

BEFORE THE ARKANSAS INSURANCE DEPARTMENT

In re Rule 123

WHITE RIVER MEDICAL CENTER
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AID No. _____

COMPLAINT

INTRODUCTION

1. White River Medical Center (“White River”) submits this Complaint to the Insurance Commissioner for the State of Arkansas (“Commissioner”) and the Arkansas Insurance Department (“AID”) in response to policies implemented by Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively “Novo”) that restrict distribution of drugs to 340B contract pharmacies and therefore violate Section 604(c) of Arkansas Act 1103, the “340B Drug Pricing Nondiscrimination Act,” codified at Ark. Code Ann. § 23-92-604(c), and its implementing regulations under AID Rule 123, Ark. Admin. Code 054.00.123-4(c). Contact information for Novo is attached at Exhibit A.

2. The 340B Program, established at 42 U.S.C. § 256b (“340B Program”), requires pharmaceutical manufacturers to sell “covered outpatient drugs” at discounted prices to certain statutorily defined health care providers, known as “covered entities,” as a condition of the manufacturer’s drugs being covered as a benefit under the Medicaid and Medicare Part B insurance programs.

3. White River is a covered entity that qualifies for and participates in the 340B Program. Like many covered entities, White River purchases discounted drugs through the 340B Program, but relies on third-party pharmacies, referred to as “contract pharmacies,” to dispense self-administered drugs to its patients. Under these contract pharmacy arrangements, White River purchases 340B discounted drugs that are shipped via a drug wholesaler to one of White River’s contract pharmacies and then dispensed to White River’s patients.

4. Beginning January 1, 2021, Novo adopted a policy to restrict distribution of covered outpatient drugs if the drugs are ordered through a 340B wholesaler account associated with a contract pharmacy. Letter from Novo to covered entities (Dec. 1, 2020), Exhibit B; Letter from Novo to covered entities (Jan. 24, 2022), Exhibit C.

5. Arkansas Act 1103 prohibits manufacturers from placing restrictions on the distribution of 340B drugs to contract pharmacies. Ark. Code Ann. § 23-92-604(c). AID’s Rule 123 implements the requirements and prohibitions of Act 1103. *Id.* § 23-92-606; AID Rule 123 (Sept. 30, 2022), Ark. Admin. Code 054.00.123 (“Rule 123”). Rule 123 went into effect on September 30, 2022.

6. Act 1103 and Rule 123 require Novo to distribute 340B drugs to White River without restriction. Ark. Code Ann. § 23-92-604(c); Ark. Admin. Code 054.00.123-4(c). Novo’s policy restricting distribution of 340B drugs to contract pharmacies is, therefore, unlawful. Accordingly, White River requests that the Commissioner initiate an investigation into Novo’s restrictive policy for violation of Act 1103 and Rule 123.

JURISDICTION

7. AID and the Commissioner have jurisdiction to review and investigate violations of the Act 1103 and Rule 123 laid out in this Complaint. Ark. Code Ann. § 23-61-103(a) assigns the responsibility for administration of the Arkansas Insurance Code to the Commissioner.

PARTIES

8. White River is a non-profit, acute care hospital located in Batesville, Arkansas that provides care to patients in north central Arkansas. White River is part of the White River Health System. Pursuant to 42 U.S.C. § 256b(a)(4)(L), White River has participated in the 340B Program as a disproportionate share hospital (“DSH”) since 2009 (340B ID No. DSH040119).

9. White River provides healthcare services in a primarily rural area that spans ten counties in north central Arkansas: Independence, Izard, Sharp, Stone, and parts of Cleburne, Fulton, Jackson, Lawrence, Van Buren, and White. Affidavit of Maggie Williams, Pharm.D., Executive Director of Pharmacy for White River (“Williams Aff.”) ¶ 2, Exhibit D; White River Health, *About Us*, <https://whiteriverhealth.org/about-us#about> (last accessed Nov. 7, 2022).

10. The median household income in White River’s service area ranges from \$31,792 to \$48,972, with 15% to 25% of the population in each county living below the federal poverty level. Williams Aff. ¶ 7. All counties within White River’s service area report a lower median income than the average for the entire state of Arkansas. Williams Aff. ¶ 7.

