UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

Sheila Gluesing, individually and on behalf of all others similarly situated,

Plaintiff,

v.

PRUDENTRX LLC & CAREMARK RX, LLC,

Defendants.

Case No. _____

CLASS ACTION COMPLAINT

Jury Trial Demanded

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Plaintiff Sheila Gluesing brings this action on behalf of herself individually and on behalf of a plaintiff class (the "Class") of similarly situated individuals pursuant to Rule 23 of the Federal Rules of Civil Procedure. She brings this action for treble damages under the Employee Retirement Income Security Act (ERISA) and the Racketeer Influenced Corrupt Organizations Act against PrudentRx LLC ("PrudentRx") and Caremark Rx, LLC ("Caremark") and demand a trial by jury.

I. Nature of Action

1. PrudentRx runs a fraudulent enterprise that deprives patients of the benefits of patient copay assistance funding and increases patients' healthcare costs. PrudentRx has teamed up with pharmacy benefit manager ("PBM") Caremark and Caremark's affiliated specialty pharmacy, CVS Specialty Pharmacy, to divert hundreds of millions, if not billions, of dollars in funding meant to help patients, to insurance plans and enrich themselves instead. Through this scheme, they knowingly and intentionally ensure patients bear additional healthcare costs.

2. The scheme has five main elements. *First*, PrudentRx, Caremark, and CVS Specialty Pharmacy flout statutory constraints on copay costs for specialty medications. *Second*, PrudentRx inflates targeted patients' copays to siphon all available funding out of patient copay assistance programs. *Third*, PrudentRx, Caremark, and CVS Specialty Pharmacy use the threat of prohibitively expensive coinsurance to coerce patients to provide PrudentRx with access to their copay assistance program accounts. *Fourth*, they divert the assistance meant for patients, and instead provide it to health plan sponsors, while keeping for themselves 25% of the purloined funds. And *fifth*, they force patients to shoulder additional healthcare expenses they would not have incurred in the absence of the PrudentRx Copay Program.

3. The patients that PrudentRx, Caremark, and CVS Specialty Pharmacy target are some of the most vulnerable. These targeted patients are managing serious health conditions like cancer; multiple sclerosis; and autoimmune disorders like Crohn's Disease, ulcerative colitis, and

psoriatic arthritis. Their conditions are complex and expensive to treat: the specialty medications needed to attack cancer, slow the progression of multiple sclerosis, or stave off the harms of autoimmune diseases carry sticker prices of tens, if not hundreds, of thousands of dollars per year. Insurers (including both insurance companies and employers that sponsor health plans for their employees) and their affiliated PBMs (like Caremark) negotiate steep discounts (known as rebates) off these prices. But they do not share those savings with patients, leaving the average patient on the hook for copays[1] that can reach several thousands of dollars every month.

4. None but the wealthiest of patients could hope to shoulder these crushing healthcare costs. For instance, even for a drug bearing a comparatively low patient cost of $250, 70% of patients are forced to make the difficult decision to skip filling their life-sustaining, or even life-saving, medications. Patients who cannot afford to fill their prescriptions face worse health outcomes: unaffordable prescriptions can lead to a severe deterioration of their condition, relapses, permanent disability, or even death.

5. In addition to the rebates meant to benefit plans and PBMs, many drug manufacturers offer financial assistance specifically intended to help patients afford their essential specialty medications. These manufacturers operate patient copay assistance programs—programs that will cover part or all of a patient's cost-sharing obligations. For patients with complex diseases treated by specialty medications, this relief is a lifeline—sometimes literally. With the help of patient copay assistance programs, patients can afford to protect their health while minimizing the risk of financial ruination from their healthcare expenses.

[1] Except where otherwise noted, the term "copay" in this Complaint is generally meant to encompass both a fixed amount paid by or on behalf of the patient at the point of sale as well as co-insurance, which is a percentage of the cost of the product paid by or on behalf of the patient at the point of sale.

6. PrudentRx, founded in 2020, purports to exploit a non-existent loophole in the federal healthcare laws to nullify the beneficial effects of patient copay assistance on patients' health and financial wellbeing.

7. The Patient Protection and Affordable Care Act ("ACA") imposes several patient-protective limits on the ability of health plan sponsors (i.e., insurers and employers) to avoid paying for healthcare. First, it imposes cost-sharing limitations: an upper limit on the total expenses health plan sponsors and their affiliated PBMs can force patients to incur for their healthcare each year. Plans may impose healthcare costs on patients through several mechanisms. One is the deductible a patient must satisfy before the plan sponsor is responsible for a single penny of healthcare coverage. Another is a copay or coinsurance—the portion of each medical intervention (from prescriptions to lab tests, doctor's office visits to hospital admissions) patients are responsible for. The average deductible is nearly $2,000; while copays can vary based on the type of care, the average copay for specialty medications is 26% of the medication's list price. Without guardrails, these costs could dwarf the benefit of health insurance. The ACA provides these guardrails, and it caps the sum of these expenses by imposing an annual cost-sharing limit.

8. Second, the ACA prohibits insurers from evading this limit by ignoring payments made towards patients' annual cost-sharing limits. The statute defines cost-sharing to include all deductibles, coinsurance, copays, or similar charges (among other expenses[2]) for covered services. This includes not only to payments made by a patient out of their own pocket, but also to payments made on behalf of the patient.

[2] To prevent insurers from evading the law by playing semantics, the law adds a catch-all to the definition of cost-sharing in a separately numbered sub-paragraph, including within the definition any other expenditure required of an insured individual which is a qualified medical expense with respect to essential health benefits covered under the plan. 42 U.S.C. § 18022(c)(3)(ii).

9. Yet, PrudentRx designed a program, the PrudentRx Copay Program, that, it claims, evades these patient-protective rules. It recruited Caremark to help market its scheme, and together PrudentRx and Caremark have deployed CVS Specialty Pharmacy to help operationalize it.

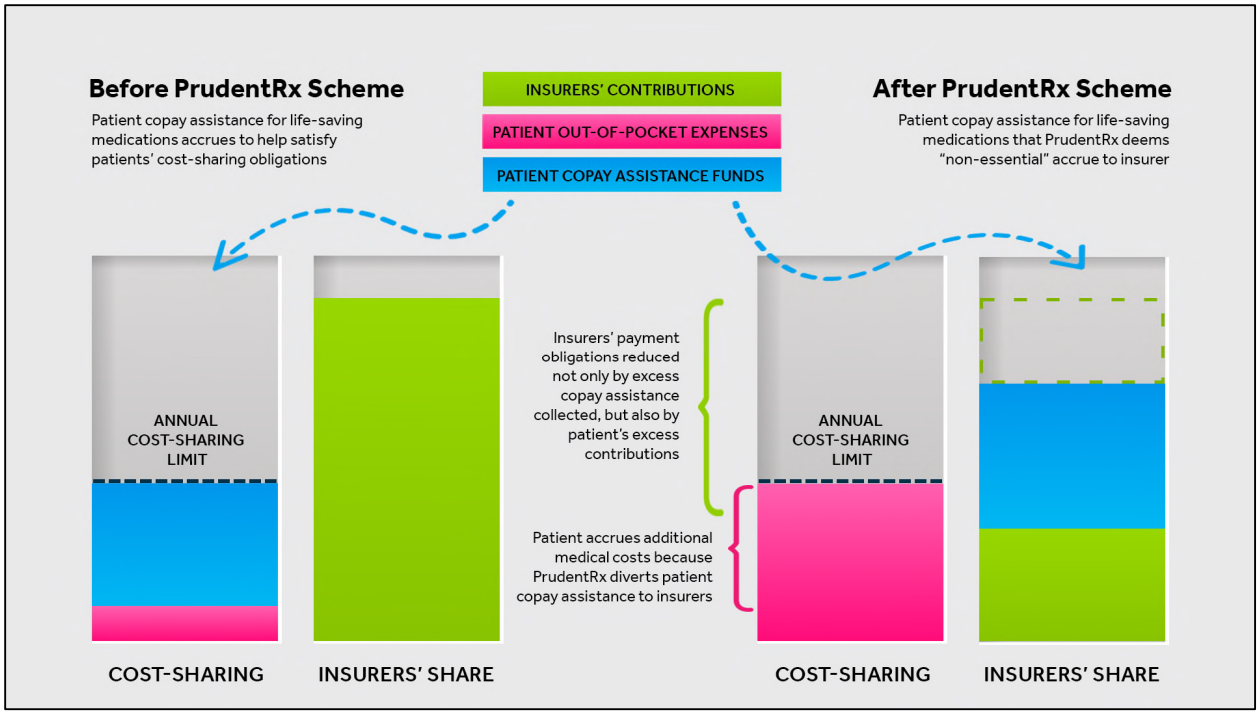
10. The PrudentRx Copay Program declares some specialty medications "non-essential health benefits." The determination of which drugs the Program targets as non-essential does not actually have anything at all to do with how essential the drugs are. Some of the drugs are so essential that patients can die without them. Rather, PrudentRx decides what medications are "non-essential health benefits" based on the amount of patient copay assistance available for those medications. That is because PrudentRx, Caremark, and CVS Specialty Pharmacy claim that copays and deductibles for non-essential health benefits do not count as cost-sharing, so those copays can be as high as they want—higher even than a patient's annual limits.

11. Under the PrudentRx Copay Program, PrudentRx sets a 30% coinsurance for targeted medications—a sum high enough to ensure that each year, the Program extracts the full amount of patient copay assistance from a manufacturer's patient copay assistance program. But not one penny of that assistance benefits patients. Rather, PrudentRx, Caremark, and CVS Specialty Pharmacy give that assistance intended for patients instead to health plan sponsors and insurers, diminishing the sponsor's obligations to pay for patients' prescription drug needs.

12. PrudentRx aggressively markets the Program to health plan sponsors. Once a sponsor has agreed to join the Program, PrudentRx targets patients from the plan's membership rolls based on the prescriptions they fill. It then automatically enrolls these "eligible members" in the Program. Any member who opts out of the Program or who does not affirmatively enroll in any patient copay assistance program is then responsible for the 30% coinsurance on their targeted medication(s).

13. To induce targeted patients to remain enrolled, Defendants promise patients that they will pay zero dollars for their specialty medications if they participate in the PrudentRx Copay Program. But none of the thousands of dollars per patient in patient copay assistance, collected ostensibly on behalf of targeted patients, count towards those patients' deductibles or annual cost-sharing limitations. As a result, targeted patients must pay for other medical care such as laboratory testing or diagnostic imaging, doctor's visits, or other medical interventions that they would not otherwise have to—or at least would pay less for. Because Defendants deprive targeted patients of the expense-mitigating benefits of patient copay assistance, these patients must shoulder all those expenses themselves. Because of the PrudentRx Copay Program, targeted patients must pay thousands of dollars more per year than they would otherwise have to pay if Defendants did not flout the ACA's rules.

