

HHS to Continue 340B “Orphan” Drug Rule

In July 2013 the U.S. Department of Health and Human Services



(HHS) issued a final regulation allowing 340B covered entities (public safety-net health providers) to purchase orphan drugs at the discounted 340B prices even when the drugs aren't used to treat the rare disease or condition for which the drug obtained orphan status. However, in May 2014, the U.S. Court for the District of Columbia vacated the HHS regulation stating that HHS did not have the proper authority to issue the regulation. **HHS Response** In response, HHS publicly stated on June 18, 2014 that the court's ruling did not invalidate its interpretation of the statute and indicated it planned to move forward with its interpretation. HHS continued by saying that it "continues to stand by the interpretation described in its published final rule, which allows the 340B covered entities affected by the orphan drug exclusion to purchase orphan drugs at 340B prices when orphan drugs are used for any indication other than treating the rare disease or condition for which the drug received an orphan designation." **What You Should Consider** If you currently benefit from the HHS final regulation, you need to move forward with caution. First, the legal battle will likely continue and the outcome is uncertain. Second, HHS has placed some responsibilities on health care providers and other participants. Specifically, manufacturers must follow the agency's interpretation or they may lose their pharmaceutical pricing agreement and may lose Medicaid reimbursement for their products. Additionally 340B covered entities subject to the orphan drug exclusion will remain "responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act." These compliance obligations can be complicated and if you need assistance with your compliance be sure to contact one of our health care attorneys to discuss your legal responsibilities. Image: Thinkstock/Fuse