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CMS releases annual health insurance exchanges final rule

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On April 18, 2019, the Centers for Medicare & Medicaid Services (CMS) released the Notice of Benefit and Payment Parameters final rule for 2020 (2020 Payment Notice) applicable to qualified health plans (QHPs) offered on health insurance exchanges.[1]

The regulatory changes made in the 2020 Payment Notice reflect the Trump administration's stated objectives of enhancing flexibility, affordability, program integrity, and market stability, while reducing the regulatory burden of the Affordable Care Act (ACA).

This alert highlights aspects of the 2020 Payment Notice rule-making relating to the Trump administration's drug pricing reform efforts. CMS proposed several policies aimed at encouraging enrollee utilization of generic drugs over brand drugs, but finalized only one of its proposals. The key drug-related provisions of the 2020 Payment Notice include:

- **Finalized – proposal to not count manufacturer brand drug cost-sharing assistance toward the annual out-of-pocket limit where a generic equivalent is also covered.** For plan years beginning on or after January 1, 2020, to the extent permissible under applicable state law, non-grandfathered health plans may choose not to count toward an enrollee's annual limitation on cost sharing any form of direct support offered by drug manufacturers to the enrollee to reduce or eliminate out-of-pocket costs for prescription brand drugs that have an available and medically appropriate generic equivalent. CMS defined the term "generic" as "a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is approved."

  In addition, CMS clarified that this policy does not apply where (i) the generic equivalent is not available or medically appropriate; or (ii) an enrollee is determined through an appeals process under 45 C.F.R. § 147.136 or a drug exception process under 45 C.F.R. § 156.122(c) to require the brand drug.

  CMS also clarified that this policy does not apply where contrary to applicable state law. Several states are considering laws that would require issuers to count assistance provided by manufacturers toward patient cost-sharing limits, and some states have already enacted such laws.

[1] The final rule, copy available here, was released by the Department of Health and Human Services, but has yet to be published by the Office of the Federal Register. Minor changes could be made.

- **Not finalized – proposal to exclude cost sharing for brand drugs from the annual out-of-pocket limit where a generic equivalent is also covered**. CMS proposed a few variations on permitting non-grandfathered health plans not to count cost sharing toward the annual cost-sharing limit where an enrollee chooses a brand drug over an available and medically appropriate generic equivalent. One variation would have allowed a non-grandfathered health plan, that covers both a brand prescription drug and an available and medically appropriate generic equivalent, to count the cost sharing for the brand drug toward the annual out-of-pocket maximum only up to the amount of the cost sharing for the generic equivalent. Alternatively, CMS considered whether an issuer could except the entire amount of the cost sharing for the brand drug from the annual cost-sharing limit. CMS also considered requiring issuers to do the same. CMS declined to finalize any of these proposals at this time, "in light of commenters concerns about the complexity of implementing this proposal," and indicated that it will continue to consider points raised by commenters.
- **Not finalized – proposal to allow mid-year formulary changes when a new generic equivalent of a brand prescription drug comes to market.** CMS also proposed to permit qualified health plan issuers to adopt mid-year formulary changes when a generic equivalent of a prescription drug becomes available on the market, within a reasonable time after that drug becomes available. Issuers would have been able to modify plan formularies mid-year to add the generic equivalent, and/or to remove the brand drug from their formulary or move the brand drug to a different cost-sharing tier. CMS declined to finalize the proposal at this time, "given the complexity of the issue, and the challenges of balancing the interests of consumers with the importance of mitigating the effects of rising prescription drug costs." However, CMS said it would continue to consider mid-year formulary changes and might provide guidance on this issue in the future. In the meantime, to the extent issuers make mid-year formulary changes consistent with applicable state law, CMS said that it expects issuers to continue to provide consumer protections that are generally consistent with current industry practice (such as pre-approval by a pharmacy and therapeutics committee, reasonable advance notice to affected enrollees, and access to an appeals process through which enrollees may gain access to the drug when clinically appropriate).

If you have any questions about the 2020 Payment Notice, please contact any of the listed Hogan Lovells lawyers.

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