Employers Beware:

Understanding the Costs and Liability Risks of Health Insurance Copay Accumulator Programs

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1 Introduction

Kristen Catton is a part-time nurse case manager from Columbus, Ohio, with multiple sclerosis.¹ Ms. Catton's condition is well-managed on her current medication: She can walk comfortably, see clearly, and work. Previous treatments failed to control her physical symptoms or to prevent repeated flare-ups.² In May 2018, Ms. Catton was shocked to learn that her employer-sponsored health plan required her to pay \$3,600 per month for her medication until she met her family health plan's \$8,800 annual pharmacy deductible.³ Up to that point, she had received copay assistance from the manufacturer of the medication. Copay assistance, as used herein, refers to drug maker-funded discount cards provided to patients to help them cover the cost of their prescription copayments or coinsurance. Copay assistance allows an individual who may not otherwise be able to afford a particular medication to pay little to nothing for the copay⁴ while also contributing toward the plan's annual deductible or annual limitation on cost sharing (i.e., maximum out-of-pocket limit).

This year, Ms. Catton's health plan implemented a new policy, referred to as a "copay accumulator" program, in which the plan stopped counting manufacturer copay assistance towards toward her deductible. As a result, once she reached the drug maker's cap on copay assistance,⁵ she was responsible for the monthly copays as well as the

Copay Accumulator
Programs =
plans stop counting
manufacturer copay assistance
towards patients' deductible.

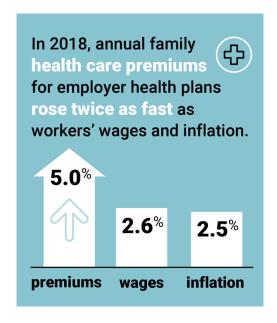
entire deductible. Whereas, in the past, manufacturer copay assistance allowed her to meet her deductible amounts sooner, it now just delayed her out-of-pocket expenses, allowing the insurer to collect the copay assistance intended to aid Ms. Catton in addition to the full deductible from Ms. Catton—double-dipping, in essence.⁶ Unable to afford the monthly copays, Ms. Catton is considering rationing her medication rather than switching to the alternative treatments that previously failed to control her condition.

Employers have a vested interest in the health and wellbeing of their employees; healthy employees tend to be more productive and have lower rates of absenteeism.⁷ As such, many employers offer comprehensive health insurance benefits to their employees in efforts to maintain a healthy workforce. Yet, employers and health insurers alike are faced with the difficult challenge of controlling plan costs in a country that spends more on health care than any other country in the world.⁸ As a result, many employers are looking to reduce the costs associated with health insurance in various ways, including by adopting copay accumulator programs. However, such programs carry a risk of liability and could increase costs for both employers and employees rather than provide savings. This paper presents an overview of copay accumulator programs, the legal risks and economic impact of such programs, and recommendations to employers for best practices when selecting health benefits.



2 The Issue

In 2018, annual family premiums for large employer-sponsored health plans rose five percent, averaging approximately \$19,600.9 While employees contributed approximately \$5,500 toward the average cost of coverage, employers paid the remaining \$14,100.10 These increases outpaced the rise in workers' wages (2.6 percent) and inflation (2.5 percent).11 In efforts to control costs, many employers now offer high deductible health plans ("HDHPs") to their employees. According to a recent report, 70 percent of large employers offer at least one HDHP,12 and a survey from the National Business Group on Health found that 39 percent of large employers offer only HDHPs as opposed to a combination of HDHPs and traditional health plans.13 HDHPs do not provide benefits for the plan year until the plan enrollee has met the minimum deductible under law.14



HDHPs require a minimum deductible of \$1,350 for self-only plans and \$2,700 for family plans; however, the average deductible in 2018 is \$2,166 for self-only coverage and \$4,331 for family coverage, according to a report from Benefitfocus. ¹⁵ Moreover, federal regulations permit insurers to offer HDHPs with deductibles as high as \$6,650 for individual plans and \$13,300 for family plans. ¹⁶

Nearly half of adults

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HDHPs are attractive to employees as well because such plans offer lower monthly premiums. A survey from the National Center for Health Statistics found that 43.4 percent of adults with employment-based coverage enrolled in an HDHP.¹⁷ Yet, HDHPs can serve as a barrier to treatment for employees who take prescription medications: High deductibles combined with high copays or coinsurance can be cost prohibitive for employees who require expen-

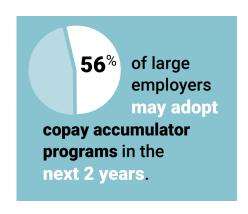
sive medications.¹⁸ For example, a 2016 study found that employees enrolled in HDHPs are more likely to have trouble paying their medical bills and are more likely to forego or delay medical care due to high out-of-pocket costs than employees in a traditional plan.¹⁹

Historically, privately-insured individuals who cannot afford their copays, including those enrolled in employer-sponsored plans, have often been able to obtain a significant but finite amount of aid each year from brand-name drug manufacturers' copay assistance programs.²⁰ In 2016, individuals enrolled in



commercial insurance plans used some form of copay assistance to cover the cost of brand prescriptions 20 percent of the time.²¹ Coupon cards are intended to count toward patients' copays or coinsurance as well as their deductibles.²² In some instances, individuals have received tens of thousands of dollars in assistance.²³ These programs have been especially helpful for individuals enrolled in HDHPs in which individuals are required to pay significantly higher out-of-pocket costs in the first few months of enrollment until deductibles are reached.

Yet, copay accumulator programs are becoming more and more common in employer-sponsored plans. According to a National Business Group on Health survey of 140 multistate employers with at least 5,000 employees, 17 percent of respondents reported that they have already adopted a copay accumulator program, and 56 percent say they are considering putting such a program in place for 2019 or 2020.²⁴ Under such programs, once the copay assistance runs out, the individual is again faced with an inability to afford his or her medication.



Some argue that copay accumulator programs are intended to "encourage" patients to select or switch to lower-cost alternative treatments.²⁵ However, such programs may be viewed more accurately as a punitive measure that forces patients to switch or stop taking their treatment because they cannot afford their high copays or coinsurance once assistance is exhausted. Moreover, in many instances, alternative treatments are not available for many individuals who depend on copay assistance.²⁶ According to a recent study, over 50 percent of the medications for which copay assistance is available have no generic substitute at all or only had another therapeutic equivalent, but similarly priced, brand drug.²⁷ As such, plan enrollees who require such treatments may be unable to switch to a less expensive alternative. In particular, copay accumulator programs negatively affect individuals whose conditions are frequently treated by drugs in higher-cost tiers, such as rheumatoid arthritis, hemophilia, cancer, HIV, hepatitis C, and multiple sclerosis, for example.²⁸

Other insurer names for copay accumulator programs include:

- Coupon Adjustment:
 Benefit Plan
 Protection Program
- Out of Pocket
 Protection Program
- Specialty Copay Card Program
- Copay Card True Program Accumulation

Furthermore, copay accumulator programs may come as a surprise to most plan enrollees given the lack of notice and poor transparency of such programs. The names used by major insurance companies and pharmacy benefit managers ("PBMs") for these programs (e.g., Coupon Adjustment: Benefit Plan Protection Program, Out of Pocket Protection Program, and Specialty Copay Card Program) suggest that copay accumulator programs provide a benefit to enrollees rather than to the health plan.²⁹ Other plans have made it difficult to locate or understand the accumulator language in the plan documents, using incomprehensible terminology, and others still have imple-



mented programs without providing any written notice to plan enrollees.³⁰ As a result, many individuals are ill-prepared to afford their copays or coinsurance once assistance runs out. Moreover, while HDHPs are generally associated with lower insurance premiums, HDHPs with copay accumulator programs mask the true burden of the deductibles on plan enrollees without providing an associated discount in premium payments.

Finally, employers must be mindful that copay accumulator programs can impact the health and wellbeing of their employees, and they can also pose legal risks and increase costs for the employer.

Copay accumulator programs can impact health and wellbeing of employees as well as pose legal risks and increase costs for employers.



3 Federal Legal Doctrines Applicable to Copay Accumulator Programs

Employers considering adopting copay accumulator programs should be aware that, in doing so, they increase their risk for liability. Such programs can potentially violate federal laws, including the Patient Protection and Affordable Care Act ("ACA"), the Federal Trade Commission Act ("FTCA"), and the Employee Retirement Income Security Act ("ERISA"), and their implementing regulations.

A. The Patient Protection and Affordable Care Act

Employer-sponsored plans may violate several provisions of the ACA and its implementing regulations if they include copay accumulator programs that result in plan enrollees making payments in excess of annual maximum out-of-pocket limits, single out specific health conditions, or fail to adequately disclose the terms of such programs. These violations may result in hefty fines for employers.

1) Cost-Sharing Limitations

Copay accumulator programs could potentially violate the ACA's annual limitation on cost-sharing requirements if the sum of the amount that the manufacturer contributes in copay assistance and the amount the plan enrollee pays in copays or coinsurance exceeds the annual limit on out-of-pocket costs. All non-grandfathered health plans, including employer-sponsored plans, must ensure that any annual cost-sharing imposed under the plan does not exceed the limitations set out by law.³¹ The term "cost-sharing" includes "any expenditure required by or on behalf of an enrollee," including deductibles, coinsurance, copays, or similar charges required of plan enrollees with respect to essential health benefits ("EHBs") covered by the plan.³² EHBs are ten categories of items and services defined by the ACA that non-grandfathered individual and small group health plans must cover.³³ One of those categories is prescription drugs.³⁴ While large group health plans are not required to offer EHBs, if they choose to offer such benefits, then the ACA annual limit on cost-sharing applies to those benefits.³⁵

In 2018, the annual cost-sharing limit is \$7,350 for self-only plans and \$14,300 for family plans.³⁶ The 2019 limits will increase to \$7,900 and \$15,800 respectively.³⁷ These annual limitations on cost-sharing are sometimes referred to as maximum out-of-pocket ("MOOP") limits.³⁸ The self-only MOOP applies to each individual, regardless of





whether the individual is enrolled in a self-only plan or in a family plan.³⁹ Only out-of-pocket costs spent on EHBs count toward the calculation of the MOOP limit.⁴⁰

When a drug manufacturer provides copay assistance for a medication to an individual enrolled in a plan that offers EHBs, it is making an out-of-pocket payment for an EHB on behalf of the plan enrollee to the health plan. Given that the regulatory definition of cost-sharing includes expenditures made "by or on behalf of" an enrollee,⁴¹ manufacturers' payments should count toward the annual MOOP limit. Yet, when a plan implements an accumulator program, the plan receives the amount offset by the copay card from the drug manufacturer, which was intended to assist the plan enrollee in meeting his or her copay obligations. The plan then also receives the full copay from the plan enrollee, thereby exceeding the deductible.⁴² The amount contributed through copay assistance, in addition to the amount contributed by the plan enrollee, could exceed the MOOP limit. For example, if a plan enrollee's deductible is \$6,000, the drug manufacturer provides the enrollee with \$6,000 in copay assistance, and the plan enrollee also pays an additional \$6,000 out-of-pocket. The health plan, consequently, receives a total of \$12,000, which exceeds the \$7,350 individual MOOP limit by \$4,650. Therefore, in some instances, copay accumulator programs likely violate the ACA's cost-sharing limitations.

