profit commercial pharmacies at the expense of competitor pharmacies owned by 340B covered entities, which is both without any pro-competitive justification and contrary to the purpose of the 340B program.

We believe the unprecedented market dominance of a combined CVS-Aetna would allow the new company to force 340B providers to accept even lower reimbursement rates to the detriment of their patients. The combined entity's market power would enable it to discriminate against 340B providers with impunity. Faced with losing a substantial amount of their business, 340B covered entity-owned pharmacies would have no choice but to accept whatever reimbursement terms are offered by the company, depriving covered entities of the savings they need to fulfill their safety-net mission. As previous Division officials have observed regarding the alleged cost efficiencies that would result from health insurance mergers, "consumers do not benefit when sellers … merge simply to gain bargaining leverage."[12]

In addition, CVS's practice of forcing 340B providers and their contract pharmacies to accept reduced reimbursement rates potentially violates state "any willing provider" and patient protection laws and certainly runs counter to the spirit of those laws. The insurance law of Mississippi, a co-plaintiff in this case and among the states identified as having anti-competitive effects from the proposed acquisition,[13] prohibits benefit differentials among pharmacies and provides that beneficiaries may choose any pharmacy that has agreed to participate in the plan according to the insurer's terms, which must be offered "under identical reimbursement terms."[14] Likewise, North Carolina—another state that suffered anti-competitive effects from the proposed

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[9] *See* Safety Net Hospitals for Pharmaceutical Access, Demonstrating the Value of the 340B Program to Safety Net Hospitals and the Vulnerable Patients They Serve (June 29, 2011), http://www.340bhealth.org/images/uploads/340B_Value_Report_06-29-11.pdf.

[10] *HRSA's Ryan White HIV/AID Program Overview, 2018*; available at https://hab.hrsa.gov/sites/default/files/hab/Publications/factsheets/program-factsheet-program-overview.pdf .

[11] *Id.*

[12] Speech by Assistant Attorney General Bill Baer, Remarks as Prepared for the Delivery at the New Health Care Industry Conference: Integration, Consolidation, Competition in the Wake of the Affordable Care Act at Yale University (Nov.13, 2015).

[13] Compl. ¶¶ 29, 34.

[14] Miss. Code Ann. § 83-9-6(3)(e), (5).

acquisition[15]— prohibits benefit differentials among participating pharmacies.[16] These state insurance laws clearly prohibit the type of discriminatory reimbursement terms that CVS is forcing 340B covered entity pharmacies to accept.

Any willing provider laws generally require insurers to accept pharmacies into their networks that are willing to accept the insurer's established terms and conditions. Many of these laws explicitly prohibit discrimination against different types of providers, which includes differences in reimbursement. For example, Kentucky's any willing provider law prohibits insurers from discriminating against any provider that is located within the geographic coverage area of a health benefit plan;[17] and in Virginia, insurers cannot set terms and conditions for preferred provider status that discriminate unreasonably against or among providers.[18] CVS's recent notices that it is reducing reimbursement rates to pharmacies owned by 340B covered entities may result in many of these pharmacies leaving the market, which will affect the ability of consumers to choose pharmacies. The insurance law of Arkansas—also suffering from this acquisition's anti-competitive effects[19]— prohibits insurers from directly or indirectly imposing a monetary penalty, including a reduction in reimbursement, that would affect a beneficiary's choice of providers.[20]

For the above reasons, we oppose the proposed acquisition, even if Aetna directs its interests in the individual prescription drug plan business. Preventing the acquisition will be instrumental in helping to protect and support the ability of 340B covered entities to continue treating their disadvantaged patient populations and in protecting consumer choice of pharmacies. Thank you for the opportunity to comment on this important matter.

Sincerely,

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*

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[15] Compl. ¶¶ 29, 35.
[16] N.C.G.S.A. § 58-51-37(c)(5), (e).
[17] Ky. Rev. Stat. Ann. § 304.17A-270.
[18] Va. Code Ann. § 38.2-3407(B). Differences in prices among hospitals or other institutional providers produced by a process of individual negotiations with providers or based on market conditions, or price differences among providers in different geographic regions do not constitute unreasonable discrimination. *Id.*
[19] Compl. ¶¶ 29, 34-35.
[20] Ark. Code Ann. § 23-99-204(a)(1)(A).

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*