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Will CMS Drive Further Changes to 340B?

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There are now multiple proposals in the House and Senate for substantive changes to the 340B Drug Discount Program. The odds of a legislative "fix" to 340B are increasing. But independent of congressional action, is CMS signaling that additional changes to 340B may be coming?

The most significant recent change to 340B came courtesy of CMS, not HRSA. Effective January 2018, CMS, relying on its authority over the Medicare Hospital Outpatient Prospective Payment System (OPPS), effectively cut Medicare Part B reimbursement for 340B drugs in the hospital outpatient setting by almost 30%. Most hospital and ambulatory surgical center reimbursement for Medicare Part B 340B drugs went from the standard ASP plus 6%, down to ASP minus 22%. Accompanying the new OPPS rule, CMS issued Frequently Asked Questions (FAQs), discussing the mandatory use of modifiers when billing 340B drugs under the OPPS. While the OPPS rule implementing the payment reduction is the subject of ongoing litigation, to date the Medicare Part B payment reduction remains in full force and effect.

The President's **2018 budget** touted the potential savings from the Part B reimbursement cut but then went further, proposing "reforms to improve 340B Program integrity to ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations." In addition to imposing unspecified reporting requirements on the use of 340B proceeds, the President's budget would further change hospitals' Medicare reimbursement for 340B drugs by "requiring a minimum level of charity care for hospitals to receive a payment adjustment related to uncompensated care." Again, Medicare (*i.e.,* CMS), not HRSA, is the driver of the proposed change. No details or numbers were provided as part of the 2018 budget proposal.

We previously **blogged** about some of the highlights of CMS' recently published **2019 Final Rules for Medicare Advantage and Part D Plans**, and the accompanying **2018 Call Letter**. However, when CMS published those materials, they also published an update to the **FAQs** on billing 340B drugs under the OPPS – but it goes beyond the OPPS, as illustrated by the following questions from the FAQs:

> *Question: How are Medicare Advantage plans impacted by the new payment policy for 340B acquired drugs?*
>
> *Answer: MAOs that contract with a facility/provider eligible for 340B drugs can negotiate the terms and conditions of payment with the provider/facility. CMS cannot interfere in the payment rates that MA organizations and providers enter through contracts.*
>
> *When paying a facility/provider eligible for 340B drugs on a non-contract basis the MA plan pays the non-contract provider/facility the amount they would have received under Original Medicare payment rules less the plan allowed cost sharing collected from the MA enrollee.*

Plans and payors are well aware of the issues raised by the 340B Drug Discount Program. Building off the Medicare Part B reimbursement cut, CMS seems to be signaling that it will not interfere if MA plans also want to restrict how they use Medicare funds to reimburse providers for drugs purchased through 340B.

HRSA recognizes that without legislative authorization, it has limited authority to implement operational changes to 340B. CMS is essentially asserting that it has broader authority over Medicare (and Medicaid) than HRSA has over 340B – and CMS is not averse to using that authority to reform 340B.

So even if Congress does not act on any of the pending proposals, will CMS be the vehicle to bring further reform to 340B? We will all be waiting and watching for what comes next.

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