Figure A: Comparison of patients' costs before and after enrollment in the PrudentRx Copay Program



14. The Court should enjoin PrudentRx and Caremark from continuing to operate the PrudentRx Copay Program. Their conduct violates provisions of the ACA incorporated by ERISA, which governs private, employer-sponsored health plans. ERISA and the ACA prohibit insurance companies, plan sponsors, or their vendors like PrudentRx and Caremark from charging copay amounts beyond the annual cost-sharing limitation. But the PrudentRx Copay Program does just that by imposing high copays and failing to count those copays toward the patient's annual cost-sharing limit—even where the patient pays those costs themselves.

15. PrudentRx, Caremark, and CVS Specialty Pharmacy should also be required to make restitution for the intended financial harm to targeted patients. They conduct the PrudentRx Copay Program as an illicit racketeering enterprise (the "PrudentRx Copay Assistance Fraud Enterprise") in violation of RICO. Most, if not all, patient copay assistance programs' terms of service expressly require that the patient copay assistance benefit solely the patient; many prohibit patients from collecting patient copay assistance if they are subject to a program like the PrudentRx Copay Program. Yet PrudentRx, Caremark, and CVS Specialty Pharmacy mislead these programs into disbursing patient copay assistance for ineligible targeted patients. And they do so through a pervasive pattern of mail and wire fraud. In so doing, the Program causes financial harm to targeted patients.

16. Defendants' scheme violates ERISA, and their conduct violates RICO. They are causing real and continuing harm to targeted patients like Ms. Gluesing and the Class. They should be enjoined from continuing to operate the PrudentRx Copay Program and required to repay the patients they have harmed.

II. Parties

17. Plaintiff Sheila Gluesing, a citizen and resident of Iowa, receives health insurance through Wellmark Health Plan of Iowa ("Wellmark"), an independent licensee of the Blue Cross

and Blue Shield Association. Ms. Gluesing currently takes Dupixent (dupilumab), a biologic medication approved for the treatment of atopic dermatitis. Dupixent is an expensive drug. To help patients afford the medication, Dupixent's manufacturers, Sanofi and Regeneron, offer a patient copay assistance program called Dupixent MyWay®, which provides copay assistance annually to patients prescribed Dupixent. Wellmark participates in the PrudentRx Copay Program and enrolled Ms. Gluesing in the Program. As a result, Ms. Gluesing has been deprived of the benefit of the patient copay assistance that Dupixent MyWay® offers and forced to incur excess healthcare expenses.

18. Defendant PrudentRx LLC is a company founded in 2020, organized under the laws of Florida, and headquartered at 7901 4th Street North, Suite 300, St. Petersburg, Florida. The company's application for a Service Mark filed with the U.S. Patent and Trademark Office reads: "PrudentRx provides co-pay program related services to plan sponsors that include guidance on plan benefit design for specialty products and assistance to members to secure available copay assistance for specialty drugs through the various patient assistance programs available to them."

19. Defendant Caremark Rx, LLC is a Delaware limited liability company with its principal place of business at One CVS Drive, Woonsocket, Rhode Island. It is a wholly owned indirect subsidiary of CVS Health Corporation. Caremark engages in the business of providing pharmacy benefit services and is the largest pharmacy benefit manager in the United States. In 2023, Caremark administered approximately 34% of all prescription claims in the United States.

20. Through one or more direct and indirect subsidiaries, Caremark Rx, LLC also operates a specialty pharmacy, commercially known as "CVS Specialty Pharmacy." As used in this complaint, both "Caremark" and "CVS Specialty Pharmacy" refer to Caremark Rx LLC:

"Caremark" refers to this defendant's PBM business, and CVS Specialty Pharmacy" refers to its specialty pharmacy business.

III. Jurisdiction and Venue

21. This action arises under RICO, 18 U.S.C. § 1964(c), and ERISA, 29 U.S.C. § 1132(a)(3). Under RICO, Ms. Gluesing seeks damages for her harms and for those suffered by members of the Class resulting from PrudentRx, Caremark, and CVS Specialty Pharmacy's unlawful conduct. Under ERISA, Ms. Gluesing seeks injunctive relief for herself and for the Class preventing Defendants from continuing to harm patients. This Court has federal question subject matter jurisdiction under 28 U.S.C. § 1331 and 29 U.S.C. § 1132(e)(1).

22. Defendant Caremark is headquartered in this district; is licensed to do business and does business in this District; and transacts its affairs and conducts interstate trade and commerce, in substantial part, in this District. Defendant PrudentRx also does business within this district and conducts interstate trade and commerce, in substantial part, in this district. Venue is thus appropriate within this district under 18 U.S.C. § 1935 (RICO) and 29 U.S.C. § 1132(e)(2) (ERISA) as well as 28 U.S.C. § 1391(b) and (c) (general venue provisions).

23. The activities of PrudentRx and its co-conspirators, as described herein, were within the flow of, were intended to, and did have direct, substantial, and reasonably foreseeable effects on the interstate commerce of the United States.

24. No other forum would be more convenient for the parties and witnesses to litigate this case.

IV. Class Action Allegations

25. Ms. Gluesing brings this action, under Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), as a representative of a Class defined as:

> All persons enrolled in the PrudentRx Copay Program who have been prescribed a brand-name drug subject to the PrudentRx Copay Program for which there is no available generic alternative and have thereafter paid for any health care expense in excess of what would have been paid in the absence of the PrudentRx Copay Program from January 1, 2020 to present and continuing until the effects of Defendants' wrongful conduct cease.

The Class includes all targeted patients coerced into remaining enrolled in the PrudentRx Copay Program, as well as all targeted patients who opted out of the PrudentRx Copay Program and instead paid the 30% coinsurance for their targeted medications. Excluded from this Class are Defendants' officers, directors, management, employees, and agents, as well as the persons responsible for benefits administration at any health plan that joined the PrudentRx Copay Program.

26. Within this Class, and with respect specifically to the first cause of action below, there is a subclass (the "ERISA Subclass") pursuant to Federal Rule of Civil Procedure 23(c)(5), defined as:

> All members of the Class enrolled in a non-grandfathered employer-sponsored healthcare plan subject to ERISA.

27. Members of the Class are so numerous that joinder is impracticable. There are many ways to categorize commercial health insurance: as explained in more detail below, one is by who bears the risk of the insurance. For some plans, called "self-funded plans," an employer, union, or other entity funds the insurance, and pays claims, directly from its own accounts. For other plans, called "fully insured plans," an employer, union, or other entity pays an insurance company to bear the risk for them. Caremark administers the prescription benefits for more than 100 million Americans. Of those, 47% (or approximately 47 million individuals) receive their health insurance benefits through a fully insured plan and the other 53% (approximately 53 million) are members of a self-funded health plan.

28. For fully funded health plans, Caremark's affiliated insurer, Cigna, or another insurer that partners with Caremark for prescription drug benefits, like Wellmark, carries the insurance risk. It is therefore reasonable to expect that these insurance companies exploit the PrudentRx Copay Program on all their fully insured plans to minimize their own costs—meaning more than 47 million patients are subjected to the PrudentRx Copay Program through fully funded insurance coverage. There is a lack of publicly available information regarding how many self-funded plans have joined the PrudentRx Copay Program. But in 2021, only one year after the launch of the PrudentRx Copay Program, Caremark boasted that more than 400 clients had adopted the Program, representing 3.2 million covered lives. Assuming (conservatively) that self-funded plans accounting for only 10% of Caremark's self-funded covered lives at present participate in the Program, that would mean more than 5.3 million patients receive their health benefits through a self-funded plan enrolled in the PrudentRx Copay Program.

29. In total then, more than 52 million patients receive their benefits through health plans participating in the PrudentRx Copay Program. Even if less than 2% of those patients receive prescriptions for specialty medications and are, therefore, targeted patients, the number of Class members still exceeds 1 million.

30. The identity of Class members is readily ascertainable from information and records in Defendants' possession. Caremark administers the pharmacy benefit for all Class members, meaning that it has detailed records of the medications prescribed to its members; which patients were prescribed targeted medications; and the amount paid for those medications by patients, patient copay assistance programs, and Caremark (which Caremark then charges to the plan). Furthermore, PrudentRx maintains detailed records of patients that it and its co-conspirators enrolled in the PrudentRx Copay Program, and CVS Specialty Pharmacy maintains records of the

patients for whom it collects patient copay assistance from manufacturer patient copay assistance programs. PrudentRx and Caremark rely on this data to prepare detailed monthly invoicing reports for participating health plans from which they calculate their fees for administering the service.

31. Ms. Gluesing's claims are typical of the claims of Class members. She and all Class members were damaged by the same wrongful conduct of Defendants—i.e., PrudentRx, Caremark, and CVS Specialty Pharmacy imposed cost-sharing in violation of the ACA and ERISA, and the same unlawful PrudentRx Copay Assistance Fraud Enterprise caused them to pay more for their healthcare than they would have in the absence of Defendants' unlawful conduct.

32. Ms. Gluesing's counsel has extensive experience in the prosecution of complex and class action litigation, including ERISA and RICO class action litigations, with particular experience in complex litigation involving the healthcare industry. Counsel possesses the resources and expertise needed to vigorously litigate the case for the Class.

33. Ms. Gluesing will fairly and adequately protect and represent the interests of Class members. Her interests and those of counsel fully align with, and are not antagonistic to, the interests of Class members. Ms. Gluesing can and will carry out the duties incumbent on Class representatives to protect the interests of all Class members.

34. With respect to Ms. Gluesing's damages claims on behalf of the Class, questions of law and fact common to the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

35. Questions of law and fact common to the Class include:

a. Whether covered prescription medications constitute essential health benefits under the ACA;

b. Whether payments made by patient copay assistance programs constitute cost-sharing payments within the meaning of the ACA;

c. Whether all copays must count toward a patients' cost-sharing limit;

d. Whether the PrudentRx Copay Program's structure violates the ACA;

e. Whether Defendants agreed, explicitly or implicitly, to form the PrudentRx Copay Assistance Fraud Enterprise;

f. Whether the PrudentRx Copay Assistance Fraud Enterprise constitutes an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4);

g. Whether PrudentRx conducted, or participated in the conduct of the PrudentRx Copay Assistance Fraud Enterprise;

h. Whether Caremark conducted, or participated in the conduct of the PrudentRx Copay Assistance Fraud Enterprise;

i. Whether CVS Specialty Pharmacy conducted, or participated in the conduct of the PrudentRx Copay Assistance Fraud Enterprise;

j. Whether Defendants committed mail fraud in furtherance of the PrudentRx Copay Assistance Fraud Enterprise;

k. Whether Defendants committed wire fraud in furtherance of the PrudentRx Copay Assistance Fraud Enterprise;

l. Whether Defendants engaged in a pattern of racketeering activity in operating the PrudentRx Copay Assistance Fraud Enterprise;

m. Whether Defendants misrepresented to targeted patients the financial impact of the PrudentRx Copay Program on patients' cost-sharing expenses for healthcare;

n. Whether Defendants caused misrepresentations to be made to patient copay assistance programs regarding targeted patients' eligibility to receive patient copay assistance funds;

o. Whether Defendants proximately caused financial harm to targeted patients;

p. Whether targeted patients were among the intended or foreseeable victims of Defendants' scheme to defraud; and

q. The quantum of damages in the aggregate.

36. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Such treatment will permit many similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class action mechanism, including providing injured persons a method of obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in managing this class action.

