Ryan White Clinics 340B for 340B Access

April 15, 2022

Mark Snyder - Vice President, Global Therapeutic Area Communications
Gilead Sciences
300 New Jersey Ave, NW, Suite 650
Washington, D.C. 20001
Via email: Mark.Snyder@gilead.com

Re: Gilead Science Contract Pharmacy Policy

Dear Mr. Snyder,

I am writing to follow up on our March 4, 2022, letter to Charles Clapton outlining RWC-340B's concerns with Gilead Science's (Gilead) changes to its Advancing Access® Medication Assistance Program (MAP) and the rising price of Descovy®. We appreciate that Mr. Clapton forwarded RWC-340B's letter to you and appreciate your telephone call informing me that a representative from Gilead would be contacting me in the following weeks to address RWC-340B's concerns. However, we are writing this letter to address a different Gilead policy that affects RWC-340B members.

As you know, on March 15, Gilead announced that, effective May 2, 2022, it will implement a new "Contract Pharmacy Integrity Initiative" with respect to Gilead's brand drugs to treat the Hepatitis C virus (HCV), under which it will no longer honor contract pharmacy arrangements with 340B covered entities, including grantees, unless the covered entity submits 340B contract pharmacy claims through the 340B ESP™ platform or qualifies for one of Gilead's limited exceptions. RWC-340B objects to the new policy and asks that Gilead address this new issue in its follow-up communication to our March 4 letter. Further, although RWC-340B appreciates that Gilead has made some limited exceptions to its new contract pharmacy, RWC-340B asks that Gilead exempt all Ryan White clinics (RWCs) that participate in the 340B program from its new policy.

As stated in our March 4 letter, RWC-340B is a national association of HIV/AIDS health care clinics and service providers receiving support under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act.[1] RWC-340B members are highly dependent on the 340B program to support their mission of providing care to patients living with HIV/AIDS, many of whom also have HCV. Without access to the discounted pricing available through the 340B program, RWC-340B members would be forced to provide fewer services and/or serve fewer patients. RWC-340B members are therefore committed to doing their part to protect the integrity of the program. RWC-340B members share Gilead's concerns about diversion and duplicate discounts. To that end, RWC-340B regularly educates its members – via webinars, technical assistance and peer-to-peer counseling – on the importance of establishing safeguards to protect against these compliance issues, including routinely performing self-audits to ensure those safeguards are working.

[1] Ryan White Clinics for 340B Access, *About Us*, https://rwc340b.org/about-us/.

RWC-340B has carefully reviewed and solicited legal advice on Gilead's new contract pharmacy policy and has concluded that Gilead is prohibited from making access to 340B drugs contingent on participation in the 340B ESP™ program. For the reasons provided below, RWC-340B asks that Gilead immediately reverse its position on contract pharmacy arrangements, at least for RWCs, and comply with its statutory and contractual obligation to offer 340B pricing on all covered outpatient drugs, including those dispensed through contract pharmacy arrangements with RWC-340B members.

Although Gilead's new contract pharmacy policy is limited to brand HCV drugs, RWC-340B is very concerned that Gilead will expand its policy to include drugs used to treat HIV/AIDS. Limiting access to 340B discounts for HIV/AIDS drugs would have a devastating impact on RWC-340B members because our members are highly dependent on access to those drugs to carry out their mission treating individuals living with HIV/AIDS and preventing further infections. RWC-340B members require continued access to Gilead's HIV/AIDS drugs through all contract pharmacy arrangements to continue to provide comprehensive care to their patients. RWC-340B objects to Gilead's contract pharmacy policy as it applies to HCV or any drug that Gilead manufacturers.

We urge Gilead to reverse its policy or, at the very least, make an exception to its policy for RWCs. Unless Gilead makes these changes, RWC-340B will be forced to consider filing a petition on behalf of its members under the 340B administrative dispute resolution (ADR) process authorized at 42 C.F.R. § 10.20–24. We describe in detail below our analysis of the legality of Gilead's policy and the reasons that it should be reversed for RWCs. In addition to these issues, Gilead should reverse its policy in order to avoid the costs and time associated with defending itself before an ADR panel.

I. GILEAD MUST HONOR CONTRACT PHARMACY ARRANGEMENTS

Gilead's March 2022 letter states that, effective May 2, 2022, pharmacies registered as contract pharmacies for 340B hospitals and federal grantees are no longer be eligible for bill to/ship to orders of its brand name HCV products[2] (referred to in this letter as "HCV drugs") unless the pharmacy submits 340B contract pharmacy claims data to the 340B ESP™ platform. Our understanding is that, under Gilead's policy, 340B covered entities that elect not to submit claims data through the 340B ESP™ program and do not operate an in-house, outpatient pharmacy, will only receive 340B pricing on HCV drugs dispensed through a single contract pharmacy location designated through the 340B ESP™ website. We understand further that, if a 340B covered entity dispenses drugs at 340B prices through a wholly-owned pharmacy, Gilead will only ship 340B priced HCV drugs to that pharmacy and will not ship it to the covered entity's contract pharmacies.