11. White River’s mission is “to provide quality healthcare and improve the health of our communities” and it champions a vision that allows it “to provide an environment where patients choose to receive care, employees desire to work, physicians want to practice, and families and visitors feel welcome.” Williams Aff. ¶ 3; White River Health, *About Us*, <https://whiteriverhealth.org/about-us#about> (last accessed Nov. 7, 2022).

12. From 2017 to 2021, White River was named one of the top 100 rural and community hospitals by the Chartis Center for Rural Health. White River Health System 2021 Annual Report, Exhibit E. White River provides patient care services covering a wide variety of specialties, including cancer care, rheumatology, infusion services, inpatient rehabilitation, orthopaedics, pulmonary rehabilitation, surgical services, emergency care, interventional pain management, outpatient therapy, diabetes care, radiology, women & newborn health, heart health, mental health, palliative care, sleep disorders, and wound healing. White River Health System, *Medical Services*, <https://whiteriverhealth.org/medical-services> (last accessed Nov. 7, 2022).

13. From October 2020 to September 2021, the White River Health System provided a total of \$5,185,792 in charity care, with \$4,632,970 attributable to care provided at White River's facilities. Annual Report, Exhibit E; Williams Aff. ¶ 12. The funding that White River realizes through its contract pharmacies allows it to provide this level of charity care without suffering a catastrophic financial loss. Williams Aff. ¶ 12.

14. White River prioritizes partnerships with the community to promote wellness. White River's Community Engagement Division supports relationships with local public schools and community partners to promote service, wellness, and community involvement. Williams Aff. ¶ 8; White River Health, *About Us: Community Involvement*, <https://whiteriverhealth.org/about-us#community>, (last accessed Nov. 7, 2022). Community engagement events focus on improving access to healthcare, promoting physical activity, and encouraging careers in healthcare. *Id.* White River also partners with University of Arkansas Community College in Batesville to provide free mental health services to students and offer mental health first aid training. *Id.*

15. White River does not operate an in-house retail pharmacy. Arkansas law prohibits White River from holding a license as a retail pharmacy. Ark. Code Ann. §§ 17-92-605(d) and 17-92-607. White River must therefore rely exclusively on contract pharmacy arrangements to dispense 340B discounted drugs to its patients. Williams Aff. ¶ 13.

16. White River relies on the funding from its contract pharmacy arrangements to help provide its most financially needy patients access to low-cost health care and related services that are not funded in whole or part by a patient's health insurance. Examples of the healthcare services or programs that White River funds through its contract pharmacy arrangements include:

- an oncology clinic that provides coordinated cancer care, including a "Cancer Nurse Navigator" that assists patients throughout their cancer journey, as well as financial assistance for patients that qualify;
- a rheumatology clinic that treats patients with rheumatic diseases such as rheumatoid arthritis, lupus, osteoarthritis, and vasculitis;
- two infusion centers; and
- the Community Engagement Division.

Williams Aff. ¶¶ 8-11.

17. Without 340B savings and contract pharmacy arrangements, White River would have to drastically scale back or eliminate the services provided in the oncology and rheumatology clinics, and its two infusion centers. Williams Aff. ¶ 19.

18. White River also operates a "340B Savings Plan" Program, which provides 340B discounted drugs to indigent patients through contract pharmacies. Williams Aff. ¶ 24.

19. Novo is a pharmaceutical manufacturer of covered outpatient drugs that participates in the 340B Program.

20. Novo produces a variety of drug treatments and products, including treatments and products for diabetes, obesity, and serious chronic diseases, Novo Nordisk, *Annual Report*

2021, at 6.¹ Novo manufactures at least fourteen different diabetes medications and is one of only three manufacturers that distributes diabetes medications in the United States. Novo Nordisk, *Products: Diabetes Treatments*;² Maia Anderson, *Novo Nordisk to End 340B Discounts on Drugs Dispensed at Community Pharmacies*, Becker’s Hospital Review (Dec. 8, 2020).³ In 2021, Novo Nordisk’s annual revenue was \$22.401 billion, a 15.18% increase from 2020. Macrotrends, *Novo Nordisk Revenue 2010-2022*.⁴

BACKGROUND

I. The 340B Drug Pricing Program

21. Congress established the 340B Program in 1992 by enacting Section 602 of the Veterans Health Care Act of 1992. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71. That legislation amended the Public Health Service Act with a new Section 340B, codified at 42 U.S.C. § 256b.

22. The 340B Program is administered by the Office of Pharmacy Affairs, a division of the Health Resources and Services Administration (“HRSA”) within the United States Department of Health and Human Services (“HHS”).