2) Nondiscrimination Provision

Employer-sponsored plans that implement copay accumulator programs that only apply to specific health conditions may violate the ACA's nondiscrimination provision. The ACA and its implementing regulations prohibit covered entities from providing and administering health insurance in a discriminatory manner based on disability.⁴³ Prohibited forms of discrimination include limiting claim coverage, imposing additional cost sharing, implementing benefit designs, or requiring any other limitations or restrictions on coverage that discriminate on the basis of disability.⁴⁴

Covered entities includes those that operate a health program or activity, any part of which receives federal financial assistance from the U.S. Department of Health and Human Services ("HHS").⁴⁵ Federal financial assistance is defined broadly and includes grants, loans, subsidies, insurance contracts, and other types of assistance.⁴⁶ Therefore, any employer receiving any financial support from HHS would be subject to the ACA's nondiscrimination provision.

In determining whether a health plan discriminates on the basis of disability, the ACA applies Section 504 of the Rehabilitation Act of 1973 ("Rehabilitation Act").⁴⁷ The Rehabilitation Act defines "disability" as a physical or mental impairment that substantially limits one or more major life activities of an individual.⁴⁸ Major life activities include "caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, and working."⁴⁹ Certain major bodily functions are also considered major life activities, including "functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions."⁵⁰ Disability is determined on a case-by-case basis rather than based on a list of recognized medical conditions.⁵¹



Some plans explicitly apply copay accumulator programs to certain conditions. For example, a health plan offered by a nationwide home-improvement based retailer states that its copay accumulator program only applies to plan enrollees who receive treatment for cancer, HIV, and multiple sclerosis, among other specifically enumerated conditions.⁵² Numerous courts have determined that individuals with such conditions have met the definition of disability under the Americans with Disabilities Act Amendments Act of 2008 ("ADA"). ADA cases are instructive for an ACA claim given that both the ACA and the ADA have adopted the Rehabilitation Act's definition of disability. In Alston v. Park Pleasant, the U.S. Court of Appeals for the Third Circuit noted that, although disability is determined on a case-by-case basis under the ADA, "cancer can - and generally will - be a qualifying disability...."53 In Oehmke v. Medtronic, the U.S. Court of Appeals for the Eighth Circuit held that the plaintiff's Hodgkin's lymphoma, a form of blood cancer, was an impairment that qualified as a disability because cancer treatment suppressed the plaintiff's immune system, and "the functioning of one's immune system is a major life activity."54 Likewise, in the landmark case, Bragdon v. Abbott, the Supreme Court found that HIV was a disability because it substantially limits major life activities, including reproduction.55 In Cyr v. United Parcel Services, Inc., the U.S. District Court for the District of Massachusetts found that a plaintiff's multiple sclerosis was a disability because when she experienced flare ups, she had difficulty walking and balancing, was unable to climb stairs, had to urinate as often as every 30 minutes, had trouble lifting her daughter, and did not leave her home.56

If an employer receiving federal financial assistance implements a health plan with a copay accumulator program that singles out specific conditions, such benefit design may be considered discriminatory on the basis of disability under the ACA.⁵⁷ Such programs impose additional cost-sharing requirements on individuals with such disabilities. An individual with cancer who is enrolled in the home improvement retailer's plan, for instance, would be required to pay 100 percent of the plan's deductible out of pocket, whereas an individual receiving copay assistance for a condition not included in the plan's copay accumulator program would only need to pay the deductible minus the amount received in copay assistance. Therefore, the nondiscrimination provision of the ACA may be violated.

3) Discrimination Based on Health Status

Copay accumulator programs may violate the federal protection against discrimination on the basis of health status if the programs only apply to specific health conditions. The Public Health Services Act ("PHSA"), as added by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and amended by the ACA, prohibits discrimination against plan enrollees based on health status.⁵⁸ The law states that group health plans, including employer-sponsored plans, may not establish "rules for eligibility" based on any of the following "health status-related factors in relation to the individual or a dependent of the individual: (1) health status; (2) medical condition (including both physical and mental illnesses)."⁵⁹ "Rules for eligibility" include rules relating to "benefits (including rules relating to covered benefits, benefit restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles)."⁶⁰

Some copay accumulator programs only apply to a list of medications that treat specific conditions, such as HIV, hepatitis C, multiple sclerosis, and psoriasis.⁶¹ Therefore, these plans arguably impose different



cost-sharing rules based on medical conditions, and individuals with listed conditions may have to pay more in copayments than individuals with conditions not specified in the copay accumulator program language. If individuals in the latter group receive copay assistance, they can apply such assistance to their deductibles, thereby paying less out of pocket than similarly situated enrollees. Therefore, such copay accumulator programs may discriminate on the basis of health status in violation of the ACA and other federal laws.

4) Preexisting Condition Protections

Copay accumulator programs may violate the ACA's preexisting condition protections if they only apply to specific health conditions and discourage individuals from enrolling in a health plan. The ACA prohibits health insurance issuers and group health plans, including, with limited exceptions, employer-sponsored plans,⁶² from imposing any preexisting condition exclusion with respect to plan coverage.⁶³ The PHSA, as added by the ACA, defines a preexisting condition exclusion as "a limitation or exclusion of benefits (including denial of coverage) based on the fact that the condition was present before the date of enrollment for such coverage."⁶⁴ Therefore, the presence of a condition on the date of enrollment must be the reason for a limitation.⁶⁵ The preexisting condition exclusion provision "establishes a general prohibition on any plan benefit design that serves to discourage enrollment for individuals with high cost conditions."⁶⁶ Similarly, the ACA's implementing regulation prohibits insurers from "employing marketing or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs."⁶⁷

A recent investigation of Florida health plans illustrates how insurers may use their benefit designs to intentionally deter individuals from enrolling in a health plan based on a preexisting condition. In 2014, the AIDS Institute and the National Health Law Program ("NHeLP") filed a complaint with HHS against four Florida-based health insurers for actively deterring individuals with HIV and AIDS from enrolling in the insurers' health plans based on the individuals' preexisting conditions.⁶⁸ The health plans placed most, if not all, antiretroviral therapies for the treatment of HIV in the highest formulary tier, making copays cost prohibitive for many plan enrollees.⁶⁹ As such, the insurers had structured their formularies in a manner to discourage individuals with HIV and AIDS from selecting their plans.⁷⁰ In response to the complaint, the Florida Office of Insurance Regulation ("FLOIR") issued a memo requiring health insurers to ensure that their plans' benefit designs do not unfairly discriminate.⁷¹ FLOIR also instituted its own investigation into the four insurers, resulting in the insurers agreeing to reduce cost-sharing for HIV medications and a \$500,000 judgement against one of the insurers for failing to cooperate with investigators.⁷²

Analogous to a plan that placed all medications to treat a particular condition on the highest formulary tier, some employers' health plans include copay accumulator programs that apply only to specific health conditions, such as HIV, hepatitis C, cancer, psoriasis, and cystic fibrosis.⁷³ In fact, accumulator programs may be a more significant deterrent to employees with these health conditions because the programs limit manufacturer assistance to help these patients afford their copay obligations regardless of formulary tier. Individuals who engage in comparative research before enrolling in a plan may identify copay accumulator language that singles them out and be deterred from enrolling in the plan because



all applicable treatments would be inadequately covered. Instead, employees with such conditions may opt to enroll in exchange plans or other non-employer-sponsored plans that do not contain such a program. Therefore, such a copay accumulator program could effectively serve as a preexisting condition exclusion.

5) Summary of Benefits and Coverage and Plain Language Requirements

Copay accumulator programs that are not adequately disclosed and are difficult for average consumers to understand may violate the ACA's summary of benefits and coverage ("SBC") and plain language requirements. The ACA requires group health plans, including employer-sponsored plans, to provide a brief, written SBC to plan applicants.⁷⁴ SBCs must also contain a description of the coverage, including the cost-sharing provisions of the coverage, such as copay obligations and any exceptions, reductions, and limitations of the coverage.⁷⁵ Specifically, SBCs must list when cost-sharing for a covered in-network service does not apply to the annual MOOP limit.⁷⁶

Copay accumulator programs are exceptions, limitations, or reductions of coverage given that such programs exclude copay assistance from counting toward deductibles and MOOP limits. Therefore, accumulator programs arguably must be disclosed in SBCs. However, many plans do not disclose such programs in SBCs, and instead, either disclose such information in the full plan description or do not disclose such information at all.⁷⁷ This lack of disclosure in SBCs contributes to the overall low awareness of copay accumulator programs and their impact on plan enrollees. Therefore, plans that fail to disclose copay accumulator programs in their SBCs may be in violation of the ACA's SBC requirements.

6) Complaints under the ACA

Employees may be able to bring a private claim if a health plan's accumulator program violates the ACA's nondiscrimination provision.⁷⁸ In such case, compensatory damages may be available.⁷⁹ Also, to the extent that an employer designs benefits in violation of an ACA provision that is incorporated into ERISA, the plan enrollee would have a right of action under ERISA, as discussed in more detail below.

Moreover, employers should be forewarned that while there is no private cause of action to bring a lawsuit under the other provisions of the ACA discussed herein, consumers may file a complaint with their state insurance department, HHS's Office for Civil Rights, HHS's Center for Consumer Information and Insurance Oversight, or the U.S. Department of Labor, depending on the type of health plan they have, if

they believe that their employer's health plan violates the statute.⁸⁰ Additionally, employers who violate the provisions of the ACA discussed herein may be responsible for a \$100 excise tax per day per individual to whom the violation relates.⁸¹ The maximum excise tax for a single employer is \$500,000 per year.⁸²

Copay accumulator plans may violate state and federal consumer protection laws, exposing employers to lawsuits and up to \$500,000 in violations.



B. Federal Trade Commission Act

Copay accumulator programs may violate the FTCA because they may be unfair and deceptive. The Federal Trade Commission ("FTC") has the authority to prevent businesses, including insurers and employers, from using unfair or deceptive acts or practices affecting commerce under Section 5 of the FTCA.⁸³ Violations of the FTCA could result in civil penalties for employers.

