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CMS to Reduce 340B Drug Payments to Hospitals by US$1.6 Billion

On November 13, 2017, Centers for Medicare & Medicaid Services (CMS) within the US Department of Health and Human Services (HHS) published the final rule revising the Medicare hospital Outpatient Prospective Payment System (OPPS) for CY2018. Among a number of changes, the final rule dramatically reduces Medicare Part B payments to hospitals for separately payable drugs purchased at a discount through the 340B Program by an average of 28%.

Currently, Medicare pays hospitals the Average Sales Price (ASP) plus 6% for a separately payable drugs (ASP+6%) regardless of whether the hospital purchased the drug at a discount through the 340B Program.[1] Under the final rule, Medicare will pay hospitals ASP minus 22% for separately payable drugs purchased through the 340B Program. The change will reduce payments to 340B hospitals by an estimated US$1.6 billion that will be redirected to payment for other services within the OPPS.

Background

The 340B Program was established by section 340B of the Public Health Service Act by the Veterans Health Care Act of 1992 and is administered by the Health Resources and Services Administration (HRSA) within the HHS. The 340B Program allows participating hospitals and other healthcare providers to purchase certain "covered outpatient drugs" at discounted prices from drug manufacturers. The statutory intent of the 340B Program is to maximize scarce federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive.[2]

The 340B statute defines the healthcare providers that are eligible to participate in the program (covered entities). In addition to federal healthcare grant recipients, covered entities include hospitals with a Medicare disproportionate share hospital (DSH) percentage above 11.75%, critical access hospitals (CAHs), children's hospitals with a DSH adjustment greater than 11.75%, sole community hospitals (SCHs) with a DSH adjustment percentage of 8.0% or higher, rural referral centers (RRCs) with a DSH adjustment percentage of 8.0% or higher and freestanding cancer hospitals with a DSH adjustment percentage above 11.75%.[3]

OPPS Final Rule

CMS' stated goal is to better align Medicare payment for separately payable drugs with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B Program to allow covered entities, including eligible hospitals, to stretch scarce resources in ways that enable hospitals to continue providing access to care for Medicare beneficiaries and other patients.[4] While recognizing the intent of the 340B Program, CMS believes it is inappropriate for Medicare to subsidize other activities through Medicare payments for separately payable drugs.[5]

Adopting a study prepared by MedPAC, CMS believes that the estimated average minimum discount of 22.5% of the ASP adequately represents the average minimum discount that a 340B participating hospital receives for separately payable drugs under the OPPS.[6] Given data limitations, CMS did not attempt to calculate the precise discount for each hospital, but believes that the analysis from the MedPAC report is appropriate and can be replicated by interested parties.[7] As MedPAC notes in its analysis, its estimate was conservative and the actual average discount experienced by 340B hospitals is likely much higher than 22.5% of the ASP.[8]

For CY 2018, the applicable payment rate for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program will be reduced from ASP+6% to ASP minus 22.5%.[9] Not all hospitals are subject to the payment reductions. SCHs, children's hospitals and PPS-exempt cancer hospitals are excluded from this payment reduction in CY 2018.[10]

1 82 Fed. Reg. 52494 (Nov. 13, 2017).

2 The House report that accompanied the authorizing legislation for the 340B Program stated: "In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rept. No. 102–384(II), at 12 (1992)). 82 Fed. Reg. 52493 (Nov. 13, 2017).

3 Public Law 111–148, section 7101.

4 82 Fed. Reg. 52495 (Nov. 13, 2017).

5 *Id.*

6 82 Fed. Reg. 52496 (Nov. 13, 2017); estimated by MedPAC in its May 2015 Report to Congress, page 7.

7 *Id.*

8 82 Fed. Reg. 52496 (Nov. 13, 2017).

9 82 Fed. Reg. 52622 (Nov. 13, 2017).

10 *Id.*

CMS estimates that OPPS payments for separately payable drugs, including the 20% beneficiary copayments, will decrease by approximately US$1.6 billion in CY2018.[11] Because the payment reduction is implemented in a budget neutral manner within the OPPS, the reduced payments for separately payable drugs purchased through the 340B Program will increase payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount.[12]

The final rule will also establishes two modifiers to identify whether a drug billed under the OPPS was purchased under the 340B Program – one for hospitals that are subject to the payment reduction and another for hospitals not subject to the payment reduction but that acquire drugs under the 340B Program.[13]

The 340B Program payment changes will reduce payments to all non-excepted hospitals, but will have a more dramatic effect on urban, major teaching hospitals with 500 or more beds.[14]

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11 82 Fed. Reg. 52623 (Nov. 13, 2017).
12 *Id.*
13 82 Fed. Reg. 52362 (Nov. 13, 2017).
14 82 Fed. Reg. 52627 (Nov. 13, 2017); Table 88 – Estimated Impact of the CY 2018 Changes for the Hospital Outpatient Prospective Payment System.

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