37. Ms. Gluesing knows of no special difficulty encountered in maintaining this action that would preclude its maintenance as a class action.

V. Factual Allegations

38. The PrudentRx Copay Program—conceived of by PrudentRx, marketed by PrudentRx and Caremark, and operated by PrudentRx, Caremark, and CVS Specialty Pharmacy—flouts the patient-protective federal health insurance laws to seize copay assistance meant for patients. It has twin goals: to help health plans mitigate their payment obligations for specialty medications, and to ensure patients cannot access copay assistance. Through the Program,

Defendants defy federal law; mislead copay assistance programs into benefiting health plans and enriching Defendants rather than helping patients; and deprive patients of copay assistance, forcing patients to pay for healthcare expenses exceeding what the ACA allows.

A. The ACA provides important protections to American healthcare consumers.

39. The ACA is a comprehensive health care reform law that has increased health insurance coverage for millions of Americans. The ACA built upon existing health insurance systems with changes to Medicare, Medicaid, and employer-sponsored coverage, and introduced regulated health insurance marketplaces for those without access to employer- or government-sponsored insurance.

40. Prior to its enactment in 2010, many Americans were uninsured or underinsured due to the unaffordability of health insurance and exclusions based on preexisting conditions. Those who did have health insurance often faced extremely high costs and coverage limits.

41. The ACA protects patients from prohibitively high health care costs and prevents insurers from denying coverage to patients just because those patients suffer from chronic medical conditions. The statute protects those with preexisting conditions and provides access to essential health benefits, including prescription drugs. It established minimum standards of coverage for most private health insurance plans in the U.S., including employer-sponsored plans and plans sold on the individual and small group markets.

1. The ACA imposes an annual limit on patients' cost-sharing expenses.

42. Cost-sharing refers to the portion of costs for covered healthcare services for which the patient is responsible. The ACA itself defines the term "cost-sharing":

> The term "cost-sharing includes—
>
> (i) Deductibles, coinsurance, copayments, or similar charges; and

> (ii) Any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of title 26) with respect to essential health benefits covered under the plan.

Many plans incorporate all these types of cost-sharing when a policyholder uses their benefits, with the specifics depending on the service provided and whether the patient has met their annual deductible.

43. The ACA also enumerates limited exceptions to the definition of cost-sharing:

> Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.

44. Under the ACA, most health plans must have an annual cost-sharing limit. This limit is set by regulation and varies from year to year. For a single individual, it was set to $8,150 in 2020; $8,550 in 2021; $8,700 in 2022; and $9,100 in 2023. The limit for 2024 is $9,450 and will be $9,200 in 2025.

45. Cost-sharing limits are distinct from deductibles. A deductible is an amount the patient must pay before the health plan will pay for most types of benefits. For example, in a plan with a $2,000 deductible that covers medical services at 80%, the policyholder would need to spend $2,000 before the plan will pay 80% of the cost of medical services. Until the deductible is met, the patient is responsible for 100% of the cost of their medical services and any other healthcare expenses; thereafter, the patient is responsible for only 20% (a coinsurance amount).

46. Unlike a deductible, an annual cost-sharing limitation caps the overall a policyholder's annual responsibility. Once a patient reaches that limit, the plan pays 100% of covered, in-network services and the patient is responsible for $0.

2. Any sums paid by or on behalf of patients towards covered health care, including prescriptions, legally must count towards patients' annual limits.

47. Individual and small group marketplace health plans are required to provide coverage for essential health benefits. These essential health benefits encompass 10 categories of healthcare services, including prescription medications. Thus, under the ACA, prescription medications are essential health benefits that individual and small group plans must cover. Plans that meet these minimum coverage requirements are called Qualified Health Plans.

48. Unlike individual and small-group health plans, the ACA does not require large-group health plans, including most employer-sponsored plans, to cover all ten categories of essential health benefits. However, almost all such plans do cover the essential health benefits, including prescription drugs especially, to ensure the employer's benefits offerings attract and retain employees.

49. Qualified Health Plans and non-grandfathered[3] employer-sponsored plans are subject to the ACA's rules limiting cost-sharing expenses for enrollees. These plans must comply with the ACA's annual limitation on cost-sharing. Therefore, any cost-sharing imposed by a plan must count towards the plan's annual limits. The three federal agencies tasked with implementing the ACA—the Department of Health & Human Services ("HHS"), the Department of Labor, and the Department of the Treasury—have confirmed that non-grandfathered large group health plans, including employer-sponsored plans, must have an annual cost-sharing limitation that caps a patient's responsibility for covered services.

[3] A very small number of health plans have remained nearly completely unchanged since before March 23, 2010, when the ACA went into effect. These plans, known as "grandfathered" plans, are exempt from the ACA's rules.

50. Copays paid for prescription medications—including manufacturer assistance paid on a patient's behalf—must count toward a plan's annual cost-sharing limits. Under the regulations currently in effect, insurers may only exclude manufacturer assistance for brand-name medication from cost-sharing where there is a generic version of the drug available.

B. Specialty medications place extraordinary cost burdens on the patients who need them.

51. Despite these patient-protective provisions of the ACA, most commercial health plans still impose considerable costs on enrollees. These include a patient's premium (which averages about $117 a month for employer-sponsored coverage and $477 per month for a plan on the health insurance marketplace); an annual deductible (on average, $1,922 for employer-sponsored plans and $3,825 for healthcare exchange plans); and, most often, coinsurance (a percentage of the cost of care) or copays, each time a patient uses their insurance benefit. Thus, even though patients' annual cost-sharing expenses for deductibles and copays are capped, the average American could still be on the hook for more than $10,000 in medical expenses.

52. Most Americans cannot afford these costs: 75% of U.S. adults worry about their ability to afford an unexpected medical bill, half say it is difficult to afford healthcare costs, and one in four report that they or a family member had problems paying for health care in the past year.

1. Specialty medications can cost patients thousands of dollars a month.

53. The affordability problem is particularly acute in the prescription medication context. More than 20% of adults have skipped or postponed filling a prescription because of cost, another 20% have resorted to over-the-counter alternatives, and about 1 in 10 say they have rationed medications due to costs. Patient copays, in particular, can place severe financial burdens on patients. A recent study revealed that if a patient's copay is equal to or greater than $250, 70% of patients cannot afford to fill the prescription, and are forced to forego care that their physician

has deemed essential. Even half that cost poses an insurmountable financial hurdle for more than half of Americans: 55% of patients cannot afford a $125 copay.

54. Specialty medication prices well exceed patients' financial tolerances for prescriptions. In 2020, the average specialty medication carried a list price of $84,442 a year ($7,036 per month), and that price has increased faster than the rate of inflation each year since. Today, the average specialty medication can cost in excess of $200,000 a year ($16,667 per month). To shift more of the burden of these expensive medications onto patients, half of all employer-sponsored health plans impose steep costs for specialty medications: the average specialty medication coinsurance is 26% (an average that has been sharply skewed by the PrudentRx Copy Program). An average patient on one of these specialty medications thus faces monthly payment obligations of $1,829 (26% of $7,036)—or even $4,333 (26% of $16,667)—to fill a single prescription.

2. PBMs shift a larger share of specialty medication costs away from insurers and onto patients.

55. Health insurers outsource the administration of prescription medications to middlemen—PBMs like Caremark. Despite evidence that (a) high drug costs lead patients to forgo their prescriptions, and (b) skipping prescribed medications leads to worse health outcomes, PBMs have enriched themselves and their health-plan partners at the expense of patients.

56. For example, PBMs negotiate steep reductions off the sticker price, or list price, of brand name prescription medications—called rebates. These rebates can reach 50 percent or more of a medication's list price. PBMs share these rebates with health plans, but not patients. When a patient's prescription drug benefit requires them to pay a percentage of the drug cost, PBMs calculate that percentage off the high list price, not the net price. To use an example: if a medication costs $1,000, the PBM negotiated a $500 rebate, and a patient must pay a 20% coinsurance for that

medication, the patient will pay $200 (i.e., 20% of the list price) and the PBM will pay $300. So in reality, the patient that reasonably believes they are paying for 20% of a prescription is actually paying 40% of the medication's true cost.

57. PBMs also shift additional costs to patients by exploiting the PBMs' corporate structure. Today, most of the largest PBMs, including Caremark, are part of large, vertically integrated corporate conglomerates that each include nearly every level in the pharmaceutical supply chain. For example, Caremark (a PBM) and CVS Specialty Pharmacy (a specialty pharmacy) are both within the same corporate conglomerate as CVS Health Corporation, as an insurer (Aetna), brick-and-mortar pharmacies (CVS Pharmacies), a mail-order pharmacy (CVS Caremark Mail Service Pharmacy), a substantial array of healthcare providers (like the CVS Minute Clinics and Signify Health), and a pharmaceutical company (Cordavis Limited) which produces private-labelled medications.

58. PBMs steer patients needing specialty medications to their affiliated specialty pharmacies, requiring patients to fill all prescriptions for specialty medications at their affiliated pharmacies (in Caremark's case, CVS Specialty Pharmacy). The FTC recently performed an analysis that showed that 55% of all prescriptions for specialty medications filled between 2017 and 2022 by patients whose pharmacy benefits are administered by two large PBMs were filled at those PBMs' affiliated pharmacies.

59. PBMs like Caremark use this mechanism to keep the high profits from specialty medications within their own corporate structure. While specialty medications initially were those that require special handling or close monitoring (e.g., drugs that mut be stored at precise temperatures, drugs administered through transfusion, or drugs where the difference between an effective dose and a dangerous dose is small and require monitoring), there is no regulatory or

statutory definition of a "specialty medication." Nor are "specialty medications" a different category of benefits under the ACA. A specialty medication is whatever a PBM says it is. So PBMs, including Caremark, designate particularly expensive (and therefore, lucrative) medications as specialty medications, and then require patients to fill their specialty prescriptions at their affiliated pharmacies. And because patients have no choice but to use PBMs' affiliated pharmacies, the specialty pharmacies like CVS Specialty Pharmacy can charge higher costs for those specialty medications than other pharmacies would.

60. Through these and other mechanisms, PBMs and the corporate conglomerates of which they are a part reap behemoth profits. In 2023 alone, CVS Health generated approximately $357.8 billion in total revenue. Of this, $186.8 billion—more than half—came from its Health Services segment, which includes Caremark and CVS Specialty Pharmacy. In the same year, CVS Health reported $8.3 billion in pure profit, nearly doubling the company's $4.3 billion profit in 2022.

C. Patients who need expensive specialty medications depend on patient copay assistance to help manage their healthcare costs.

61. Given the expense of specialty medications and the tactics of PBMs like Caremark to shift those costs to patients, most patients cannot afford their cost-sharing obligations for specialty medications on their own.

62. To help patients surmount this financial hurdle, most pharmaceutical manufacturers of expensive brand-name medications offer patient copay assistance programs to help cover some or all of patients' costs for expensive prescription medications. Patients enrolled in a manufacturer's copay assistance program typically receive a copay card, which they can then present to their pharmacy when filling their prescription.

