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Guest Column: Compliance Considerations for Copay Accumulator Programs

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As the cost of prescription drugs continue to rise, employers and employees alike are looking for ways to control their expenses. One approach is to leverage financial assistance programs offered by some prescription drug

manufacturers. These programs are commonly set up so that the prescription drug manufacturer covers all or a portion of an individual's out of pocket costs for a prescription drug, whether the cost is in the form of a deductible, co-payment or other cost sharing requirement.

While these financial assistance programs provide access to prescription drugs the individual may otherwise have not been able to afford, they raise the question of how the payments provided by these programs should be counted toward any applicable health insurance cost sharing limits, if at all.

Copay Accumulator Program

One approach, referred to as a "copay accumulator program," does not count the value of any prescription drug manufacturer assistance payments toward the deductible or other cost sharing limits.

For example, assume the out-of-pocket cost for a prescription drug is \$2,000 with \$1,500 of that amount paid for by a prescription drug manufacturer assistance program and the remaining \$500



Alex O'Connor

paid by the individual. Under a copay accumulator program, only the \$500 actually paid by the individual would be applied to any cost sharing limits; the \$1,500 manufacturer contribution would not be counted.

While copay accumulator programs can make financial sense for a group health plan, there are compliance factors that should be considered before implementing the approach. In particular, conflicting guidance from the Department of Health and Human Services (HHS) and the Internal Revenue Service (IRS) leaves open some important questions.

IRS Guidance

The IRS takes the position in Notice 2004-50 that only the amounts actually paid by an individual should be counted against the deductible in the high-deductible health plan (HDHP) context. Under the IRS guidance, an HDHP would only count the amount paid by an individual for a prescription drug, not any payments provided by a prescription drug manufacturer, against the applicable cost sharing limits.

HHS Guidance

HHS takes the position that financial assistance provided by a prescription drug manufacturer for brand-name drugs is required to be counted toward any cost-sharing limits if there is not a medically appropriate generic equivalent prescription drug available. Effectively, a copay accumulator program could not be applied to brand name prescription drugs without a medically appropriate generic equivalent drug.

The guidance from HHS and IRS conflicts. There are situations where the IRS guidance directs a plan to not count the prescription drug manufacturer assistance toward cost sharing limits, but HHS guidance does. It is unclear which guidance should be followed in those situations. HHS issued regulations in 2020 to address the conflict, but those regulations were vacated in favor of the HHS position stated above. Plan sponsors who need to comply with both HHS and IRS guidance should discuss with counsel the best path forward in light of the conflicting guidance.

State Law Considerations

On top of federal law considerations, some states have passed their own laws addressing the use of copay accumulator programs. Some states prohibit the use of copay accumulator programs entirely. Whether or not you need to comply with these state laws will depend on the state where the insurance policy is issued. Note that self-funded plans are generally subject only to federal law requirements and do not have to comply with most state insurance laws.

Key Takeaways:

Employers who are considering implementing copay accumulator programs should familiarize themselves with the legal guidance surrounding how prescription drug manufacturer assistance payments should be treated for cost sharing limit purposes. Employers may be well served to work with their legal counsel to determine the best approach for them in light of the conflicting guidance.

