

CMS Takes Another Swing at 340B Reimbursement Cuts. Will It Be Strike Three?



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The [proposed 2020 Outpatient Prospective Payment \(OPPS\) rule](#) was published on August 9, 2019. Buried in the 819 pages of proposed changes and justifications, CMS took another swing at cutting Medicare Part B reimbursement rates for 340B drugs. CMS opened its discussion of 340B provisions in the 2020 OPPS proposed rule by first stating it was keeping in effect [the 340B reimbursement cut first implemented though the 2018](#) OPPS rule. The 2018 OPPS rule slashed most hospitals' Part B reimbursement for 340B drugs from Average Sales Price (ASP) plus 6% down to ASP less 22.5%, a reduction of almost 30%.

In the 2020 proposed OPPS rule, CMS does acknowledge that actual implementation of the 2018 OPPS 340B reimbursement change was blocked due to a [successful court challenge](#). However, CMS goes on to use the 2020 proposed rule to attempt to put that controversy to bed by significantly reducing the size of that cut. Specifically,

CMS wants to use the 2020 OPSS rule to potentially implement a payment reduction that is a fraction of what it originally proposed, reducing Part B reimbursement for 340B drugs from ASP plus 6% to ASP plus 3%, which is a 3% reduction in Part B reimbursement instead of a 30% reduction. Actual implementation of the proposed change depends on the final outcome of an appeal of that court challenge.

So is this just a face saving measure for CMS? And will it be enough to put an end to the existing litigation? To understand the potential ramifications of the CMS proposal, we need to know how we got here.

Court Enjoins 2018 OPSS Rule Cut Part B Reimbursement for 340B Drugs

By [statute](#), CMS retains the authority to adjust OPSS drug reimbursement to approximate hospitals' average acquisition cost for drugs or, if acquisition cost is not available, the reimbursement may be "as calculated and adjusted by the Secretary for purposes of this paragraph." Relying on that statutory authority, CMS used the [2018 OPSS rule](#) to "adjust" Part Medicare B reimbursement for 340B drugs from the standard of ASP plus 6% down to ASP minus 30%. CMS justified slashing the OPSS reimbursement rate because, while 340B acquisition costs are confidential, multiple studies supported the belief that ASP plus 6% was significantly beyond the hospitals' average acquisition cost for 340B drugs. The change went into effect on January 1, 2018. Hospitals sued.

After the initial suit was dismissed on technical grounds, and appeal of that dismissal was upheld, a new lawsuit was filed. In late December 2018, the suing plaintiffs scored their first legal victory and obtained an injunction preventing further enforcement of the OPSS Part B reimbursement cut for 340B drugs. The Court [ruled](#) that CMS acted *ultra vires*, or beyond its authority, when it implemented the Medicare Part B OPSS reduction for 340B drugs, holding that a reimbursement cut approximating 30% was just too extreme to qualify as an "adjustment." The Court found support for this view in a 2004 Court of Appeals decision, [Amgen v. Smith](#), holding that the statutory authority to adjust OPSS payments "did not give the Secretary the absurdly broad power to make drastic adjustments...and term it an equitable adjustment." Strike One.

However, the Court stopped short when it came to the plaintiffs' request for retroactive restitution and a reallocation of payments going forward as the appropriate remedial measure. The 2018 reimbursement cut was implemented in January 2018 with other payment adjustments because of a requirement that OPSS adjustments be budget neutral but had already been in effect for almost a year. The Judge recognized his ruling could "wreak havoc" on the already complex administration of the OPSS. Instead, he issued an injunction that solely applied to the 340B reimbursement change and ordered supplemental briefing on the manner, scope, and implementation of a future remedy.

The parties filed multiple briefs with the Court on the issue of a remedy. Among the contentions:

- Plaintiffs contend that based on the injunction, the only proper remedy is for

the court to order CMS to make covered entities whole for the millions of dollars they assert they lost after the 2018 rule went into effect. Plaintiffs alleged that collectively, the improper change in Medicare Part B reimbursement for 340B drugs cost covered entities \$25 million/week during the time it was in effect.

- CMS contends that because of the recognized disruption to the OPPS as well as the resulting increase in costs to beneficiaries through Medicare deductibles and co-payments, the only appropriate remedy is to keep the injunction in place while remanding the dispute to CMS to allow the Agency to use its expertise to devise an appropriate administrative remedy. The Agency reminded the Court that the 2018 (and 2019) OPPS was premised on budget neutrality, and the plaintiffs' proposed remedy did not appropriately account for other payment adjustments that were part of the OPPS.

Meanwhile, the 2019 OPPS rule had already come out, extending the 340B reimbursement cut in Part B to non-excepted off-campus out-patient departments. Relying on his December 2018 opinion, on May 6, 2019 the same judge [enjoined](#) enforcement of that rule change. Strike Two. In that same ruling, after considering all the briefing on a proposed remedy for 2018 rule, the judge remanded both the 2018 and 2019 OPPS rules to CMS to devise appropriate remedial measures on the issue of Medicare Part B 340B reimbursement. The Court retained jurisdiction of the dispute so it could "reconsider the remedy if the agency fails to fulfill its responsibilities in a prompt manner."

