Regulatory Alert Email

Federal judge makes final judgment: HRSA's 340B interpretive rule stands

Last week, a US District Judge issued a final judgment in the ongoing orphan drug dispute, rejecting requests from Pharmaceutical Research and Manufacturers of America (PhRMA) to invalidate an interpretive rule set forth by the Department of Health and Human Services's (HHS's) Health Resources and Services Administration (HRSA) involving orphan drug discounts related to the 340B Program. The two sides have been at odds over whether hospitals subject to the orphan drug exclusion may purchase orphan drugs at 340B prices when used to treat non-orphan indications.

The history

HRSA initially published a final legislative rule in July 2013 to implement the Affordable Care Act's (ACA's) 340B orphan drug exclusion, which applies only to critical access hospitals (CAH), sole community hospitals (SCH), rural referral centers (RRC), and free-standing cancer hospitals (CAN). HRSA's rule stated that, while these hospitals were excluded from buying orphan drugs under 340B to treat the rare disease or condition for which the drug received its orphan designation, they were allowed to purchase orphan drugs at 340B pricing when used to treat other conditions or diseases. PhRMA filed suit, claiming that HRSA lacked the Congressional authority to issue this type of legislative rule.

In May, we informed you that US District Judge Rudolph Contreras ruled against HHS, stating that HHS had no authority to implement new regulations regarding the ACA's orphan drug exclusion. As a result of this ruling, some drug wholesalers began notifying their customers that they would be removed from 340B contract pricing for orphan drugs.

In July, HRSA responded by issuing an interpretive rule that would continue to allow hospitals subject to the orphan drug exclusionto purchase orphan drugs through the 340B Program when the drugs are not used to treat the rare conditions for which the orphan drug designation was given. HRSA defended the interpretive rule, saying that it is essential to providing clarity in the marketplace, maintaining the 340B program savings for newly-eligible entities, and protecting the financial incentives for manufacturing orphan drugs designated for a rare disease or condition, as indicated in the ACA.

PhRMA's latest move was designed to prevent all orphan drug purchases under the 340B Program, regardless of the condition for which the drug is used.

What the final judgment means

This final judgment rules that PhRMA's efforts to block the interpretive rule are outside the original court decision and states that PhRMA will need to file a new lawsuit to challenge HRSA's subsequent actions. Judge Contreras dismissed all requests from PhRMA to declare the rule invalid or to order an extra briefing on whether the rule should stand. PhRMA has not commented on whether they will challenge the new ruling.

Although HRSA says the interpretive rule is nonbinding, drugmakers could still face severe penalties – up to and including being excluded from Medicaid – if they violate the statutory text of the orphan drug policy, which was stated in the ACA.

This case has since raised major questions about HRSA's ability to issue other 340B regulations. A proposed rule believed to contain significant reforms was sent to the White House Office of Management and Budget (OMB) in April. The rules were set to be released in June however; there have been no new updates on its release.

As further developments become available regarding this ruling, we will continue to alert you about how it may affect you.