1) An Unfair Act or Practice

An unfair act or practice is one that "(1) causes or is likely to cause substantial injury to consumers; (2) cannot be reasonably avoided by consumers; and (3) is not outweighed by countervailing benefits to consumers or to competition."84

a) Substantial Injury

Copay accumulator programs are likely to cause substantial injury to consumers because such individuals are effectively double-billed.⁸⁵ In its policy statement on unfairness, the FTC has stated that "in most cases, a substantial injury involves monetary harm, as when sellers coerce consumers into purchasing unwanted goods or services.... Unwarranted health and safety risks may also support a finding of unfairness."⁸⁶ The injury may be considered substantial if it causes a small amount of harm to a large number of people.⁸⁷

With a copay accumulator program, the consumer spends a prolonged amount of time in the deductible phase while the plan collects payments from the patient twice—first in the form of manufacturer copay assistance and second in the form of out-of-pocket costs, thereby "double-dipping."88 These contributions may be substantial given that some copay assistance maximums are in the tens of thousands of dollars.89 Consumers who are prescribed more costly medications may not be able to afford their treatments.90 For example, according to a recent study, 10 percent of individuals with cancer abandoned their prescriptions if their treatment cost \$10, 32 percent abandoned their treatment if it cost between \$100 and \$500, and nearly 50 percent abandoned their treatment if the medication cost \$2,000.91 As such, these individuals may experience monetary harm.

Additionally, not only are insurers effectively receiving double payment to the detriment of consumers, but there also may be an unwarranted health and safety risk. Specifically, individuals who have not met their deductible and cannot afford their medication without copay assistance may ration, stop taking, or switch treatments and experience adverse events.⁹²

Moreover, consumers may be coerced into purchasing unwanted plans when the impacts of accumulator programs are unclear to the consumers at the time of purchase. As previously discussed, such programs fail to adequately convey that the consumer does not receive the value of manufacturer's coupon, as intended. Programs also use language that is difficult to understand and terms that misleadingly imply that the consumer will receive a benefit. Therefore, without fully comprehending the effect of accumulator programs, consumers may purchase an unwanted health plan.



b) Unable to Avoid Injury

Consumers who enroll in plans with copay accumulator programs are not reasonably able to avoid injury. A consumer cannot reasonably avoid injury from an act or practice if "it interferes with his or her ability to effectively make decisions." The FTC has noted that consumers must be able to maintain free and informed consumer choice. The FTC explained that "consumers may act to avoid injury before it occurs if they have reason to anticipate the impending harm and the means to avoid it."

Here, a consumer may not be able to make an informed decision because the plan has essentially withheld material information on cost-sharing responsibilities until after the consumer has committed to purchase the health plan. Some health plans have implemented copay accumulator programs with language stating that the plan "reserves the right to not apply manufacturer or provider cost-sharing assistance program payments (e.g., manufacturer cost-sharing assistance, manufacturer discount plans, and/or manufacturer coupons)" to the plan deductible or MOOP. Other plans have adopted copay accumulator programs without disclosing the existence of such programs to plan enrollees. For example, according to the AIDS Institute, a Florida insurer has adopted a copay accumulator program without describing it anywhere in the plan's written documentation. In both instances, it is unclear to the plan enrollee whether he or she will be permitted to use copay assistance toward the deductible. Without that information available, the enrollee cannot avoid injury.

Likewise, a consumer may not be able to make an informed decision because, oftentimes, the language used to describe copay accumulator programs is misleading. Plans refer to such programs as "out-of-pocket protection" or "benefit plan protection." These descriptions imply that the plan is conferring a benefit onto the plan enrollee, and then use convoluted language that the average consumer cannot comprehend. 99 Therefore, due to this lack of transparency, the average consumer is unlikely to be able to reasonably avoid the injury that results from copay accumulator programs.

c) Not Outweighed by Countervailing Benefits to Consumers or to Competition

The substantial injury likely to be caused to consumers by copay accumulator programs is not likely outweighed by countervailing benefits to consumers or to competition. Instead, they result in consumers paying more for their prescriptions than they would without such programs. The health plan collects twice the amount owed by the consumer as a deductible without any counterbalancing discount in premium payments that would be expected from an increase in deductible requirements. Moreover, while some health insurers argue that copay accumulator programs are beneficial because they steer consumers toward less expensive medications, studies have shown that the majority of medications for which copay assistance is available do not have lower cost generic alternatives. Instead, because copayment accumulator programs are often misleading or not properly disclosed, consumers who would otherwise have selected a competing health plan without a copay accumulator program do not do so. Instead

Additionally, copay accumulators are unlikely to provide any competitive benefits to the employer. For example, when drug makers offer rebates, PBMs and insurers often retain profits from such



rebates rather than passing them on to employers and consumers. ¹⁰³ The same is likely the case for any potential profits resulting from copay accumulator programs. Therefore, employers are unlikely to receive cost-savings from copay accumulator programs. As a result, the substantial injury likely to be caused to consumers by copay accumulator programs is not likely outweighed by countervailing benefits to consumers or to competition.

2) Deceptive Act or Practice

Copay accumulator programs may also be considered deceptive under the FTCA. An act is deceptive if it is (1) a representation, omission, or practice that misleads or is likely to mislead the consumer; (2) a consumer's interpretation of the representation, omission, or practice is considered reasonable under the circumstances; and (3) the misleading representation, omission, or practice is material.¹⁰⁴ Intent to deceive is not a required element.¹⁰⁵

a) Representation, Omission, or Practice that Misleads or Is Likely to Mislead

Copay accumulator programs often include misleading language. Under the first prong of the test, an act or practice may be deceptive if it is likely to mislead consumers.¹⁰⁶ Deception is not limited to situations in which a consumer has actually been misled. The representation may be an express or implied claim or promise and may be in writing or oral.¹⁰⁷ Additionally, an omission of information may be considered deceptive if disclosure of the omitted information is necessary to prevent a consumer from being misled.¹⁰⁸

Plans have used misleading language to describe their copay accumulator programs. For example, an American multinational food, snack, and beverage corporation's health plan used the following language to describe its accumulator program:

The amount paid by a Co-Pay Assist Program is not an amount that is paid by you and you are not required to repay that amount. For this reason, such amounts are not credited to your deductible or out of pocket maximum. However, the actual amount that you do pay for the medication (if any) after the Co-Pay Assist Program payment has been applied to your cost, is credited to your deductible and out of maximum, because like any other copay, this amount is actually paid by you. 109

The average health plan enrollee is not likely to be able to understand what this language is trying to convey because it is neither clear nor to the point. As such, it is likely to mislead.

Other plans use terminology, such as "Pharmacy Coupon Adjustment Changes,"¹¹⁰ the "Copay Card True Program Accumulation,"¹¹¹ and the "Out of Pocket Protection Program."¹¹² These terms are misleading because they do not convey that plan enrollees will be denied financial support. Instead,



by using such words as "true" and "protection," they sound as though they provide plan enrollees with a benefit. Moreover, they distort the plain meaning of the word "coupon." The common notion of a coupon is that it entitles the holder of the coupon to a discount for a particular product.¹¹³ However, with copay accumulator programs, the discount or value is conveyed to the health plan instead.

Some health plans have not disclosed that they have implemented copay accumulator programs in any of the written plan documentation.¹¹⁴ Such an omission is likely to mislead individuals into believing that copay assistance will count toward their deductible when, in fact, it does not. This omission can be especially misleading because it removes the practice of counting copay assistance toward deductibles upon which consumers may have relied for years. Moreover, as discussed below, ERISA likely requires the disclosure of copay accumulator programs, and so the omission violates a statutory duty. In light of such a statutory duty, it is highly plausible that individuals will be misled by its omission. Therefore, such programs are likely to mislead consumers.

b) Consumer's Interpretation Is Considered Reasonable

A consumer's failure to understand the terms of a misleading copay accumulator program would be reasonable. Under the second prong of the test, the act or practice is considered from the perspective of the "reasonable consumer" (i.e., how reasonable members of the target audience would interpret the representation or omission). ¹¹⁵ If a representation "conveys two or more meanings to reasonable consumers and one meaning is misleading, the representation may be deceptive under the circumstances, even if the consumer's interpretation is not shared by a majority of the consumers in the relevant class, so long as a significant minority of such consumers is misled. ^{"116} Additionally, a reasonable consumer may not anticipate the impact of an accumulator program if he or she has relied upon the health plan's prior allowance of assistance to count toward the deductible for years.

When a copay accumulator program is not disclosed at all, reasonable persons would not know that such a program exists. Additionally, language implying that copay accumulator programs convey a benefit onto the consumer, such as "out-of-pocket protection" or "benefit plan protection," followed by convoluted language describing copay accumulator programs, conveys two different meanings. Finally, a reasonable consumer would not be able to interpret a plan that fails to use plain language to describe its copay accumulator program. Therefore, a reasonable plan enrollee may be misled by copay accumulator programs.

c) The Misleading Representation, Omission, or Practice is Material

Copay accumulator programs are material to employees who require copay assistance. Under the third prong of the test, a representation, omission, or practice is considered material if it is likely to affect a consumer's decision to purchase or use a product or service. Information about benefits or restrictions on the availability or use of a product or service is material. Omissions are presumed to be material if the entity knew or should have known that consumers needed the omitted information to make an informed choice about the product or service.



Copay accumulator programs are material for individuals 1) who require expensive treatment, 2) who want to stay on their medication or for whom there is no less costly alternative available, and 3) who cannot afford their deductible without copay assistance. These programs have significant negative impacts on consumers who have historically been able to apply their copay assistance toward their deductible, and thereby been able to meet their deductibles sooner. Deductibles may be as high as \$7,350 for self-only HDHPs and \$14,300 for family HDHPs, and therefore, would have a material impact on the average consumer's health plan decision making. Consequently, if consumers who rely on copay assistance were adequately educated on the existence and implications of copay accumulator programs, they likely would not choose to enroll in health plans that include such programs. Therefore, copay accumulator programs are material terms within a health plan, and as such, may be considered deceptive under the FTCA.

3) Complaints under the FTCA

As with most ACA provisions, employers should be forewarned that, while there is no private cause of action to bring a lawsuit under the FTCA, consumers may file a complaint if they believe that their employer's health plan violates the statute. The FTC may then investigate complaints and take legal action against the employer or health plan. A party who violates the FTCA is liable for a civil penalty, and the FTC may seek consumer redress.

