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Insights

2018 CMS OPPS Final Rule Significantly Impacts 340B Covered Entities

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By: Leah S. Mannweiler

340B covered entities are facing major changes in the way the discount drug program is reimbursed and administered. On November 1, 2017, CMS made available its 2018 Outpatient Prospective Payment System Final Rule ("Final Rule").[1] The Final Rule implements, in total, drastic reimbursement cuts to Medicare Part B payment for certain drugs acquired through the 340B Program and other program participation requirements CMS threatened in its 2018 OPPS Proposed Rule.[2] The Medicare Part B payment rate is currently set at Average Sales Price ("ASP") plus 6%. Effective January 1, 2018, CMS' will reduce Medicare payment for certain 340B covered entities to ASP minus 22.5%. The net effect reimburses certain covered entities at 26.89% less for affected 340B-acquired drugs.

While discussing the changes at length, CMS used the Final Rule to explain the reduced coinsurance liabilities Medicare beneficiaries will experience under the new reimbursement scheme.

CMS makes clear that the reimbursement changes only impact Disproportionate Share Hospitals ("DSHs") and Rural Referral Centers ("RRCs"). On the other hand, sole community hospitals ("SCHs"), children's hospitals, PPO-exempt cancer hospitals, and critical access hospitals ("CAHs") are unaffected.

Additionally, CMS concedes the Final Rule, as constructed, means that only those providers or locations reimbursed under the OPPS are affected. As such, 340B-aquired drugs administered or dispensed in non-excepted hospital off-campus outpatient departments ("HOPDs") are exempt from these changes. Non-excepted HOPDs are off-campus hospital locations added after November 2, 2015 and reimbursed under the Physician Fee Schedule. In essence, these exempt locations may prove strategically valuable to DSH and RRC covered entities facing steep reimbursement cuts at OPPS-reimbursed practice locations.

Further, CMS finalized administrative/operational rule changes requiring close consideration by ***all*** covered entity types. Effective January 1, 2018, CMS is requiring covered entities to attach modifiers to claims for drugs purchased through the 340B program. Specifically, DSH and RRC providers must be add a "JG" modifier to any HCPCS code for 340B-acquired drugs, which will prompt the reduced payment rate of ASP minus 22.5%. Similarly, SCHs, Children's Hospitals, and PPO-exempt cancer hospitals must use a "TB" modifier for any 340B-acquired drugs, representing a CMS data collection effort. On the other hand, CMS is not requiring CAH or non-excepted HOPDs to include a modifier.

The Final Rule represents significant changes for 340B covered entities. Krieg DeVault's Health Care Practice Group is prepared to affected providers in navigating these changes to ensure effective, compliant 340B program participation. Please contact Leah S. Mannweiler at (317) 238-6222 or lmannweiler@kdlegal.com should you have any questions.

[1] https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-23932.pdf

[2] https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-14883.pdf