Although RWC-340B's members appreciate that Gilead has made certain exceptions to its new contract pharmacy policy, they are nevertheless deeply concerned that Gilead is improperly restricting access to 340B discounts on HCV drugs. This is especially concerning given Gilead's recent changes to its Advancing Access MAP and the unprecedented price increase for Descovy®. As explained in more detail below, Gilead's refusal to provide 340B pricing for HCV drugs to RWCs and other covered entities through contract pharmacy arrangements is a clear violation of the 340B statute, Gilead's pharmaceutical pricing agreement (PPA) with the Secretary of the U.S. Department of Health and Human Services (HHS), and state agency law. Moreover, Gilead's refusal to honor contract pharmacy arrangements for RWCs and other covered entities is premature given actions taken by HHS and the Health Resources and Services

[2] The drugs subject to this new policy are Epclusa® (sofosbuvir / velpatasvir), Harvoni® (ledipasvir / sofosbuvir), Sovaldi® (sofosbuvir) and Vosevi® (sofosbuvir/velpatasvir/voxilaprevir).

Administration (HRSA) as well as pending litigation on the subject. The new policy will also have a significant deleterious impact on patient care.

Obligations Under the 340B Statute, PPA and State Agency Law

As you know, the Medicaid drug rebate statute states that a manufacturer's drugs will not be covered by Medicaid or Medicare Part B unless the manufacturer signs a PPA with HHS.[3] The PPA requires a drug manufacturer to provide 340B covered entities with "covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[4] Thus, rather than being a voluntary decision, manufacturers must offer these discounted prices without placing any restrictions on where the covered entity requests that the discounted drugs be delivered, including to contract pharmacies.[5] The 340B statute does not give manufacturers the right to withhold 340B pricing from covered entities simply because they elect to have drugs shipped to contract pharmacies. In fact, HRSA stated in its 1996 contract pharmacy guidelines that if a covered entity directs a manufacturer to make a drug shipment to its contract pharmacy, there is "no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance."[6] Therefore, Gilead's refusal to provide 340B prices on HCV drugs dispensed to RWC patients by contract pharmacies is a clear violation of the "must offer" requirements of the 340B statute and PPA.

Since the inception of the 340B program, manufacturers have been prohibited from conditioning the sale of 340B drugs based on how a covered entity chooses to dispense the drugs. In its 1994 "Entity Guidelines", HRSA responded to a comment that manufacturers should only be required to sell covered outpatient drugs directly to covered entities and not to contract pharmacies, notwithstanding the fact that manufacturers sell directly to covered entities even through contract pharmacy arrangements.[7] HRSA responded that it is customary for manufacturers to recognize contract pharmacies and that "[m]anufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective."[8] Here, Gilead is placing restrictive conditions on 340B covered entities by denying access to 340B drugs at their contract pharmacies (subject to limited exceptions), which undermines the objectives of the 340B statute. Similarly, in announcing its "Ceiling Price and Manufacturer Civil Monetary Penalties" final rule (CMP Final Rule), HRSA stated that "[m]anufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity."[9] Even if Gilead had evidence that RWC-340B members were not in compliance with 340B program requirements (which it does not), the CMP Final Rule forbids Gilead from withholding 340B pricing on HCV drugs purchased by RWC-340B members, including drugs dispensed by RWC-340B members' contract pharmacies.

While it is true that contract pharmacy arrangements are not addressed explicitly in the 340B statute, HRSA has long recognized that covered entities have the right to enter into contract pharmacy arrangements under state law. In its 1996 contract pharmacy guidelines, HRSA stated that "[a]s 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."[10] Under state agency law "a

[3] 42 U.S.C. § 1396r-8(a)(1).
[4] *Id*. § 256b(a).
[5] 61 Fed. Reg. 43,550, at 43,551 (Aug. 23, 1996).
[6] *Id*. at 43,549-50.
[7] 59 Fed. Reg. 25,110, at 25,111-12 (May 13, 1994).
[8] *Id*.
[9] 82 Fed. Reg. 1210, 1,223 (Jan. 5, 2017).
[10] 61 Fed. Reg. at 43,550.

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."[11] HRSA has recognized that "even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs."[12] In fact, the statute is silent as to "permissible drug distribution systems."[13] HRSA also stated that its contract pharmacy guidance did not create a new right for covered entities or impose a new burden on manufacturers, but was "simply recognizing an existing right that covered entities enjoy under state law."[14] As an agent of the covered entity, the contract pharmacy is simply distributing 340B drugs on behalf of the RWC or other covered entity as permitted under agency law.

HRSA has also recognized a covered entity's right to distribute 340B drugs through an agent in the CMP Final Rule.[15] HRSA explained in commentary that manufacturers are required to offer drugs at the 340B ceiling price to covered entities and that this requirement applies "regardless of the distribution system."[16] Furthermore, a manufacturer's "[f]ailure to ensure the covered entities are receiving the 340B ceiling prices through a third party" may result in CMPs.[17] Gilead is therefore impeding RWC-340B members' rights under the CMP Final Rule to provide 340B drugs through a contract pharmacy by not offering 340B pricing on brand HCV drugs which, according to the CMP Final Rule, exposes Gilead to fines and other penalties.