C. ERISA

Under ERISA, an employer acting as a plan administrator may breach its disclosure duties if it does not disclose to plan enrollees that it has adopted a copay accumulator program. Additionally, an employer acting in the capacity of a plan fiduciary may breach its duty not to mislead plan enrollees if the health plan's copay accumulator program includes material misrepresentations.

ERISA is a federal law that protects the interests of individuals enrolled in employer-sponsored health plans.¹²⁴ ERISA requires plan administrators to provide plan information to enrollees, establishes standards of conduct for fiduciaries, and sets forth enforcement provisions to ensure plan funds are protected and that enrollees receive their benefits.¹²⁵ In every employee benefit plan, there are certain individuals that act as fiduciaries on behalf of plan enrollees.¹²⁶ A fiduciary is someone who exercises control or authority over the plan management, assets, or administration.¹²⁷ For example, fiduciaries may include plan trustees or plan administrators.¹²⁸ Fiduciaries must act in the best interest of the plan enrollees for the exclusive purpose of providing benefits while also defraying reasonable expenses of the plan.¹²⁹

1) Breach of Obligation to Disclose

A plan administrator could breach its obligation to disclose if he or she does not properly inform plan participants of the existence of a copay accumulator program. Administrators have a duty to make certain affirmative disclosures to plan beneficiaries.¹³⁰ For example, they must provide plan enrollees with a



summary plan description.¹³¹ The summary plan description must include information on any cost-sharing provisions, any limits on benefits under the plan, and the extent and circumstances under which medications are covered by the plan.¹³² Administrators also must provide plan enrollees with a Summary of Material Modifications ("SMM").¹³³ Material modifications in a group health plan include any modifications to the plan that an average plan participant would consider to be an important reduction in covered services or benefits.¹³⁴ Reductions in covered services or benefits include modifications that reduce existing benefits or narrow the circumstances under which benefits are paid.¹³⁵ Plan administrators must distribute SMMs to plan participants within 60 days after the material reduction was adopted.¹³⁶

Copay accumulator programs qualify as cost-sharing provisions because they impact the amount that plan enrollees must pay out of pocket to meet their annual deductible. Accumulator programs may also be considered limits on benefits because such programs place limitations on which types of payments (e.g., payments made by drug manufacturers as opposed to payments made by plan enrollees) will count toward the annual deductibles and MOOP limits. Finally, copay accumulator programs impact the extent and circumstances under which medications are covered by the plan because the programs explicitly prohibit assistance used to pay for medications' copayments from counting toward the deductible or the MOOP limit. Therefore, plan administrators have a duty to include information about copay accumulator programs in their summary plan descriptions.

Additionally, copay accumulator programs are material reductions because the average plan participant that receives copay assistance is significantly impacted by such a program. The participant may have to pay thousands of dollars more out of pocket until the annual deductible or MOOP limit is reached. Copay accumulator programs are reductions in covered benefits because they take away existing benefits. Without such programs, plan enrollees are permitted to apply copayment assistance from drug manufacturers toward their annual deductibles and MOOP limit. Copay accumulator programs also narrow the circumstances under which benefits are paid because, pursuant to such programs, plan enrollees must pay out-of-pocket costs, such as copays, for a longer duration until they meet their annual deductible. Therefore, if a plan adopts an accumulator program after the plan year has begun, then such program is a material reduction that must be disclosed in the SMM.¹³⁷

If a plan fails to disclose that it has adopted a copay accumulator program altogether, as was the case with a Florida insurer's plan,¹³⁸ then the plan administrator may breach ERISA's duty of disclosure.

2) Breach of Duty Not to Mislead

Courts have held that fiduciaries have a duty not to mislead enrollees about plan information.¹³⁹ A fiduciary breaches this duty if he or she makes a statement that would likely mislead a reasonable person in making an informed decision in pursuing benefits to which the person may be entitled.¹⁴⁰ Some courts have held that such misleading statements must be made deliberately (*i.e.*, knowingly or intentionally).¹⁴¹Some plan documents include copay accumulator language that is so poorly written that



it would be difficult to argue that the fiduciary was unaware of a copay accumulator program description's misleading nature. For instance, one employer's 2017 copay accumulator program states:

Specialty Medication Copay Card Benefit

The standard copayment for specialty drugs is \$75 for up to a 30-day supply. Effective January 1, 2017, you will no longer be given credit toward the accumulation of the annual out-of-pocket maximum for benefits that are paid by manufacturer assistance or copay cards for certain specialty medications. In order to accomplish this, the plan will set the copayment to match these assistance programs. These copayment levels may change from time to time to be consistent with the available programs. ¹⁴²

This description is misleading. First, the title introducing this material implies that the information describes a *beneficial* aspect of the plan, not an aspect that is adverse to the enrollee's interests. Furthermore, this provision is not drafted in plain language. The language is neither concise, nor likely understandable by many individuals.

Additionally, the language used in the American multinational food, snack, and beverage corporation's health plan, described above, is also not clearly written and likely not understandable by many plan participants.¹⁴⁴ As such, describing copayment accumulator programs in this way could mislead the average person in making an adequately informed decision when selecting a particular health plan. Therefore, a fiduciary that uses, or supervises and approves the use of, such language could potentially breach its duty not to mislead, thereby violating ERISA.

3) Remedies under ERISA

A plan enrollee may sue a plan administrator or other fiduciary for "appropriate equitable relief" for ERISA violations, including breaches of obligations to disclose and fiduciary duties. ¹⁴⁵ Equitable relief may include a declaration that the plan or disclosures are misleading and an injunction against enforcing the terms of a copay accumulator as written. Equitable relief could also include restitution to plan enrollees. ¹⁴⁶



4 State Legal Doctrines that Apply to Copay Accumulator Policies: Unfair and Deceptive Trade Practice Acts

As discussed in this section, it is substantially harder for employees to bring claims against their employers under state laws in light of the broad preemptive reach of ERISA. Nevertheless, health insurers may face investigations from state insurance commissioners and lawsuits if they implement copay accumulator programs that violate certain states' unfair and deceptive trade practice acts. These insurer investigations and lawsuits may impact employer-sponsored health plans.

A. Note on ERISA's Preemption Doctrine and Unfair and State Deceptive Trade Practice Acts

While employer-sponsored health plans containing copay accumulator programs may violate certain state laws, many of these state claims will be preempted by ERISA.¹⁴⁷ ERISA expressly supersedes state laws related to employee health benefit plans.¹⁴⁸ If the purpose of a lawsuit is to essentially recover benefits from an ERISA plan, then that lawsuit is preempted under ERISA.¹⁴⁹ As such, individuals cannot sue employers to recover ERISA plan benefits based on tort, contract, or other state common law theories.¹⁵⁰

ERISA preemption does not apply to state laws that regulate insurance.¹⁵¹ This exception is only applicable to fully-insured ERISA plans, and does not apply to self-insured ERISA plans.¹⁵² Fully-insured ERISA plans are those in which the employer purchases the health insurance policy from an insurance company that is liable for health care claims, whereas self-insured plans are those in which an employer is responsible for paying employees' and dependents' medical claims.¹⁵³

Similar to the FTCA, state unfair and deceptive trade practice acts are generally intended to protect consumers from predatory business practices.¹⁵⁴ Though such laws vary from state to state, every state has at least one consumer protection law that prohibits deceptive trade practices, such as false or misleading advertising and other fraudulent marketing practices.¹⁵⁵ Oftentimes, trade practice acts fall within the state's insurance code, and are, therefore, laws that regulate insurance.

Circuits are split as to whether ERISA preempts state trade practice acts. Some courts have held that such laws are preempted because they result in a lawsuit to recover benefits from an ERISA plan. Others, such as the U.S. Court of Appeals for the Ninth Circuit, have held that unfair and deceptive trade practices are not preempted because they create an "independent legal duty to refrain from engaging in unfair and deceptive business practices." 157



It is important to note that even in jurisdictions under which ERISA does not preempt state trade practice acts, only the health insurance company providing a fully-insured plan, and not the employer, can be sued for violations of such laws. Under ERISA, an employer that implements a self-funded health plan cannot be deemed "an insurance company" or as "engaged in the business of insurance." Nevertheless, in the case of copay accumulator policies, if an insurance commissioner finds that the health insurer has engaged in unfair and deceptive trade practices, such a determination will still have a trickledown effect on fully-insured employer-sponsored plans that have adopted accumulator programs, and such practices will still need to be changed.

B. State Unfair and Deceptive Trade Practice Acts

Copay accumulator programs may violate some states' unfair and deceptive trade practice laws if such programs include false or misleading information, collect fees above and beyond the amounts listed in the health plan, or result in discrimination. Likewise, some states' unfair competition laws may be violated if a company engaged in an "unlawful" practice. Therefore, if the company's health plan violates another law, such as the ACA, a plan enrollee may be able to bring a claim against the health insurer under the state law.

1) Washington State's Consumer Protection Act

Washington State law was analyzed in this section because the 9th Circuit has ruled that Washington State's Consumer Protection Act is not preempted by ERISA.¹⁵⁹

a) Unfair Competition and Practices

Under the Washington Consumer Protection Act, businesses are prohibited from engaging in "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." This state law is not preempted by ERISA. As the U.S. Court of Appeals for the Ninth Circuit explained in *Hansen v. Group Health Cooperative*, under ERISA, a state law is fully preempted if (1) the plaintiff could have brought the claim under ERISA; *AND* (2) there is no other independent legal duty that is implicated by the defendant's action. According to the Ninth Circuit, the Washington Consumer Protection Act creates "an independent duty to refrain from engaging in unfair and deceptive business practices." Therefore, if a business violates the Washington Consumer Protection Act, the second prong of the ERISA preemption doctrine is not met. 163

A violation of Washington's Consumer Protection Act occurs if the insurer committed (1) an unfair or deceptive act or practice, (2) occurring in trade or commerce, (3) affecting the public interest, and (4) injury with causation."¹⁶⁴

Unfair or Deceptive Act or Practice

An insurer commits an unfair or deceptive act or practice if it violates a separate Washington law pertaining to deceptive or unfair conduct or if it engages in conduct that has the capacity



to deceive, even unintentionally.¹⁶⁵ The "capacity-to-deceive" test is intended to deter deceptive conduct before injury occurs.¹⁶⁶ The Washington state legislature has deemed certain insurance laws to be unfair trade practices, including the statute against false information and advertising¹⁶⁷ and misrepresentation of policies.¹⁶⁸

Washington state law on false information and advertising states that a health insurer cannot publish or disseminate "false, deceptive or misleading representation or advertising in the conduct of the business of insurance." As previously explained, some health plans include misleading statements to describe their copay accumulator programs, and others have failed to disclose copay accumulator programs altogether. This results in higher out-of-pocket costs for plan enrollees and reductions in benefits paid. These types of omissions and misrepresentations are likely to mislead individuals into believing that copay assistance will apply to their deductibles when, in fact, it does not, especially if they have historically been able to apply their copay assistance toward their deductible. Therefore, these misrepresentations or omissions would constitute a violation of Washington state's false information and advertising law.