23. Section 340B—in conjunction with certain related provisions in Section 1927 of the Social Security Act—requires a manufacturer of outpatient drugs to sign a pharmaceutical pricing agreement (“PPA”) and PPA addendum as a condition of the manufacturer’s drugs being covered as a health benefit under the Medicaid and Medicare Part B insurance programs.

¹ https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2022/novo-nordisk-annual-report-2021.pdf.

² <https://www.novonordisk-us.com/products/diabetes.html>.

³ https://www.beckershospitalreview.com/pharmacy/novo-nordisk-to-end-340b-discounts-on-drugs-dispensed-at-community-pharmacies.html?oly_enc_id=4024E1600890H5Y.

⁴ <https://www.macrotrends.net/stocks/charts/NVO/novo-nordisk/revenue#:~:text=Novo%20Nordisk%20annual%20revenue%20for.a%206.33%25%20increase%20from%202019.>

24. The PPAs “require that the manufacturer offer each covered entity 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.” 42 U.S.C. § 256b(a)(1). The “ceiling price” is “equal to the average manufacturer price for the drug under title XIX of the Social Security Act [Medicaid] in the preceding calendar quarter,” reduced by a rebate percentage calculated under Medicaid. *Id.* § 256b(a)(1)-(2).

II. Contract Pharmacy Arrangements

25. Contract pharmacies, as the name suggests, are pharmacies that contract with health care providers. Typically, drugs dispensed by contract pharmacies are purchased under a “bill to/ship to” arrangement (also referred to as a contract pharmacy distribution arrangement) in which the drugs are billed to the health care provider but shipped to the contract pharmacy. *See FAQs, What Is a “Ship to Bill to” Arrangement?* HRSA (July 2020). The provider-purchaser takes title to the drugs but not physical possession of them and directs their shipment, usually by a wholesaler, to the contract pharmacy, which then takes physical custody of the drugs and dispenses them on the provider’s behalf.

26. Contract pharmacy distribution arrangements are not unique to the 340B Program. They are a well-established means for non-profit health care providers to dispense drugs to their patients. *See, e.g.,* Fed. Trade Comm’n, University of Michigan Advisory Opinion Letter to Dykema Gossett (Apr. 9, 2010)⁵; 134 Cong. Rec. H6971-02 (1988) (statement of Rep. Charlie Rose) (“[H]ealth centers often include onsite pharmacies, or agreements with community pharmacists to ensure that the medicines needed to treat or control these chronic conditions are available”); *Social Security and Welfare Proposals, Hearing Before the H. Comm. on Ways and*

⁵ <https://www.ftc.gov/sites/default/files/documents/advisory-opinions/university-michigan/100409univmichiganopinion.pdf>.

Means, 91st Cong. 2129 (1969) (statement of Jacob W. Miller, Chairman, Comm. Pub. Affs., Am. Pharm. Ass'n) (stating that “[as] I am sure you are aware, many health care facilities do not maintain their own onsite pharmaceutical services ... [r]ather, they look to the community pharmacies to provide such service on a contract basis”).

27. HRSA recognizes that many covered entities lack in-house pharmacies and cannot participate in the 340B program unless they acquire drugs through bill to/ship to arrangements with contract pharmacies. *Id.* (“only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500)”). Many covered entities choose not “to expend precious resources to develop their own in-house pharmacies” because the requirements to obtain a pharmacy license are complex and operating a pharmacy can be expensive. Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. at 43,550.

28. In 1996 and 2010, HRSA issued guidance clarifying that the 340B statute requires pharmaceutical manufacturers to provide 340B discounts on covered outpatient drugs when ordered by covered entities via contract pharmacies. Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also* Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010). HHS’ 1996 contract pharmacy guidelines also acknowledged that drug manufacturers were already, either directly or through wholesale distributors, shipping 340B drugs purchased by covered entities to contract pharmacies. 61 Fed. Reg. at 43,550.

29. In its 1996 guidance, HRSA explained why contract pharmacy arrangements are essential to the success of the 340B Program:

Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize

prescription drugs for many of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies.

Contract Pharmacy Services, 61 Fed. Reg. at 43,550. The agency's guidance "encouraged" covered entities that did not operate their own licensed pharmacies to use contract pharmacy services. *Id.* at 43,555.

