COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIVISION _____
CIVIL ACTION NO. _____

ELECTRONICALLY FILED

KENTUCKY PRIMARY CARE ASSOCIATION PLAINTIFF

v. **VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

COMMONWEALTH OF KENTUCKY,
KENTUCKY CABINET FOR HEALTH AND
FAMILY SERVICES DEFENDANT

Serve: Daniel Cameron, Attorney General
Office of the Attorney General
700 Capitol Avenue, Suite 118
Frankfort, KY 40601-3449

Serve: Eric Friedlander, Secretary
Kentucky Cabinet for Health and Family Services
Office of the Secretary
275 East Main Street
Frankfort, KY 40601

Comes the Plaintiff, Kentucky Primary Care Association ("KPCA"), by counsel, and for its Verified Complaint for Declaratory and Injunctive Relief against the Commonwealth of Kentucky, Kentucky Cabinet for Health and Family Services ("CHFS"), states as follows:

INTRODUCTION

1. This case concerns the 340B Policy and Procedures Manual ("the 340B Manual") issued on November 8, 2019, by the Department of Medicaid Services within CHFS. A true and accurate copy of the 340B Manual is attached as **Exhibit A**. It is also available online at https://chfs.ky.gov/agencies/dms/dpo/ppb/Documents/340BPolicyandProceduresManual.pdf.

2. The 340B Manual concerns the interplay between two federal programs that both require drug manufacturers to provide discounts on drugs that are dispensed to certain types of patients. These programs are known as the 340B Program and Medicaid Drug Rebate Program (hereinafter "Medicaid Rebate Program").

3. In short, the 340B Program requires drug manufacturers to sell drugs to certain statutorily defined healthcare providers treating underserved populations (known as "Covered Entities") at discounted prices, which the Covered Entities can then dispense to any of their patients regardless of whether the patients are insured or what type of insurance the patients have. The Covered Entities are permitted to bill patients' insurers at the drug's non-discounted rate, meaning that the value of the discount is kept by the Covered Entity and reinvested into services provided to low-income and uninsured individuals.

4. Conversely, the Medicaid Drug Rebate Program requires drug manufacturers to provide rebates to states on drugs that have been dispensed to the state's Medicaid beneficiaries. The rebates that are received are split between the federal and state governments, with the federal government retaining the significant majority of the rebates.

5. The 340B Program and the Medicaid Drug Rebate Program overlap, but are not totally coextensive. Not all 340B patients are Medicaid beneficiaries, and not all Medicaid beneficiaries are treated by 340B Covered Entities. But, there are a significant number of Medicaid beneficiaries who are indeed treated by 340B Covered Entities.

6. Further, it is unlawful for a state to receive a Medicaid rebate on a drug that was purchased at a 340B discounted price; this is commonly referred to as the prohibition against "duplicate discounts."

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7. Starting April 1, 2020, the 340B Manual requires providers, including pharmacies, to include at the time of submitting a Medicaid claim for reimbursement a designation (hereinafter referred to as the "Identifier") on a claim in which 340B drugs were dispensed. No Identifier is required if non-340B drugs were dispensed.

8. DMS will refrain from submitting a Medicaid rebate only if an Identifier is included on the claim—meaning that, if no Identifier is included, DMS will submit a rebate.

9. The requirement to include the Identifier on a claim is not located in any existing statute or regulation, and instead is an entirely new mandatory rule.

10. Despite the fact that it imposes wholly new mandatory requirements on providers, the 340B Manual was not promulgated as a regulation in accordance with Kentucky's Administrative Procedure Act. This plainly violates KRS 13A.100.

11. Pharmacies face substantial obstacles complying with the 340B Manual's new requirement. Many pharmacies are unwilling to take on the potential liability associated with incorrectly assigning the Identifier to a claim. Further, many pharmacies would have to make costly changes to their internal software in order to be able to include the Identifier on a claim.

12. Accordingly, because many pharmacies will be unable to include the Identifier on a claim when the 340B Manual takes effect on April 1, 2020, Covered Entities will be forced to inform these pharmacies to refrain from dispensing 340B drugs to Medicaid beneficiaries in order to avoid duplicate discounts—even though many of those Medicaid beneficiaries will have been treated at Covered Entities and therefore would be eligible for 340B.

13. As a result, when the 340B Manual takes effect and many pharmacies begin dispensing non-340B drugs to all Medicaid beneficiaries, Covered Entities—including members of KPCA—will receive significantly less 340B revenue as they otherwise would have. Instead,

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the drug manufacturers' discounts will be provided in the form of rebates to the federal and state governments.

14. As detailed below, the implementation of the 340B Manual will cause immediate and irreparable harm to the members of KPCA that participate in the 340B Program and also serve Medicaid beneficiaries. Without the 340B revenue reinvested into its operations, these members' ability to serve low-income and uninsured individuals will be significantly hindered—which is particularly alarming given the COVID-19 crisis and the opioid crisis currently facing the Commonwealth. It is impossible to quantify exactly how much revenue these members will lose due to the implementation of the 340B Manual, although it is expected to be significant.

15. Consequently, for the reasons given below and in KPCA's simultaneously filed Motion for Injunctive Relief, this Court should enter immediate relief enjoining the implementation of the 340B Manual as a violation of KRS 13A.100.

THE PARTIES

16. The office of the Plaintiff, Kentucky Primary Care Association ("KPCA"), is located at 651 Comanche Trail, Frankfort, Kentucky. KPCA was founded in 1976 as a not-for-profit 501(c)(3) corporation of community health centers, rural health clinics, primary care centers, and all other organizations and individuals concerned about access to healthcare services for the state's underserved rural and urban populations. KPCA members are providers of primary care—first contact, broadly trained physicians, physician assistants, nurse practitioners, behavioral health providers, dental providers, pharmacists, and other professionals delivering whole-person healthcare. KPCA is charged with promoting the mutual interests of its members, with a mission to promote access to comprehensive, community-oriented primary healthcare services for the underserved.

