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340B Litigation Update: Hospitals Must Take Steps to Comply with Final Rule

Significant Medicare Part B reimbursement rate cuts and burdensome claim modifiers apply to certain drugs purchased by hospitals through the 340B drug discount program **effective on Jan. 1, 2018** after a federal judge declined to hear a case brought by 340B stakeholders. Read the opinion [here](#) and Polsinelli's analysis of CMS's 2018 OPPS payment adjustment rule (Final Rule) [here](#).

The Court's ruling arrives on the heels of Congress's recent repeal of the Affordable Care Act's individual insurance coverage mandate. **In aggregate, these two developments could increase pressure on safety net hospitals' bottom lines as they provide more uncompensated care while facing reduced payment rates and burdensome claim submission requirements. As a result, 340B hospitals need to assess their existing billing processes and implement modifiers to avoid overpayment and False Claims Act risks.**

This update explores the recent ruling by the DC District Court, the fate of future legal challenges to CMS's payment reduction, and what all 340B-participating hospitals need to do to comply with CMS's Final Rule.

Court Allows CMS to Proceed with 340B Payment Reductions and Modifiers for Now

The legal challenge to halt the cuts, brought by the American Hospital Association and other 340B stakeholders, was dismissed on Dec. 29, 2017, on jurisdictional grounds. Judge Rudolph Contreras of the United States District Court for the District of Columbia dismissed the case for failure to present a claim for reimbursement to HHS for a final decision. Specifically, the Court held that the Social Security Act requires that a specific claim for benefits be presented to HHS before the issue is subject to judicial review.

Practically speaking, this means that a plaintiff must submit a claim for Part B reimbursement for a separately payable 340B drug using the appropriate modifier and receive the reduced payment rate from CMS before bringing an action. Once this occurs, the Court will determine whether plaintiff has exhausted all administrative remedies (i.e., appeals within HHS). Because appeals of the matter at issue would likely be "futile," we believe that it is likely that the Court will excuse plaintiffs from prong two of the jurisdictional analysis and move to the merits of the case once the case is refiled. The issue that the Court will decide is whether CMS exceeded its statutory authority when it issued its Final Rule.



Because the Court’s dismissal appears to be a temporary setback, some of the parties to the original suit have already signaled their intent to re-file once the rate cut impacts specific claims.

CMS’s 340B Payment Adjustment Final Rule Impacts All 340B Hospitals

Until the Court rules on the merits of the case, and barring a legislative fix by Congress, all hospitals, including hospitals that are excepted from the 340B payment adjustment, must implement CMS’s modifiers on OPPS claims to identify when a patient receives a 340B drug. There seems to be a common misunderstanding that certain hospitals are completely exempt from CMS’s 340B provisions in the Final Rule. While it is true that some hospitals may not face a reimbursement reduction for 340B drugs, all OPPS facilities are required to use some form of a modifier to signify when 340B drugs are used.

Given the complexities and billing risks involved, we encourage all 340B hospitals to carefully review CMS’s Final Rule and its Dec. 13, 2017 subregulatory guidance found [here](#) to determine which requirements apply and when they apply.

Below are a few key takeaways followed by a chart that CMS developed that summarizes the new modifier requirements by provider type and drug status indicator as found in Addendum B to the OPPS. Addendum B can be found [here](#).

- The modifiers apply to OPPS claims (Bill Type 13X) beginning Jan. 1, 2018.
- CMS will use the JG modifier to adjust payments to ASP minus 22.5 percent; the TB modifier is for informational purposes.
- Hospitals subject to the payment adjustment must also append the TB modifier to claims for pass-through 340B drugs.
- Critical access hospitals are not paid under the OPPS and are exempt from CMS’s modifiers and payment adjustments.
- The payment reduction does not apply to **rural** sole community hospitals (SCHs), children’s hospitals and PPS-exempt cancer hospitals.
- 340B DSH hospitals can avoid the payment reduction if classified, for Medicare payment purposes, as a **rural** SCH. Rural SCHs are exempt from the payment adjustment. This exemption is based on CMS’s classification of the hospital for Medicare payment purposes, **not** HRSA’s classification for 340B purposes.
- Non-excepted off-campus provider departments under Section 603 of the Bipartisan Budget Act will not face the ASP minus 22.5 percent payment reduction, at least for now. See our analysis of Section 603 [here](#).
- It’s unclear if providers must use modifiers when a manufacturer voluntarily offers pricing at or near the 340B ceiling price (e.g., orphan drugs to rural hospitals).

Hospital Type (determined by CMS)	Pass-through Drug (SI “G”)	Separately Payable Drug (SI”K”)	Vaccine (SI”F” “L” or “M”)	Packaged Drug (SI “N”)
Paid under the OPPS, Subject to the 340B Payment Adjustment				
DSH Hospital	TB	JG	N/A	TB or JG, Optional
Medicare Dependent Hospital	TB	JG	N/A	TB or JG, optional
Rural Referral Center	TB	JG	N/A	TB or JG, optional
Non-Rural Sole Community Center	TB	JG	N/A	TB or JG, optional
Paid under the OPPS, Excepted from the 340B Payment Adjustment for 2018				
Children’s Hospital	TB	TB	N/A	TB or JG, optional
PPS-Exempt Cancer Hospital	TB	TB	N/A	TB or JG, optional
Rural Sole Community Hospital	TB	TB	N/A	TB or JG, optional
Not Paid under OPPS				
CAH	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Maryland Waiver Hospital	TB, Optional	TB, Optional	N/A	TB or JG, Optional
Non-Excepted Off-Campus PBD	TB	TB	N/A	TB or JG, Optional

Source: Centers for Medicare and Medicaid Services





To learn more about these issues, to review and discuss operational challenges presented by the Final Rule, or to discuss potential strategies to address these operational challenges, please contact the author or your Polsinelli attorney. For more information on Polsinelli's 340B practice, please click [here](#).



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For questions regarding this information or to learn more about how it may impact your business, please contact one of the authors, a member of our **340B Drug Pricing Program** practice, or your Polsinelli attorney.

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