Similarly, Washington state law on misrepresentation of policies prohibits health insurers from making a "misrepresentation of the terms of any policy or the benefits or advantages promised thereby."¹⁷⁰ Insurers' use of descriptions that are difficult to interpret or disguise the punitive effect of copay accumulator programs are in violation of Washington state law prohibiting such conduct because they misrepresent the terms of the policy. Therefore, copay accumulator programs may constitute an unfair or deceptive act or practice.

Occurring in Trade or Commerce

Copay accumulator programs are part of health insurance plans, and therefore, occur in trade or commerce. Washington law broadly defines the terms "trade" and "commerce" to include the "sale of assets or services, and any commerce directly or indirectly affecting the people of the state of Washington."¹⁷¹ When an insurer sells a health plan to Washington residents, it is selling a service that directly affects people of the state. Therefore, health plans containing copay accumulator programs occur in trade or commerce.

Affecting the Public Interest

To violate the Washington State Consumer Protection Act, the deceptive or unfair trade practice must affect the public interest. Washington state's legislature has explicitly stated that the business of insurance affects the public interest. Therefore, given that a copay accumulator program is part of a health insurance plan, this element is met.

Injury and Causation

To violate the Washington State Consumer Protection Act, the deceptive or unfair trade practice must cause an injury to the plaintiff. Copay accumulators cause injury to plan enrollees because accumulator programs require enrollees to pay the full deductible amount



on top of any copay assistance they receive. If they cannot afford to do so, they may have to switch to a different, potentially less effective medication, which could result in adverse events or they could abandon their medication altogether if no alternative treatment is available. Therefore, copay accumulator programs may cause injury to plan enrollees and, as such, may violate Washington State's Consumer Protection Act.

b) Prescription Benefit Regulations

If insurers institute copay accumulator programs, they may violate Washington state insurance regulations concerning prescription drug benefits. Insurers are required under Washington state regulations to include in policies a "clear statement explaining" the use of any incentives for generic drug use and any other limitations of the prescription drug benefit.¹⁷³ Proponents of copay accumulator programs say they are intended to steer plan enrollees toward lower cost, generic medications.¹⁷⁴ However, most health insurance plans do not disclose such intent in the plan language describing copay accumulator programs, and are therefore, in violation of this regulation.¹⁷⁵ Additionally, copay accumulator programs are limitations on prescription drug benefits because they do not allow copay assistance for a filled prescription to count toward the deductible. If a plan fails to disclose the existence of such a plan, then the health insurer may be in violation of this regulation.

The financially punitive nature of copay accumulator programs also violates a Washington state regulation prohibiting the imposition of ancillary charges for prescription drugs beyond copayments and coinsurance as a cost control measure.¹⁷⁶ A copay accumulator program can be accurately described as imposing an additional or ancillary charge for prescription drug benefits because it requires the plan enrollee who is utilizing a copayment assistance program to contribute the copay assistance received from the drug manufacturer as well as the full amount to the plan. Therefore, this double charge of the plan deductible is prohibited by Washington state regulation.

2) Investigations and Lawsuits

Under trade practice acts, state attorneys general or insurance commissioners have the authority to investigate insurers' actions, seek injunctions, and in some states, impose civil and criminal penalties.¹⁷⁷ Additionally, some states, such as Michigan, New Jersey, Oregon, and Washington, allow parties to bring a private cause of action.¹⁷⁸ For example, under California's Unfair Competition Law, individuals can petition the court for an injunction.¹⁷⁹ Therefore, if an employer's fully-insured health plan includes a copay accumulator program that violates a trade practice act, the insurer that administers the program could be investigated or sued, which could potentially lead to changes in benefit design.



5 Policy Considerations and Recommendations

In addition to the increased chance of liability, employers must also consider economic and legislative factors when weighing the risks and benefits of copay accumulator programs.

A. Copay Accumulator Programs Are Not Cost Effective

PBMs and insurance agents and brokers have marketed copay accumulator programs as a tool for employers to save money. Some argue that copay accumulator programs are necessary because copay assistance encourages individuals to use more expensive medications for which employers bear the burden. Therefore, copay accumulators give plan enrollees "skin in the game" and will lead to better decisions as consumers. This argument assumes that (1) plan enrollees using necessary medications act as "rational consumers" and have the information they need to do so; and (2) an effective substitute exists. However, in some cases, neither of these assumptions may be true. According to a recent study, over 50 percent of the medications for which copay assistance is available have no generic substitute at all or only have therapeutically equivalent brand drugs, which are equally as expensive. 181

In instances where lower cost alternatives do not exist, plan enrollees subject to copay accumulators are more likely to ration or stop taking their medications altogether once the financial assistance cap is reached. Where lower cost alternatives do exist, plan enrollees who are stable on their current medications may feel financial pressure to switch to alternatives that are not effective for them or that could result in adverse events. As discussed in Ms. Catton's case, she had tried several other treatment options, which failed to manage her symptoms, so she preferred to ration her current medication rather than switch. Individuals who do not adhere to their treatment program have higher medical expenses, including increased office visits and hospitalization, resulting from adverse events, relapses, and disease progression. As such, any cost savings that employers receive on the pharmaceutical side of the health plan will likely be outweighed by the increased spending on the medical side of the plan.

Employers may experience indirect costs as well. With a decrease in adherence comes an increase in the days an employee misses to address adverse events, disease progression, or relapses, or to seek treatment. Diminished health and overall happiness of employees can result in decreased productivity and reduced profits for the employer. Furthermore, medical benefits are a recruiting tool, and employers should consider the impact on trying to attract top tier talent with subpar benefits.

Finally, there is no guarantee that any additional funds that an insurer or PBM collects from the patient and retains through copay accumulator programs will be actualized by employers with fully-insured health



plans. In the case of rebates, for instance, insurers and PBMs often retain profits rather than passing them to employers and consumers.¹⁸⁷ The same is likely the case for any potential cost savings resulting from copay accumulator programs. Therefore, although employers cite managing health care costs as a reason for choosing HDHPs with copay accumulators, such choices may have the opposite effect.

B. Employers Should Anticipate Legislative Action to Address Copay Accumulator Policies

Employers should expect that policymakers will enact legislation to protect consumers from misleading or discriminatory copay accumulator programs. Many patient advocacy and professional organizations are actively working towards this outcome. For example, the Medical Society of Virginia recently passed a resolution to urge the Virginia State Corporation Commission Bureau of Insurance to investigate insurers' copay accumulator programs. Likewise, in May 2018, the AIDS Institute sent letters to all state attorneys general and insurance commissioners requesting that they investigate copay accumulator programs. In July 2018, a group of 58 patient, provider, and consumer organizations jointly signed a letter to insurance commissioners requesting a similar outcome.

Patient advocacy organizations have also defeated legislative efforts to protect copay accumulator programs. Earlier this year, Rhode Island introduced legislation that would have expressly permitted health insurers to adopt copay accumulator programs. However, several members of the patient advocacy community submitted written and oral comments on the negative impacts that such a bill would have on patients. As a result, sponsors revised the bill to expressly prohibit health plans from adopting copay accumulator programs. Additional legislative efforts to prohibit or restrict copay accumulator programs are likely. In anticipation of such action, it is not worthwhile to adopt such programs

C. Recommendations for Best Practices

In light of the risk for liability, increased costs, reduced quality of life for employees, and high likelihood of legislative fixes, employers should not adopt copay accumulator policies.

If employers do choose to adopt such policies, they should take several actions to reduce liability and improve access to medications for employees for whom such treatments are medically necessary. First, employers should offer more than one plan option to employees, at least one of which should not include a copay accumulator program. Second, copay accumulator programs should not be offered in HDHPs because they are cost-prohibitive for individuals who require more expensive treatments for which lower cost alternatives do not exist.

If an employer does opt to include a copay accumulator program in a standard, non-HDHP, then certain guardrails should also be put into place. Any copay assistance received must be applied to the plan's MOOP limit even if it is not applied to the deductible in order to comply with the ACA. The health plan should not single out specific disease states and conditions because doing so is discriminatory. The plan should also allow individuals who require treatment for which no lower cost generic alternative exists to



obtain an exception from the copay accumulator requirements through a simple, speedy, and consumer-friendly exemption process. The health plan should include consistent definitions, terminology, and descriptions that are in plain language, and instructions on the exception process, so employees are not misled. For example, instead of using the term "copay accumulator program," which is confusing and nondescript, or "out-of-pocket protection," which implies that such a program confers a benefit on the plan enrollee, plans can use the term "deductible surcharge" or "copay assistance exclusion." Plans can use the following description:

Copay assistance will not be applied toward your annual deductible; however, copay assistance will be applied toward your maximum out-of-pocket limit. Copay assistance is defined as "discounts, coupons, pharmacy discount programs or similar arrangements that are provided by drug manufacturers or pharmacies to assist you in purchasing prescription drugs (including any prescription drug discount/coupons provided to pharmacies when you fill a prescription). 193

Additionally, plan administrators should make it easy for employees to locate copay accumulator language by including the language on the plan's website, in the SBC, and in the full plan documentation. Definitions must be included in the plan's glossary. Employers should notify employees in advance of open enrollment that the plan is adopting a copay accumulator program and explain what such a program entails. Finally, employers should not adopt a copay accumulator program mid-year after employees are already locked into a plan and have no ability to choose an alternative plan.

These steps will allow diligent employees to select a plan that best meets their own needs. These recommendations may also lower the risk of liability and costs for employers without impeding employees' access to medically necessary treatments.



6 Conclusion

Employers are under increased pressure to reduce costs related to health care plans. As such, many have adopted copay accumulator programs. However, such programs not only limit access to necessary treatment for employees who take prescription medications, they also can place employers at risk for liability.

Copay Accumulator

Programs =

plans stop counting

manufacturer copay assistance
towards patients' deductible.

Ultimately, these programs may result in increased costs for the employer. Moreover, legislative action limiting copay accumulator programs is also foreseeable. For these reasons, employers are best advised to reject copay accumulator programs. Those who nevertheless choose to implement such programs should adopt the best practices recommended herein.



