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This Year May be a Game Changer for 340B Drug Discount Program, Take Two

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I previously said that the year 2014 may be a game-changer for the 340B Drug Discount Program. Increasing HRSA audits, a lawsuit over the 340B Orphan Drug Rule, and HRSA's promise to issue a 340B mega-regulation, all pointed to major changes in how the 340B Program operates. However, the HRSA audits had limited effect, the court invalidated the Orphan Drug Rule, and the reverberations of the Orphan Drug litigation killed the 340B mega-regulation.

January 2018 began with a new 340B reimbursement rule and new litigation over that rule posing a very real threat to how hospitals use 340B drugs. Then Congress issued a formal Report on legislative and regulatory modifications needed in the 340B Program. Will 2018 finally be the game-changing year for 340B?

340B Medicare Part B Reimbursement Cut Is in Effect

In late 2017, I reported on CMS' implementation of a Medicare reimbursement cut for most hospitals and ambulatory surgical centers. Effective January 1, 2018, Medicare Part B reimbursement for 340B drugs went from AWP plus 6% down to AWP minus 22.5%. The rule also required hospitals and facilities that bill Medicare through the Outpatient Prospective System to utilize specified modifiers for 340B drugs, regardless of whether or not the reimbursement cut is applicable to that facility.

I also reported that advocacy groups were prepared to challenge the reimbursement cut in court. That challenge ultimately failed: the court dismissed the lawsuit, ruling that because the Medicare cut was not yet in effect, the case was not properly before the court.

A 28.5% cut in 340B reimbursement will necessarily have a huge impact on hospitals' use of 340B drugs. So expect to see continuing and multi-pronged challenges to the rule. The advocacy groups have already filed an appeal of the court's dismissal of their lawsuit. I anticipate that individual hospitals will also file administrative challenges to the newly reduced Medicare Part B reimbursement rate.

Congressional Report and Recommended Changes to 340B

In 2017, the House Energy and Commerce Subcommittee on Government Oversight and

Investigations held multiple hearings on 340B. In a July hearing, officials from HRSA, GAO and HHS-OIG faulted the 340B statute for failing to empower HRSA with sufficient authority to effectively oversee the 340B Program. In an October hearing, testimony from five different 340B covered entities exposed inconsistencies in how the entities calculate 340B savings and a lack of transparency in how those covered entities use those resulting saving.

A promised third hearing focused on 340B contract pharmacies was never scheduled. On January 10, 2018, the Energy and Commerce Committee issued a Report on its review of the 340B Program, complete with specific recommendations for legislative changes.

The Committee's Report included the following findings:

- Congress failed to clearly identify the intent or purpose of the 340B Program.
- HRSA lacks sufficient regulatory authority and sufficient resources to adequately oversee the 340B Program.
- The lack of defined reporting requirements for covered entity expenditures and revenue means there is no consistent accounting for 340B Program uses and benefits.

The Committee's Report also questioned tying 340B eligibility to hospital DSH status, given DSH status is based on inpatient metrics while 340B can only be used for outpatient drugs.

The Committee's Report made various recommendations, including the following:

- Congress should clarify the intent and purpose of the 340B Program.
- Congress should empower HRSA to clarify 340B Program requirements, monitor and track how the 340B Program is used, and ensure that low-income and uninsured patients directly benefit from 340B.
- Congress should ensure that relevant stakeholders have access to 340B ceiling prices as well as require covered entities to disclose information about annual 340B savings and revenue.
- Congress should clearly define charity care and establish a mechanism for reporting and monitoring charity care.
- Congress should reassess whether DSH status is an appropriate metric for 340B Program eligibility.

Energy and Commerce Chair Representative Greg Walden did not say he had drafted legislation to implement the recommendations made in the Report. Instead, he said that he expected the Committee to discuss overhauling the 340B Program in light of the Report. Representative Walden did not rule out addressing the Medicare Part B reimbursement cut as part of any legislative overhaul.

And Then There Is Medicaid

As if the Medicare Part B reimbursement reduction and potential Congressional action were not

enough, there are Medicaid changes afoot for 340B.

As previously discussed, the 2016 changes to the AMP rule carried implications for 340B. By April 2017, all state Medicaid Plans had to be amended so that state Medicaid reimbursement for drugs was based on actual acquisition cost. For 340B drugs that meant states had to cap Medicaid reimbursement at the 340B ceiling price. Most states have adopted regulations to comply with the federal mandate.

A number of states went further in redesigning their Medicaid reimbursement methodology. HHS-OIG previously reported on concerns with 340B contract pharmacy procedures that fail to identify Medicaid and/or Medicaid managed care beneficiaries before billing for 340B drugs, leading to duplicate discounts. In 2017, a number of states, including Ohio and Oregon, eliminated those concerns by prohibiting 340B contract pharmacies from carving in Medicaid beneficiaries. Last week, as part of its proposed budget, California went further, proposing to eliminate any 340B entity from carving in Medicaid beneficiaries, so that California could lawfully collect rebates on all drugs reimbursed by Medicaid.

So once again there are a lot of moving parts in 340B. Will 2018 be a game-changing year for 340B? We will have to stay tuned.

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