63. Patient copay assistance programs typically offer to provide financial assistance equal to a patient's cost-sharing obligation for a specialty medication, up to a maximum amount per year. Sometimes, patient copay assistance programs will require a patient to pay a nominal amount, such as $5, before the program assists with the rest of the patient's expenses.

64. These patient copay assistance programs exist to benefit patients—to ensure that patients can afford the prescription medications deemed essential to their health by their medical professionals. They help by defraying the high patient costs associated with specialty medications. They are not meant to help health plans defray their costs.

65. Manufacturers Regeneron and Sanofi, for example, offer the Dupixent MyWay® program to help patients afford their Dupixent prescriptions. The terms of that program, however, make clear that Regeneron and Sanofi intend that money to help only patients:

> The program is intended to help *patients* afford DUPIXENT. Patients may have insurance plans that attempt to dilute the impact of the assistance available under the program. In those situations, the program may change its terms.

Likewise, AbbVie provides patient copay assistance to patients prescribed Humira, a medication used to treat several autoimmune disorders, called Humira Complete®. In Humira Complete®'s terms and conditions, AbbVie makes it clear: the program is intended solely for the benefit of the patient. Likewise, Johnson & Johnson, the manufacturer of Stelara, provides patient copay assistance through its Stelara withMe® program. The program's terms and conditions state that Johnson & Johnson designed that assistance solely for the benefit of the patient.

D. PrudentRx and its co-conspirators Caremark and CVS Specialty Pharmacy divert patient copay assistance away from the patients that need it and toward those patients' insurers.

66. As explained above, the ACA imposes limits on the amount an insurer can require a patient to pay toward their healthcare expenses each year. Responsibility for the cost of any

covered healthcare beyond those limits falls on the health plan sponsor. There are only narrow exceptions to this rule, as HHS has explained: (1) "monthly premiums"; (2) "[a]nything [a patient] spend[s] for services [their] plan does not cover"; (3) "[o]ut-of-network care and services"; and (4) "[c]osts above the allowed amount for a service that a provider may charge." Only two of these four categories are relevant to prescription drug coverage. If the patients' plan does not cover a prescription, or if the patient's pharmacy is out-of-network, the patient's payments for those drugs do not count towards their annual cost-sharing limits.

67. PrudentRx, Caremark, and CVS Pharmacy, however, have constructed a scheme premised on the notion that they can ignore the ACA's patient protections and misappropriate patient copay assistance to line the pockets of insurers and enrich themselves, while forcing patients to bear a larger portion of their medical costs than the law allows.

68. As explained above, Defendants' scheme has five main elements. *First*, they circumvent statutory constraints on cost-sharing for specialty medications. *Second*, PrudentRx sets targeted patients' reported cost-sharing to maximize the amount of money that it can siphon out of patient copay assistance programs. *Third*, PrudentRx, Caremark, and CVS Specialty Pharmacy use the threat of prohibitively expensive coinsurance to coerce patients to remain enrolled in the PrudentRx Copay Program and enroll in pharmaceutical manufacturers' patient copay assistance programs. *Fourth*, they leverage the PrudentRx Copay Program to collect assistance meant for patients and instead provide it to health plan sponsors. And *fifth*, they force patients to incur additional healthcare expenses they otherwise would not have incurred in the absence of the PrudentRx Copay Program. Each facet of this scheme is explained in detail in the sections below.

1. PrudentRx claims to have found a loophole in the ACA that allows it to evade the ACA's patient-protective requirements.

69. PrudentRx claims that a loophole in the ACA allows health plan sponsors to shift costs to patients that must, under federal law, be borne by a health plan.

70. According to PrudentRx, it can designate expensive specialty medications with generous patient copay assistance programs as "non-essential health benefits," regardless of how critical that medication is for a patient's health or even their very survival. Under PrudentRx's reading, a health plan may cover a drug yet deem that drug "non-essential" so long as the plan otherwise covers the bare minimum number of other drugs as essential health benefits.

71. A health plan must cover "*at least*. . . [t]he same number of prescription drugs in each category and class as the EHB-benchmark plan." The regulations, therefore, set minimum coverage standards. Each state sets its own EHB-benchmark plan. Utah's benchmark plan requires coverage for the fewest medications. It would, therefore, permit PrudentRx to designate the maximum number of medications as non-essential in support of its scheme.

72. According to PrudentRx, any drugs above the number required by Utah's EHB benchmark plan can be covered, yet deemed "non-essential health benefits," and thus excluded from the patient-protective provisions of the ACA. This, PrudentRx theorizes, means that any payments by or on behalf of patients for those medications need not count towards patients' cost-sharing limits. In effect, PrudentRx's scheme takes the regulatory *minimum* drug coverage and treats it as the *maximum* level of coverage the plan must offer.

73. This purported "loophole" is not a loophole at all, as it violates the express requirements of the ACA. The plain text of the ACA requires that all copayments and coinsurance for covered medications are subject to the cost-sharing limitation, regardless of whether those costs are for EHBs.

2. PrudentRx created the PrudentRx Copay Program to shift insurers' payment obligations onto patient copay assistance programs and patients themselves.

74. Based on its strained interpretation of the ACA and its regulations, PrudentRx created the PrudentRx Copay Program.

75. On information and belief, PrudentRx analyzed the various states' benchmark plans to identify the plan that allows health plan sponsors to provide the least amount of coverage to its members in terms of prescription benefits. That plan is Utah's.

76. PrudentRx requires all health plan sponsors and insurers to use only the Utah state benchmark and prohibits its clients from picking a different benchmark, even though this requirement violates guidance from HHS that instructs insurers and benefit plans to select benchmark plans based on their primary place of business.

77. The PrudentRx Copay Program targets medications in 56 specific therapeutic categories. These categories include medications that treat serious, often life-threatening conditions like cancer; Hepatitis C; cystic fibrosis; multiple sclerosis; hemophilia; and inflammatory diseases like Crohn's Disease, atopic dermatitis, psoriasis, and psoriatic arthritis. Treatments for these targeted conditions are complex, and the medications that constitute best practices for their treatment are often very expensive.

78. PrudentRx selected the targeted therapeutic categories based on the costs of medications in those classes.

79. Once PrudentRx identified the targeted therapeutic categories of medications, PrudentRx identified the medications within those categories with the most generous patient copay assistance programs and carved them out of participating health plans' standard benefit design. PrudentRx has targeted more than 480 medications.

80. PrudentRx then claims that none of these targeted medications qualify as essential health benefits for participating plans. This allows PrudentRx to fully leverage all of the patient copay assistance dollars to offset health plan sponsors' pharmacy benefit coverage obligations. Additionally, by designating the targeted medications non-essential health benefits, the PrudentRx Copay Program shifts additional medical costs for services other than that medication onto patients. This is because PrudentRx asserts that payments by patient copay assistance programs for essential health benefits count towards patients' annual cost-sharing limit, but payments made for non-essential health benefits do not.

81. Often, many patients who must take expensive specialty medications to treat complex and life-threatening conditions are able to satisfy their deductible, and even their entire annual cost-sharing limit, using funds provided by patient copay assistance programs rather than paying out of their own pocket. But the PrudentRx Copay Program does not allow a patient to satisfy any part of their cost-sharing obligations through funds provided by patient copay assistance programs. As a result, a patient who would normally satisfy all or part of their cost-sharing obligations through patient copay assistance funding must instead pay for additional medical care for which, absent the PrudentRx Copay Program, their health plan would have to cover.

82. The PrudentRx Copay Program thus has two goals: to enrich plans, Caremark, and PrudentRx with excessive patient copay assistance payments meant to benefit patients, not plans; and to allow plans to shift additional healthcare costs onto patients.

3. PrudentRx, Caremark, and CVS Specialty Pharmacy automatically enroll targeted patients in the PrudentRx Copay Program, with the threat of financial ruination if they opt out.

83. Caremark and PrudentRx market the PrudentRx Copay Program to health plan sponsors. After convincing a health plan sponsor to sign up, Caremark executes an agreement with that sponsor, and PrudentRx automatically enrolls targeted patients in the Program.

84. While Defendants give patients the choice of opting out after enrollment, few patients do. This is by design: PrudentRx sets the copay for each targeted medication at 30% of the medications' list price. And because PrudentRx enforces its incorrect interpretation of the ACA's essential health benefits and cost-sharing provisions, those 30% copayments could—over the course of months or a year, add up to tens or, in some cases, hundreds of thousands of dollars. So, most patients acquiesce to the PrudentRx Copay Program, because they cannot afford to do otherwise.

i. PrudentRx, Caremark, and CVS Specialty Pharmacy coerce patients into remaining enrolled in the PrudentRx Copay Program and require them to enroll in patient copay assistance programs.

85. It is PrudentRx's job to convince targeted patients to remain enrolled in the PrudentRx Copay Program and to help patients enroll in relevant patient copay assistance program—often by walking them through the steps—so that PrudentRx, Caremark, and CVS Specialty Pharmacy can secure the patient copay assistance dollars for participating health plans.

86. PrudentRx uses prescription claims data shared by Caremark to identify targeted patients and automatically enroll them in the PrudentRx Copay Program. Those targeted patients receive a welcome letter and phone call from PrudentRx with information about the Program as it pertains to their medication(s). Targeted patients must enroll in an available patient copay assistance program, "as required by a manufacturer," PrudentRx claims.

87. PrudentRx and Caremark emphasize to plans that it is "essential" for targeted patients to speak with a PrudentRx "Advocate" within 5 days of receiving the welcome letter to become fully enrolled in and avoid being opted out of the Program. Then representatives call targeted patients, sometimes multiple times a day, to ensure they follow through. This urgent language and aggressive pursuit of targeted patients, coupled with the threat of having to pay a 30% coinsurance on their specialty medications, ensures that targeted patients will speak with PrudentRx representatives.

88. CVS Specialty Pharmacy aids PrudentRx in these efforts. PrudentRx pesters targeted patients already enrolled in a patient copay assistance program to call CVS Specialty Pharmacy; and CVS Specialty Pharmacy requires those patients to provide their patient copay assistance account number. And when a targeted patient who has not enrolled in a patient copay assistance program submits a prescription for a targeted medication to CVS Specialty Pharmacy, representatives at the pharmacy "warm transfer" the patient to a PrudentRx representative to complete their enrollment process. PrudentRx calls this invasive outreach a "high-touch, seamless proactive multi-channel member engagement process."

ii. PrudentRx, Caremark, and CVS Specialty Pharmacy retaliate financially against targeted patients that refuse to sign up for patient copay assistance programs.

89. A targeted patient might decline to sign up for a patient copay assistance program despite being bombarded by phone calls and letters from PrudentRx, and despite CVS Specialty Pharmacy putting them in touch with PrudentRx sales representatives. PrudentRx designed the PrudentRx Copay Program to punish those patients.

90. PrudentRx, Caremark, and CVS Specialty Pharmacy set up the PrudentRx Copay Program to capitalize on funding from patient copay assistance programs, so they have inflated targeted patients' copays to bill the patient copay assistance program. If a patient opts out of the

PrudentRx Copay Program or does not enroll in a patient copay assistance program, PrudentRx informs them, Defendants charge the patient that inflated 30% coinsurance on specialty medications eligible for the PrudentRx Copay Program after satisfying any applicable plan deductible. And because PrudentRx has designated the medications as non-essential health benefits, the payment of the 30% coinsurance is not applicable to the targeted patient's annual cost-sharing limit.