7 References

- Michelle Andrews, Why Some Patients Getting Drugmakers' Help Are Paying More, NPR (May 30, 2018) https://www.npr.org/sections/health-shots/2018/05/30/615156632/why-some-patients-getting-drugmakers-help-are-paying-more.
- ² Id
- 3 Id. It should be noted that the Patient Protection and Affordable Care Act caps individuals' maximum out-of-pocket costs at \$7,350 in 2018 even if individuals are in family plans. Therefore, the \$8,800 could potentially include costs owed for family members. Embedded Self-Only Annual Limitations on Cost Sharing FAQs, CMS (May 8, 2015), https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/hhs-guidance-embedded-self-only-annual-limitation-on-cost-sharing-fags.pdf.
- ⁴ "Copay" is used this in this paper interchangeably with both "copayment" and "coinsurance."
- ⁵ Drug companies typically provide each patient with a finite amount of copayment assistance per year. Id.
- Simi Mathew, Copay Accumulators: The Deductible Double-Dip, MANAGED CARE (Aug. 2, 2018), https://www.managedcaremag.com/pharmdcorner/copay-accumulators-deductible-double-dip.
- Rebecca J. Mitchell & Paul Bates, Measuring Health-Related Productivity Loss, Apr. 14(2) POPULATION HEALTH MGMT. 93 (2011).
- Irene Papanicolas, et al., Health Care Spending in the United States and Other High-Income Countries, 319(10) JAMA 1024 (Mar. 13, 2018).
- Premiums for Employer-Sponsored Family Health Coverage Rise 5% to Average \$19,616; Single Premiums Rise 3% to \$6,896, KAISER FAMILY FOUNDATION (Oct. 3, 2018), https://www.kff.org/health-costs/press-release/employer-sponsored-family-coverage-premiums-rise-5-percent-in-2018/.
- ¹⁰ Id.
- ¹¹ Id.
- Stephen Miller, High-Deductible Plans More Common, but So Are Choices, SOCIETY FOR HUMAN RESOURCE MANAGEMENT, (Feb. 9, 2018), https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/high-deductible-plans-more-common-but-so-are-choices.aspx.
- John Tozzi & Zachary Tracer, Some Big Employers Moving Away from High Deductible Health Plans, INSURANCE JOURNAL (June 26, 2018), https://www.insurancejournal.com/news/national/2018/06/26/493273.htm.
- ¹⁴ Embedded Self-Only Annual Limitation on Cost Sharing FAQs, supra note 3.
- ¹⁵ 26 C.F.R. § 601.602; Stephen Miller, *supra* note 12.
- Publication 969 (2017), Health Savings Accounts and Other Tax-Favored Health Plans, IRS (2017), https://www.irs.gov/publications/p969#en_US_2017_publink1000204083; HDHP deductible requirements can be offset when paired with a health savings account, which allows HDHP enrollees only to contribute their own pre-tax money, up to \$3,450 for individuals and up to \$6,900 for family plans, and use these contributions to pay for medical care until the plan deductible is met, as well as copays and coinsurance. Id.
- Robin A. Cohen & Emily P. Zammitti, High-Deductible Health Plan Enrollment Among Adults Aged 18-64 With Employment-based Insurance Coverage, 317 NCHS DATA BRIEF (Aug. 2018), https://www.cdc.gov/nchs/data/databriefs/db317.pdf.
- 7 Reasons the Cheapest Health Plan May Not Be Right for You, KAISER PERMANENTE, https://wa-health.kaiserpermanente.org/why-the-cheapest-health-plan-may-not-be-right-for-you/ (last visited Oct. 21, 2018).
- Robin A. Cohen & Emily P. Zammitti, High-Deductible Health Plans and Financial Barriers to Medical Care: Early Release of Estimates from the National Health Interview Survey, 2016, NATIONAL CENTER FOR HEALTH STATISTICS (June 2017), https://www.cdc.gov/nchs/data/nhis/earlyrelease/ERHDHP_Access_0617.pdf.
- ²⁰ Copay Assistance Programs: The Landscape Today and After Part D, 2(1) J. ONCOLOGY PRACTICE 15 (Jan. 2006).
- ²¹ Karen Van Nuys, A Perspective on Prescription Drug Copayment Coupons, USC SCHAEFFER (Feb. 2018), https://healthpolicy.usc.edu/wp-content/uploads/2018/02/2018.02_Prescription20Copay20Coupons20White20Paper_Final-1.pdf.
- ²² Carl E. Schmid, New Accumulator Adjustment Programs Threaten Chronically III Patients, HEALTH AFFAIRS (Aug. 31, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/.



- ²³ See e.g., David Lazarus, They're Called 'Co-Pay Accumulators,' and They're a Way Insurers Make You Pay More for Meds, LA TIMES (Apr. 27, 2018), http://www.latimes.com/business/lazarus/la-fi-lazarus-healthcare-copay-accumulators-20180427-story.html.
- ²⁴ Michelle Andrews, *supra* note 1.
- ²⁵ Michelle Andrews, supra note 1.
- ²⁶ Jaque King et al., Rising Cost of Specialty Drugs in Michigan and the United States: A Case Example for Multiple Sclerosis, CENTER FOR HEALTHCARE RESEARCH & TRANSFORMATION (Dec. 12, 2017), https://www.chrt.org/publication/rising-cost-of-specialty-drugs-in-michigan-and-the-united-states-a-case-example-for-multiple-sclerosis/.
- ²⁷ Michelle Andrews, supra note 1.
- ²⁸ Carl E. Schmid, supra note 22.
- Specialty Cost Management, CVS HEALTH, https://payorsolutions.cvshealth.com/programs-and-services/specialty/specialty-cost-management (last visited Nov. 2, 2018); Sonali Prusty, Three Drug-Pricing Controls Emerge in U.S. Market, PHARMALIVE (Aug. 9, 2018), https://www.pharmalive.com/three-drug-pricing-controls-emerge-in-u-s-market/.
- ³⁰ Carl Schmid, Hidden Policies: The Search for Copay Accumulator Policies in Florida Qualified Health Plans, DRUG CHANNELS (June 7, 2018), https://www.drugchannels.net/2018/06/hidden-policies-search-for-copay.html.
- ³¹ 42 U.S.C. § 300gg-6(b); 42 U.S.C. § 18022(c).
- ³² 42 U.S.C. § 18022(c); 45 C.F.R. § 155.20.
- ³³ 42 U.S.C. § 18022(b); 42 U.S.C. § 300gg-6.
- 34 42 U.S.C. § 18022(b)(1)(f).
- 35 Affordable Care Act Implementation FAQs Set 18, CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.html (last visited Oct. 21, 2018).
- ³⁶ Id.
- ³⁷ Id.
- FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation, CMS (Apr. 20, 2016), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-31_Final-4-20-16.pdf.
- ³⁹ Id.
- ⁴⁰ 42 U.S.C. § 18022(c); 45 C.F.R. § 155.20.
- ⁴¹ 45 C.F.R. §155.20.
- 42 David Lazarus, supra note 23.
- ⁴³ 42 U.S.C. § 18116; 45 C.F.R § 92.207; 45 C.F.R § 92.208(a).
- ⁴⁴ 45 C.F.R § 92.207.
- ⁴⁵ 45 C.F.R § 92.4(4).
- ⁴⁶ 45 C.F.R § 92.4.
- ⁴⁷ Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376 (May 18, 2016 (final rule codified at 45 C.F.R. Part 92), https://www.federalregister.gov/documents/2016/05/18/2016-11458/nondiscrimination-in-health-programs-and-activities. This definition of disability is also used in the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008.
- ⁴⁸ 42 U.S.C. § 12102(1)(A).
- ⁴⁹ 42 U.S.C. § 12102(2)(A).
- ⁵⁰ 42 U.S.C. § 12102(2)(B)
- ⁵¹ 42 U.S.C. § 12102(4).
- 52 2017 Your Benefits Summary, THE HOME DEPOT ORANGE LIFE (2017), https://secure.livethehealthyorangelife.com/files/17_US_Full-time_Benefits_Summary.pdf. [(hereinafter "The Home Depot Plan Summary")].
- Alston v. Park Pleasant, No. 16-1464 (3d Cir., Feb. 15, 2017) (However, the court in this case ultimately ruled that the individual did not meet the definition of disability because her cancer did not substantially limit one or more major life activity.).
- ⁵⁴ Oehmke v. Medtronic, Inc., 844 F.3d 748, 756 (8th Cir. 2016).
- ⁵⁵ Bragdon v. Abbott, 524 U.S. 624 (1998).
- ⁵⁶ Cyr v. United Parcel Serv. Inc., C.A. No. 09-cv-30077-MAP (D. Mass. 2011).
- While courts have not yet had an opportunity to decide this issue, the AIDS Institute and the National Health Law Program were successful in making similar arguments alleging that insurers were using their formularies to discriminate against individuals with HIV / AIDS. There, insurers placed all medications that treated the condition in the highest cost-sharing tiers. In response to those complaints, state insurance commissioners conducted investigations and ordered insurers to change their formularies. Will Cases Spur More Focus on 'Disability' –and What Does that Mean for Payers?, SPECIALTY PHARMACY NEWS (July 2014), https://www.ebglaw.com/content/uploads/2014/08/Specialty-Pharmacy-News1.pdf.