30. In 2010, HRSA published guidance clarifying that covered entities are permitted to contract with multiple contract pharmacies to receive distribution of 340B drugs for dispensation to the covered entity's patients. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272.

31. The ability to enter into and use contract pharmacy distribution arrangements is particularly important to non-profit hospitals such as White River. Arkansas Code §§ 17-92-605(d) and 17-92-607 specify that non-profit, tax exempt, and governmentally funded hospitals are prohibited from holding a license as a retail pharmacy. Like most 340B hospitals in Arkansas, White River has no means to fill retail prescriptions with 340B discounted drugs except through contract pharmacies.

32. Access to 340B-priced drugs through contract pharmacies allows covered entities to enhance their role as the nation's healthcare "safety net," providing care and treatment to the neediest individuals, regardless of ability to pay. Contract pharmacy arrangements are a vital and indispensable tool for 340B covered entities because they help covered entities to offset the costs of uncompensated or under-compensated care, enabling covered entities to maximize their resources to meet the health care and pharmaceutical needs of the fragile communities they serve. Without contract pharmacy arrangements, many covered entities would be forced to restrict access significantly or, in some cases, cease operations. For these reasons, ensuring

access to 340B drugs at contract pharmacies and protecting against manufacturer interference with the distribution of 340B drugs through contract pharmacies, which results in a depletion of covered entities' limited resources, are of critical importance to covered entities and the patients they serve.

III. Arkansas Act 1103 and Rule 123

33. In May 2021, the Arkansas Legislature passed Act 1103, titled the “340B Drug Pricing Nondiscrimination Act.” Ark. Code Ann. §§ 23-92-601–606. Act 1103 prohibits several commercial practices that prevent Arkansas covered entities from receiving drugs discounted by the 340B Program. Two of the provisions in the statute protect a covered entity’s right to receive 340B drugs distributed to contract pharmacies within the state of Arkansas. The law states that pharmaceutical manufacturers may not “[p]rohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer.” *Id.* § 23-92-604(c)(1). The law also states that a manufacturer may not “[d]eny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.” *Id.* § 23-92-604(c)(2).

34. The legislative history of Act 1103 makes clear that the Arkansas legislature understood the importance of contract pharmacy arrangements for both Arkansas covered entities and Arkansas retail pharmacies and that the legislature intended to protect such arrangements from unfair methods of competition and unfair trade practices like those imposed by Novo. *To Establish the 340B Drug Pricing Nondiscrimination Act, Hearing on H.B. 1881 Before the Ark. House of Representatives, 93d Gen. Assembly Regular Session (Ark. 2021)*

(statement of Rep. Michelle Gray) (stating that “[l]ast year one manufacturer . . . decided that they would no longer ship . . . medications to the contract pharmacy;” the manufacturer said that “[i]f Hospital does contract with a pharmacy . . . we are no longer going to send medications there because we are trying to limit the amount of drugs that we send at a reduced price;” and Act 1103 is aimed to protect Arkansas “patients, our pharmacies, [and] our hospitals.”) (An audio recording of the hearing on file with White River’s attorney).

35. Act 1103 charges the Commissioner with promulgating rules to implement the statute. Ark. Code Ann. § 23-92-606. On September 19, 2022, AID issued Rule 123 to implement the requirements of Act 1103. Section IV of Rule 123 includes the same language as Ark. Code Ann. Section 23-92-604(c) establishing the right of covered entities in Arkansas to receive 340B-priced drugs distributed to contract pharmacies.

36. Section VI of Rule 123 states that the “penalties, actions or orders, as authorized under Ark. Code Ann. Sections 23-66-209 [Hearings] and 23-66-210 [Cease and Desist Orders], shall apply to violations of this Rule.” Ark. Admin. Code 054.00.123-6.

37. Act 1103 and Rule 123 addresses manufacturers’ responsibilities regarding the distribution of 340B-priced drugs, while the 340B statute addresses manufacturers’ responsibilities to establish and offer the 340B ceiling price, as described in the PPA.

IV. Novo’s Restrictive Contract Pharmacy Policy

38. As a manufacturer participating in the 340B Program, Novo signed a PPA and PPA Addendum. Accordingly, Novo’s outpatient drugs are covered as a health benefit under state Medicaid programs and Medicare Part B because Novo agreed to provide covered outpatient drugs to covered entities at statutorily calculated ceiling prices.

