A Practical Look at OIG's New Compliance Guidance

On November 6, 2023, for the first time in 15 years, HHS OIG issued a new reference guide for the health care compliance community – **the General Compliance Program Guidance, or GCPG**. While the GCPG does not set new legal standards and largely reinforces existing guidance, it is a tremendous tool to help health care and life sciences companies advance their compliance efforts. Indeed, within its 91 pages, the GCPG provides the most comprehensive and user-friendly trove of health care compliance insights, tips, and guidance ever provided by the federal government.

Read the full alert **here**.

Significant 340B Drug Pricing Program Litigation May Impact 340B Scope

Two recent federal court cases signal new significant developments with respect to the 340B Drug Pricing Program. Specifically: (1) new federal district court litigation challenging a recent HRSA Notice involving 340B Program "child site" registration and eligibility; and (2) a court decision in other litigation that implicates the scope of the 340B "eligible patient" definition. Details regarding these developments are in the client alert.

Read the client alert **here**.

2023 State Drug Transparency Law Development Update

In October 2021, we **reported** on an uptick in the passage of state drug price transparency legislation. As an update to that report, as of October 2023, approximately 22 states have now passed drug price transparency laws creating new requirements for drug manufacturers.

Each state has its own unique set of requirements, but reporting is often completed via an online portal administered by the state's implementing agency. Generally, these laws require manufacturers to report pricing and other information related to the cost, development, and sale of drugs to the state or state-affiliated entities. Some states will use this data to produce public reports about the cost of prescription drugs with the goal of creating pricing transparency for drug manufacturers as well as to educate the state legislature and public about the drug pricing process.

Read the full alert **here**.

United States: Trends of Agency Scrutiny on Pharmaceutical Transactions Expected to Shift Amid Rise in Deal Activity (GCR)

Despite the threatening rhetoric, the early years of the Biden Administration largely followed previous regimes with respect to antitrust enforcement in the life sciences space. Pharmaceutical transactions in particular encounters the expected amount of agency scrutiny, with most proceeding without an extended investigation and, in contrast to deals in the tech space, did not become testing grounds for more novel theories of competitive harm. This

trend might be changing just as deal activity icked up in early 2023. **Antitrust & Competition** co-chairs **Arman Oruc** and **Andrew Lacy**, partner **Elliot Silver**, and associate **Charlie Stewart** explain more in **GCR's The Guide to Life Sciences**.

Read the in the press highlight **here**.