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17. The Defendant, Commonwealth of Kentucky, Kentucky Cabinet for Health and Family Services ("CHFS") is an agency of the Commonwealth of Kentucky located in Frankfort, Franklin County, Kentucky. Contained within CHFS is the Department for Medicaid Services ("DMS"), which administers Kentucky's Medicaid program.

VENUE AND JURISDICTION

18. Venue and jurisdiction of this action properly lie in the Franklin County Circuit Court, as the Defendant, CHFS, is an agency of the Commonwealth of Kentucky with its headquarters located in Franklin County, Kentucky.

OVERVIEW OF THE 340B PROGRAM

19. The 340B Program is a federal program authorized by the Veterans Health Care Act of 1992. Administered by Health Resources & Services Administration ("HRSA"), an agency of the U.S. Department of Health and Human Services, the program is intended to help participating healthcare providers "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." *See* H.R. Rep. No. 102-384(II), at 12 (1992).

20. The 340B Program requires drug manufacturers to sell drugs to certain statutorily defined "Covered Entities" at a reduced price. The 340B price of a given drug is determined by a statutorily defined formula.

21. The definition of "Covered Entities" includes, but is not limited to, Federally Qualified Health Centers ("FQHCs"), as defined by § 1905(l)(2)(B) of the Social Security Act.

22. FQHCs are community-based healthcare providers that receive federal funds from HRSA to provide primary care services in underserved areas. FQHCs must meet a stringent set of requirements, including providing care on a sliding fee scale based on ability to pay and operating under a governing board that includes patients.

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23. Typically, a large proportion of FQHCs' patients are Medicaid beneficiaries, but not all FQHC patients are Medicaid beneficiaries. FQHCs also serve patients enrolled in Medicare and uninsured patients, as well as patients with private health insurance.

24. Ten members of KPCA are FQHCs that serve both Medicaid beneficiaries and non-Medicaid patients in the Commonwealth of Kentucky (hereinafter referred to as the "KPCA Medicaid FQHCs").[1] Because they are FQHCs, these ten members of KPCA are Covered Entities within the meaning of the 340B Program

25. Participation in the 340B Program is optional for Covered Entities. If they elect to participate in the 340B Program, Covered Entities may dispense drugs purchased through the 340B Program (hereinafter "340B drugs") to their patients, regardless of whether the patient has insurance, the type of insurance the patient has, or whether the patient is insured through government programs like Medicaid or Medicare.

26. Covered Entities may dispense 340B drugs to their patients through their own in-house pharmacies. Alternatively, Covered Entities may enter into arrangements with retail pharmacies to dispense 340B drugs on behalf of the Covered Entity; these pharmacies are known as "contract pharmacies." Thus, patients of Covered Entities may fill their prescriptions at contract pharmacies such as Walmart, CVS, Walgreens, Kroger, etc.

27. When using a contract pharmacy, the covered entity purchases the 340B drugs from the drug manufacturers at the discounted price and then provides the drugs to the contract pharmacies to dispense to 340B patients.

[1]These KPCA Medicaid FQHCs are: Big Sandy Health Care, Inc., in Prestonsburg, KY; Cumberland Family Medical Center, Inc., in Russell Springs, KY; Family Health Centers, Inc., in Louisville, KY; Mountain Comprehensive Health Corporation, in Whitesburg, KY; Lewis County Primary Care Center, Inc. d/b/a Primary Plus, in Vanceburg, KY; Fairview Community Health Center, in Bowling Green, KY; Health Help, Inc. d/b/a White House Clinics, in McKee, KY; HealthPoint Family Care, Inc., in Covington, KY; Regional Health Care Affiliates d/b/a Health First Community Health Center, in Providence, KY; A + Healthcare, LLC, in Brownsville, KY.

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28. Typically, rather than keeping separate physical inventories of 340B drugs versus non-340B drugs, contract pharmacies keep "virtual inventories." Briefly, and as a general matter, once a contract pharmacy receives 340B drugs from a Covered Entity, the drugs become part of the contract pharmacy's general inventory. Any of the drugs in the contract pharmacy's physical inventory can be dispensed to any patient who needs them, regardless of 340B status.

29. The Covered Entity then retroactively identifies how much of the drug was dispensed to 340B patients at contract pharmacies and places a corresponding order with drug manufacturers to replenish contract pharmacies' stock. This retroactive analysis is typically performed with the aid of a third-party administrator, which helps the Covered Entity identify which Medicaid beneficiaries seen by a given contract pharmacy were its patients and therefore depleted the contract pharmacy's virtual stock of 340B drugs.

REVENUE GENERATED FROM THE 340B PROGRAM

30. A key aspect of the 340B Program is that it permits Covered Entities to generate revenue by purchasing drugs at the discounted 340B price while charging patients and insurers (including government insurers like Medicaid or Medicare) the non-340B price of the drug. Thus, the entire amount of the 340B discount provided by the drug manufacturers is kept by the Covered Entity.

31. The revenue generated from the 340B Program is an essential part of FQHCs' operating budgets. Indeed, FQHCs are statutorily required to reinvest 340B revenue into their services. *See* 42 U.S.C. § 254b(e)(5)(D).

32. The KPCA Medicaid FQHCs use 340B revenue to provide a variety of services to underserved populations for which no billing stream exists.

33. For example, the KPCA Medicaid FQHCs use 340B revenue in a variety of impressive ways: to pay for care provided to uninsured patients, assist non-Medicaid low-income

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individuals with copays, employ community health workers, provide transportation to patients who do not qualify for Medicaid transportation, provide translation services to patients, run emergency food programs, run school-based satellite clinics, run smoking cessation clinics, run health literacy programs, test qualify improvement plans, purchase much-needed medical equipment, pay for extended hours at clinics, purchase property to expand clinic locations, provide substance use disorder treatment, and provide mental health treatment.