Gilead's Policy Changes Are Premature

For the above reasons, it is our strong belief that Gilead lacks the legal authority to refuse to offer RWC-340B members 340B pricing on HCV drugs dispensed by RWC-340B members' contract pharmacies. More importantly, it is clear that HRSA shares our opinion. As you know, on May 17, 2021, HRSA sent letters to six drug manufacturers announcing that the manufacturers' refusal to honor contract pharmacy arrangements resulted in overcharges and directly violates the 340B statute.[18] HRSA sent an identical letter to a seventh manufacturer on October 4, 2021. HRSA subsequently sent a second letter to these manufacturers, alerting them that the agency has referred the matter to the HHS-Office of the Inspector General (OIG), in accordance with the CMP Final Rule.[19] All seven of these manufacturers have filed lawsuits challenging the letters and raising other claims.[20] And these are not the only lawsuits that have been

[11] *Id*., citing to Restatement of Agency 2d § 17 (1995).
[12] *Id*.
[13] *Id*. at 43,549.
[14] *Id*. at 43,550.
[15] The CMP Final Rule's definition of an "instance of overcharging" provides "Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC ordered. This includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, ***or agent***." 82 Fed. Reg. 1,210, 1,230 (March 6, 2017) (emphasis added); *see also* 42 C.F.R. § 10.11(b)(1).
[16] 82 Fed. Reg. at 1,226.
[17] *Id*. at 1,225.
[18] The letters can be found on HRSA's Program Integrity webpage at https://www.hrsa.gov/opa/program-integrity/index.html.
[19] *Id*. HRSA sent letters to Eli Lilly, AstraZeneca, Novartis, Novo Nordisk, Sanofi, and United Therapeutics on September 22, 2021, and to Boehringer Ingelheim on March 29, 2022.
[20] Second Amended Complaint, *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. July 9, 2021), ECF No. 86; Amended Complaint (Second), *Eli Lilly & Co, et al v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. May 27, 2021), ECF No. 103; Second Amended Complaint for Declaratory and Injunctive Relief, *Sanofi-Aventis U.S., LLC v. Becerra*, No. 3:21-cv-00634-FLW-LHG (D.N.J. May 25, 2021), ECF No. 78; Amended Complaint, *Novo Nordisk Inc., et al v. Becerra*, No. 3:21-cv-00806-FLW-LHG (D.N.J. May 25, 2021), ECF No. 40; Complaint, *Novartis Pharmaceuticals Corp. v. Becerra*, No. 1:21-cv-01479-DLF (D.D.C. May 31, 2021), ECF No. 1; *United Therapeutics Corp. v Becerra*, 1:21-cv-01686-DLF (D.D.C. June 23, 2021), ECF No. 1; Complaint, *Boehringer Ingelheim Pharmaceuticals, Inc. v. Becerra*, No. 1:21-cv-02826-DLF (D.D.C. Oct. 25, 2021), ECF No. 1.

filed in connection to HRSA's 340B contract pharmacy program. RWC-340B, as well as other national advocacy organizations and covered entities have filed their own lawsuits challenging the manufacturers' restrictive policies and HRSA's inaction to enforce its contract pharmacy guidelines against the manufacturers.[21] HHS responded to these lawsuits by finalizing regulations that give covered entities, as well as manufacturers, an administrative dispute resolution (ADR) process for hearing and adjudicating disputes.[22] Shortly thereafter, manufacturers' trade group PhRMA filed suit challenging the ADR rule on both procedural and substantive grounds.[23] Four decisions have been rendered at the federal district court level and all four have been appealed. Because these lawsuits are still pending and have not been resolved, we think it is premature for Gilead to implement its restrictive contract pharmacy policy at this time.

The timing of Gilead's policy is especially problematic because the court decisions issued to date are split on whether HRSA has authority to require 340B pricing through a contract pharmacy. Two of the court decisions held that drug manufacturers cannot impose unilateral restrictions or conditions on 340B discounts for drugs dispensed through contract pharmacy arrangements.[24] The other two courts refused to decide the issue of whether the manufacturers' limitations on contract pharmacy arrangements were permissible.[25] RWC-340B is confident that, when the pending lawsuits and appeals are finally resolved, Gilead will be subject to binding judicial precedent clarifying that its obligation to offer 340B pricing on contract pharmacy drugs is unconditional. Gilead would be prudent to retract its recent contract pharmacy policy until these lawsuits are resolved. If Gilead proceeds with its current policy and the government's position is vindicated by the courts, HRSA will likely send it a cease-and-desist letter similar to the letters HRSA sent to the seven manufacturers mentioned above. Likewise, Gilead will undoubtedly be required to repay any 340B discounts that it refused to provide as of May 2, 2022. Waiting until the lawsuits are resolved is therefore in the best interests of Gilead, RWC-340B members, and most importantly, the vulnerable patient population our members serve.

Repaying RWCs and other covered entities is not the only consequence Gilead will face. It also risks being fined under HRSA's CMP Final Rule. HRSA's cease-and-desist letters state that manufacturers' "failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the [CMP Final Rule]."[26] The prospect of HHS taking action against drug manufacturers that restrict access to contract pharmacy arrangements became more real when HRSA sent a second letter to the seven drug manufacturers regarding the agency's referral to the HHS-OIG. HHS has, therefore,

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[21] Amended Complaint, *Ryan White Clinics for 340B Access v. Azar*, No. 1:20-cv-2906 (D.D.C. Nov. 23, 2020) (stayed Jan. 13, 2021); Complaint, *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar*, No. 1:20cv3032 (D.D.C. Oct. 21, 2020) (stayed Jan. 13, 2021).

[22] According to the Office of Management and Budget website, HRSA will be proposing a new ADR regulation (proposed rule) to revise the current ADR rule. Office of Management and Budget, 340B Drug Pricing Program; Administrative Dispute Resolution, 0906-AB28, Dec. 10, 2021, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0906-AB28.

