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Via Electronic Communication

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Re: WEA Trust's Copay Accumulator Program

Dear Mr. Nickels and Mr. Lukazewski:

The undersigned patient advocacy groups and professional associations are writing about WEA Trust's recent decision to implement a copay accumulator program for specialty drugs. We are concerned that such program will negatively impact patients' ability to afford their medications, especially amidst the COVID-19 pandemic and the resulting economic recession. We are also concerned that this mid-year formulary change could violate certain federal and state laws.

A. WEA Trust's Formulary Change

On June 9, 2020, WEA Trust sent a letter to medical practices that prescribe or administer specialty drugs to WEA Trust plan enrollees. The letter states "if you currently use a copay assistance program, starting June 1, 2020, only the actual amount you pay will be counted toward your maximum out-of-pocket limit." This type of policy is commonly referred to as a copay accumulator program. Also, it is important to note that the effective date of this formulary change occurs after the plan year has begun.

B. Copay Accumulator Programs

Historically, privately insured individuals who cannot afford their copayments or coinsurance have been able to obtain aid from copayment assistance programs and the value of the assistance has contributed toward the patient's deductible and maximum out-of-pocket limit. These programs have been especially helpful for individuals enrolled in high deductible health plans in which the patient is required to pay significantly high out-of-pocket costs until the deductible is reached. However, under copay accumulator programs, once copayment assistance runs out, the plan enrollee is again faced with an inability to afford his or her medication. In some instances, there are no generic alternatives, and patients may be forced to ration their medications or abandon treatment altogether.[1] As a result, they can experience disease progression, relapse, and other adverse events, thereby increasing health care utilization.[2]

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[1] https://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/
[2] https://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/

In the case of brand medications for which no generic alternatives exist, patients may be forced to use compounded drugs or off-label drugs not indicated for their condition. Yet, the U.S. Food and Drug Administration (FDA) has stated that compounded products do not have the same safety, quality, and efficacy assurances as FDA-approved drugs.[3] For example, just last year, a Massachusetts federal court sentenced a former supervisory pharmacist of a compounding center to eight years in prison in connection with a nationwide fungal meningitis outbreak that killed 64 and caused infections in 793 patients.[4] The outbreak was caused by poorly compounded products.[5]

Recognizing the harmful impact that copay accumulator programs can have on patients' ability to afford medications, the Centers for Medicare and Medicaid Services (CMS) has actively discouraged their use. For example, CMS issued the Notice of Benefit and Payment Parameter (NBPP) for 2020, which prohibited the use of copay accumulator programs for certain health plans in instances in which a brand medication was prescribed to a patient and no generic alternative was available.[6] Although CMS revised this rule in the NBPP 2021, the agency still stated in the final NBPP 2021 that it believed that plans would continue to allow assistance to count toward deductibles and annual limits, and the agency encouraged plans to only use copay accumulator programs to steer enrollees to lower cost generic medications when available.[7] CMS stated multiple times that it anticipated that the impact on patients would be minimal as long as health plans continued with their current policies (i.e., plans that had not previously implemented a copay accumulator program did not choose to adopt such a policy).[8] Additionally, in June 2020, CMS released a proposed rule on value-based purchasing. Here too, CMS highlighted the harms of copay accumulator programs, noting that "the health plan delay[s] the application of its plan benefit to the patient to the detriment of the patient or consumer."[9]

Millions of American across the country rely on cost-sharing assistance to afford their medications. Such assistance is only helpful if it can be counted toward patients' deductibles or maximum out-out-pockets limits. This is especially problematic during the COVID-19 pandemic when unemployment rates are dramatically increasing every week, and individuals are struggling more than ever to afford their medications. When this policy was implemented in June 2020, Wisconsin's unemployment rate was 8.6 percent, which is 2.5 times higher than the previous