91. PrudentRx deliberately designed the PrudentRx Copay Program to create these harsh and coercive consequences for targeted patients who do not acquiesce to their health plan taking their patient copay assistance funding. And they depend on this to ensure that the PrudentRx Copay Program scheme works. If targeted patients could just say no and opt out—which would deprive PrudentRx, Caremark, and CVS Specialty Pharmacy of the opportunity to divert patient copay assistance to themselves and the health plan—it would defeat the PrudentRx Copay Program's purpose.

92. As a result of PrudentRx's aggressive and harassing outreach and the threat of having to pay a 30% coinsurance, 99.9% of targeted patients (according to PrudentRx) remain in the PrudentRx Copay Program. As one patient with multiple sclerosis reported, they felt forced to enroll because otherwise they would have to pay thousands of dollars for their medication.

iii. The PrudentRx Copay Program's $0 medication cost to patients is not a benefit: it is a sham.

93. To convince targeted patients to enroll in the PrudentRx Copay Program, PrudentRx, Caremark, and CVS Specialty Pharmacy tell targeted patients that, if they enroll in the Program, they will enjoy a $0 copay for their qualifying specialty medications. But the $0 copay offer is a sham. Not only does the SaveOn Program and its "$0 copay" offer provide no benefit to targeted patients, it leaves them worse off than they were before for two reasons.

94. *First*, the $0 copay offer is a sham because it does not help targeted patients save money on their specialty medications. Most, if not all, targeted patients *already* received their specialty medications for no cost out-of-pocket before being subjected to the PrudentRx Copay Program. Patient copay assistance programs have—for years prior to the founding of PrudentRx—provided financial assistance to cover patients' cost-sharing obligations. The PrudentRx Copay Program does not offer any new benefit to targeted patients; instead, it offers new barriers to targeted patients' ability to afford their healthcare. The only benefit is to PrudentRx, Caremark, CVS Specialty Pharmacy, and their plan partners: the Program diverts patient copay assistance funds to enrich plans and Defendants.

95. *Second*, the PrudentRx Copay Program is not designed to help patients. It is designed to conceal Defendants' scheme. The Program's $0 feature is not benevolence. It is self-preservation—a means of protecting their scheme from detection. PrudentRx, Caremark, and CVS Specialty Pharmacy ensure that a targeted patient never faces a surprise bill for their specialty medication because without surprise bills, there is less likelihood a targeted patient will uncover their scheme.

96. In the past, health insurers and PBMs have tried other types of programs to divert patient copay assistance funds for their own benefits. One was known as a copay accumulator adjustment program which collected the maximum amount of patient copay assistance at the beginning of the year and excluded it from the patient's annual cost-sharing limits. Once the patient copay assistance funding dried up, patients were surprised to discover that none of the patient copay assistance funds collected counted toward their cost-sharing obligations. Suddenly, late into their plan year, unsuspecting patients faced steep and unanticipated medical costs. This led to outcry from patients and healthcare advocates. The reaction was quick and severe: 23 states have

banned insurers within their regulatory authority from deploying accumulator adjustment programs; another 17 have similar legislation pending.

97. So insurers and PBMs switched tactics, introducing what became known as a copay maximizer. Copay maximizers accomplish the same thing as copay accumulators, except they spread the collection of patient copay assistance out over the course of the year, so patients do not face the surprise bills that led to outcry against accumulators.

98. The PrudentRx Copay Program is little more than a maximizer program in fancy dress. It bears many of the hallmarks of maximizer programs—maximizing copay assistance program payments without any benefit to targeted patients, resulting in increased healthcare costs to those patients—but wraps the scheme in the guise of a legalistic (but not legal) argument about how the patients' life-saving medications are "non-essential."

99. PrudentRx designed—and PrudentRx, Caremark, and CVS Specialty Pharmacy operate—the PrudentRx Copay Program to avoid patient backlash that could frustrate their scheme. By touting a $0 cost to targeted patients who enroll, the trio seems to hope, patients will not complain, and the Program can persevere where other programs have faltered. The $0 cost to patients is, therefore, not benevolence, but an effort to conceal the Program's harm to patients.

4. Defendants collect funds from patient copay assistance programs even when targeted patients are ineligible for that funding.

100. The lynchpin of the PrudentRx Copay Program is a scheme to deceive patient copay assistance programs into paying PrudentRx's artificially inflated copays. The Program does not work—it has no purpose—unless PrudentRx and Caremark can collect excessive patient copay assistance funds meant to benefit *patients* and divert them to benefit the *plan* and enrich administrators like themselves.

101. PrudentRx, Caremark, and CVS Specialty Pharmacy team up to mislead patient copay assistance programs into turning over copay assistance to benefit plans and Defendants themselves in at least five ways. *First*, they set targeted patients' purported copays as a percentage of list price to help their scheme evade detection. *Second*, they mislead these programs into believing targeted patients are responsible for paying astronomically high cost-sharing for their specialty medications when the patient is actually responsible for $0. *Third*, they coach unwitting patients to sign up for patient copay assistance programs for which they are ineligible as a result of their enrollment in the PrudentRx Copay Program. *Fourth*, they evade some patient copay assistance programs' requirement that a patient bear a small amount of copay obligation out of pocket. And *fifth*, they conceal their wrongfully obtained copay assistance as payments by an insurer, using a fictitious insurance "plan" that is really just PrudentRx behind the scenes. Each of these tactics, which help ensure that the PrudentRx Copay Program can function as intended, is discussed below.

i. The PrudentRx Copay Program's 30% copay requirement helps hide its unlawful scheme while ensuring maximum enrichment for PrudentRx, Caremark, and CVS Specialty Pharmacy.

102. Establishing a 30% coinsurance across all PrudentRx Copay Program medications, rather than setting a targeted patient's copay to the exact amount of copay assistance available, serves dual purposes: (a) to avoid manufacturers' detection of the PrudentRx Copay Assistance Fraud Enterprise, and (b) to coerce targeted patients into acquiescing to the PrudentRx Copay Program.

103. With respect to the former objective, Defendants seek to collect 100% of the available copay assistance. But if they set the copay for monthly prescription refills to exactly one twelfth of the available copay assistance (or the copay for 90-day refills to one quarter of the available assistance), manufacturers could easily identify targeted patients subjected to the

PrudentRx Copay Program. The average maximum amount of copay assistance available for Hepatitis C medications, for example, is $6,600 per fill. A manufacturer could easily screen for $6,600 copay assistance withdrawals, reason that the patient in whose name that money was withdrawn were subject to the PrudentRx Copay Program, and enforce the terms and conditions of the patient copay assistance program prohibiting or limiting copay assistance to those patients.

104. On the other hand, patient cost-sharing for specialty medications is commonly calculated as coinsurance—a percentage of the cost of the medication. So, by collecting a percentage of a medications' cost, PrudentRx, Caremark, and CVS Specialty Pharmacy could evade detection.

105. No copay assistance program offers assistance amounting to more than 30% of the cost of these specialty medications. So, setting a 30% coinsurance for targeted patients would allow PrudentRx, Caremark, and CVS Specialty Pharmacy to capture all of the manufacturer-offered assistance, but make it more difficult for manufacturers to identify assistance funds withdrawn by the PrudentRx scheme.

ii. PrudentRx, Caremark, and CVS Specialty Pharmacy misrepresent targeted patients' copay obligations to patient copay assistance programs to extract excess funds.

106. As described above, PrudentRx sets patients' coinsurance to 30% of the cost of their specialty medications to collect the maximum amount of assistance available from patient copay assistance programs each year. When a targeted patient enrolled in the PrudentRx Copay Program submits a prescription for a targeted medication to CVS Specialty Pharmacy, CVS Specialty Pharmacy represents to the patient copay assistance program that the targeted patient is responsible for thousands, sometimes tens of thousands, of dollars in copays.

107. These representations are fundamentally at odds with what Defendants tell targeted patients. They tell targeted patients that their actual financial responsibility is $0, so long as they enroll in the program.

108. Nevertheless, PrudentRx, Caremark, and CVS Specialty Pharmacy's representations to the patient copay assistance programs enable them to collect thousands of dollars in targeted patients' names. Defendants do not apply that money to the targeted patient's cost sharing obligations.

iii. Most targeted patients are ineligible for patient copay assistance funds because they are subject to the PrudentRx Copay Program—but PrudentRx, Caremark, and CVS Specialty Pharmacy collect those funds anyway.

109. Many patient copay assistance programs have noticed the effects of the PrudentRx Copay Program and have changed their terms of service to ensure that only patients benefit. Most, if not all, patient copay assistance programs' terms of service make clear that the programs are intended solely to benefit the patient, not the health plan or PBM.

110. Targeted patients forced to enroll in the PrudentRx Copay Program and other maximizers are not eligible for patient copay assistance or find their eligible assistance significantly reduced. Most patient copay assistance programs expressly say so in their terms of service. AbbVie, for example, reduces the copay funding available for Skyrizi patients from $14,000 annually to $4,000 annually, allowing them to restore eligibility for the full copay assistance only if the maximizer removes Skyrizi from the maximizer's targeted drug list. Likewise, Pfizer expressly eliminates eligibility for its cancer drug Sutent for any patient enrolled in a copay maximizer program. And Eli Lilly & Company, the maker of Taltz, states that a patient is not eligible for, and prohibited from using, the Taltz Savings Card Program if the patient's health

plan operates a program in which coverage, reimbursement, or patient costs for a product in some way varies based on the availability of a manufacturer copay program.

111. Yet PrudentRx, Caremark, and CVS Specialty Pharmacy nevertheless force targeted patients to sign up for these patient copay assistance programs. PrudentRx's "high touch" outreach to targeted patients after a health plan signs up for the PrudentRx Copay Program is to walk patients through the sign-up process for these programs. PrudentRx-trained representatives tell patients exactly what to say to manufacturers to frustrate copay assistance programs' efforts to screen for patients enrolled in copay assistance programs. Upon information and belief, PrudentRx leads targeted patients to unwittingly mislead the patient copay assistance program into allowing ineligible members to enroll.

iv. Some patient copay assistance funds require participating patients to pay a small portion of a medication's cost—but PrudentRx, Caremark, and CVS Specialty Pharmacy evade these requirements.

112. Not all patient copay assistance programs cover 100% of a patient's cost-sharing obligation. Some require patients to cover a nominal amount—often between $5 and $50—of the copay out of pocket. Under the terms of such programs, the patient must pay that amount; any patient on a health plan with a plan design that claims to eliminate the patient's cost-sharing obligations is not eligible to receive patient copay assistance. Patient copay assistance programs implement these rules for a simple, commonsense reason: it ensures that patient copay assistance reaches only those patients who must pay something for their medications.

113. Yet PrudentRx, Caremark, and CVS Specialty Pharmacy deceive manufacturers by concealing their interference with patient copay assistance programs.

