Insight

CMS Moves Toward Much-Needed 340B Reforms

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In order for a manufacturer's drugs to be covered by the Medicaid program, the manufacturer must agree to participate in the 340B Drug Pricing Program (340B). Under the 340B program, manufacturers must provide discounts to eligible health care providers for covered outpatient drugs. As the federal government pays for roughly 40 percent of all prescription drugs in the United States,[1] these discounts are intended to allow "scarce Federal resources [to be stretched] as far as possible." However, because the law does not require the health care providers who receive these discounts to pass their savings along to consumers, many question whether the program's goal is being met and if reforms are needed. To that end, the Centers for Medicare and Medicaid Services (CMS) proposed last week to adjust the Medicare reimbursement rate for drugs obtained through 340B and provided to Part B enrollees.[2]

Background

The 340B program was established in response to the development of an unintended consequence of Medicaid's "best price" policy. Because no exception to the "best price" policy was provided for drug manufacturer's charitable giving—in which medicines were provided for free or at an extreme discount for uninsured and low-income patients, most of those donations disappeared and hospitals were often left footing the bill. In response, Congress amended the Public Health Service Act, adding Section 340B, which set a ceiling price (essentially, the price charged to Medicaid after statutory rebates are accounted for under the "best price" policy) that drug manufacturers may charge for such drugs provided to "covered entities." [3] This change thus formalized and expanded the former practice of charitable giving by mandating minimum discounts be provided to certain hospitals and other outpatient centers.

While these discounts were intended to be targeted to uninsured and low-income patients, the number of entities eligible for such discounts has increased dramatically over the years—particularly with the expanded definition of a "covered entity" provided in the Affordable Care Act (ACA)—and the broad definition of "qualified patient" for whom these discounts must be provided. Further, current law does not require that these discounts be passed on to either the patient and/or the insurer, including the Federal government, paying for drugs obtained through the 340B program. Patients and taxpayers are therefore not necessarily benefitting from the mandated discounts.

In addition to the discounts provided directly through 340B, the same law provides for the creation of Prime Vendor Program (PVP) which can provide entities additional savings beyond the 340B discount. According to the Department of Health and Human Services (HHS), PVP participants receive an estimated average discount of 10 percent of the 340B price.[4]

Proposed Rule

On July 13, 2017, CMS issued a proposed rule that would, among other things, change the Medicare Part B

reimbursement rate for drugs obtained through 340B. Currently, Medicare pays providers for covered 340B drugs just as it does for any other drug covered under Medicare Part B: the average sales price (ASP) plus six percent of the ASP. This payment formula is set in statute and the six percent add-on serves as an administrative dispensing fee, common among prescription drug reimbursement formulas. Under the proposed rule, CMS would instead pay for drugs obtained at a discount through the 340B program and provided to Medicare beneficiaries ASP – 22.5 percent.[5] This payment change will more closely reflect the actual acquisition cost faced by hospitals for such drugs, as explained below.

Potential Impact

If this proposal goes into effect, Medicare beneficiaries and taxpayers stand to reap significant savings. Because beneficiaries pay their coinsurance (20 percent under Medicare Part B) based on Medicare's reimbursement rate, beneficiaries will pay significantly less for the same drug as a result of this change. Medicare will also save substantial amounts. According to MedPAC, 48 percent of Medicare Part B drug spending goes to 340B hospitals and totaled $3.5 billion in 2013, up from 22 percent and $0.5 billion in 2004.[6] Much of this increased spending is a result of the dramatic increase in the number of entities participating in 340B. Between 2005 and 2014, the number of hospitals participating in 340B grew from 583 to 2,140, largely as a result of the ACA's expansion of eligible entities.[7]

To illustrate potential savings, imagine the average sales price of a drug is $100. Under current law, Medicare would pay the provider $106 and the beneficiary would pay $21.20. Under this new proposal, Medicare would instead pay $77.50 and the beneficiary would pay $15.50. Total savings to Medicare and the beneficiary for that drug would be $34.20.

As for the hospitals—recent reports suggest the impact to their bottom line should be minimal. Again, the total dollar value at stake, based on 2013 Medicare expenditures, is roughly $1 billion. Revenue from the top seven non-profit hospitals alone, as ranked by U.S. News & World Report, totaled nearly $34 billion in 2015, while their charity care fell to $272 million.[8] Further, the proposed new payment rate is based on findings from multiple government agencies regarding the average amount of savings received by entities participating in 340B. In May 2015, the Medicare Payment Advisory Commission (MedPAC) reported that, on average, 340B hospitals receive a *minimum* discount of 22.5 percent of the ASP.[9] The HHS Office of the Inspector General (HHS OIG) found that in 2013 payments made by Medicare Part B and the coinsurance paid by beneficiaries for 340B drugs were 58 percent higher than the ceiling price which may have been charged to the hospitals to obtain the drugs; this difference between the cost to the hospital and the reimbursement amount allowed hospitals to retain approximately $1.3 billion that year from 340B discounts alone.[10] The Government Accountability Office (GAO) has found 340B participation to be associated with higher Medicare expenditures: in 2012, average spending per Medicare beneficiary at 340B hospitals was more than double expenditures at non-340B hospitals, and this difference was not explained by patients' health status.[11] Finally, there are a plethora of other programs designed to provide safeguards to hospitals treating significant numbers of uninsured and underinsured patients, including the Disproportionate Share Hospital (DSH) program and bad debt payments made by Medicare—though both of these programs could also use reform.[12]

Additional Reforms Still Needed

As outlined by the American Action Forum here and by the aforementioned reports from the GAO, MedPAC, and HHS OIG, the 340B program suffers from a lack of appropriate benchmarks for determining program eligibility, clear guidance regarding use of savings, and necessary program oversight. The House Energy and Commerce Subcommittee on Oversight recently held a hearing highlighting the lack of resources available to

provide proper oversight in the 340B program. Accordingly, non-compliance rates between FY2012-FY2016 ranged from 63 to 82 percent.[13] The program no longer seems to be serving its intended purpose and warrants substantial reform.

The proposal outlined by CMS is a worthwhile first step in providing much-needed reform to this ever-expanding program. But it just serves as a band-aid, attempting to mitigate the impact of the underlying problems. Congress should work to enact additional reforms that ensure program integrity, and that savings are distributed appropriately.

[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html

[2] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-13.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending

[3] https://www.hrsa.gov/opa/programrequirements/publiclaw102585.html

[4] https://www.hrsa.gov/about/budget/budgetjustification2017.pdf

[5] https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-14883.pdf

[6] http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0

[7] http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0

[8] http://www.politico.com/interactives/2017/obamacare-non-profit-hospital-taxes/

[9] http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0

[10] https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf

[11] https://www.gao.gov/assets/680/670676.pdf

[12] http://www.gao.gov/assets/680/678127.pdf

[13] http://docs.house.gov/meetings/IF/IF02/20170718/106269/HHRG-115-IF02-20170718-SD002.pdf