34. Without the 340B revenue, the KPCA Medicaid FQHCs would not be able to provide nearly as many of the services currently provided to underserved populations—which would leave many of our most vulnerable citizens without access to medical care, substance abuse treatment, and mental health treatment.

35. For example, Michael Stanley, the CEO of Grace Community Health Center d/b/a Grace Health—one of the KPCA Medicaid FQHCs serving approximately 35,000 patients in Southeastern Appalachian Kentucky—testified before the Senate Committee on Health and Welfare that a decrease in 340B revenue would result in the following for Grace Health's operations:

(a) Closing school-based health services in Clay, Whitley, Knox, Bell, and Leslie Counties, which places nurses and nurse practitioners in the schools and accounts for over fifty jobs;

(b) Discontinuing the provision of free and discounted medication to patients on the sliding fee scale program (200% or less of the federal poverty level);

(c) Discontinuing pharmacy services, including chronic disease state management clinics, Medication Therapy Management, and Medication Adherence/Synchronization Programs;

(d) Discontinuing case management services, which manages high-risk patients and audits quality initiatives;

(e) Discontinuing providing medication, counseling services, behavioral health, and medication monitoring to pregnant women and other patients with alcohol/opioid addiction;

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(f) Decreasing the number of patients cared for regardless of their ability to pay.

OVERVIEW OF THE MEDICAID REBATE PROGRAM

36. The Medicaid Rebate Program was created under the Omnibus Budget Reconciliation Act of 1990. Under the Medicaid Rebate Program, drug manufacturers must provide a rebate to Medicaid on the cost of their drugs in order for states to receive federal funding for use of their products.

37. The federal Centers for Medicare & Medicaid Services calculates a unit rebate amount ("URA") for each drug based on a defined formula. The URA is equal to the discount that drug manufacturers provide to covered entities under the 340B Program.

38. In order to calculate the amount of the rebate due, the state conducts a retroactive analysis and multiplies the URA by the number of units it paid for a given drug on behalf of Medicaid beneficiaries over a set period of time. The state then submits an invoice to the drug manufacturer for the total rebate.

39. The Medicaid rebates collected from drug manufacturers are shared by the federal government and states based on the state's current federal medical assistance percentage.

40. Several factors affect a state's current federal medical assistance percentage, and so the exact split between the federal and state government varies. As a general matter, however, in Kentucky, the federal government receives on average 75% of the rebates, while the Kentucky Department for Medicaid Services ("DMS") receives on average only 25% of the rebates.

THE INTERACTION BETWEEN THE 340B PROGRAM AND THE MEDICAID REBATE PROGRAM

41. Drug manufacturers are required to provide a price discount on the cost of drugs dispensed to Medicaid beneficiaries under either the 340B Program *or* the Medicaid Rebate Program, but not both.

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42. It is unlawful for a state to claim a Medicaid rebate for a drug that was purchased under the 340B Program. This is commonly referred to as the prohibition on "duplicate discounts."

43. When a Covered Entity enrolls in the 340B Program, it must choose whether it will "carve in" or "carve out" its Medicaid fee-for-service ("FFS") and Medicaid managed care organization ("MCO") patients, respectively.

44. Carve-in means that the Covered Entity will use 340B drugs for Medicaid beneficiaries, while carve-out means that it will not use 340B drugs for Medicaid beneficiaries. A Covered Entity can change its carve-in/carve-out designation with HRSA on a quarterly basis.

45. HRSA maintains a list of Covered Entities that carve-in 340B drugs for Medicaid FFS patients, known as the Medicaid exclusion file ("MEF").

46. Additionally, Kentucky law provides that contract pharmacies must carve out Medicaid FFS patients. *See* 907 KAR 23:020 § 4(6)(c); *see also* Kentucky State Plan Amendment KY-17-001.

47. However, HRSA does not maintain a list of Covered Entities that carve-in 340B drugs for Medicaid MCO patients—which are the vast majority of Kentucky Medicaid beneficiaries.

48. Accordingly, the MEF is of no use when trying to avoid duplicate discounts with respect to the vast majority of Kentucky Medicaid beneficiaries.

49. In addition, unlike with Medicaid FFS, Kentucky law does not dictate whether contract pharmacies must carve-in or carve-out Medicaid MCO patients.

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THE 340B MANUAL

50. On November 8, 2019, DMS issued the first version of the 340B Manual. It was to take effect on January 1, 2020. DMS did not issue the 340B Manual as a regulation and did not go through the rulemaking process required by Kentucky's Administrative Procedures Act.

51. Nonetheless, even though it was not issued as a regulation, DMS accepted comments through an informal notice-and-comment process. KPCA, among others, submitted comments.

52. DMS then moved back the effective date of the 340B Manual to April 1, 2020, and adjusted some of its language. Again, DMS did not issue the 340B Manual as a regulation and did not go through the rulemaking process required by Kentucky's Administrative Procedures Act.

53. In its current form, the 340B Manual creates a new rule, which did not previously exist in any statute or regulation, mandating that providers identify at the time of submitting a Medicaid claim to DMS for reimbursement whether drugs were purchased through the 340B Program.

54. Effective April 1, 2020, the 340B Manual requires a provider to add a certain indicator to the claim if the drug that was dispensed was a 340B drug ("the Identifier"); conversely, no indicator is added if the patient received a non-340B drug.

55. The 340B Manual further states that DMS will decide whether to collect a rebate on a given claim based on whether the Identifier is present on the claim. Under the 340B Manual, DMS will refrain from submitting a Medicaid rebate only if an Identifier is included on the claim—meaning that, if no Identifier is included, DMS will submit a rebate.

56. Problematically, while in-house pharmacies at a Covered Entity can more easily determine whether a given claim is 340B, contract pharmacies typically do not have sufficient

information at the time of submitting a Medicaid claim for reimbursement to determine whether the patient was treated by a Covered Entity.