39. Despite honoring contract pharmacy arrangements for nearly three decades, effective January 1, 2021, Novo adopted a policy to cease providing discounts to hospital covered entities when drugs are distributed to contract pharmacies.

40. By letter dated December 1, 2020, Novo informed HRSA of its plan to cease facilitating “‘bill-to/ship-to’ distribution of 340B product to a contract pharmacy for any of the six ‘hospital’ covered entity types” beginning January 1, 2021. Letter from Farruq Jafery, VP Pricing, Contract Operations & Reimbursement, Novo to Rear Admiral Krista Pedley, Director, Office of Pharmacy Affairs (Dec. 1, 2020), Exhibit F. On the same day, Novo sent a similar notice to covered entities entitled “Notice Regarding Limitation on Hospital Contract Pharmacy Distribution.” Letter from Novo to covered entities, Exhibit B. Under Novo’s policy, hospital covered entities that do not maintain an on-site pharmacy may request to designate a *single* retail contract pharmacy location to accept bill-to/ship-to orders.⁶ *Id.*

41. In response to Novo’s restrictive contract pharmacy policy, effective January 1, 2021, White River’s drug wholesaler(s) blocked purchases of Novo’s drugs if White River specified shipment to a contract pharmacy. For example, one of White River’s wholesalers, Cardinal Health Inc., has blocked access to Novo’s products through White River’s 340B account at its contract pharmacies. Some of White River’s contract pharmacies have taken similar actions that also block distribution of 340B drugs to contract pharmacies. For example, White River’s price availability file for its 340B accounts at its Walgreens’ contract pharmacies shows that Novo’s products (labeler code 00169) are not included in response to Novo’s restrictive contract pharmacy policy. (The Walgreens’ price file is hundreds of pages long and

⁶ White River’s designated retail contract pharmacy is Ash Flat Pharmacy in Ash Flat, AR.

too voluminous to submit as an exhibit to this Complaint. White River can provide a screenshot of the price file upon request.)

42. Approximately one year after Novo announced its restrictive policy, it revised its policy to allow 340B hospital covered entities to designate one additional pharmacy to receive shipment of specialty drugs at 340B prices. Letter from Novo to covered entities (Jan. 24, 2022), Exhibit C.

V. White River's Contract Pharmacy Distribution Arrangements and Damage Caused by Novo's Unlawful Restrictions

43. White River serves a very large area that includes approximately 100,000 people. It has entered into contract pharmacy arrangements across that service area to dispense 340B drugs on White River's behalf. Williams Aff. ¶ 6. White River entered into contract pharmacy arrangements across its service area to allow it to provide 340B-priced drugs to patients that qualify for its drug discount program, referred to as the 340B Savings Plan Program, at the patient's local pharmacy. Williams Aff. ¶¶ 24-25.

44. White River does not operate an in-house retail pharmacy for self-administered drugs because Arkansas law prohibits it from doing so. White River relies exclusively on outside retail pharmacies to receive and dispense self-administered drugs at 340B prices.

45. White River has contract pharmacy distribution arrangements registered with HRSA for 29 retail pharmacies in Arkansas. HRSA, *340B Office of Pharmacy Affairs Information System*, <https://340bopais.hrsa.gov/ContractPharmacySearch> (last updated Nov. 7, 2022). White River has contract pharmacy agreements with locally owned pharmacies, specialty pharmacies, and pharmacies owned by chain organizations, including Kroger, Wal-Mart, and Walgreens. *Id.* For non-profit hospitals like White River, the contract pharmacy model is indispensable and allows White River to pay for drugs needed by its patients who cannot afford

the drugs and to pay for clinics and support services for its patients that are not covered by insurance. For example, White River uses revenues from its contract pharmacy arrangements to help pay for the operation of its oncology clinic, rheumatology clinic, and the infusion centers. Williams Aff. ¶¶ 9-11, 15. White River also relies on revenues from its contract pharmacy arrangements to provide health and wellness services to individuals through its Community Engagement Division. Williams Aff. ¶ 8.

46. Novo's refusal to distribute self-administered drugs at 340B prices to all but two contract pharmacies designated by White River has severely impacted White River's ability to provide low-cost drugs to its most financially needy patients. In calendar year 2020, prior to Novo implementing its restrictive contract pharmacy policy, White River was able to assist 124 individuals across nine contract pharmacies to save a combined total of \$195,000 in drug costs associated with diabetes care for the 2020 calendar year. Williams Aff. ¶ 25. In 2021, following implementation of Novo's policy, White River was only able to assist four patients at its one designated retail contract pharmacy. Williams Aff. ¶ 25.

