Ryan White Clinics for 340B Access

September 11, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Manufacturer Actions Violating 340B Statute Requirements

Dear Secretary Azar:

On behalf of our member organizations, Ryan White Clinics for 340B Access (RWC-340B) is writing to request that the Department of Health and Human Services (HHS) initiate enforcement actions, in the form of civil monetary penalties, against drug manufacturers Eli Lilly and Company, Sanofi SA, Novartis Pharmaceuticals, and AstraZeneca PLC for failing to comply with their obligations under the 340B drug pricing program (340B program) to offer 340B pricing on drugs dispensed by contract pharmacies.

We understand that you are aware of certain manufacturers' withdrawal from the 340B contract pharmacy program because of previous letters addressed to you by manufacturers, 340B stakeholders, and most recently via a letter from Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ), Health Subcommittee Chairwoman Anna G. Eshoo (D-CA), and Oversight and Investigations Subcommittee Chair Diana DeGette (D-CO). We also understand that the Health Resources and Services Administration told several news outlets this week that it is considering whether the manufacturers' actions violate the 340B statute. We are writing to voice our concerns about the manufacturers' actions and to explain both why those actions violate the 340B statute and why HHS both has the authority to rectify them and must act to do so.

RWC-340B is an association of HIV/AIDS health care clinics and service providers that receive funding under the Ryan White CARE Act, either through a primary grant or subgrant, and participate as covered entities in the 340B program. Ryan White clinics are dedicated to caring for low-income and vulnerable patients living from HIV/AIDS and, as you have acknowledged, "are serving on the frontlines of this pandemic, supporting clients and communities at higher risk from COVID-19."[1] Ryan White clinics achieve viral suppression rates far above the average national viral suppression rate. This success in viral suppression rates results in fewer transmissions of the HIV/AIDS virus and is instrumental in helping to achieve the goal of the Trump Administration to end the HIV/AIDS epidemic by 2030. Safety net

[1] Health and Human Services (HHS) Secretary Alex Azar, HHS Awards $90 Million to Ryan White HIV.AIDS Program Recipients for COVID-19 Response, April 15, 2020, available at https://www.hhs.gov/about/news/2020/04/15/hhs-awards-90-million-ryan-white-hiv-aids-program-recipients-for-covid-19-response.html.

providers like our members rely on the savings generated from the 340B program to help achieve these health outcomes and to finance their mission of serving low-income patients. Ryan White providers are especially dependent on their 340B contract pharmacy arrangements to meet the pharmacy needs of their patients and to help finance their fight to end the HIV/AIDS epidemic in this country.

Since 1996, both the HRSA and HRSA's Office of Pharmacy Affairs (OPA) have allowed 340B covered entities to dispense 340B drugs to their patients through pharmacies contracted to act on their behalf. In the Federal Register notice approving contract pharmacy arrangements, HRSA stated that the 340B statute requires manufacturers to ship 340B drugs to whatever location the 340B covered entity directs:

> The [340B] statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities. It has been the Department's position that ***if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance***.[2]

The agency also stated that its contract pharmacy guidelines neither created new law or new rights for covered entities nor new duties for manufacturers:

> The guidelines explain how the Department intends to administer the 340B, further explain the statutory language by clarifying the meaning given by the Department to particular words or phrases, and do not exceed the purpose of 340B or conflict with any of its provisions. We ***believe that these guidelines create no new law and create no new rights or duties***.... By issuing guidelines in this area, [we agree that] ODP [predecessor agency to OPA] is not seeking to create a new right but ***rather is simply recognizing an existing right that covered entities enjoy under State law.***[3]

HRSA's 1996 contract pharmacy guidelines provided guidance for covered entities to enter into a single contract pharmacy arrangement for each of their sites, although the guidance also acknowledged that the statute imposed no such limit on covered entities' rights to enter contract pharmacy arrangements. In 2010, HRSA revised its guidelines to confirm that covered entities could have multiple contract pharmacy arrangements.[4] In the updated 2010 guidelines, HRSA again stated that contract pharmacy

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[2] 61 Fed. Reg. 43,549-50 (Aug. 23, 1996) (emphasis added).

[3] *Id*. at 43,550 (emphasis added). From the same Federal Register notice: "As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. As a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance. Restatement of Agency 2d § 17 (1995)." *Id.*

[4] 75 Fed. Reg. 10,272 (Mar. 5, 2010).

arrangements do not create new rights for covered entities and do not add new obligations or burdens for manufacturers:

> This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. HRSA has used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration. Contract pharmacy service guidelines have been considered by HRSA to be ''interpretative rules and statements of policy'' exempt from notice and comment rulemaking under the APA.[5]

For 24 years, HRSA's contract pharmacy guidance, which elucidates the rights of 340B covered entities and obligations of manufacturers under both the 340B statute and state agency law, has provided additional channels for covered entities to provide 340B drugs to eligible patients. Indeed, as stated by HRSA in its 1996 guidance, many covered entities do not operate their own retail pharmacies and "it would defeat the purpose of the 340B program" if they could not use affiliated pharmacies to distribute 340B drugs.[6] The branch of HRSA that administers Ryan White Parts A and B grants states that grant costs must be reasonable and must not exceed the costs that a prudent person would pay.[7] Clearly, participation in the 340B program is a prudent use of a grantee's limited resources. Other kinds of grantees, such as federally qualified health centers, are subject to similar cost-control standards, which is why HRSA has urged all grantees and sub-grantees to enroll in the 340B program. Recent actions by manufacturers that refuse to honor contract pharmacy arrangements will have a direct adverse effect on the financial resources of Ryan White clinics and their ability to continue to provide comprehensive services to their vulnerable patients.

