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Recent Developments Impacting Drug Pricing and the 340B Program: Part 2

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340B LITIGATION UPDATE

- ***American Hospital Association et al. v. Azar*, No. 1:18-cv-2084, U.S. District Court for D.C., before Judge Rudolph Contreras**
 - Plaintiffs include the American Hospital Association, the Association of Academic Medical Centers, America's Essential Hospitals, and certain safety net hospitals
 - On December 27, 2018, Judge Contreras granted a permanent injunction striking the reimbursement cut for 340B drugs finalized in the CY 2018 OPPS Final Rule
 - On May 6, 2019, Judge Contreras extended the prior ruling to incorporate the CY 2019 cuts into the litigation and remanded without vacatur to HHS to determine appropriate remedies
 - CMS has appealed this decision

- **CY 2020 OPPS Proposed Rule**
 - CMS proposes to continue the lower rate of ASP – 22.5% for 340B drugs in CY 2020
 - CMS is soliciting comments on appropriate remedies and 340B drug reimbursement rates moving forward
 - CMS anticipates that if the ruling is upheld, it would propose a remedy for CY 2018 and 2019 as well as changes to CY 2020 rates in its CY 2021 rulemaking

CIVIL MONETARY PENALTIES FINALIZED

- **Manufacturer Civil Monetary Penalties (CMPs)**
 - After multiple delays, HRSA implemented its final rule regarding 340B ceiling prices and CMPs on January 1, 2019
 - Manufacturers that knowingly overcharge 340B covered entities may be liable for CMPs of up to \$5,000 per instance

- **Public database now available**
 - 340B ceiling price database is now accessible online through the Office of Pharmacy Affairs Information System (OPAIS)

GENESIS LITIGATION AND HRSA AUDITS

- ***Genesis Health Care, Inc. v. Azar*, No. 4:19cv-01531-RBH, U.S. Dist. Court S.C. Florence Division, before Judge Bryan Harwell**
 - HRSA concluded that Genesis, a South Carolina FQHC, violated the 340B statute by failing to maintain auditable records and diverting 340B drugs to non-eligible patients after a June 2017 audit
 - As a result, HRSA notified Genesis that it would be considered ineligible to participate in the 340B program as of January 1, 2016
 - On June 28, 2018, Genesis filed a lawsuit against Secretary Azar, et. al, claiming that HRSA's audit findings failed to justify the decision to remove Genesis from the 340B program
 - On June 6, 2019, HRSA voluntarily voided its audit findings and closed the audit, and the district court subsequently dismissed the case

- **Practical implications**
 - 340B covered entities may be able to challenge HRSA audits on procedural grounds in federal court
 - However, given the case was dismissed prior to any court ruling on the substantive issues, some uncertainty remains

Today's Presenters



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