57. This means that contract pharmacies generally cannot determine, at the time of claim submission, whether the drugs dispensed to the patient should be counted as 340B drugs or non-340B drugs in their virtual inventory.

58. Further, even if they did have sufficient information at the time of claim submission to determine a patient's 340B status, many contract pharmacies—and particularly national chains of retail pharmacies—face significant economic obstacles in complying with the 340B Manual. Many contract pharmacies have informed KPCA that their software must be changed in order to allow the contract pharmacies to add the Identifier. These contract pharmacies also report that implementing such a change in software would require a significant investment of time and money.

59. Accordingly, because these contract pharmacies cannot include the Identifier on claims, Covered Entities will be forced to inform these contract pharmacies to refrain from dispensing 340B drugs to Medicaid beneficiaries in order to avoid duplicate discounts—even though many of those Medicaid beneficiaries will have been treated at Covered Entities and therefore would be eligible for 340B.

60. Consequently, once the 340B Manual goes into effect, Covered Entities will not receive 340B revenue on many Medicaid claims involving drugs dispensed from contract pharmacies. Instead, the drug manufacturers' discount will be collected through the Medicaid Rebate Program and will be split between the federal and state government, with the majority of the discount going to the federal government.

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IRREPARABLE INJURY CAUSED BY THE 340B MANUAL

61. The end result of the 340B Manual is that the majority of the discounts provided by drug manufacturers for drugs dispensed to Medicaid beneficiaries treated by Kentucky FQHCs will be provided to the federal government through the Medicaid Rebate Program. Conversely, if the drug manufacturers' discounts were provided to the FQHCs through the 340B Program, 100% of the discounts would stay in the Commonwealth and would be reinvested in providing care to Kentucky's underserved populations.

62. The decrease in 340B revenue resulting from the implementation of the 340B Manual will likely have a massive impact on the operating budgets of the KPCA Medicaid FQHCs, and will be extremely damaging to the KPCA Medicaid FQHCs' ability to operate and provide medical services to low-income and uninsured individuals.

63. The majority of patients treated by KPCA Medicaid FQHCs are Medicaid MCO beneficiaries. In addition, a great deal of those patients fill their prescriptions at contract pharmacies. Thus, a great deal of the KPCA Medicaid FQHCs' 340B revenue comes from Medicaid claims involving drugs filled at contract pharmacies.

64. As stated above, and as attested to by Michael Stanley before the Senate Committee on Health and Welfare, a loss of 340B revenue could result in the discontinuation or significant decrease in the KPCA Medicaid FQHCs' abilities to provides services such as paying for care provided to uninsured patients, assisting non-Medicaid low-income individuals with copays, employing community health workers, providing transportation to patients who do not qualify for Medicaid transportation, providing translation services to patients, running emergency food programs, running school-based satellite clinics, running smoking cessation clinics, running health literacy programs, testing qualify improvement plans, purchasing much-needed medical equipment, paying for extended hours at clinics, purchasing property to expand

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clinic locations, providing substance use disorder treatment, and providing mental health treatment.

65. In addition, as are medical providers across the country, the KPCA Medicaid FQHCs are facing enormous pressures to combat both the recent COVID-19 pandemic and the ongoing opioid crisis. With decreased 340B revenue, the FQHCs will be further handicapped in meeting those already daunting public health challenges.

66. Further, while it is expected to be substantial, the KPCA Medicaid FQHCs cannot quantify or calculate the decrease in 340B revenue that will result from the implementation of the 340B Manual. Many factors will affect how much 340B revenue a FQHC will receive once the 340B Manual goes into effect, such as whether a Medicaid patient decides to fill their prescription at an in-house or contract pharmacy, or how large the 340B discount is on a drug compared to the drug's normal price. Thus, the KPCA Medicaid FQHCs have no way of precisely tracking whether a change in their 340B revenue is due to their Medicaid patients happening to need drugs that have smaller discounts or whether it is because contract pharmacies are refusing to designate drugs as 340B.

COUNT I: DECLARATION OF RIGHTS

67. The Plaintiff, KPCA, restates, realleges, and reiterates the allegations set forth in paragraph numbers 1 through 66 above as if they were fully set forth herein.

68. An actual, real, and justiciable controversy regarding the validity of the 340B Manual exists between the Defendant and the KPCA.

69. KPCA has associational standing to bring this claim. The ten members of KPCA who are Covered Entities under the 340B Program and who also serve Medicaid beneficiaries would otherwise have standing to sue in their own right, the interests KPCA seeks to protect in this lawsuit—avoiding the decrease of funding for care provided to uninsured and low-income

individuals in Kentucky—are germane to KPCA's purpose, and neither the claim asserted nor the relief requested requires the participation of KPCA's individual members in the lawsuit.

70. The relevant provisions of KRS 13A.100 state (italics added):

> Subject to limitations in applicable statutes, any administrative body that is empowered to promulgate administrative regulations *shall, by administrative regulation*, prescribe, consistent with applicable statutes:
>
> **(1)** Each statement of general applicability, policy, procedure, memorandum, or other form of action that implements; interprets; prescribes law or policy; describes the organization, procedure, or practice requirements of any administrative body; or affects private rights or procedures available to the public.

71. The 340B Manual implements the CHFS's policy for its Department of Medicaid Services and,

(a) states that it will not collect rebates for all fee-for-service and managed care 340B claims submitted via the National Council for Prescription Drug Programs (NCPDP) D.0 format with the value of "20" in field 420-DK, Submission Clarification Code;

(b) states that providers, including contract pharmacies, are responsible for correctly identifying claims dispensed with 340B purchased drugs and to ensure rebates are not collected; and

(c) states that providers shall submit both FFS and MCO claims with claim-level indicators set forth in the policy manual.

72. The Defendant's failure to promulgate the 340 Manual as a regulation violates KRS 13A.100, as it is a statement of policy or other form of action that implements, interprets and prescribes law or policy, and is therefore required by KRS 13A.100 to be promulgated as a regulation.