[23] Complaint, *PhRMA v Becerra*, No. 8:21-cv-00198-PWG (D. Md. Jan. 22, 2021), ECF No. 1.

[24] Order, *Eli Lilly & Co, et al v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. Oct. 29, 2021), ECF No. 144; Opinion, *Sanofi-Aventis U.S., LLC v. Becerra*, No. 3:21-cv-00634-FLW-LHG (D.N.J. Nov. 5, 2021), ECF No. 110; Opinion, *Novo Nordisk Inc., et al v. Becerra*, No. 3:21-cv-00806-FLW-LHG (D.N.J. Nov. 5, 2021), ECF No. 69; Memorandum Opinion, *Novartis Pharmaceuticals Corp. v. Becerra*, No. 1:21-cv-01479-DLF (D.D.C. Nov. 5, 2021), ECF No. 32; Memorandum Opinion, *United Therapeutics Corp. v Becerra*, 1:21-cv-01686-DLF (D.D.C. Nov. 5, 2021), ECF No. 32; Order, *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. Feb. 16, 2022), ECF No. 113.

[25] Memorandum Opinion, *Novartis Pharmaceuticals Corp. v. Becerra*, No. 1:21-cv-01479-DLF; *United Therapeutics Corp. v Becerra*, 1:21-cv-01686-DLF (D.D.C. No. 5, 2021), ECF No. 32; Order, *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. Feb. 16, 2022), ECF No. 113.

[26] HRSA Letters to manufacturers, *supra* note 19.

formally asked the OIG to initiate enforcements actions against these manufacturers under of the CMP Final Rule. For these reasons, Gilead is subjecting itself to potential CMPs by refusing to recognize RWC-340B members' contract pharmacy arrangements. Even worse, Gilead could incur criminal liability under the False Claims Act.[27]

Adverse Impact on Patient Care

The purpose of the 340B program is to enable covered entities to "stretch scarce Federal resources as far as possible," allowing the covered entity to reach more eligible patients and provide more comprehensive services.[28] The 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 non-340B reimbursement represents the very benefit that Congress intended to give covered entities when it established the 340B program.[29] RWCs and other covered entities use 340B revenue in a variety of ways to benefit the vulnerable patients they serve. The Government Accountability Office found that providers use 340B revenue to offset losses incurred from treating some patients, to continue providing existing pharmaceutical and clinical services, to lower drug costs for low-income patients, to serve more patients, and to provide additional services, such as case management, to facilitate access to appropriate care.[30] RWCs rely on the revenue generated from their contract pharmacy arrangements to subsidize their care of patients who are uninsured, underinsured or medically vulnerable. In many cases, the grant that an RWC receives is simply not sufficient to cover the cost of care that the RWC provides. Gilead's restrictive policies therefore threaten the quality and availability of care for underserved populations that benefit the most from such arrangements.

Not only does Gilead's refusal to honor contract pharmacy arrangements undermine the function and purpose of the 340B program, but its restrictive policy also undercuts the commitment of RWCs to providing health care and support services for people living with HIV/AIDS who are coinfected with HCV. RWCs have a well-documented history of maximizing their resources to educate, support, and treat people living with HIV/AIDS (PLWH), an infectious disease that is a primary focus for eradication by this Administration. HRSA's HIV/AIDS Bureau (HAB) has identified HCV screening and treatment among HIV-infected patients as a priority.[31] According to a report from HRSA, approximately one in five PLWH is coinfected with the HCV.[32] Moreover, HCV-related liver disease has become one of the leading causes of non-AIDS-related death among PLWH.[33] RWCs are, therefore, not only critical when it comes to providing HCV treatment to PLWH, but also take steps to address barriers that limit access to HCV treatment. However, many of our members do

[27] HHS has stated that drug manufacturers that do not provide 340B pricing to contract pharmacies could face a False Claims Act lawsuit. *See,* letter from Robert P. Charrow, General Counsel, HHS, to Anat Hakim, Senior VP and General Counsel, Eli Lilly Company (Sept. 21, 2020). In a letter responding to a request by Eli Lilly and Company (Lilly) for a pre-enforcement advisory opinion on Lilly's refusal to honor contract pharmacy arrangements, HHS stated that a lawsuit under the False Claims Act "is a potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors." *Id.*

[28] H.R. Rep. No. 102-384, pt.II (Sept. 22, 1992).

[29] Opinion, *Sanofi-Aventis U.S., LLC v. Becerra*, No. 3:21-cv-00634-FLW-LHG (D.N.J. Nov. 5, 2021), ECF No. 111; Opinion, *Novo Nordisk Inc., et al v. Becerra*, No. 3:21-cv-00806-FLW-LHG (D.N.J. Nov. 5, 2021), ECF No. 70; *see also* HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act* (July 2005).

[30] GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, at p. 17 (Sept. 2011).

[31] Laura Cheever, MD, HRSA's Ryan White HIV/AIDS Program Observes Hepatitis Awareness Month, Advances Efforts to Eliminate HIV/HCV Coinfection, HIV.gov (May 8, 2019), https://www.hiv.gov/blog/hrsa-s-ryan-white-hivaids-program-observes-hepatitis-awareness-month-advances-efforts-eliminate.

[32] HRSA HAB, *HIV and Hepatitis C Coinfection: HRSA Progress and Efforts Around Curing Hepatitis C Among People Living With HIV* (2017), https://ryanwhite.hrsa.gov/livinghistory/2017.

