In a striking blow to 340B hospitals, the Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) released a final Medicare Outpatient Prospective Payment System (OPPS) rule adopting its earlier proposal to significantly reduce Medicare reimbursement for separately payable outpatient drugs purchased by hospitals under the 340B program. The final rule confirms that CMS will drop the reimbursement rate from the average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. The payment changes are scheduled to take effect on January 1, 2018.

Citing the large growth in provider participation in the 340B Program and the increasing prices for drugs administered under Medicare Part B to hospital outpatients, CMS’ stated goal is to align Medicare payment with the amounts hospitals are actually spending to acquire the drugs. CMS relied on a May 2015 Medicare Payment Advisory Commission (MedPAC) Report to Congress to determine the new formula. While MedPAC estimated that the ASP minus 22.5 percent figure that CMS ultimately adopted was the “lower bound of the average discount” on drugs paid under the Medicare OPPS, MedPAC’s March 2016 Report to Congress recommended a reduction in payment to ASP minus 10%, which would have allowed 340B hospitals to realize, on average, a financial benefit for participating in
The Financial Impact of the Changes to 340B Hospitals

The OPPS changes will have a significant impact on 340B participating hospitals. CMS estimated that the change will result in a $1.6 billion reduction in OPPS payments to 340B hospitals for separately payable drugs—an additional estimated reduction of $700 million over the $900 million estimate from the proposed rule. While CMS had requested comments in the proposed rule on how to redistribute the savings to target hospitals that treat low-income patients, the final rule instead redistributes the amounts saved by the 340B payment reductions by increasing OPPS payments for non-drug services.

CMS is exempting rural sole community hospitals, children’s hospitals, and PPS-exempt cancer hospitals from the new drug payment reductions for calendar year 2018; they will continue to be paid at ASP + 6%. The exempted hospitals will need to report 340B utilization to Medicare for information and tracking purposes.

Litigation is Expected

The changes to Medicare payment are likely to be challenged in court by one or more groups of stakeholders, including the American Hospital Association. In comments submitted on the proposed rule, multiple groups contended that CMS lacks authority to implement such large payment changes or to single out 340B hospitals for reductions, and may not otherwise contravene the intent and scope of the 340B Program without further Congressional action. These challenges will likely play out in courts as CMS implements the new rule and while Congress continues to debate the future of the 340B Program.

No Impact on Non-Excepted Hospital Outpatient Departments

The changes to Medicare’s reimbursement also create new incentives for off-campus hospital outpatient departments (HOPD). Since January 1, 2017, new off-campus hospital outpatient departments that do not fall within an exception (non-excepted HOPDs) are not eligible for payment under the OPPS, and instead receive a reduced reimbursement rate. CMS has confirmed in the final rule that the new payment reductions for 340B drugs will not be applied to non-excepted HOPDs, as their drugs are not reimbursed under OPPS. As a result, the use of 340B drugs by a non-excepted HOPD will not impact the HOPD’s Medicare reimbursement.

Implementation Challenges

In light of the new rule, 340B hospitals should prepare to come into compliance, which will require the use of a new modifier on each drug billed to Medicare OPPS that was purchased under the 340B Program. In some cases, this will require greater coordination between the hospital’s billing and pharmacy divisions to ensure the modifier is accurately applied.

We will continue to monitor the 340B Program and will update you on any further changes that may arise.