47. The difference between the prices available to White River for Novo's drugs with a 340B discount and without a 340B discount is substantial. As one example, the price for NovoLog® Mix 70-30 FlexPen, a fast-acting insulin injection for diabetics, increased by 363,138% between December 2020 when White River was able to access 340B pricing through its contract pharmacies and January 2021 when Novo ceased shipping 340B discounted drugs to contract pharmacies. Williams Aff. ¶ 26. As another example, the price for Victoza® 3Pak, 18 Mg, 3 ML Pen, a medication to address diabetes, increased by 1,118,311% between December 2020 when White River was able to access 340B pricing through its contract pharmacies and January 2021 when Novo ceased shipping 340B discounted drugs to contract pharmacies.

Williams Aff. ¶ 26. As the result of these price increases, many of White River's patients were either forced to change pharmacies or change therapies, both of which risk the patients' medication adherence and overall wellbeing. Williams Aff. ¶ 28.

48. Based on White River's calculations of the 340B savings that it has historically achieved through filling prescriptions for drugs manufactured by Novo, White River has lost approximately \$1,000,000 in contract pharmacy revenue over a 21-month period as a result of Novo's unilateral restrictions on the distribution of 340B drugs to White River's contract pharmacies. Williams Aff. ¶ 19. White River will have to cut or eliminate other services or reevaluate whether it can keep clinics open if White River loses another \$1,000,000 as the result of Novo's restrictive 340B distribution policy. Williams Aff. ¶ 19.

VI. Novo's Restrictive Contract Pharmacy Policy Is an Unfair Method of Competition and Unfair Trade Practice

49. Novo's policy to constrain distribution of drugs to White River's contract pharmacies is an unfair method of competition and unfair trade practice because it interferes with White River's ability to contract with pharmacies freely for the distribution of drugs to White River's patients.

50. Novo's policy to constrain distribution of drugs to White River's contract pharmacies is an unfair method of competition and unfair trade practice because it interferes with White River's ability to offer discounted pricing on drugs to indigent patients.

51. Novo's policy to constrain distribution of drugs to White River's contract pharmacies is an unfair method of competition and unfair trade practice because it violates Arkansas Act 1103 and Rule 123.

VIOLATION OF ACT 1103 AND RULE 123

52. White River realleges and incorporates by reference paragraphs 1–50 as if fully set forth below.

53. Effective January 1, 2022, Novo implemented a policy that interferes with the distribution of 340B drugs, a clear violation of the requirements of Arkansas Act 1103 and Rule 123, which punish unfair trade practices and protect the distribution of 340B drugs to contract pharmacies within the state of Arkansas. Ark. Code Ann. § 23-92-604(c); Ark. Admin. Code 054.00.123-4(c). Arkansas Act 1103 and Rule 123 protect contract pharmacy arrangements through two provisions. The first provision prohibits a manufacturer from interfering with contractual relationships between contract pharmacies and covered entities. It states that a drug manufacturer may not:

(1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer.

Ark. Code Ann. § 23-92-604(c)(1); Ark. Admin. Code 054.00.123-4(c)(1).

54. The second provision prohibits a manufacturer from preventing a contract pharmacy from receiving 340B-priced drugs on behalf of a covered entity. It states that a drug manufacturer may not:

(2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

Ark. Code Ann. § 23-92-604(c)(2); Ark. Admin. Code 054.00.123-4(c)(2).

55. Ark. Code Ann. § 23-92-604(c) and Section IV(c) of Rule 123 unambiguously require Novo to distribute 340B-priced drugs to White River without limitation on the location of the dispensing pharmacy or the number of dispensing pharmacies for the delivery of those drugs.

Accordingly, Novo has violated Act 1103, Ark. Code Ann. § 23-92-604(c), and Rule 123, Ark. Admin. Code 054.00.123-4(c), by refusing to distribute 340B-priced drugs to White River's contract pharmacies since July 28, 2021. Novo's failure to comply with Act 1103 and Rule 123 is an unfair method of competition and an unfair or deceptive act or practice that must be investigated and enjoined by the Commissioner. Ark. Code Ann. §§ 23-66-209(a)(1); 23-66-210.

Respectfully submitted,



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