- ⁵⁸ 42 U.S.C. § 300gg-4; See also 29 U.S.C. § 1182.
- ⁵⁹ 42 U.S.C. § 300gg-4(a); 29 C.F.R. § 2590.702.
- 60 45 C.F.R. § 146.121; 45 C.F.R. § 147.110; 29 C.F.R. § 2590.702(b)(1)(F). These provisions are in both PHSA and ERISA.
- ⁶¹ THE HOME DEPOT PLAN SUMMARY, supra note 52.
- ⁶² See 29 U.S.C. § 1181(a) (2006) (stating that insurers may only impose a preexisting condition exclusion when "(1) such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the [six month] period ending on the enrollment date; (2) such exclusion extends for a period of not more than [twelve] months (or [eighteen] months in the case of a late enrollee) after the enrollment date; and (3) the period of any such preexisting condition exclusion is reduced by the aggregate of the periods of creditable coverage"). All forms of health insurance qualify as credible coverage. See 26 U.S.C. § 9801(c)(1) (2006); 29 U.S.C. § 1181(c)(1) (2006); 42 U.S.C. § 300gg(c)(1) (2006).
- ⁶³ 42 U.S.C. § 300gg-3(a); 29 U.S. Code § 1181.
- 64 45 C.F.R. § 144.103.
- ⁶⁵ Orders v. State Teachers Ret. Sys. of Ohio, 2016 Ohio 3345 (Ohio App. 2016).
- ⁶⁶ 45 C.F.R. § 147.104(e); Administrative Complaint, Centers for Health Law & Policy Innovation v. Humana, AIDS FOUNDATION OF CHICAGO (Sept. 6, 2016), https://www.aidschicago.org/resources/content/9/2/5/documents/ocr-complaint-humana-1.pdf.
- ⁶⁷ 45 C.F.R. § 147.104(e).
- ⁶⁸ Administrative Complaint, The AIDS Institute v. Coventry Health Care Inc., supra note 66.
- ⁶⁹ Administrative Complaint, The AIDS Institute v. Coventry Health Care Inc., supra note 66.
- ⁷⁰ Consent Order, In Re: Humana Medical Plan, Inc., Case No. 186449-16-CO (Feb. 16, 2016).
- Memo to All Insurers Authorized to Write Life & Health Insurance Products in Florida, FLORIDA OFFICE OF INSURANCE REGULATION (Mar. 25, 2015), https://www.floir.com/siteDocuments/PPACANoticeToIndustry03242015.pdf.
- Consent Order, In Re: Humana Medical Plan, Inc., Case No. 186449-16-CO; Nicholas Nehamas, Second Florida Insurer Strikes Deal with State Over HIV Drugs, MIAMI HERALD (Nov. 21, 2014), https://www.miamiherald.com/news/local/community/miami-dade/article4051858.html.
- ⁷³ THE HOME DEPOT PLAN SUMMARY, supra note 52.
- ⁷⁴ 26 C.F.R. § 54.9815-2715.
- ⁷⁵ 26 C.F.R. § 54.9815-2715.
- ⁷⁶ Summary of Benefits and Coverage: Instruction Guide for Group Coverage, CMS (Feb. 2016), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Group-Instructions.pdf.
- See, e.g., Summary of Benefits and Coverage: The Home Depot Medical Plan: Deductible First Medical Plan Aetna, LIVE HEALTHY ORANGE LIFE (2019), https://secure.livethehealthyorangelife.com/files/2019-Aetna-Deductible-First-Plan-SBC-v2.pdf; THE HOME DEPOT PLAN SUMMARY, supra note 52; Summary of Benefits and Coverage: Allstate Insurance Company: Allstate Medical Savings Coverage Option, Allstate Good LIFE (2017),
 - https://www.allstategoodlife.com/ae2018/pdfs/2018_medical_savings_plan_sbc.pdf; Cafeteria Medical Plan, Allstate Good Life (2018), https://www.allstategoodlife.com/ae2018/pdfs/2018_medical_plan_spd.pdfError! Hyperlink reference not valid. [hereinafter "the Allstate Plan Summary")]; 2018 Associate Benefits Book, SMART GUIDE WALMART ONE (Jan. 1, 2018), https://smartguide.walmartone.com/smartpages/Media/Default/LeadershipGuide/Associate-Benefits-Book-Summary-Plan-Description-Standard-2018.pdf; 2018 Benefits at a Glance, SMART GUIDE WALMART ONE (2018),
- https://smartguide.walmartone.com/SmartPages/Media/Default/LeadershipGuide/benefits-at-a-glance-2018.pdf [hereinafter "the Walmart Plan Summary")].
- ⁷⁸ 45 C.F.R. § 92.302(c). However, district courts are currently split as to whether to uphold HHS's regulatory interpretation that Section 1557 of the ACA provides a private right of action for claims of unintentional discrimination in healthcare on the basis of race, color, national origin, age, sex, and disability. See Laura Briscoe v. Health Care Service Corporation, 2017 WL 5989727 at *10 (N.D. III. Dec. 4, 2017).
- ⁷⁹ 45 C.F.R. § 92.302(c).
- 80 42 U.S.C. § 300gg-91(b)(2); 42 U.S.C. § 300gg-22(a)(1)-(2).
- 81 26 U.S.C. § 4980D.
- 82 26 U.SC. § 4980D.
- 83 15 U.S.C. § 45(a); See In re CVS Caremark Corp., FTC File No. 112 3210 (Jan. 12, 2012) (consent order settling charges that CVSC misrepresented the prices of covered Medicare Part D prescription drugs); In re CVS Caremark Corp., FTC File No. 091 0106, (Jan. 12, 2012).
- 84 15 U.S.C. § 45(n).
- 85 Simi Mathew, supra note 6.
- 86 FTC Policy Statement on Unfairness, FEDERAL TRADE COMMISSION, (Dec. 17, 1980), https://www.ftc.gov/public-statements/1980/12/ftc-policy-statement-unfairness.
- 87 Id



- 88 Simi Mathew, supra note 6.
- ⁸⁹ Ramsey Baghdadi, Patient Financial Support, HEALTH AFFAIRS (Sept. 14, 2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000176/full/.
- ⁹⁰ Emergence and Impact of Pharmacy Deductibles: Implications for Patients in Commercial Health Plans, IMS INSTITUTE FOR HEALTHCARE INFORMATICS (Sept. 2015), https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/emergence-and-impact-of-pharmacy-deductibles.pdf?la=en&hash=1D397351342823EDEFDECFC4F119CCBFD56E904F.
- ⁹¹ Jalpa A. Doshi, et al., Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents, J. CLINICAL ONCOLOGY (2018), http://ascopubs.org/doi/full/10.1200/JCO.2017.74.5091.
- ⁹² Emergence and Impact of Pharmacy Deductibles: Implications for Patients in Commercial Health Plans, supra note 90; Allan Gibofsky, et al., Effects of Non-Medical Switching on Outcomes Among Patients Prescribed Tumor Necrosis Factor Inhibitors, 33(11) CURRENT MED. RESEARCH & OPINION (2017), https://www.tandfonline.com/doi/full/10.1080/03007995.2017.1375903?src=recsys; Information Regarding Insulin Storage and Switching Between Products in an Emergency, FDA (May 27, 2015), https://www.fda.gov/Drugs/EmergencyPreparedness/ucm085213.htm.
- 93 Federal Trade Commission Act Section 5: Unfair or Deceptive Acts or Practices, FEDERAL RESERVE (Dec. 2016), https://www.federalreserve.gov/boarddocs/supmanual/cch/ftca.pdf.
- ⁹⁴ Orkin Exterminating Co., Inc. v. F.T.C., 849 F.2d 1354 (C.A.11, 1988).
- ⁹⁵ Id.
- ⁹⁶ Federal Trade Commission Act Section 5: Unfair or Deceptive Acts or Practices, supra note 93.
- 97 2018 Individual Certificate of Coverage, FLORIDA HEALTH CARE PLANS (2018), http://www.fhcp.com/documents/coc/qhp-ind-2018.pdf; Copay Accumulator Language for Florida Qualified Health Plans, THE AIDS INSTITUTE, http://www.drugchannelsinstitute.com/files/AIDSInstitute-Fig2.pdf (last visited Oct. 31, 2018).
- 98 Copay Accumulator Language for Florida Qualified Health Plans, supra note 97.
- ⁹⁹ Paul Nicolaus, Copay Accumulator Programs Spark Debate, MANAGED HEALTH CARE (Aug. 30, 2018), https://www.managedhealthcareconnect.com/article/copay-accumulator-programs-spark-debate.
- 100 "Copayment," HEALTHCARE.GOV, https://www.healthcare.gov/glossary/co-payment/ (last visited Oct. 31, 2018).
- ¹⁰¹ Karen Van Nuys, supra note 21.
- 102 Federal Trade Commission Act, Section 5: Unfair or Deceptive Acts or Practices, FEDERAL DEPOSIT INSURANCE CORPORATION (Nov. 2015), https://www.fdic.gov/regulations/compliance/manual/7/vii-1.1.pdf.
- 103 Gabriela Dieguez, et al., A Primer on Prescription Drug Rebates: Insights into Why Rebates Are a Target for Reducing Prices, MILLIMAN (May 2018), http://www.milliman.com/uploadedFiles/insight/2018/Prescription-drug-rebates.pdf.
- 104 FTC Policy Statement on Deception, FEDERAL TRADE COMMISSION, (Oct. 14, 1983), https://www.ftc.gov/system/files/documents/public_statements/410531/831014deceptionstmt.pdf.
- 105 Compliance Examination Manual, FEDERAL TRADE COMMISSION, (Nov. 2015), https://www.fdic.gov/regulations/compliance/manual/7/vii-1.1.pdf.
- ¹⁰⁶ FTC Policy Statement on Deception, FEDERAL TRADE COMMISSION, supra note 104.
- ¹⁰⁷ FTC Policy Statement on Deception, FEDERAL TRADE COMMISSION, supra note 104.
- ¹⁰⁸ Federal Trade Commission Act, Section 5: Unfair or Deceptive Acts or Practices, supra note 102.
- ¹⁰⁹ Important Notice Regarding Changes to PepsiCo Health and Insurance Benefit Programs: Summary of Material Modifications, PEPSICO (Jan. 2018), https://cache.hacontent.com/ybr/R516/01698_ybr_ybrfndt/downloads/SMM2017A.pdf [(hereinafter "the Pepisco SMM")].
- 110 Jan. 1, 2018 PDL Updates Revision, UNITEDHEALTHCARE (Oct. 11, 2017), https://broker.uhc.com/articleView-19125.
- 111 A Foundations Approach to Specialty Cost Management, CVS HEALTH (June 19, 2018), https://payorsolutions.cvshealth.com/sites/default/files/cvs-health-payor-solutions-a-foundational-approach-to-specialty-management-june-2018-briefing.pdf.
- 112 Why Drug Makers Dislike Copay Accumulator Programs, EXPRESS SCRIPTS (Mar. 22, 2018), https://lab.express-scripts.com/lab/insights/drug-options/why-drug-makers-dislike-copay-accumulator-programs.
- 113 "Coupon," OXFORD ENGLISH DICTIONARY, https://en.oxforddictionaries.com/definition/coupon (last visited Oct. 31, 2018).
- ¹¹⁴ Copay Accumulator Language for Florida Qualified Health Plans, supra note 97.
- 115 Unfair or Deceptive Acts or Practices by State-Chartered Banks, U.S. FEDERAL DEPOSIT INSURANCE CORPORATION, (2004) https://www.fdic.gov/news/news/financial/2004/fil2604a.html.
- ¹¹⁶ Federal Trade Commission Act, Section 5: Unfair or Deceptive Acts or Practices, supra note 102.
- ¹¹⁷ Paul Nicolaus, supra note 99.
- ¹¹⁸ Federal Trade Commission Act, Section 5: Unfair or Deceptive Acts or Practices, supra note 102.
- ¹¹⁹ Federal Trade Commission Act, Section 5: Unfair or Deceptive Acts or Practices, supra note 102.
- ¹²⁰ Affordable Care Act Implementation FAQs Set 18, supra note 35.



