

CAAP Rule and Prescription Drug Prices

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The high costs of prescription drugs remain an important issue, with a large majority of Americans saying that lowering drug prices should be a top priority for the new Biden administration.¹ In the months before the 2020 election, the outgoing Trump administration issued a number of executive orders and rules aimed at the drug market. Most of the hastily designed measures were intended to lower prices, such as by facilitating drug importation, but are likely to be blocked by litigation.² Paradoxically, one of the rules likely to persist after 2021 actually threatens to make drug prices more burdensome for patients by affecting how patient co-payments are counted by insurers.

The Trump administration finalized a rule in July 2020 aimed at co-pay accumulator adjustment programs (CAAPs), which are programs instituted by commercial health insurers that allow insurers to ignore co-payments made by drug manufacturer assistance programs on behalf of beneficiaries when determining whether beneficiaries have reached their yearly out-of-pocket maximum. Although CAAPs are designed to incentivize use of available low-cost generic versions of brand-name prescription drugs, the final rule permits CAAPs to be applied even when no generic is available, which will leave some patients unable to afford to fill their prescriptions once manufacturer assistance limits are met.³

Many brand-name drug manufacturers have developed patient assistance programs or offer coupons to help patients with their out-of-pocket prescription drug costs. The overall benefits of such programs, however, depend on the context and availability of lower-cost options. These programs can be helpful for patients who require a brand-name drug for which there are no lower-cost alternatives. The out-of-pocket costs associated with these brand-name drugs can be a substantial financial burden, particularly for those filling prescriptions for costly drugs to treat chronic conditions. One study showed that for covered individuals with deductibles, almost 25% of prescriptions are abandoned before the yearly deductible is met because of inability to afford the prescription.⁴ In these circumstances, by covering all or some of these out-of-pocket costs, manufacturer assistance can improve overall adherence by helping

ABSTRACT

In response to brand-name drug manufacturers developing co-pay assistance programs to help patients pay high out-of-pocket costs for expensive brand-name drugs, insurers have developed co-pay accumulator adjustment programs (CAAPs) that exclude payments made by drug manufacturer assistance programs when calculating whether beneficiaries have met their yearly out-of-pocket maximums. By doing so, these programs are intended to drive beneficiaries to lower-priced generic alternatives. A rule finalized in July 2020 makes such programs permissible even when a brand-name drug does not have a generic or medically appropriate alternative, while not requiring transparency from payers about the existence of such programs. This commentary explains how CAAPs work and how this finalized rule may affect spending on prescription drugs.

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beneficiaries afford their prescriptions, at least until the beneficiary reaches the assistance limit of the program.

By contrast, when lower-cost alternatives are available—either generic versions of the same drug or other lower-cost drugs shown to be useful in treating the condition—eliminating the cost-sharing responsibilities of the patient through drug manufacturer assistance can incentivize use of brand-name drugs over the generic. Although this may benefit the patient in the immediate transaction of filling a particular prescription, it enriches the pharmaceutical manufacturer and creates economic waste within the health care system. This economic waste, in turn, increases overall spending and drives up premiums, to the detriment of all beneficiaries. For example, one study estimated that the availability of brand-name drug manufacturer coupons in the first 5 years following generic approval resulted in as much as \$120 million in extra spending for that particular drug. For drug spending overall, the study estimated an increase in retail spending of 4.6% for this 5-year period.⁵

To eliminate the perverse incentives caused by such programs, health insurers and their pharmaceutical benefit managers designed CAAPs. CAAPs prevent the costs covered by drug manufacturer assistance programs from being counted toward an individual's yearly out-of-pocket maximum—with the goal being to provide incentives for use of lower-cost drugs not covered by the manufacturer assistance programs.⁶ This out-of-pocket maximum, as set by the Patient Protection and Affordable Care Act (ACA), is an annual limit on how much commercial insurers are permitted to make beneficiaries pay for health services. Normally, each time a beneficiary pays a co-payment or coinsurance for a health service, that amount is counted toward this yearly limit. Once the limit is reached, the beneficiary is not responsible for co-payments or coinsurance for the remainder of the year.

Under a CAAP, however, if individuals have the costs of their prescriptions filled throughout the year covered entirely by an assistance program and incur no other cost sharing for other medical services rendered, they are still responsible for all co-payments and coinsurance—even if the amount paid by the drug manufacturer assistance program would have exceeded their yearly out-of-pocket maximum. In other words, only expenses actually paid by the beneficiary will count toward the yearly out-of-pocket maximum, ignoring those paid by manufacturer assistance. This is particularly problematic when the manufacturer assistance limit is met, leaving the beneficiary solely responsible for coinsurance and co-payments.

