HHS to Create New Potential Medicare Pricing Models for Cell and Gene Therapy, Drugs Subject to Accelerated FDA Approval, and “High-Value” Generics

On February 14, 2023, the U.S. Department of Health and Human Services (HHS) published a **report** identifying three models that the Center for Medicare & Medicaid Services’ (CMS) Center for Medicare & Medicaid Innovation (CMMI) will test to try to improve the affordability and accessibility of prescription drugs. The report responds to the state of prescription drug costs and access in America, as well as the widespread changes introduced by the Inflation Reduction Act of 2022 and President Biden’s **Executive Order 14087** (October 2022), both intended to help lower prescription drug costs for Americans. The three selected models will test the feasibility of methods to: (i) offer generic prescription drugs at $2 or less for Medicare patients; (ii) reduce Medicaid costs for novel cell and gene therapies through outcomes-based agreements with manufacturers on a multistate level; and (iii) improve the safety and efficacy of drugs approved through the FDA’s Accelerated Approval Program by aligning payment methods with stakeholders’ incentives. More detail on these three models is expected, and Goodwin attorneys will continue to monitor for additional guidance and any opportunities for public comment.

Read the client alert **here**.