- ¹²¹ 15 U.S.C. § 46(a).
- 122 15 U.S.C. § 46(a).
- 123 A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority, FEDERAL TRADE COMMISSION (July 2008), https://www.ftc.gov/about-ftc/what-we-do/enforcement-authority.
- 124 29 U.S.C. § 1003(a).
- ¹²⁵ Fact Sheet: What Is ERISA, EMPLOYEE BENEFITS SECURITY ADMINISTRATION, https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/what-is-erisa (last visited Oct. 31, 2018).
- 126 29 U.S.C. § 1102(a).
- 127 Fiduciary Responsibilities, U.S. Department of Labor, https://www.dol.gov/general/topic/retirement/fiduciaryresp (last visited Nov. 2, 2018).
- ¹²⁸ ld.
- 129 29 U.S.C. § 1104(a)(1)(A).
- 130 29 U.S.C. §§ 1021, 1024 (proscribing certain disclosure duties to beneficiaries); 29 C.F.R. § 2520.104b-1 (detailing fiduciary disclosure responsibilities).
- ¹³¹ 29 C.F.R. § 2520.104b-2.
- ¹³² 29 C.F.R. § 2520.102-3(j)(3).
- ¹³³ 29 C.F.R. § 2520.104b-3.
- ¹³⁴ 29 C.F.R. § 2520.104b-3(d).
- ¹³⁵ Id.
- ¹³⁶ Id.
- ¹³⁷ See, e.g., the Pepisco SMM, supra note 109.
- ¹³⁸ Copay Accumulator Language for Florida Qualified Health Plans, supra note 97.
- ¹³⁹ See, e.g., Varity Corp. v. Howe, 516 U.S. 489, 506 (1996).
- ¹⁴⁰ Krohn v. Huron Mem'l Hosp., 173 F.3d 542, 547 (6th Cir. 1999).
- ¹⁴¹ See Howell v. Motorola, Inc., 633 F.3d 552, 571-72 (7th Cir. 2011).
- ¹⁴² THE HOME DEPOT PLAN SUMMARY, supra note 52 (emphasis added).
- ¹⁴³ THE HOME DEPOT PLAN SUMMARY, supra note 52.
- ¹⁴⁴ THE PEPISCO SMM, supra note 109.
- ¹⁴⁵ 29 U.S.C. § 1132(a)(3); Mass. Mut. Life Ins. Co. v. Russell, 473 U.S. 134, 153-154 (1985).
- ¹⁴⁶ CIGNA Corp. v. Amara, 131 S. Ct. 1866 (2011); Mertens v. Hewitt Associates, 508 U.S. 248 (1993).
- 147 Matthew O. Gatewood, The New Map: The Supreme Court's Guide to Curing Thirty Years of Confusion in ERISA Savings Clause Analysis, 62 WASH. & LEE L. REV. 643 (2005).
- ¹⁴⁸ 29 U.S.C. § 1144(a).
- ¹⁴⁹ Ramirez v. Inter-Continental Hotels, 890 F.2d 760, 762 (5th Cir. 1989).
- 150 Cromwell v. Equicor-Equitable HCA Corp., 944 F. 2d 1272, 1275-76 (6th Cir. 1991); Sharona Hoffman, Step Therapy: Legal, Ethical, and Policy Implications of a Cost-Cutting Measure, 73 FOOD & DRUG L.J. 38 (2018).
- 151 29 U.S.C. § 1144(b)(2)(A); However, it should be noted that this ERISA exception does not apply to self-funded employer plans. 729 U.S.C. § 1144(b)(B).
- 152 29 U.S.C. § 1144(b)(B) (2010).
- 153 "Self-Insured Plan," HEALTHCARE.GOV, https://www.healthcare.gov/glossary/self-insured-plan/ (last visited Nov. 2, 2018); "Fully Insured Job-Based Plan," HEALTHCARE.GOV, https://www.healthcare.gov/glossary/fully-insured-job-based-plan/ (last visited Nov. 2, 2018).
- 154 Carolyn L. Carter, Consumer Protection in the States: A 50-State Report on Unfair and Deceptive Acts and Practices Statutes, NAT'L CONSUMER LAW CTR. INC. (Feb. 2009), https://www.nclc.org/images/pdf/car_sales/UDAP_Report_Feb09.pdf.
- 155 Julie Ralston Aoki, Consumer Protection: An Overview of State Laws and Enforcement, Pub. HEALTH Law CTR., http://publichealthlawcenter.org/sites/default/files/resources/phlc-fs-agconsumer-2010.pdf (last visited Nov. 2, 2018).
- ¹⁵⁶ Cox v. Blue Cross & Blue Shield of Michigan, 869 F. Supp. 501 (E.D. Mich. 1994); Ramirez v. Inter-Continental Hotels, 890 F.2d 760, 762 (5th Cir.1989).
- ¹⁵⁷ Hansen v. Group Health Cooperative, 2018 U.S. App. LEXIS 25033 (9th Cir. Sep. 4, 2018).
- ¹⁵⁸ 29 U.S.C. § 1144(b)(2)(B).
- ¹⁵⁹ Hansen v. Group Health Cooperative, 2018 U.S. App. LEXIS 25033.
- 160 WASH, REV. CODE § 19,86,020; Hansen v. Group Health Cooperative, 2018 U.S. App. LEXIS 25033.
- 161 Hansen v. Group Health Cooperative, 2018 U.S. App. LEXIS 25033 (citing Aetna Health Inc. v. Davila, 542 U.S. 200, 210 (2004)).



- ¹⁶² Id.
- ¹⁶³ Id.
- ¹⁶⁴ Hangman Ridge Training Stables, Inc. v. Safeco Title Ins. Co., 719 P.2d 531 (Wash. 1986).
- ¹⁶⁵ Id.
- ¹⁶⁶ Id.
- ¹⁶⁷ WASH. REV. CODE § 48.30.040. This statute falls within the Chapter titled "Unfair Practices and Frauds."
- 168 WASH. REV. CODE § 48.30.090. This statute falls within the Chapter titled "Unfair Practices and Frauds."
- ¹⁶⁹ WASH. REV. CODE § 48.30.040.
- 170 WASH. REV. CODE § 48.30.090.
- ¹⁷¹ WASH. REV. CODE § 19.86.010(2).
- ¹⁷² WASH. REV. CODE § 48.01.030.
- ¹⁷³ WASH. ADMIN. CODE § 284-43-5170(1)(a).
- ¹⁷⁴ Michelle Andrews, supra note 1.
- ¹⁷⁵ THE HOME DEPOT PLAN SUMMARY, supra note 52; THE WALMART PLAN SUMMARY, supra note 77; THE ALLSTATE PLAN SUMMARY, supra note 77.
- ¹⁷⁶ WASH. ADMIN. CODE § 284-43-5110(1).
- 177 File a Consumer Complaint, NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS, https://eapps.naic.org/cis/fileComplaintMap.do (last visited Nov. 2, 2018).
- ¹⁷⁸ Wash. Rev. Code § 19.86.090; Mich. Comp. Laws § 19.418(11); N.J. Stat. Ann. § 56:8-2.12; Or. Rev. Stat. § 646.150.
- ¹⁷⁹ CA. Bus. & Prof. Code § 17203.
- ¹⁸⁰ Michelle Andrews, supra note 1.
- ¹⁸¹ Michelle Andrews, *supra* note 1.
- 182 John D. Piette, et al., Cost-Related Medication Underuse Among Chronically III Adults: The Treatments People Forgo, How Often, and Who Is at Risk, 94(10) Am. J. Pub. HEALTH 1782 (Oct. 2004).
- ¹⁸³ Michael T. Eaddy, et al., How Patient Cost-Sharing Trends Affect Adherence and Outcomes, 37(1) PHARMACY & THERAPEUTICS 45 (Jan. 2012).
- ¹⁸⁴ Debanjali Mitra, et al., Association Between Oral 5-ASA Adherence and Health Care Utilization and Costs Among Patients with Active Ulcerative Colitis, 12 BIOMED CENTRAL 132 (2012); R. Halpern, et al., The Association of Adherence to Osteoporosis Therapies with Fracture, All-Cause Medical Costs, and All-Cause Hospitalizations: A Retrospective Claims Analysis of Female Health Plan Enrollees with Osteoporosis, 17(1) J MANAGED CARE PHARM. 25 (2011).
- ¹⁸⁵ Nathan L. Kleinman, et al., *Persistence and Adherence with Urinary Antispasmodic Medications Among Employees and the Impact of Adherence on Costs and Absenteesim*, 20 J. MANAGED CARE & SPECIALTY PHARMACY 1047 (Oct. 2014).
- ¹⁸⁶ Timothy Gubler, Doing Well by Making Well: The Impact of Corporate Wellness Programs on Employee Productivity, MANAGEMENT SCIENCE (Dec. 2017), http://images.transcontinentalmedia.com/LAF/lacom/making_well.pdf.
- ¹⁸⁷ Stephen Barlas, Employers and Drugstores Press for PBM Transparency, 40(3) PHARMACY & THERAPEUTICS 206 (Mar. 2015).
- 188 Copay Accumulator Programs, NATIONAL ORGANIZATION FOR RARE DISEASES, (2018) https://rarediseases.org/wp-content/uploads/2018/06/NRD-1135-CoPay_AccumulatorProg_v6.pdf.
- Investigation into Healthcare Insurance Copay Accumulator Programs, MEDICAL BOARD OF VIRGINIA https://www.msv.org/get-involved/events/msv-annual-meeting/hod-resolutions/investigation-healthcare-insurance-copay (last visited Nov. 2, 2018).
- 190 HHCAWG Copay Accumulator HIV Community to Attorneys General and Insurance Commissioners, THE AIDS INSTITUTE, http://www.theaidsinstitute.org/federal-policy/sign-letters/hhcawg-copay-accumulator-hiv-community-attorneys-general-and-insurance-c (last visited Nov. 2, 2018).
- 191 Patient, Provider, and Consumer Groups Concerned About Emerging Insurance Practice that Could Lead to Higher Out-of-Pocket Costs, ARTHRITIS FOUNDATION (July 24, 2018), https://www.arthritis.org/Documents/Sections/Advocate/Regulatory-Letters/2018-Asset-Folder/IC-Letter-Press-Statement-July-2018.pdf.
- ¹⁹² Rhode Island S. 2532 (2018).
- ¹⁹³ See THE WALMART PLAN SUMMARY, supra note 77.





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