73. The Defendant's failure to promulgate the 340 Manual as a regulation further violates KRS 13A.100, as it affects the private rights of providers by imposing upon providers the responsibility for correctly identifying claims in which 340B drugs were dispensed and the requirement to ensure that Medicaid does not collect rebates on these 340B drugs.

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74. When the 340B Manual takes effect on April 1, 2020, the ten members of KPCA who are Covered Entities and who also serve Medicaid beneficiaries will suffer immediate and irreparable harm in an amount that will be impossible to quantity precisely but that will exceed the jurisdictional minimum of this Court, as the 340B Manual will have the effect of significantly increasing the number of claims submitted for Medicaid rebates and correspondingly reducing the number of claims on which Covered Entities can collect 340B revenue.

75. Accordingly, pursuant to KRS 418.040, the Plaintiff, KPCA, is entitled to a declaration from this Court that the 340B Manual violates KRS 13A.100 and that CHFS is immediately enjoined from requiring providers to comply with the 340B Manual.

REQUESTED RELIEF

NOW THEREFORE, the Plaintiff, the Kentucky Primary Care Association, requests this Court to:

1. Issue a restraining order and/or preliminary injunction prohibiting the Defendant, CHFS, from requiring providers to comply with the provisions of the 340B Policy and Procedures Manual;

2. Enter judgment in favor of the Plaintiff, KPCA, declaring that the CHFS' issuance of the 340B Policy and Procedures Manual is a violation of KRS 13A.100 and permanently enjoining the CHFS from requiring providers to comply with the provisions of the 340B Policy and Procedures Manual; and,

3. Enter judgment in favor of the Plaintiff, KPCA, for all other relief to which it may be entitled, including but not limited to courts costs and attorneys' fees.

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Respectfully submitted,

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COUNSEL FOR PLAINTIFF

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VERIFICATION

I, John Inman, after being duly sworn, state that I am the Associate General Counsel and Director of Government Affairs of the Kentucky Primary Care Association, that I have read the foregoing Verified Complaint for Declaratory and Injunctive Relief, and that the statements set forth therein are true and accurate to the best of my information and belief.

John Inman

Subscribed and sworn by John Inman before me, a Notary Public, on this 18th day of March, 2020.

PEGGY JO TIPTON
NOTARY PUBLIC
STATE AT LARGE, KENTUCKY
COMM. #615436
MY COMMISSION EXPIRES 01/21/2023

Notary Public

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EXHIBIT A

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340B Policy and Procedures Manual

Outpatient Drugs and Physician Administered Drugs

Effective: **April 1, 2020**

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Table of Contents

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I. Purpose

This document contains the Kentucky Medicaid policies and procedures for Managed Care Organization (MCO) and Fee-for-Service (FFS) providers who participate in the 340B Drug Pricing Program. This guidance is issued to comply with federal law regarding the 340B Drug Pricing Program (42 U.S.C. 256b). This manual applies to prescription drugs billed at pharmacy point-of-sale or on the CMS 1500/837P.

II. Summary

The overlap of the 340B Drug Pricing Program and the Medicaid Drug Rebate Program creates the possibility of duplicate discounts, which are prohibited under federal law.

States are federally mandated to seek federal drug rebates on MCO claims, meaning that the potential for duplicate discounts exists for managed care claims.

Kentucky DMS utilizes the Health Resources and Services Administration's (HRSA) Medicaid Exclusion File for both Fee-for-Service and Managed Care Organization claims in order to prevent duplicate discounts.

III. 340B & Drug Rebate Program Background

The national Medicaid Drug Rebate Program was established in 1991 as a means to offset both state and federal Medicaid drug expenditures. When a drug manufacturer enters into a national rebate agreement, they are also required to enter into agreements with the 340B Drug Pricing Program.

The 340B Drug Pricing Program was designed to enable participating providers, referred to as "covered entities," to stretch scarce federal resources by obtaining covered outpatient drugs at significantly discounted prices. This program is administered by HRSA's Office of Pharmacy Affairs (OPA).

When a covered entity bills Medicaid for a pharmacy or outpatient physician-administered drug, the possibility of duplicate discounts exists due to the overlap of the Medicaid Drug Rebate and 340B Drug Pricing Programs. Therefore, when a covered entity enrolls in the 340B program, it must choose whether it will "carve-in" or "carve-out" its Medicaid FFS and MCO patients, respectively. Carve-in means that all drugs dispensed to Medicaid patients were purchased under the 340B Drug Pricing Program, while carve-out means that drugs dispensed to Medicaid patients were not purchased under the 340B Drug Pricing Program.

Additional information on the 340B Drug Pricing Program can be found at http://www.hrsa.gov/opa.

IV. Medicaid Exclusion File

HRSA communicates carve-in designations to states via the Medicaid Exclusion File (MEF) in order to alert states that Medicaid Drug Rebates should not be sought on MEF providers' drug claims.

When a covered entity chooses to carve-in, it must provide HRSA with the National Provider Identification (NPI) and/or Medicaid provider number for each site that carves in for the purpose of

inclusion in the MEF. An entry in the MEF indicates that a covered entity has chosen to carve-in for a single quarter.

A covered entity can change its carve-in or carve-out designation at any time; however, HRSA stipulates that the effective date of any such change will be the first day of a calendar quarter. Status changes for the next calendar quarter must be provided by the 15th day of the month preceding the quarter's start (March 15, June 15, Sep. 15 and Dec. 15). Changes submitted after this date will not be effective until the start of the second quarter following the change. Because the MEF is produced on the 15th day of the month preceding a quarter's start, this ensures that an entity's carve-in or carve-out election is properly reflected on the applicable quarter's MEF.

States can elect to identify 340B claims using methods other than the exclusion file (e.g. claim level indicators).

Additional information regarding the MEF can be found at https://opanet.hrsa.gov/340B.