We understand that HRSA leadership has expressed concern in response to these recent manufacturer actions, has encouraged manufacturers to continue to honor contract pharmacy arrangements, and has most recently indicated that it is considering whether the manufacturers' actions violate the 340B statute. As the guidance cited above make clear, it has been HRSA's longstanding position, left intact for over 24 years by both Democratic and Republican Administrations, that contract pharmacy rights are not a product of agency guidance but rather a requirement of the 340B statute and state agency law. In *Skidmore v. Swift & Co.*, the Supreme Court held that an agency's guidance is enforceable if it demonstrates "the degree of the agency's care, its consistency, formality, and relative expertness" and "the thoroughness evident in its consideration, the validity of its reasoning, [and] its consistency with earlier and later pronouncements."[8] HRSA's consideration of this issue in 1996, in 2010, and indeed in the 24 years of its operation was and continues to be thorough, careful and expert; it took into account

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[5] *Id.* at 10,273.
[6] 61 Fed. Reg. at 43,550.
[7] HIV/AIDS Bureau, Division of Metropolitan HIV/AIDS Programs National Monitoring Standards for Ryan White B Grantees-Final, p. 27-28, available at: https://hab.hrsa.gov/sites/default/files/hab/Global/fiscalmonitoringpartb.pdf;
HIV/AIDS Bureau, Division of State HIV/AIDS Programs National Monitoring Standards for Ryan White B Grantees-Final, p. 26-27, available at: https://hab.hrsa.gov/sites/default/files/hab/Global/fiscalmonitoringpartb.pdf.
[8] *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944); *see also United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (citations omitted); *Marmolejo-Campos v. Holder*, 558 F.3d 903, 909 (9th Cir. 2009).

public comment and feedback from all stakeholders; it has been consistent and careful in its application; and it has proven to be workable for covered entities, manufacturers, and pharmacies alike in the course of 24 years. Rather than walk away from the contract pharmacy program, HRSA should fight to protect the program with confidence, a position that a court will undoubtedly uphold under the *Skidmore* precedent and knowing that, without access to contract pharmacy arrangements, covered entities will end up providing fewer services to fewer patients in direct contravention of the 340B statute's operation and purpose

Our plea for help is due in large part to HRSA's failure to provide the Congressionally mandated means for an administrative appeal avenue that, if implemented, would have allowed covered entities to bring complaints against these manufacturers for 340B overcharges. Congress mandated that "[n]ot later than 180 days after March 23, 2010," your predecessor at HHS "shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged."[9] A refusal by a manufacturer to honor a contract pharmacy arrangement results in overcharges to the covered entity that the covered entity would be allowed to contest under the administrative procedure. Notwithstanding that mandate, and notwithstanding assurances the government made to the Supreme Court in *Astra USA, Inc. v. Santa Clara County* that the implementation of the administrative process was imminent, HHS has not implemented the process, and has publicly indicated that it has no plans to do so.[10] The Court's decision in *Astra U.S.A.* made note of the government's assurances, and the critical importance of an administrative process by which covered entities could bring claims against manufacturers.[11] By both failing to provide such a process ***and*** failing to enforce the 340B statute in light of the manufacturers' noncompliance, your Department places covered entities in the position of having a "right without a remedy," which raises serious Constitutional and procedural concerns.

RWC-340B urges you to take action to enforce the requirements of the 340B statute against these manufacturers that will essentially be overcharging covered entities for drugs dispensed by contract pharmacies to covered entity patients. There can be no doubt that HRSA has the authority to levy civil monetary penalties against manufacturers that knowingly and intentionally overcharge.[12] HRSA should exercise that authority to levy fines against the manufacturers that are flagrantly, let alone knowingly and intentionally, overcharging covered entities for the drugs they purchase and dispense through their contract pharmacies. The function of the 340B program – to facilitate the ability of safety-net providers to care for our nation's most vulnerable patients – is now more important than ever in light of the COVID-19 public health emergency that you declared.

As such, we strongly urge you to take immediate action to address this pressing concern by demanding that drug manufacturers Eli Lilly and Company, Sanofi SA, Novartis Pharmaceuticals, and AstraZeneca PLC continue to honor contract pharmacy arrangements under the 340B program. Given that Eli Lilly is currently not honoring contract pharmacy arrangements for most of its product lines and that Sanofi SA,

[9] Pub. L. 111-148 tit. VII § 7102(a), 124 Stat. 823-24 (Mar. 23, 2010), as codified at 42 U.S.C. § 256b(d)(3).
[10] *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011).
[11] *Id.* at 116.
[12] 83 Fed. Reg. 61563 (Nov. 30, 2018).

Novartis Pharmaceuticals, and AstraZeneca PLC plan to stop honoring contract pharmacy arrangements by October 1, we would construe lack of enforcement by HHS prior to October 1, 2020 as an indication that HHS has refused this request.

Thank you for your immediate consideration of this urgent request.

Sincerely,

Shannon Stephenson

President