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[3] https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers#:~:text=Compounded%20drugs%20can%20serve%20an,to%20potentially%20serious%20health%20risks.
[4] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/january-31-2018-new-england-compounding-center-pharmacist-sentenced-role-nationwide-fungal
[5] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/january-31-2018-new-england-compounding-center-pharmacist-sentenced-role-nationwide-fungal
[6] https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf
[7] The NBPP 2021 states "We appreciate commenters' concern that the proposal [to allow copay accumulator programs in instances in which generic alternatives are not available] could raise out-of-pocket costs for consumers who use brand name drugs. However, we believe the impact of such costs may be limited if issuers that currently allow these amounts to be counted toward enrollees' deductibles or their annual limitation on cost sharing continue their current behavior, which we believe will be the case." CMS also stated "we continue to encourage issuers to find innovative methods to address the market distortion that occurs when consumers select a higher-cost brand name drug over an equally effective, medically appropriate generic drug." https://www.govinfo.gov/content/pkg/FR-2020-05-14/pdf/2020-10045.pdf
[8] https://www.govinfo.gov/content/pkg/FR-2020-05-14/pdf/2020-10045.pdf
[9] https://www.federalregister.gov/documents/2020/06/19/2020-12970/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and

year.[10] Many of these individuals may now rely on marketplace exchange plans with high out-of-pocket costs.

C. State Consumer Protections

Wisconsin law protects consumers against unfair and deceptive trade practices. In particular, the law states that an insurer may not "make any agreement of insurance that is not clearly expressed in the policy to be issued."[11] However, here, when enrollees signed up for their health plan, the policy did not clearly express that it would include a copay accumulator program. In fact, it is not even clear that plan enrollees ever received notice of the change. Instead, WEA Trust sent notification out to health care providers in the middle of the plan year, after the change was already made.

Additionally, Wisconsin law states that "no person may engage in any other unfair method of competition or any other unfair or deceptive act or practice in the business of insurance."[12] Here, given that the change happened six months after the plan year has begun, plan enrollees could argue that WEA Trust is engaging in unfair and deceptive trade practices. By negatively modifying coverage, WEA Trust has changed its benefit design at a time when enrollees are still locked into their plan for the rest of the plan year. They are unable to enroll in different health plans, which may have been the only way that stable enrollees can afford their current, effective medication within a reasonable time. To prevent potentially unfair and deceptive practices, we urge you to refrain from making these negative formulary changes until the new plan year begins, at which time patients will be free to select an alternative plan.

D. Affordable Care Act Protections

WEA Trust may have violated the Patient Protection and Affordable Care Act (ACA) when it implemented a copay accumulator policy after the plan year began. The ACA applies to non-federal governmental plans, such as WEA Trust's plans.[13] The ACA's guaranteed renewability provision prohibits health plans, including WEA Trust's plans, from modifying coverage after the plan year has begun.[14] Such changes include "plan design changes," such as the implementation of a copay accumulator program.[15] Instead, changes may only be made at the time of coverage renewal.[16] Therefore, WEA Trust was not permitted to adopt a copay accumulator program in the middle of the plan year.

Thank you for considering our position on WEA Trust's copay accumulator program. The undersigned organizations would like to schedule a call with you to discuss this issue further.

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[10] https://www.weau.com/2020/07/16/wisconsin-unemployment-rate-drops-to-85-percent/#:~:text=Place%20of%20Residence%20Data%3A%20Wisconsin's,national%20rate%20of%2011.1%20percent.
[11] Wisconsin Stat. 628.34(1)(a).
[12] Wisconsin Stat. 628.34
[13] Public Health Services Act 2723(b)(1)(B); https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/nonfedgovplans.
[14] 45 C.F.R. 147.103(E)
[15] https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-08017.pdf
[16] 45 C.F.R. 146.152(E), 147.103(E)

Please contact me at policy@aimedalliance.org to arrange this call or with any questions you may have.

Sincerely,

[undersigned organizations]