V. Managed Care Organizations

Section 2501(c) of the Patient Protection and Affordable Care Act (ACA) requires state Medicaid agencies to seek rebates on drugs dispensed by Medicaid Managed Care Organizations. This means that the potential for duplicate discounts exists for both FFS and MCOs.

Due to this duplicate discount potential, if a covered entity appears on the MEF, Kentucky will exclude that provider's FFS and MCO claims from rebate invoicing. Since claims for FFS Medicaid and MCO Medicaid recipients are treated identically in regards to exclusion from rebate invoicing.

VI. Fee-for-Service: Contract Pharmacies

Contract pharmacies may not submit claims to Medicaid FFS for 340B-acquired drugs. A 340B contract pharmacy **must carve out** Medicaid FFS from its 340B operation. This verbiage is found in both the Kentucky State Plan Amendment (SPA) KY-17-00 and the Kentucky Administrative Regulation 907 KAR 23:020.

KY-17-001: Drugs acquired through the 340B Program and dispensed by 340B contract pharmacies are not covered.

907 KAR 23:020 Section 4 (6) (c): A drug dispensed by a 340B contract pharmacy shall not be eligible as a 340B transaction and shall be reimbursed in accordance with the lowest of logic as required by Section 2 of this administrative regulation plus the professional dispensing fee.

VII. Managed Care Organization: Contract Pharmacies

Contract pharmacies may submit claims to Medicaid MCO for 340B-acquired drugs, with the required 340B claim level identifiers.

VIII. Kentucky Medicaid Fee-for-Service NCPDP D.0 Billing Changes for 340B Outpatient Drug Claims

Effective **April 1, 2020**, Kentucky's Department for Medicaid Services will not collect rebates for all fee-for-service and managed care 340B claims submitted via the National Council for Prescription Drug Programs (NCPDP) D.0 format with the following:

- Value of "20" in field 420-DK, Submission Clarification Code

Providers are responsible for correctly identifying claims dispensed with 340B purchased drugs and to ensure rebates are not collected. Providers shall submit both FFS and MCO claims with the following claim-level indicators below.

Pharmacy Claims:

NCPDP Field	NCPDP Field Name	NCPDP Values
420-DK	Submission Clarification Code	20 = 340B

Physician-Administered Drug Claims:

Providers shall submit the **UD modifier** to identify 340B drugs on outpatient physician-administered drug claims. This includes outpatient hospital and outpatient professional service 340B drug claims.

- CMS 1500: Field Number: 24D Field Value: Procedures, Services, or Supplies Field Description: CPT/HCPCS & Modifier.
- 837P: Enter HCPCS code in Loop 2400 SV101-2 followed by the modifier UD. Example: J1111 billed as J1111UD.

For any physician-administered drugs not purchased through the 340B program, no code modifier is required.

IX. Additional Guidance

FAQS on the 340B program itself, as well as information on how to ask additional questions, can be found on the HRSA website.

Filed 20-CI-00275 03/18/2020 Amy Feldman, Franklin Circuit Clerk

COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIVISION _____
CIVIL ACTION NO. _____

ELECTRONICALLY FILED

KENTUCKY PRIMARY CARE ASSOCIATION PLAINTIFF

v. **MOTION OF KENTUCKY PRIMARY CARE ASSOCIATION FOR RESTRAINING ORDER**

COMMONWEALTH OF KENTUCKY,
KENTUCKY CABINET FOR HEALTH AND
FAMILY SERVICES DEFENDANT

Comes Kentucky Primary Care Association ("KCPA"), by counsel, pursuant to CR 65.03, and hereby moves the Court for the entry of a Restraining Order against the Defendant, the Cabinet for Health and Family Services ("CHFS") and persons acting in concert with it, restraining or enjoining the CHFS from issuing its 340B Policy and Procedures Manual ("340B Manual") because it improperly failed to promulgate the requirements set forth in the 340B Manual as a regulation as required by KRS 13A.100. The 340B Manual will take effect on April 1, 2020, if the requested Restraining Order is not entered. A true and accurate copy of the 340B Manual is attached to KCPA's Verified Complaint for Declaratory and Injunctive Relief as Exhibit A.

CR 65.03 provides, in relevant part:

> **(1)** When Authorized. A restraining order may be granted at the commencement of an action, or during the pendency thereof, without written or oral notice to the adverse party or his attorney only if (A) it clearly appears from specific facts shown by verified complaint or affidavit that the applicant's rights are being or will be violated by the adverse party and the applicant will suffer immediate and irreparable injury, loss or damage before the adverse party or his attorney can be

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> heard in opposition, and (B) the applicant's attorney certifies to the court in writing the efforts, if any, which have been made to give notice and the reasons supporting his claims that notice should not be required.

In support of its Motion for Restraining Order, the Plaintiff provides the following information to establish that its members will suffer irreparable injury if the requested Restraining Order is not issued and that the CHFS violated KRS 13A.100 in issuing the 340B Manual. This information is set forth under oath in KPCA's simultaneously filed Verified Complaint for Declaratory Judgment and Injunctive Relief (hereinafter "Verified Complaint"):

1) KCPA is a not for profit corporation of community health centers, rural health clinics, primary care centers and other organizations and individuals concerned about access to healthcare services for Kentucky's underserved rural and urban populations. KCPA members are providers of primary care—first contact, broadly trained physicians, physician assistants, nurse practitioners, behavioral health providers, dental providers, pharmacists, and other professionals delivering whole-person care.

2) The federal Health Resources and Services Administration ("HRSA"), an agency of the United States Department of Health and Human Services, administers the 340B Program authorized by the Veterans Health Care Act of 1992. The intent of the 340B program is to help participating healthcare providers, like the members of KPCA to stretch federal resources as far as possible in order to reach more eligible patients and provide more comprehensive services in Kentucky.

