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HHS Inspector General Critical of 340B Program Spending

+Insights

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The U.S. Department of Health and Human Services Inspector General released another report critical of the 340B program and proposed changes to reduce Medicare spending on 340B drugs.

Continuing a trend of reports critical of the 340B program, the Inspector General (IG) for the U.S. Department of Health and Human Services on November 24, 2015, released a report identifying savings that could be realized by making changes to the Medicare program's Part B drug payment rules to better harmonize Medicare payments and provider purchasing patterns under the 340B program.

The 340B program was established to allow certain nonprofit safety net entities to purchase covered outpatient drugs at significant discounts. Because Medicare and Medicaid payment for drugs under the 340B program is not discounted, covered entities can realize sizable margins from drugs purchased at 340B program discounts. Covered entities are not restricted on how they use this spread.

Earlier in 2015, the Medicare Payment Advisory Commission (MedPAC) estimated that on average the 340B acquisition cost could be as much as 22 percent below average sales price (ASP). The Government Accountability Office also found that in 2012, average spending on Part B drugs in 340B hospitals was almost 2.5 times the spending in non-340B hospitals.

In his most recent report, the IG identified 340B ceiling prices (*i.e.*, the maximum selling price for a drug under the 340B program) for 420 drug codes paid by Medicare. The IG found that Medicare paid almost $19 billion for this cohort of claims, and that as much as $3.5 billion—almost 20 percent of all spending on Part B drugs in the cohort—was spent on drugs purchased under the 340B discount program.

As much as $3.5 billion was spent on drugs purchased under the 340B program.

Medicare is required by law to set its payment rate for Part B drugs at 106 percent of the volume-weighted ASP for the drug. The law does not allow Medicare payment rates to vary based on the purchase price of the drug. It is precisely this provision that provides sizable margins to covered entities when purchasing drugs under the 340B program that are later furnished to Medicare beneficiaries.

The OIG recommends changes that could save Medicare between $162 million and $1.1 billion.

A covered entity purchasing drugs under 340B may do so at significant discounts as compared to the ASP payment limit. The actual discount varies based on a number of factors, but the IG found that the ASP payment limit exceeded the 340B ceiling price by anywhere from 25 percent to more than 100 percent.

In one particularly troubling example, the beneficiary coinsurance amount alone (20 percent of the Medicare payment limit) exceeded the 340B discounted purchase price for the drug.

Overall, the IG estimated that Medicare paid providers $1.3 billion more than their acquisition cost for Part B drugs purchased under the 340B program.

The IG presents three recommendations for legislative changes that would align Medicare spending with acquisition cost while still providing some financial relief to covered entities. Each recommendation would require congressional action to allow the Centers for Medicare & Medicaid Services to calculate different payment limits for 340B and non-340B drug purchases.

The IG's first recommendation would reduce Medicare spending on 340B drugs by $162 million by lowering the Medicare payment amount to 100 percent of ASP for drugs purchased under the 340B program. Under this option, 340B entities would retain $1.1 billion of the spread between acquisition costs and Part B payments.

The second recommendation would set Medicare payment at 85.6 percent of ASP (ASP minus 14.4 percent). This recommendation would essentially tag one-half of the $1.3 billion in excess spending as Medicare savings, thus reducing Medicare spending by $638 million and allowing 340B entities to retain the other half of the spread.

The most aggressive recommendation would set Medicare payment at 106 percent of the 340B ceiling price, resulting in Medicare spending reductions of $1.1 billion, with only $211 million of the spread retained by 340B entities.

While the OIG did not address the programmatic and policy implications of its recommended policy changes, such

implications could be far reaching for providers and pharmaceutical manufacturers alike.

Savings of the scope presented in the report are a double-edged sword. Certainly, saving more than $1 billion in taxpayer money will be an enticing target for legislators looking to pay for other spending initiatives. Reduced payment rates may also have the effect of reducing incentives to purchase product under the 340B program, which would be appealing to pharmaceutical manufacturers. However, such significant reductions in savings for hospitals could cut into hospital margins.

Critics of the 340B program, including pharmaceutical manufacturers, are expected to add this OIG report to their already robust inventory of critical findings, and to push Congress to revise the 340B program through legislation. These critics may find a receptive audience. The House Energy & Commerce Committee earlier in 2015 held hearings on the 340B program and recently floated draft legislation. While the draft legislation did not include proposals addressing Medicare payments for 340B drugs, these proposals could find their way into legislation in the near future.

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