114. When a patient copay assistance program requires a patient to pay a nominal amount out of pocket, PrudentRx acts as a so-called tertiary biller. The primary biller is the participating health plan, which covers the cost of the medication in excess of PrudentRx's inflated

copay; the secondary biller is the patient copay assistance program, which would pay most of the copay. PrudentRx pays the remainder.

115. Take the hypothetical example of a specialty medication with a monthly cost of $10,000, for which a patient copay assistance program offers up to $12,000 annually in assistance, so long as the patient pays $5 per month. Under those circumstances, PrudentRx would set its inflated coinsurance at $3,000 (30% of the medication's monthly cost); the patient copay assistance program would pay $2,995 and expect that the remaining $5 would be the patient's responsibility. But instead, PrudentRx would pay the $5 and then invoice that $5 cost back to the health plan sponsor.

116. The PrudentRx Copay Program's tertiary biller scheme allows PrudentRx, Caremark, and CVS Specialty Pharmacy to (i) violate the terms of patient copay assistance programs, (ii) evade requirements designed to ensure that the patient copay assistance program funding is actually being provided for the benefit of the patient, and (iii) keep targeted patients' payment obligations at $0 to avoid complaints from patients.

v. PrudentRx pretends to be an insurer to hide the copay assistance fraud scheme and prevent targeted patients from benefitting from the copay assistance extracted in their names.

117. PrudentRx is not an insurance company. It does not serve as an insurer for any targeted patient. But it pretends to be one to conceal its scheme.

118. When PrudentRx, Caremark, and CVS Specialty Pharmacy siphon patient assistance funds away from patient copay assistance programs, they do not record those funds as patient copay assistance in the targeted patients' prescription claims records. They know that if they did, they would have to credit those funds towards patients' annual cost-sharing limitations. They know this would lower the amount of patient assistance funding they could divert, prevent

them from forcing patients to bear additional costs, and generally defeat the entire purpose of their scheme.

119. Instead, the purloined funds first pass through PrudentRx. PrudentRx has set up a shell plan that it calls "PRx COB Override Plan." "PRx" stands for "PrudentRx." "COB" stands for "Coordination of Benefits"—industry language for the process of applying coverage from more than one insurance plan or payer to the same claim. "Override" is an admission that the PrudentRx is altering the proper flow and attribution of payments for prescription medications within the system. And "Plan" is meant to make PrudentRx's feint look like an insurance plan. The PRx COB Override Plan has a "network" of pharmacies within which it works: it is a network of one, CVS Specialty Pharmacy.

120. The PrudentRx Copay Program collects inflated patient copay amounts from targeted patients' copay assistance programs, then uses it to pay part of a patient's drug claim. Caremark, as the pharmacy benefits administrator, and CVS Specialty Pharmacy, which handles the transaction, log that pass-through as "other insurance." And they record the patients' copay or coinsurance as $0:

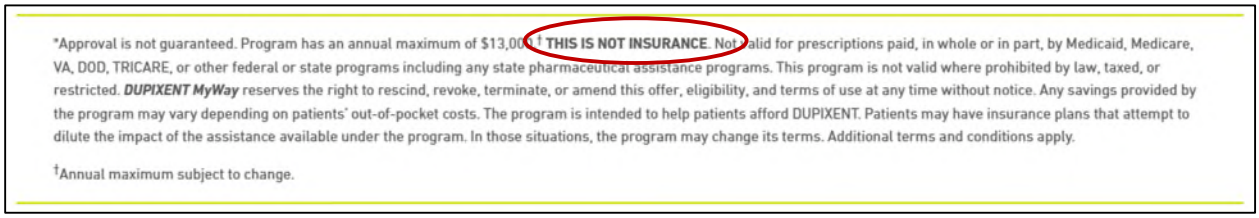
FIGURE B: Exemplar Pharmacy Claims for Prescriptions Subject to PrudentRx Copay Program

PATIENT Health Care Provider	First Date of Service	Claim Number	Amount Charged	Amount Allowed	Network Savings	Amount Paid By Health Plan	Other Insurance	Date Paid	Your Deductible	Your Copayment	Your Coinsurance	Your Amount Not Covered	Your Responsibility
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
PHARMACY PROVIDER	08/07/2024	[redacted]	$7,991.72	$3,719.53	$4,272.19	$2,603.67	$1,115.86	08/09/2024	$0.00	$0.00	$0.00	$0.00	$0.00
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
PHARMACY PROVIDER	08/30/2024	[redacted]	$7,991.72	$3,719.53	$4,272.19	$2,603.67	$1,115.86	09/11/2024	$0.00	$0.00	$0.00	$0.00	$0.00
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

121. PrudentRx is not licensed to provide insurance in any state, any U.S. territory, or the District of Columbia; nor does it purport to be a benefit plan or benefit plan administrator, despite acting like one. For example, it is not a licensed insurer in Iowa, where, purportedly, it paid a portion of Ms. Gluesing's prescription drug claims.

122. Nor are patient copay assistance programs insurance. Patient copay assistance programs routinely provide a prominent disclaimer of this fact. For example, the website for the Dupixent MyWay® program provides the following disclaimer:

FIGURE C: Excerpt of Dupixent MyWay® Copay Assistance Website



123. Accordingly, it is false and misleading to call the patient copay assistance funds collected by the PrudentRx Copay Program "other insurance." Defendants can call it "other insurance" only because PrudentRx has set up a fictious "insurer" to conceal Defendants' scheme. PrudentRx, Caremark, and CVS Specialty Pharmacy's mechanism for receiving, transferring, and logging the excess patient assistance funds they extract from patient copay assistance programs is, therefore, false and deceptive.

E. PrudentRx, Caremark, and CVS Specialty Pharmacy's scheme is very lucrative for them and for their insurer clients but harms targeted patients.

124. PrudentRx, Caremark, and CVS Specialty Pharmacy profit from the PrudentRx Copay Program. For operating the PrudentRx Copay Program on behalf of participating health plan sponsors, Caremark and PrudentRx collect a commission equaling 25% of the amount of patient copay assistance funds Defendants collect from patient copay assistance programs.

125. PrudentRx creates detailed monthly reports to calculate Defendants' earnings. These reports include the total cost of specialty medications; the total amount the health plan sponsor has saved—that is, the total amount of patient copay assistance diverted to the plan—

which it uses to calculate a plan's net savings; and, net savings by therapeutic category for the year to date.

126. The PrudentRx Copay Program is very lucrative for PrudentRx, Caremark, and CVS Specialty Pharmacy and their health-plan clients. PrudentRx touts up to 22% of client gross savings for those with the Program in place.

127. But recall that the diverted patient copay assistance funding is only half of the PrudentRx Copay Program's objective. PrudentRx also designed the Program to force targeted patients to shoulder an excessive amount of their healthcare costs. Those excess healthcare costs constitute direct financial harm to targeted plaintiffs.

1. The PrudentRx Copay Program foists additional healthcare costs on patients.

128. Under the PrudentRx Copay Program, Defendants charge targeted patients nothing for targeted medications. They tell patients that the Program is designed to help them save money on their specialty medications. This is a lie.

129. For employer-sponsored healthcare, the average deductible is $1,922, and the average cost-sharing limit is $4,346 (for individual plans purchased on states' ACA marketplaces, these numbers are slightly higher).

130. Most relatively healthy patients are lucky: absent an extraordinary emergency medical condition or injury, they never need to shoulder healthcare expenses high enough to reach their annual cost-sharing limits. But patients with chronic, expensive, lifelong conditions routinely satisfy their deductible and even hit their annual cost-sharing limits with their first couple of medication shipments each year.

131. As noted above, patients who need specialty medications face monthly costs well into the thousands of dollars. Therefore, patient copay assistance funding is essential to help defray

their high cost-sharing healthcare expenses and ensure they receive the treatment they need. Few patients can afford thousands of dollars each month in prescription medication cost-sharing obligations. Patient copay assistance programs are intended to help to mitigate those costs. Patients enrolled in patient copay assistance programs for specialty medications often strategically schedule medical care so as to not need routine office visits, lab tests, or other treatment during the first quarter of the year. For patients that can satisfy their deductible with their first few prescription drug copayments each year, this enables them to delay medical care expenses until they have satisfied their deductible, and their plan must cover some of their cost. For the unfortunate patients whose first few prescription claims exceed their annual cost-sharing limitations, this strategic scheduling can help them avoid certain medical expenses all together.

132. The PrudentRx Copay Program harms targeted patients because it deprives them of this cost management strategy. In fact, Defendants specifically designed it to do so. Because PrudentRx designates targeted patients' medications as non-essential health benefits and excludes payments for these specialty medications from calculating whether the patient has met their annual cost-sharing limitation, none of the patient copay assistance program funding collected in the patients' names benefit the patients. It does not count towards satisfying their deductible, and it does not count towards reaching their annual cost-sharing limits.

133. Therefore, the PrudentRx Copay Program forces targeted patients to cover healthcare expenses that would otherwise be mitigated by patient copay assistance program funding. So, while targeted patients' up-front cost for targeted medications is zero, the lack of progression towards their deductible or annual cost-sharing limits means they experience more cost for other medical care.

134. Consider a hypothetical patient on an average employer-sponsored health plan—one with a $1,922 deductible, a $4,346 cost-sharing limit, and a 26% coinsurance obligation for specialty medications—that is prescribed a specialty medication (Drug X) with an average $84,442 annual list price for which their insurer and affiliated PBM enjoys a $34,000 rebate, and for which the manufacturer offers up to $24,000 in patient copay assistance funding. That patient would face a $7,037 bill for their very first prescription of the medication in January—more than satisfying their deductible and exceeding their annual cost-sharing limitation with that first fill. Their cost-sharing obligation for that January prescription would, therefore, be capped at $4,346—their annual cost-sharing limit. If that patient were enrolled in the manufacturer's patient copay assistance program, the assistance program would pay $4,346, and the plan would be responsible for covering the remaining $46,096. After that, the patient would have no further healthcare expense obligations.

135. The calculus changes dramatically once a patient's health plan sponsor has joined the PrudentRx Copay Program. Under the Program, PrudentRx would designate Drug X as a non-essential health benefit and set the patient's monthly copay to 30% of the cost of Drug X, or $2,111.50 per month. Over the course of the year, the PrudentRx Copay Program would siphon $24,000 from the patient copay assistance program, and the plan would be responsible for only $26,442. But none of the $24,000 the Program collected would count toward the patient's deductible or annual cost-sharing limit. Thus, even after the manufacturer pays $24,000 in the patient's name, the patient would still be responsible for covering $4,346 in medical expenses. Therefore, this hypothetical patient would suffer $4,346 in financial harm from the PrudentRx Copay Program, as demonstrated in the table below:

Table 1: Itemization of Healthcare Expenses With and Without PrudentRx Copay Program

	Without PrudentRx	With PrudentRx
Drug X Annual List Price	$84,442	
Rebate to Plan	$34,000	
Available Copay Assistance	$24,000	
Patient Deductible	$1,922	
Patient Annual Cost-Sharing Limit	$4,346	
Expected Plan Net Cost	$46,096	
Plan-Set Copay Obligation	26%, or $1,094[4]	30%, or $2,111.05
Patient Copay Assistance Collected	$4,346	$24,000
Payment to PrudentRx	$0	$4,913.50
Plan Net Cost[5]	$46,096	$26,442
Total Payments on Behalf of Patient	$4,346	$24,000
Patient Payments Applied to Cost-Sharing Limits	$4,346	$0
Remaining Patient Contribution	**$0**	**$4,346**

136. Patients with a higher-than-average deductible or cost-sharing limitation face more significant financial harm. And patients who decide to opt out of the PrudentRx Copay Program face even more than that: they would be responsible not only for paying for other medical care up to the $4,346 cost sharing limit, but also for 30% of the list price of Drug X, or $25,332.60.