3) The 340B Program requires drug manufacturers to sell drugs to statutorily defined "Covered Entities" at a reduced or discounted price. Covered Entities include Federally

Qualified Health Centers ("FQHS"), and 10 of the FQHSs in Kentucky are members of KPCA (hereinafter the "KPCA Medicaid FQHCs").[1]

4) A key aspect of the 340B Program is that it permits Covered Entities to generate revenue by purchasing drugs for proper distribution to its members at the discounted 340B price while charging patients and insurers (including government insurers like Medicaid and Medicare) the non-340B price of the drug. The entire amount of the 340B discount provided by the drug manufacturers is retained by the Covered Entities and, in the case of FQHCs, used to fund their operating budgets and to expand the services they can provide to low-income and uninsured individuals.

5) But for the 340B revenue, the KPCA Medicaid FQHCs would not be able to provide the broad spectrum of services currently provided to underserved populations—which would leave many of Kentucky's vulnerable citizens without access to medical care, substance abuse treatment, and mental health treatment.

6) Another federal program intended to allow states to stretch their healthcare dollars is the federal Medicaid Rebate Program created in 1990. Under the Medicaid program, drug manufacturers must provide a rebate to Medicaid on the cost of their drugs in order for states to receive federal funding for the use of their drugs. The rebate for each drug is equal to the discount provided by drug manufacturers to Covered Entities under the 340B Program. Approximately 25% of the Medicaid rebate remains in Kentucky, and the balance of the rebate is returned to the federal government in Washington D.C.

[1] These KPCA Medicaid FQHCs are: Big Sandy Health Care, Inc., in Prestonsburg, KY; Cumberland Family Medical Center, Inc., in Russell Springs, KY; Family Health Centers, Inc., in Louisville, KY; Mountain Comprehensive Health Corporation, in Whitesburg, KY; Lewis County Primary Care Center, Inc. d/b/a Primary Plus, in Vanceburg, KY; Fairview Community Health Center, in Bowling Green, KY; Health Help, Inc. d/b/a White House Clinics, in McKee, KY; HealthPoint Family Care, Inc., in Covington, KY; Regional Health Care Affiliates d/b/a Health First Community Health Center, in Providence, KY; A + Healthcare, LLC, in Brownsville, KY.

7) There is some tension between the 340B Program and the Medicaid Program because drug manufacturers are required to provide a 340B discount to Covered Entities *or* the Medicaid rebate for drugs dispensed to Medicaid beneficiaries, but *not* both. It is unlawful for a state to receive a Medicaid rebate on a drug that was purchased at a 340B discounted price; this is commonly referred to as the prohibition against "duplicate discounts."

8) Many, but not all, of the individuals served by the KPCA Medicaid FQHCs are Medicaid beneficiaries.

9) When a Covered Entity's in-house pharmacy, such as those that exist within the KPCA Medicaid FQHCs, issues prescription drugs to a 340B participant who may also be a Medicaid beneficiary, it is clear that the FQHC receives the drug manufacturer's discount rather than Medicaid. Likewise, when a Medicaid beneficiary fills a prescription written by a physician at a clinic or hospital that does *not* qualify as a Covered Entity, it is clear that Medicaid receives the discount as a rebate. However, when an independent retail pharmacy (referred to as a "Contract Pharmacy") fills a prescription for a Medicaid beneficiary that was written by a physician at an FQHC, there is some confusion as to whether the 340B Covered Entity receives the discount or Medicaid receives the rebate. Of course, it is unlawful for a state to receive a duplicate discount.

10) On November 8, 2019, the Cabinet, through the Department of Medicaid Services ("DMS"), issued its 340B Manual, which was to take effect on January 1, 2020. The effective date of the 340B Manual has been delayed until April 1, 2020. The 340B Manual was not promulgated as a regulation.

11) The 340B Manual requires Contract Pharmacies to add certain indicators (an "Identifier") to a claim at the time of submitting the claim to DMS for reimbursement if a 340B

drug was dispensed in order to avoid a duplicate discount. DMS will refrain from submitting a Medicaid rebate only if an Identifier is included on the claim—meaning that, if no Identifier is included, DMS will submit a rebate.

12) Contract Pharmacies typically do not have sufficient information at the time of submitting a Medicaid claim for reimbursement to determine whether the patient was treated by a Covered Entity. This means that Contract Pharmacies generally cannot determine, at the time they submit their claim, whether the dispensed drug should be counted as a 340B drug or a non-340B drug. Contract Pharmacies do not want to be placed in the position of violating the applicable law by mistakenly assigning an Identifier to a dispensed drug.

13) Many Contract Pharmacies, particularly those that belong to national chains, face significant economic obstacles in complying with the 340B Manual, as their software must be changed to allow them to add the new Identifier. These Contract Pharmacies report that implementing the necessary change in software would require a significant investment of time and money.

14) Because the Contract Pharmacies have indicated that they will not include the new Identifier on claims in order to comply with the 340B Manual, the Covered Entities will be forced to inform the Contract Pharmacies to refrain from dispensing 340B drugs to Medicaid beneficiaries in order to avoid duplicate discounts, even though many of these Medicaid beneficiaries will have been treated by Covered Entities and eligible for the 340B discount.

15) The result of the implementation of the 340B Manual as currently drafted is that the majority of the discounts provided by drug manufacturers for drugs dispensed to Medicaid beneficiaries treated by Kentucky FQHCs will be given to the federal government through the Medicaid Rebate Program rather than to the Kentucky FQHCs. This will have a massive

negative impact on the operating budgets of the KPCA Medicaid FQHCs and will be extremely damaging to these FQHS' ability to operate and provide medical services to low-income and uninsured individuals.

16) As stated above, and as attested to by Michael Stanley before the Senate Committee on Health and Welfare, a loss of 340B revenue could result in the discontinuation or significant decrease in the KPCA Medicaid FQHCs' abilities to provide services such as paying for care provided to uninsured patients, assisting non-Medicaid low-income individuals with copays, employing community health workers, providing transportation to patients who do not qualify for Medicaid transportation, providing translation services to patients, running emergency food programs, running school-based satellite clinics, running smoking cessation clinics, running health literacy programs, testing quality improvement plans, purchasing much-needed medical equipment, paying for extended hours at clinics, purchasing property to expand clinic locations, providing substance use disorder treatment, and providing mental health treatment.