[33] *Id*.

not operate their own in-house pharmacy and therefore rely on contract pharmacies to dispense self-administered HCV drugs to their safety-net patient population. Without contract pharmacies, our members will not be able to provide 340B discounted HCV drugs to their vulnerable patient population.

The financial impact of Gilead's policy is especially concerning because it comes at a time when safety net providers are still battling the impact of the COVID-19 public health emergency (PHE) and the operational challenges that PHE continues to impose on providers. The COVID-19 pandemic has already stretched the finances and human resources of RWC-340B members, so Gilead's policy, in the words of HHS, is "at the very least, insensitive to the recent state of the economy."[34] The COVID-19 PHE has had disparate effects on various sectors of the health care industry. Drug manufacturers have largely been insulated from the financial burden of combatting COVID-19, while health care providers have suffered the brunt of the economic harm. Recent financial reports revealed that Gilead realized $27.3 billion in profits in 2021 (an 11% increase compared to 2020).[35] In light of the ongoing PHE, Gilead should reconsider its policy due to the hardship that it places on 340B safety net providers and their patients.

Limit of One Contract Pharmacy Is Unacceptable

According to Gilead's March 2022 letter, 340B covered entities that do not have an in-house pharmacy capable of dispensing 340B priced drugs may designate a "*single*" contract pharmacy location to receive, Gilead branded HCV drugs at 340B prices, on behalf of the covered entity. Limiting a covered entity to one contract pharmacy, however, conflicts with HRSA's 2010 guidance on utilizing contract pharmacy arrangements, in which HRSA recognized that multiple contract pharmacy arrangements enhance the delivery of patient care.[36] For RWC-340B members, the option to have multiple contract pharmacies is a vital component of ensuring access to care for needy patients. As stated above, the 340B statute does not allow manufacturers to determine the locations to which they will provide 340B drugs. Gilead must therefore continue to honor all contract pharmacy arrangements, not just one, and to satisfy its statutory obligation irrespective of whether a covered entity has an in-house pharmacy or not.

Gilead's decision to limit access for HCV drugs to only one retail pharmacy – either an in-house pharmacy or contract pharmacy – prevents RWCs and their patients from receiving the intended benefits of the 340B program. As stated above, many of our members do not operate their own in-house pharmacy and therefore rely on contract pharmacies to dispense self-administered HCV drugs to patients. Additionally, RWCs in rural communities are particularly dependent on 340B pricing for their patients in outlying areas. Requiring RWCs to designate only one pharmacy to access 340B discounts for Gilead HCV drugs means that those discounts will not be available for prescriptions filled by patients in these outlying areas. In addition, the restriction limiting RWCs to only one retail pharmacy also means that RWCs have limited ability to access 340B pricing for HCV drugs at contract pharmacies that rely on a central warehouse for receiving and storing drugs.

In sum, Gilead's limited exceptions allowing RWCs with an in-house pharmacy to access 340B pricing on HCV drugs only through that pharmacy, and allowing RWCs lacking outpatient, on-site dispensing pharmacies to designate only one contract pharmacy to access 340B pricing for HCV drugs, will not resolve the access problems created by

[34] Letter HHS to Eli Lilly, *supra* note 28.
[35] Gilead Sciences, Press Release, *Gilead Science Announces Fourth Quarter and Full Year 2021 Financial Results*, (Feb. 1, 2022), https://www.gilead.com/news-and-press/press-room/press-releases/2022/2/gilead-sciences-announces-fourth-quarter-and-full-year-2021-financial-results.
[36] 72 Fed. Reg. 10,272, 10,273 (March 5, 2010).

Gilead's policy. Nor will it remedy the inherent illegality of the policy itself. For these reasons, RWC-340B requests that Gilead exempt all RWCs that are eligible for the 340B program from this new, restrictive policy.

II. CONCERNS ABOUT 340B ESP™ PROGRAM

RWC-340B's concerns with Gilead's contract pharmacy policy is not limited to the restrictive conditions Gilead places on RWCs with 340B contract pharmacy arrangements. RWC-340B is also concerned by Gilead's insistence that RWCs register and submit contract pharmacy claims data through the 340B ESP™ clearinghouse platform developed by the software company Second Sight. RWC-340B understands that its members have implemented numerous safeguards to ensure they comply with the 340B statute's prohibition against duplicate discounts and diversion. Gilead asserts that the 340B ESP™ program will help achieve "greater transparency in the 340B program and will help Gilead address duplicate discounts and diversion". For the reasons described below, we respectfully disagree with Gilead's policy changes.

Request for Non-Medicaid Claims Data

Second Sight's Terms of Use state that the 340B ESP™ program will be used to "identify duplicate Medicaid, Medicare, TRICARE and commercial payer rebates that are not eligible for reimbursement" by Gilead or any other participating drug manufacturer.[37] Gilead's request for data on claims submitted to Medicare Part D, TRICARE, and commercial insurers falls outside the scope of the 340B program. The 340B statute protects a manufacturer from paying duplicate discounts on Medicaid fee-for-service claims. The Medicaid drug rebate statute protects a manufacturer from paying duplicate discounts on claims submitted to a Medicaid Managed Care Organization (MCO). Neither statute protects a manufacturer from paying a rebate to a non-Medicaid payer for a 340B drug provided to a patient covered by that payer. To the extent Gilead is protected from paying a rebate, or paying a higher rebate, to Medicare Part D, TRICARE, or private insurance plans for 340B drug claims, those protections are purely contractual in nature and do not involve 340B covered entities. We recognize that RWCs and other covered entities are responsible for preventing duplicate discounts on Medicaid fee-for-service claims. With respect to Medicaid MCO claims, we are willing to work with Gilead, the state Medicaid agency, and the Medicaid MCO plans to avoid duplicate discounts.[38] We do not, however, believe that we have any obligation to help Gilead or any other manufacturer protect itself from duplicate discounts involving non-Medicaid plans.