2. Targeted patients cannot escape the financial harm caused by the PrudentRx Copay Program.

137. Once the PrudentRx Copay Program targets a patient, they cannot avoid the Program's financial harm. PrudentRx designates a targeted drug as a non-essential health benefit

[4] One the patient in this hypothetical had satisfied their $1,922 deductible, their monthly obligation for Drug X would be 26% of the monthly cost of the drug ($7,032), or $1,094. In this hypothetical, the patient would reach their annual cost-sharing limitation in February.

[5] List price less rebate and patient contribution.

for all targeted patients. Once their health plan has implemented the Program, these patients have only four options:

a. Remain enrolled in the PrudentRx Copay Program to avoid paying thousands of dollars in coinsurance created by the Program, and be forced to pay additional medical expenses up to the annual cost-sharing limit;

b. Opt out of the Program, sign up for patient assistance on their own to cover some or all of the thousands of dollars of coinsurance, making up the potential difference between the assistance and the 30% coinsurance, and be forced to pay for additional medical expenses up to the annual cost-sharing limit;

c. Opt out of the Program, pay thousands of dollars of coinsurance for the specialty medication, and *still* be forced to cover additional medical expenses up to the annual cost-sharing; or

d. Decide to forgo their physician-prescribed, necessary medical treatment, and be forced to cover additional (and, in light of the fact that they are not taking a necessary medication, enhanced) medical expenses up to the annual cost-sharing limit.

138. In light of the hopeless position that the PrudentRx Copay Program puts targeted patients in many patients feel they have no other choice but to remain enrolled in the Program.

3. PrudentRx, Caremark, and CVS Specialty Pharmacy's scheme creates a benefit design that discriminates against certain patients.

139. The ACA prohibits health insurers from discriminating against patients on the basis of race, color, national origin, sex, sexual orientation, gender identity, age, or disability. HHS's regulations implementing this prohibition prohibit health plan sponsors from "impos[ing] additional cost sharing or other limitations or restrictions on coverage" or having "benefit designs

that discriminate on the basis of . . . disability . . . in health insurance coverage or other health-related coverage." The PrudentRx Copay Program violates the statute and these regulatory provisions.

140. Medications targeted by PrudentRx, Caremark, and CVS Specialty Pharmacy in the PrudentRx Copay Program are those used to treat conditions that constitute disabilities. This includes, for example, cancer, multiple sclerosis, and cystic fibrosis. Cancer is a disability under the Americans with Disabilities Act. So is multiple sclerosis. And cystic fibrosis.

141. The PrudentRx Copay Program constitutes a benefit design that treats patients differently on the basis of their disability: the Program deprives patients with certain disabilities of access to patient copay assistance for their medications; and it imposes additional cost-sharing obligations on patients with disabilities.

142. The designation of targeted medications as non-essential health benefits based only on utilization and cost, not on efficacy or necessity, discriminates against patients with disabilities that happen to be treated by higher-cost medications. PrudentRx, Caremark, and CVS Specialty Pharmacy, therefore, violate the ACA's prohibitions on discrimination.

4. PrudentRx, Caremark, and CVS Specialty Pharmacy disproportionately harm minorities and other marginalized groups.

143. In addition to discriminating against targeted patients on the basis of their disabilities, PrudentRx, Caremark, and CVS Specialty Pharmacy's scheme may disproportionately harm minorities and other marginalized groups.

144. A recent study concluded that even though patients of all races utilize patient copay assistance programs at similar rates, the potential for a patient to be subjected to a copay adjustment program like PrudentRx's, which takes away that assistance, is much higher among non-White

patients versus White patients. The study's authors quantified that disparity: non-Whites are 27% more likely to be exposed to programs like the PrudentRx Copay Program than Whites.

5. PrudentRx, Caremark, and CVS Specialty Pharmacy have fraudulently concealed the harm to patients from the PrudentRx Copay Program.

145. PrudentRx, Caremark, and CVS Specialty Pharmacy have affirmatively and fraudulently concealed their patient copay assistance fraud by various means and methods since 2020.

146. PrudentRx and Caremark set the inflated copays charged by the PrudentRx Copay Program to 30% of the list price of the drug because that amount would ensure they could extract all available copay assistance while concealing their scheme. Upon information and belief, they believed a uniform 30% copay could provide a defensible explanation for their copay assistance fund withdrawals.

147. PrudentRx, Caremark, and CVS Specialty Pharmacy actively conceal the harm caused to patients by the PrudentRx Copay Program. They tout that targeted patients will pay zero dollars for their targeted specialty medications and thus save money on those prescriptions. But they do not disclose that this leads, dollar for dollar, to increased cost-sharing obligations for other healthcare expenses. This omission makes PrudentRx's, Caremark's, and CVS Specialty Pharmacy's statements about the PrudentRx Copay Program materially misleading.

148. These materially misleading statements concealed the harm to targeted patients and did not reveal facts sufficient to put Ms. Gluesing or other Class members on inquiry notice. While targeted patients may have noticed that their cost-sharing expenses increased after their health plan partnered with the PrudentRx Copay Program, healthcare expenses have increased every year. This alone is not sufficient to put a reasonable person on notice that targeted patients' healthcare expenses increased because of, rather than just after, their health plan joined the PrudentRx Copay

Program. An ordinary person acting reasonably diligently would not have had the time, resources, or specialized training to uncover the misconduct that Ms. Gluesing, through counsel highly experienced in racketeering fraud class action litigation, alleges herein.

149. Furthermore, PrudentRx takes pains to prevent the discovery of its deceit. When targeted patients contact PrudentRx, PrudentRx instructs them on how to apply to copay assistance programs, telling them exactly what to say, ensuring that patients do not disclose, expressly or inadvertently, PrudentRx's interference to the assistance programs.

150. And to ensure that its instructions to unwitting targeted patients that result in misrepresentations to copay assistance programs are not discovered, PrudentRx holds these calls in secret. When a patient phones PrudentRx, the first question asked by a PrudentRx representative is whether there is any other person on the line with the patient. This is not necessary to protect patient confidentiality: a patient can choose to have a third party assist in their medical decision making or learn about their medical expenses. Rather, upon information and belief, PrudentRx does this to prevent anyone—such as patient care advocates from patient copay assistance programs, healthcare access advocates from nonprofits dedicated to patients with complex diseases, or benefits consultants—from joining targeted patients in conversations with PrudentRx representatives and uncovering Defendants' scheme.

151. Ms. Gluesing and other members of the Class thus had neither actual nor constructive knowledge of the facts giving rise to her claim for relief. They did not discover, nor could they have discovered through the exercise of reasonable diligence, the existence of Defendants' fraudulent scheme to increase their cost-sharing obligations until shortly before filing this Complaint.

152. Ms. Gluesing exercised reasonable diligence at all times. She could not have discovered PrudentRx, Caremark, or CVS Specialty Pharmacy's misconduct sooner by exercising reasonable diligence because of Defendants' deceptive and secretive actions to conceal their misconduct.

153. Since discovering the possibility that PrudentRx, Caremark, and CVS Specialty Pharmacy's fraudulent misconduct harmed not just patient copay assistance programs but also targeted patients, Ms. Gluesing has diligently examined Defendants' behavior regarding increasing patients' cost-sharing obligations, their coordination regarding the same, their joint purpose to harm targeted patients, and the effects of such conduct through publicly available sources, such as Defendants' public statements and media coverage. Once this investigation revealed a basis for filing this claim, Ms. Gluesing promptly did so.

154. PrudentRx, Caremark, and CVS Specialty Pharmacy's fraudulent concealment of their wrongful misconduct has tolled and suspended the running of the statute of limitations concerning the claims and rights of action arising from the conspiracy, including all parts of the class period earlier in time than the four years immediately preceding the date this action was filed.

155. PrudentRx, Caremark, and CVS Specialty Pharmacy's misconduct has also resulted in a continuing violation. These continuing violations have tolled and suspended the running of the statute of limitations concerning the claims and rights of action arising from the conspiracy, including all parts of the class period earlier than the four years immediately preceding the date of this Complaint.

VI. Impact on Interstate Commerce

156. PrudentRx, Caremark, and CVS Specialty Pharmacy's efforts to divert patient copay assistance have substantially affected interstate commerce.

157. At all material times, PrudentRx, Caremark, and CVS Specialty Pharmacy marketed, promoted, and administered the PrudentRx Copay Program in a continuous and uninterrupted flow of commerce across state lines and throughout the United States.

158. At all material times, PrudentRx, Caremark, and CVS Specialty Pharmacy transmitted funds, contracts, invoices, information, and other forms of business communications across state and national lines and throughout the United States.

159. In furtherance of their scheme, PrudentRx, Caremark, and CVS Specialty Pharmacy employed the U.S. mail, interstate carriers, and the interstate wire lines.

VII. Causes of Action

COUNT I: VIOLATIONS OF ERISA, 29 U.S.C. § 1132(a)(3) by the ERISA Subclass against all Defendants

160. Ms. Gluesing repeats and incorporates by reference all preceding paragraphs and allegations.

161. At all relevant times, Defendants Caremark and PrudentRx have acted as fiduciaries of the ERISA plans they administer under 29 U.S.C. § 1001(21)(A), including, but not limited to, though the following fiduciary acts:

a. By failing to recognize copay amounts paid by patients for prescriptions subject to the PrudentRx Copay Program as counting toward the patients' annual cost-sharing balances;

b. By contacting participants and beneficiaries by letter and by phone to instruct them on how to either sign up for patient copay assistance or link their patient copay assistance account to the PrudentRx Copay Program;

c. By paying, or causing plans to pay, inflated copays for participants and beneficiaries in the PrudentRx Copay Program, but charging those inflated amounts to those who opted out;

d. By administering and paying claims for pharmacy benefits through a sham insurance plan that covers the coinsurance amounts for drugs subject to the PrudentRx Copay Program; and

e. By paying, or causing plans to pay, a portion of the cost-sharing drug manufacturers require patients to pay to be eligible for manufacturer patient copay assistance.

162. As fiduciaries, Defendants Caremark and PrudentRx must discharge their duties in the interests of participants and beneficiaries and in accordance with ERISA.