After much back and forth, on July 10, 2019, at CMS's urging, the Court rescinded its retention of jurisdiction and entered [a final](#) judgment enjoining enforcement of the 2018 and 2019 340B reimbursement cuts in the OPPS. The judgment keeps the limited injunctions in place but allows for the Court of Appeals to take up an expedited review of the propriety of the 2018 (and 2019) Medicare Part B reimbursement cut for 340B drugs. An expedited appeal schedule was [ordered](#), with briefing scheduled to be completed by October 11, 2019.

What the 2020 OPPS Means for 340B and the Pending Litigation

So what exactly does the 2020 proposed OPPS rule mean for 340B?

Importantly, the proposed rule makes clear that CMS considers the 2018 and 2019 OPPS, and its 340B reimbursement changes, valid. Most of the discussion around 340B in the proposed 2020 OPPS rule regurgitates CMS's original rationale for the 2018 and 2019 rule changes. Therefore, if CMS wins at the Court of Appeals, the injunction would be lifted and the Medicare Part B 340B reimbursement cuts outlined in those rules will be reinstated retroactive to the effective date of the respective rules.

The proposed change to 340B reimbursement in the 2020 OPPS is really just CMS's backstop if they lose at the Court of Appeals. If the Court of Appeals upholds the District Court and find the 340B reimbursement cuts were improper, there is still the open issue of the appropriate remedy for the 11½ months the cuts were in effect.

Thus, through the 2020 OPPS, CMS seeks and proposes public comment on whether a

Medicare Part B reimbursement rate of ASP plus 3% for 340B drugs is appropriate. CMS clearly believes that implementing such a change qualifies as a remedial measure because it still “results in payment rates that are well above the actual” hospital purchase costs for 340B drugs, meaning hospitals will still profit off of Part B reimbursements for 340B drugs. CMS is not definitive on whether this “remedy” should be implemented retroactively to 2018 or merely going forward and seeks public comment on the alternatives.

Recognizing that implementing this “remedy” may not satisfy all parties or the Court, CMS also seeks comments on whether the Agency should make a lump sum payment to the covered entities tied to demonstrated harm each suffered during the weeks in which the 2018 OPPS reimbursement change was in effect, based on data regarding drugs billed using the 340B modifier required as part of the 2018 OPPS.

However, if CMS wins at the Court of Appeals, all bets are off, and Medicare Part B reimbursement for 340B drugs in the OPPS will revert to ASP minus 22.2%. And you can be sure that CMS will attempt to retroactively adjust 340B drug reimbursements and recoup Part B payments for the time in which the stay was in effect.

Will the Proposed Changes in the 2020 OPPS be CMS’s Strike Three?

If CMS loses at the Court of Appeals, it clearly hopes that the Court will consider its implementation of a 3% reduction in Part B reimbursement for 340B drugs to be an “adjustment” that is within CMS’s authority to implement. CMS may win on that point. But will CMS persuade plaintiffs, or the Courts, that such a change is an appropriate and sufficient remedial measure for the period of time in which the 30% Part B reimbursement reduction was (improperly) in effect? In other words, will CMS really succeed in persuading plaintiffs or the Courts that modifying Part B reimbursement for 340B drugs to ASP plus 3% really makes the covered entities whole for what the plaintiffs estimate to be \$25 million/week in losses over approximately 50 weeks? CMS cannot realistically expect the plaintiffs to be satisfied, without something more by way of a remedy.

However, CMS recognizes that it is not just plaintiffs or the Court that it needs to satisfy. Hospitals that do not acquire drugs through 340B may cry foul on implementing the proposed 2020 OPPS change in 340B reimbursement and/or awarding 340B hospitals lump sum or individual remedial payments, saying that the proposals inequitably reward 340B covered entities at their expense and violate the statutory mandate for budget neutrality in the OPPS.

Moreover, Medicare beneficiaries have yet to weigh in. CMS justified much of the 2018 OPPS 340B reimbursement change on concerns for Medicare beneficiaries. Theorizing that Part B reimbursements for 340B drugs far exceed hospital acquisition costs, CMS argued that the Medicare Part B deductible and 20% cost-sharing requirements meant that beneficiaries were directly harmed by the inflated 340B Medicare Part B drug reimbursement costs. If a fractional Part B reimbursement adjustment from ASP plus 6% to ASP plus 3% still results in overinflated drug costs -- and profits -- for hospitals, beneficiaries are still bearing a significant portion of those overinflated costs. But when it comes to the ongoing

litigation at least, the beneficiaries are relegated to the bleachers and are not a meaningful player.

So will the 2020 OPPS rule be strike three for CMS's attempts to reduce Medicare Part B reimbursement for 340B drugs? To know that, we first must know how the Court of Appeals rules. If the parties stick to the briefing schedule in the expedited appeal of the 2018 and 2019 Medicare Part B 340B reimbursement cuts, we may not have to wait until next year for an answer.

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