A manufacturer is permitted to audit the records of a 340B covered entity that "directly pertain to the entity's compliance with the requirements" of the duplicate discount and diversion prohibitions.[39] Manufacturers do not have the right, however, to audit covered entities with respect to duplicate discounts that are related to Medicare Part D, private insurance or other non-Medicaid claims. RWC-340B members cooperate with good faith inquiries from

[37] Second Sight added the requirement to submit Medicare Part D and TRICARE claims data in the January 2022 version of the 340B ESP™ Terms of Use. 340B ESP™ Terms of Use § 3.4, available at https://340besp.com/terms-of-use#section1 (last updated April 6, 2022) ("Terms of Use"). This change broadened the universe of claims covered entities must submit through the 340B ESP™ platform.

[38] The burden of protecting manufacturers from Medicaid MCO duplicate discounts falls on the state Medicaid agency, not the covered entity. So, although covered entities have a role to play, ultimate responsibility for avoiding MCO duplicate discounts lies with the state.

[39] 42 U.S.C. § 256b(a)(5)(C). The requested claims data does not implicate the prohibition against diversion.

manufacturers related to the prohibition on duplicate discounts and diversion because they are committed to supporting the integrity of the 340B program. We also recognize a manufacturer's right to conduct a more formal audit of covered entities under the statutory provision above. But again, Gilead's request for claims data far exceeds the bounds of a good faith inquiry because the requested non-Medicaid claims could not be the precursor to a more formal audit and Gilead has not stated any basis for believing that it is subject to duplicate discounts on Medicaid claims submitted by covered entities or that covered entities are engaged in diversion. It seems very unlikely that diversion issues would arise with drugs used to treat HCV, which require that an RWC monitor the patient closely over an extended period.

RWC-340B is aware that Second Sight recently updated its Terms of Use in response to feedback from 340B covered entities. One of the recent changes is to require covered entities that participate in 340B ESP™ to agree that commercial payers and rebate claims processors may "link" contract pharmacy claims data submitted by covered entities with "identifiable rebate data" processed by such commercial payers or rebate claims processor.[40] RWC-340B is concerned that this will allow private payers to use contract pharmacy claims data to change their reimbursement practices in a way that discriminates against RWC-340B members and their contract pharmacies. Private payers are increasingly offering payment rates to RWC-340B members and their pharmacies that are far less than the rates paid for drugs that are purchased outside the 340B program. Some private payers have even suggested reducing reimbursement rates for all retail drugs purchased by covered entities regardless of whether the drugs are purchased through the 340B program or not. The benefit of the 340B program is intended for eligible safety net providers, not private payers. We are wary of any effort or program that could be used to support discriminatory reimbursement practices by payers. We appreciate the importance of privately negotiated manufacturer rebate arrangements with Part D and private plans because these arrangements are used to generate preferred placement on the plans' formularies. But formulary placement is strictly a business issue between the manufacturer and payer. It is not an issue that is necessarily within the interests of RWCs and their patients, let alone an issue requiring RWCs' support and involvement.

Use of Contract Pharmacy Claims Data

RWC-340B is also concerned that the current Terms of Use allow Second Sight, manufacturers, and other third parties to use contract pharmacy claims data in a way that goes beyond the scope of identifying or resolving duplicate discounts. The 340B ESP™ Terms of Use state that the covered entity gives Second Sight "a worldwide, sublicensable, non-exclusive, royalty-free, perpetual, irrevocable license to collect, process, disclose, create derivative works of and otherwise use the Covered Entity Claims Data (Data License) for **the purposes set forth herein, including specifically pursuant to Sections 3.4 and 3.5**."[41] Section 3.4 states that Second Sight may combine the contract pharmacy claims data with rebate data to identify what Second Sight considers to be "Ineligible Rebates"[42] and Section 3.5 states that Second Sight may disclose and sub-license contract pharmacy claims data to manufacturers and other third parties "under the same Terms as applicable to us for the purpose of identifying Ineligible Rebates."[43]

Ideally those terms will limit how manufacturers and other third parties use contract pharmacy data and would provide RWC-340B members with some protections from potential nefarious uses of their contract pharmacy data. However, RWC-340B views the provisions addressing the use of the contract pharmacy data as vague and potentially

[40] Terms of Use § 1.16.
[41] 340B ESP™ Terms of Use § 3.1 (emphasis added).
[42] *Id*. § 3.4.
[43] *Id*. § 3.5.

problematic. For example, stating that Second Sight can use claims data "for the purposes set forth herein, **including** specifically pursuant to Sections 3.4 and 3.5," suggests that Second Sight is leaving open the possibility that it will expand allowable uses of data in future iterations of the Terms of Use.[44] Additionally, although the Terms of Use state that Second Sight will not attempt to "re-identify or de-anonymize" the contract pharmacy data,[45] the Terms of Use allow participating manufacturers, commercial payers, rebate claims processors or state Medicaid agencies to "link the Covered Entity Claims Data with identifiable complete rebate data possessed by such entities."[46]

Constraints on how Gilead and other manufacturers use contract pharmacy data is particularly important to RWC-340B and our members. In addition to our concerns that such usage may support efforts by private payers to impose discriminatory pricing terms on RWCs, RWC-340B is concerned that Gilead could use contract pharmacy claims data to RWC-340B members' detriment by requesting unnecessary audits for periods before the RWC began participating in 340B ESP™ or mischaracterizing how the 340B program operates. Thus, RWC-340B requests that Gilead provide assurances that Second Sight, manufacturers and other third parties that obtain contract pharmacy data will use such data to identify duplicate discounts only and will not use RWC-340B members' data for purposes that are not specifically provided for in the Terms of Use.