163. When enrolling plan participants and beneficiaries in the PrudentRx Copay Program and operating the PrudentRx Copay Program, Defendants Caremark and PrudentRx have violated numerous provisions of ERISA, including, but not limited to, as follows:

a. Failing to count prescription drug copays toward the plan participant or beneficiary's annual cost-sharing limitation balance, in violation of 42 U.S.C. § 300gg-6(b), as incorporated in ERISA at 29 U.S.C. 1185d(a)(1);

b. Instructing plan participants and beneficiaries on how to obtain patient copay assistance from drug manufacturers by, in part, misrepresenting or omitting material facts and causing patients to make misrepresentations to drug manufacturers, in violation of their duty of loyalty under 29 U.S.C. § 1104(a)(1); and

c. Failing to perform their duties in the best interests of plan participants and beneficiaries and instead operating the PrudentRx Copay Program scheme to benefit themselves, in violation of 29 U.S.C. § 1104(a)(1).

164. By violating numerous provisions of ERISA, Defendants Caremark and PrudentRx also violate their obligation to execute their duties consistent with ERISA, in violation of 29 U.S.C. § 1104(a)(1)(D).

165. As a result of these breaches of fiduciary duty and violations of ERISA, Ms. Gluesing and the Class are entitled to equitable relief in the form of an injunction prohibiting Defendants Caremark and PrudentRx from operating the PrudentRx Copay Program scheme.

166. In addition, Ms. Gluesing and the Class are entitled to attorneys' fees, costs, and litigation expenses under 29 U.S.C. § 1132(g).

COUNT II: VIOLATION OF THE RACKETEER INFLUENCED CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1962(c) by the Class against all Defendants

167. Ms. Gluesing repeats and incorporates by reference all preceding paragraphs and allegations.

168. Defendant PrudentRx LLC is a "person" within the meaning of 18 U.S.C. § 1961(3).

169. Defendant Caremark is a "person" within the meaning of 18 U.S.C. § 1961(3).

170. The PrudentRx Copay Program constitutes an association-in-fact enterprise—the PrudentRx Copay Assistance Fraud Enterprise—within the meaning of 18 U.S.C. § 1961(4), consisting of: (i) PrudentRx LLC, including its employees and agents; and (ii) Caremark Rx, LLC, in its capacities both as PBM and as specialty pharmacy, including its employees and agents.

171. The defendant "persons" are each distinct from the PrudentRx Copay Assistance Fraud Enterprise.

172. The PrudentRx Copay Assistance Fraud Enterprise fits within the meaning of 18 U.S.C. § 1961(4) and consists of a group of "persons" that have created and maintained systematic links for a common purpose: to profit by diverting patient copay assistance funds and forcing patients to bear the cost of additional healthcare expenses as a result.

173. PrudentRx conducts or participates in the conduct of the affairs of the PrudentRx Copay Assistance Fraud Enterprise. PrudentRx conceived of the PrudentRx Copay Program, developing and promoting a plan to exploit a perceived loophole in the ACA and its regulations. It analyzed states' benchmark healthcare plans to identify the plan (Utah's) that was most permissive of the scheme. It analyzes, and continuously monitors, therapeutic categories of medications in that benchmark plan to identify medical conditions treated by expensive medications, and it identifies lucrative manufacturers' patient copay assistance programs for medications in those classes worth exploiting. PrudentRx recruited Caremark to help operationalize the PrudentRx Copay Program. It sets inflated copays for targeted medications. It created and has maintained a "PrudentRx drug list" for participating health plans. It identifies targeted patients from participating health plans' prescription claims data, engages in a letter-writing and phone-call campaign to coerce patients to provide their copay assistance account information to the PrudentRx Copay Program, and coaches targeted patients on exactly what to say to dupe patient copay assistance programs into providing funding. It administers the PrudentRx Copay Program as it applies to enrolled targeted patients. And it prepares detailed reports of the patient copay assistance collected in the names of, but not for the benefit of, targeted patients; the "savings" to participating

health plans; and the fraudulently reduced net cost to the plans, which it then transmits to Caremark via the wires.

174. Caremark conducts or participates in the conduct of the affairs of the PrudentRx Copay Assistance Fraud Enterprise. It markets the PrudentRx Copay Program to its health plan sponsor clients, entering into agreements with participating health plans sponsors. It provides, via the wires, detailed prescription claims data from participating health plans to PrudentRx for the purpose of identifying targeted patients and aiding PrudentRx in preparing reports to be sent to participating health plans. And it receives from CVS Specialty Pharmacy and/or PrudentRx excessive copayments collected from patient copay assistance programs and disburses these funds to participating health plans, then bills the plans for its services and charges a fee on behalf of PrudentRx equal to 25% of the patient copay assistance collected.

175. CVS Specialty Pharmacy conducts or participates in the conduct of the affairs of the PrudentRx Copay Assistance Fraud Enterprise. It connects targeted patients with PrudentRx representatives in aid of efforts to coerce patients into participating in the PrudentRx Copay Program. CVS Specialty Pharmacy transmits prescription drug claim information, including the artificially inflated copays set by PrudentRx and Caremark, to patient copay assistance programs; collects those inflated copays; and transmits them via the wires to be apportioned between PrudentRx, Caremark, and participating health plans.

176. Defendants may want to claim that they have not conducted or participated in the conduct of the PrudentRx Copay Assistance Fraud Enterprise because health plans, and not them, are responsible for the design and implementation of the Program. But that is not true. Caremark, CVS Specialty Pharmacy, and PrudentRx tell participating health plans what to do, not the other way around. PrudentRx tells prospective clients (i.e., health plan sponsors):

a. They *must* use Utah's state benchmark, and "cannot pick a different benchmark";

b. They must adopt Caremark's Advanced Control Specialty Formulary® for non-specialty medications and Caremark's Exclusive Specialty or Enhanced Exclusive Specialty formularies for specialty medications;

c. They must restrict the pharmacies at which targeted patients can fill specialty prescriptions, even if they otherwise allow patients to choose their pharmacy;

d. They must adopt Caremark's "True Accumulation" product;

e. They "must have or be willing to make . . . specialty drugs included in a covered class listed within the PrudentRx program drug list set at a 30 percent coinsurance"; and

f. They "must allow PrudentRx to send letters to targeted members."

177. PrudentRx, Caremark, and CVS Specialty Pharmacy conduct and participate in the conduct of the affairs of the PrudentRx Copay Assistance Fraud Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1) and 1961(5). This pattern includes hundreds, if not thousands, of instances of mail fraud in violation of 18 U.S.C. § 1341; hundreds, if not thousands, of instances of wire fraud in violation of 18 U.S.C. § 1343; and travel in interstate and foreign commerce in aid of a racketeering enterprise in violation of 18 U.S.C. § 1952, as described above.

178. The PrudentRx Copay Assistance Fraud Enterprise engages in and affects interstate commerce because, *inter alia*, it alters and affects the means by which health insurance plans sold in interstate commerce; exploits patient copay assistance programs that provide aid to patients in all 50 states; and alters targeted patients' cost of specialty medications shipped by CVS Specialty Pharmacy in interstate commerce.

179. The scheme devised by PrudentRx, Caremark, and CVS Specialty Pharmacy and operationalized through the PrudentRx Copay Assistance Fraud Enterprise amounts to a common course of conduct intended to (a) deceive patient copay assistance programs into disbursing excessive patient copay assistance, often for targeted patients who (by virtue of being subject to the PrudentRx Copay Program) were not eligible to receive those funds; then (b) divert patient copay assistance to benefit their health plans clients rather than patients; such that (c) targeted patients are deprived of the ability to offset some of their healthcare costs with patient copay assistance funds; and, as a result, (d) force patients to bear additional healthcare costs.

180. All of PrudentRx, Caremark, and CVS Specialty Pharmacy's racketeering activity is related, has similar purposes, involves the same or similar participants and methods of commission, and has similar results affecting similar victims, including Ms. Gluesing.

181. The pattern of racketeering activity alleged herein and the PrudentRx Copay Assistance Fraud Enterprise are separate and distinct from each other. Defendants engage in the pattern of racketeering activity alleged herein for the purpose of conducting the affairs of the PrudentRx Copay Assistance Fraud Enterprise.

182. As a result of Defendants' fraudulent activities, targeted patients like Ms. Gluesing incur healthcare expenses that they would not have to incur but for the PrudentRx Copay Assistance Fraud Enterprise, resulting in increased healthcare costs for Ms. Gluesing and all members of the Class.

183. Ms. Gluesing and others similarly situated have suffered, and continue to suffer, injury by reason of PrudentRx, Caremark, and CVS Specialty Pharmacy's fraudulent scheme and the success of the PrudentRx Copay Assistance Fraud Enterprise. Ms. Gluesing and other members of the Class have paid, collectively, hundreds of millions if not billions more in healthcare expenses

than they would have in the absence of the fraudulent course of conduct underlying the PrudentRx Copay Assistance Fraud Enterprise.

184. Defendants' racketeering activity is the direct and proximate cause of Ms. Gluesing's and the Class's injuries.

185. Ms. Gluesing's injuries are caused by PrudentRx, Caremark, and CVS Specialty Pharmacy's racketeering activity. By conducting the PrudentRx Copay Assistance Fraud Enterprise through a pattern of racketeering activity, Defendants directly cause patients to pay more for their healthcare needs. But for their unlawful conduct, targeted patients like Ms. Gluesing and members of the Class would be able to apply patient copay assistance funds to their deductible and annual cost-sharing limits, thus avoiding excess health care expenses.

186. Ms. Gluesing's injuries are directly caused by PrudentRx, Caremark, and CVS Specialty Pharmacy's racketeering activity. The PrudentRx Copay Assistance Fraud Enterprise causes two categories of harm: (i) harm to patient copay assistance programs in the form of excessive disbursements from the programs; and (ii) harm to patients that are deprived of the opportunity to avail themselves of the patient copay assistance programs' funding and thus forced to incur additional healthcare expenses.

187. This second category of harm is experienced directly by targeted patients like Ms. Gluesing and members of the Class, and there is no other individual or entity more directly harmed. Therefore, there is no other plaintiff or Class of plaintiffs better situated to seek a remedy for the economic harms of PrudentRx, Caremark, and CVS Specialty Pharmacy's fraudulent scheme.

188. By virtue of these violations of 18 U.S.C. § 1962(c), and pursuant to 18 U.S.C. § 1964(c), PrudentRx LLC, and Caremark RX LLC are jointly and severally liable to Ms. Gluesing

and the Class for three times the damages sustained, plus the cost of this suit, including reasonable attorneys' fees.

189. This cause of action is not dependent upon, or subsidiary to, Count I, in that Defendants' conduct violates RICO regardless of whether their conduct is also in violation of ERISA.

VIII. DEMAND FOR JUDGMENT

WHEREFORE, Sheila Gluesing, on behalf of herself and the Class, respectfully requests that the Court:

A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare Ms. Gluesing as representative of the Class;

B. Enter a judgment of joint and several liability against Defendants in favor of Ms. Gluesing and the Class;

C. Permanently enjoin Defendants from operating the PrudentRx Copay Program;

D. Award the Class treble damages in an amount to be determined at trial, plus interest in accordance with the law; and

E. Award such further and additional relief as is necessary to correct for the effects of Defendants' unlawful conduct, as the Court may deem just and proper under the circumstances.

IX. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Sheila Gluesing, on behalf of herself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: December 26, 2024

Respectfully Submitted,

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