17) In addition, as are medical providers across the entire country, the KPCA Medicaid FQHCs are facing enormous pressures to combat both the recent COVID-19 pandemic and the ongoing opioid crisis. With decreased 340B revenue, the FQHCs will be further handicapped in meeting those already daunting public health challenges.

18) Further, while it is expected to be substantial, the KPCA Medicaid FQHCs cannot quantify or calculate the decrease in 340B revenue that will result from the implementation of the 340B Manual. Many factors will affect how much 340B revenue a FQHC will receive once the 340B Manual goes into effect, such as whether a Medicaid patient decides to fill their prescription at an in-house or Contract Pharmacy, or how large the 340B discount is on a drug

compared to the drug's normal price. Thus, KPCA Medicaid FQHCs have no way of precisely tracking whether a change in their 340B revenue is due to their Medicaid patients needing drugs that have smaller discounts or whether it is because Contract Pharmacies are refusing to designate drugs as 340B.

19) There can be no doubt that the implementation of the 340B Manual will cause the KPCA and its members to suffer substantial irreparable injury.

20) In addition, there can be no doubt that KPCA presents a substantial question on the merits. KRS 13A.100, the regulation addressing the promulgation of regulations, states, in relevant part:

> Subject to limitations in applicable statutes, any administrative body that is empowered to promulgate administrative regulations shall, by administrative regulation, prescribe, consistent with applicable statutes:
>
> (1) Each statement of general applicability, policy, procedure, memorandum, or other form of action that implements; interprets; *prescribes law or policy*; describes the organization, procedure, or practice requirements of any administrative body; or affects private rights or procedures available to the public. (Italics added)

21) The 340B Manual implements the CHFS' policy for its Department of Medicaid Services and,

> (a) states that it will not collect rebates for all fee-for-service and managed care 340B claims submitted via the National Council for Prescription Drug Programs (NCPDP) D.0 format with the value of "20" in field 420-DK, Submission Clarification Code;
>
> (b) states that providers, including contract pharmacies, are responsible for correctly identifying claims dispensed with 340B purchased drugs and to ensure rebates are not collected; and
>
> (c) states that providers shall submit both FFS and MCO claims with claim-level indicators set forth in the policy manual.

22) The CHFS' failure to promulgate the 340 Manual as a regulation violates KRS 13A.100, as it is a statement of policy or other form of action that implements, interprets and prescribes law or policy, and is therefore required by KRS 13A.100 to be promulgated as a regulation. The sidestepping of the regulatory process resulted in the 340B Manual being published without going through the required legislative and private citizen review and comment process. This required review and comment process could have enabled CHFS to promulgate a regulation to address duplicate discounts without irreparably injuring all Covered Entities.

23) The CHFS' failure to promulgate the 340 Manual as a regulation further violates KRS 13A.100, as it affects the private rights of providers, such as Contract Pharmacies, by imposing upon providers the responsibility for correctly identifying claims in which 340B drugs were dispensed and the requirement to ensure that Medicaid does not collect rebates on these 340B drugs.

24) Likewise, the equities are in KPCA's favor. Entering the requested Restraining Order is in the public's interest, as it will ensure that 100% of the discounts from drug manufacturers for drugs dispensed to Medicaid beneficiaries will stay in the Commonwealth to be reinvested into services provided to low-income and uninsured populations during a public health crisis, rather than mostly going to the federal government. In addition, the requested Restraining Order would merely preserve the status quo and keep in place the system that currently exists.

25) Counsel for KPCA is forwarding a copy of this Motion and the Verified Complaint to counsel to CHFS simultaneously with their filing.

26) In addition, when the 340B Manual takes effect on April 1, 2020, the ten members of KPCA who are Covered Entities and who also serve Medicaid beneficiaries will

suffer immediate and irreparable harm in an amount that will be impossible to quantity precisely but that will exceed the jurisdictional minimum of this Court, as the 340B Manual will have the effect of significantly increasing the number of claims submitted for Medicaid rebates and correspondingly reducing the number of claims on which Covered Entities can collect 340B revenue.

27) No injunction or restraining order has been granted or refused by any Circuit Judge in this matter.

CONCLUSION

KPCA meets all the requirements for a Restraining Order pursuant to CR 65.03. KPCA presents a substantial question on the merits, as the 340B Manual creates a mandatory rule that was not previously codified in any statute or regulation and that affects the private rights of providers by imposing upon them the responsibility for correctly identifying claims in which 340B drugs were dispensed and the requirement to ensure that Medicaid does not collect rebates on these 340B drugs. This violates KRS 13A.100, as the 340B Manual is a statement of policy or other form of action that implements, interprets and prescribes law or policy, and is therefore required to be promulgated as a regulation.

Further, unless the requested Restraining Order is issued, when the 340B Manual takes effect on April 1, 2020 (approximately two weeks from now), the Covered Entities will suffer immediate and irreparable injury because they will lose badly needed funds, resulting in the discontinuation or significant decrease in the KPCA Medicaid FQHCs' abilities to provide services to low-income and uninsured individuals. These funds will be lost while the KPCA Medicaid FQHCs are facing enormous pressures to combat both the recent COVID-19 pandemic and the ongoing opioid crisis. Not only with the KPCA Medicaid FQHCs be harmed, but so will the individuals who are improperly deprived from receiving the health services which they so

badly need. In addition, entering the Restraining Order will merely preserve the status quo and will not harm the Defendant, CHFS.

Accordingly, pursuant to CR 65.03, this Court should enter the requested Restraining Order and immediately enjoin the CHFS from requiring providers to comply with the provisions of the 340B Policy and Procedures Manual.

Respectfully submitted,

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