Potential Exposure Under HIPAA and Other Federal and State Privacy Laws

The Health Insurance Portability and Accountability Act (HIPAA) privacy rule governs the use and disclosure of protected health information (PHI) held by health plans, health care clearinghouses, and any health care provider that transmits health information in an electronic form.[47] RWC-340B members are governed by HIPAA and, as a result, are responsible for maintaining the privacy and security of their patients' PHI. They could incur significant liability if a breach were to occur. RWC-304B is therefore concerned about the kind of data being requested from our members for the 340B ESP™ platform and the potential implications that may arise should PHI be inadvertently used, disclosed, or accessed.

HIPAA data breaches expose health care providers to serious financial, legal, and reputational harm. Hence, it is important that our members fully understand the risk of submitting PHI (including de-identified PHI) and alleviate any of the potential liability in the case of a breach. RWC-340B appreciates that Second Sight has revised the indemnification provision in the 340B ESP™ Terms of Use to require Second Sight to indemnify 340B covered entities from any claims or actions resulting from 1) the "unauthorized disclosure" of contract pharmacy claims submitted to the 340B ESP™ platform, or 2) a "security incident or breach" impacting the 340B ESP™ platform that results in an obligation to notify governmental authorities.[48] Section 6.3 of the Terms of Use, however, appear to limit Second Sight's liability to $100.00.[49] RWC-340B also appreciates that Second Sight recently updated its Terms of Use to provide additional information about the claims data de-identification process[50] and that Second Sight is willing to enter into a Business Associate Agreement (BAA) with covered entities that participate in the 340B ESP™ program. The BAA is not available on the 340B ESP™ website, but our attorneys obtained a copy several months ago. That BAA, however, contains only those terms required under the HIPAA regulations. Second Sight has stated that it will not accept any edits to the BAA,

[44] *Id*. This language was added in the April 6, 2022, version of the Terms of Use.
[45] *Id*. § 1.15.
[46] *Id*. § 3.5.
[47] 45 C.F.R. § 164.104.
[48] Terms of Use § 7.2.
[49] *Id*. § 6.3.
[50] *Id*. § 1.14.

depriving covered entities of the opportunity to include any additional protections. Moreover, the 340B ESP™ Terms of Use make clear that the de-identification process depends on the RWC uploading the requested data into the platform properly, which places additional administrative burdens and pressure on RWC-340B members to ensure that the data is properly loaded, and only the data requested is provided.[51]

Participation in the 340B ESP™ program could also expose RWC-340B members to liabilities under other federal and/or state privacy laws should there be any inadvertent or improper disclosure of PHI. HIPAA provides baseline requirements governing the disclosure of health information. Other federal and state privacy laws require health care providers to obtain additional consent before disclosing a patient's health information. They may also impose another layer of notification and remediation requirements should health information be improperly exposed.[52] RWC-340B members therefore need to consider not only the HIPAA implications of Gilead's data request, but also the more stringent privacy laws with which health care providers must sometimes comply when handling their patients' PHI.

Terms of Use Put RWC-340B Members at an Unfair Disadvantage

As stated above, RWC-340B thanks Second Sight for updating its 340B ESP™ Terms of Use in response to the concerns expressed by covered entities. Although the updated Terms of Use address some of RWC-340B's concerns, certain provisions remain or were recently added that we believe put RWCs at an unfair disadvantage and expose RWC-340B members to undue risk.

As noted above, RWC-340B appreciates that Second Sight now provides indemnification for covered entities for the unauthorized disclosure, breach, or security incident involving contract pharmacy claims data. The updated Terms of Use, however, still include a vaguely worded limitation of liability clause that limits Second Sight's liability for direct damages caused by issues with the 340B ESP™ platform up to $100.00.[53] Moreover, the covered entity would be required to "assume control of the defense and settlement" of any claims against Second Sight, and pay all costs associated with that defense, including attorneys' fees.[54] As such, we find it unfair to RWCs that voluntarily register for 340B ESP™ to agree to an indemnification provision that could impose additional costs on them. Furthermore, because there is no consideration between the parties in the current Terms of Use, the Terms of Use may not be binding on RWC-340B members or Second Sight.