In theory, by ignoring payments made by manufacturer assistance programs on behalf of beneficiaries for high-cost drugs, commercial insurers can incentivize use of lower-cost alternatives. The success of CAAPs therefore requires 3 things: (1) Lower-cost alternatives must exist, such as in the form of generic versions of the brand-name drug or generic versions of drugs in the same class that have

TAKEAWAY POINTS

This article describes a recently finalized CMS rule addressing the permissibility of co-pay accumulator adjustment programs when no generic is available.

- ▶ This rule should be narrowed to situations in which a generic is available and medically appropriate, where such programs have the ability to incentivize use of lower-cost alternatives.
- ▶ If the rule cannot be narrowed, it should be amended to require transparency from payers so that beneficiaries are able to anticipate future co-payments after they reach the manufacturer assistance program limit or, in the alternative, payers should affirmatively notify beneficiaries of the existence of such programs.

similar clinical benefits; (2) beneficiaries must know that these restrictions on manufacturer assistance exist and therefore be able to choose the lower-cost alternative; and (3) beneficiaries must be in a position so that, if not for these restrictions, they would have met their yearly out-of-pocket limits and benefited from being excused from coinsurance and co-payments for a portion of the year. If any of these requirements is not met, a beneficiary is likely to accept the immediate benefits of manufacturer assistance for prescription drug co-payments or coinsurance instead.

The Trump administration's final rule removes the first 2 requirements listed above and gives insurers substantial latitude to institute CAAPs under the ACA. Starting in 2021, it would permit insurers to prevent coupons and other forms of direct assistance from drug manufacturers from being applied to the patient's yearly out-of-pocket maximum. When it was first proposed, the rule included language limiting insurers' exclusion of drug manufacturer assistance to situations in which a generic was available and medically appropriate.⁷ But the final rule from July 2020 removed that language, giving insurers the option to exclude direct drug manufacturer assistance from a beneficiary's yearly out-of-pocket maximum, regardless of whether a generic is available. This means that for beneficiaries who rely on brand-name drugs for which a generic alternative is not available, drug manufacturer assistance will not help them get to their yearly out-of-pocket maximum if the plan utilizes such a CAAP, which will eventually translate to increased cost sharing on the individual. For those with chronic diseases or who rely on medications for which a generic is not available and depend on direct manufacturer assistance to mitigate costs at the pharmacy counter, the end of manufacturer assistance may mean reduced adherence to their medications and negative health effects.

The finalized rule explained that CMS expects insurers to "be transparent" in the plan documents as to whether drug manufacturer assistance counts toward a beneficiary's out-of-pocket maximum when filling generic or brand prescriptions. However, despite receiving public comments raising concerns about what appears to be optional disclosures, the agency declined to implement mandatory disclosures, leaving the insurers to decide how transparent to make their plan documents.³ The discretionary disclosures leave beneficiaries vulnerable. A study assessing consumers' understanding of terms such as deductible, co-pay, coinsurance,

and out-of-pocket maximum revealed that many Americans do not understand these terms well—with only 14% of those surveyed correctly identifying the definitions of all 4 terms.⁸ When it comes to CAAPs, this understanding is even more limited, with one study reporting important inconsistencies with transparency about CAAPs in plan designs, including plans with no information at all about the existence of a CAAP.⁹

CMS missed an opportunity to finalize aspects of the rule that could incentivize generics and chose not to mandate transparency—2 choices that could lead to increased out-of-pocket costs for beneficiaries. In 2021, CMS should focus primarily on narrowing CAAPs to situations in which a generic alternative is medically appropriate and available, similar to the original proposal in 2019. Narrowing the rule in this way will ensure that the tool is aimed at increasing use of low-cost generics and will protect beneficiaries who benefit from manufacturer assistance for brand-name drugs that do not have lower-cost alternatives.

If CMS cannot narrow the rule effectively, it should, in the alternative, revisit the mandatory disclosures and lay out a framework for informing beneficiaries of the benefits and detriments of accepting direct drug manufacturer assistance. Although it is unclear how effective such disclosures will be, given consumers' limited understanding of complex plan designs, broad CAAPs coupled with a lack of transparency will likely lead to unnecessary surprises for beneficiaries.

Use of CAAPs should be reserved to incentivizing medically appropriate and available generics in an effort to lower overall prescription drug costs. When using CAAPs in less restricted situations, plan documents must not only explicitly state that drug manufacturer assistance will not be applied to annual out-of-pocket maximums, but also explain that beneficiaries will be subjected to cost sharing once the manufacturer assistance limits are met.

Without these disclosures, beneficiaries may be forced to abandon prescriptions because of unforeseen additional co-pays. ■

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