The current Terms of Use also provide Second Sight with the ability to amend the posted terms "from time to time", and state that it is the covered entity's responsibility to be aware of and comply with such changes by "checking and reading these Terms from time to time".[55] Although the Terms of Use state that Second Sight may provide advance notice of revisions to the Terms, RWC-340B is concerned that the Terms provide Second Sight or Gilead the ability to change the structure of the 340B ESP™ system without first informing participating RWCs and allowing them sufficient

[51] 340B ESP™ Terms of Use § 1.16, available at https://340besp.com/terms-of-use#section1 (last updated January 2022).
[52] E.g., 42 C.F.R. Part 2 imposes restrictions on the use and disclosure of certain substance use disorder patient health records. The Minnesota Medical Records Privacy Act requires health care providers obtain patient permission before disclosing health information, even for treatment purposes. (*See* Minn. Stat. 144.293). New York's data security protections laws impose additional risk mitigation requirements on health care providers in regard to inadvertent disclosures. (*See* N.Y. Gen. Bus. Law§ 899-aa.) Health care providers in New York are also required to notify state officials should a breach of private information occur. (*Id.*)
[53] 340B Terms of Use § 6.3.
[54] *Id*. § 7.1.
[55] *Id*. § 11.6.

time to decide whether to continue participation. Additionally, a change to the 340B ESP™ system could void the entire Expert Determination report, which Second Sight relies on to maintain HIPAA compliance.

Covered entities have long protested that Second Sight should give them explicit notice when making material changes to the Terms of Use, especially if those changes relate to claims submission, de-identification and reporting procedures. Not only has Second Sight refused to adopt covered entities' notice recommendations, Second Sight recently changed the Terms of Use to state that, in the event it changes the Terms of Use in the future, an RWC's continued use of the 340B ESP™ platform constitutes acceptance of the amended Terms of Use. An RWC can choose to drop out by asking Second Sight to deactivate its 340B User ID, but that will not shield it from the risks it incurred prior to termination. Under the new language added by Second Sight, the company may continue to use claims data for the purposes outlined in the version of the Terms of Use that was in effect at the time the RWC terminates its User ID. Neither of these two changes are within the interests of RWC-340B members or their vulnerable patient population.

Potential Breach of Contract Pharmacy Agreements

RWC-340B is concerned that providing the requested 340B claims data could lead to a breach of by its members of their agreements with various parties, including contract pharmacies, third-party administrators, prescription benefit managers, and others. While we have not asked our members to review each of their agreements in preparation of this letter, we are concerned that certain provisions within those contracts could be obstacles to our members' participation in the 340B ESP™ program. For example, 340B contracts often include confidentiality provisions that could potentially be breached if the RWC provides claims data to the 340B ESP™ program. These contracts almost always include provisions that require the parties to comply with federal and state law. As stated above, we have concerns about the risks imposed on our members associated with the 340B ESP™ program under HIPAA and state privacy laws. Those concerns are compounded by the fact that any non-compliance would result in a breach by our members of their 340B contract pharmacy agreements.

Additionally, RWC-340B is aware that when 340B ESP™ was first introduced, certain 340B third-party administrators and specialty pharmacies expressed concerns about submitting contract pharmacy claims data to 340B ESP™. For example, Optum Specialty & Diplomat sent a letter to customers, including many RWC-340B members, stating that it was concerned about potential violations of federal privacy laws, including HIPAA. CVS Wellpartner also informed its customers that it would only authorize the covered entity to submit Medicaid fee-for-service data (and Medicaid managed care data "if desired") to 340B ESP™, but would not authorize the covered entity to submit any data related to Medicare Part D claims or commercial claims because that data is not required for 340B compliance. It is RWC-340B's understanding that 340B third-party administrators and specialty pharmacies are now willing to assist covered entities that choose to submit data to the 340B ESP™ platform so long as certain safeguards are in place. For example, Optum has informed covered entities that it will assist covered entities as long as long as the data is secure and de-identified.[56]

Although contract pharmacies and third-party administrators have noted their willingness to cooperate, RWC-340B members will still be required to review each of their contractual arrangements related to their contract pharmacies to determine if participating in the 340B ESP™ program would comply with those arrangements. It is

[56] Email on file with RWC-340B outside counsel.

possible, even likely, that a review of those contracts will uncover other issues that would have to be addressed before RWC-340B members could safely enroll in 340B ESP™.[57]

Undue Administrative Burden

Finally, RWC-340B is concerned that the process of gathering, compiling, and submitting the requested contract pharmacy claims data to the 340B ESP™ platform will impose an undue administrative burden on its members. Frequently asked questions posted on the website of 34B ESP™ state that covered entities are required to submit data to the 340B ESP™ platform on a bi-weekly basis. Many of RWC-340B's members have several contract pharmacy arrangements that are registered on the Office of Pharmacy Affairs Information System (OPAIS). Each member will be required to make arrangements for each of these pharmacies and their third-party contract pharmacy claims administrator to send the requested claims data in a timely manner to ensure that they meet the bi-weekly deadline. RWC-340B assumes that, in certain instances, our members' pharmacies may be required to reorganize, reformat, or otherwise manipulate the data to ensure that the data files contain the specific data points that Gilead seeks. Therefore, RWC-340B is concerned that the additional time it will take our members to collect and prepare this data will be much greater, not taking into account the added administrative burden.

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We welcome the opportunity to speak with you about our requests, to provide more detail about the reasons for those requests, and to work together to ensure that RWCs can be most effective in our fight to prevent HIV/AIDS.

Sincerely,

Shannon Stephenson

Shannon Stephenson
President, RWC-340B

cc: Peggy Tighe, Principal, Powers Law

[57] In addition, because the submission of claims data could be viewed as providing something of value to Gilead, the parties will need to make sure the 340B ESP™ program does not create undue risk under federal and state anti-kickback laws.