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August 11, 2017

Submitted electronically via Regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
PO Box 8013
Baltimore, MD 21244-1850

Re: CMS-1678-P; Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule

Dear Sir or Madam:

The Pew Charitable Trusts (Pew) is pleased to offer comments on the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Proposed Rule.[1] Pew is an independent, nonpartisan research and public policy organization dedicated to serving the American public. Our drug spending research initiative is focused on identifying policies that would allow public programs to better manage spending on pharmaceuticals while ensuring that patients have access to the drugs that they need.

Our comments address the proposal to reduce Medicare Part B payments to hospitals participating in the 340B Drug Discount Program. From 2004 to 2013, Part B payments to hospitals that participate in the 340B program increased more than 500 percent – from $0.5 billion to $3.5 billion.[2] Overall, Part B spending in 340B hospitals appears approximately proportionate to participation in the program: 45% of acute care hospitals in Medicare participate in 340B, accounting for 48% of all Part B payments (most recent data available, 2014 and 2013, respectively).[3] As the proposed rule notes, the current 340B payment methodology creates an incentive for hospitals to increase drug utilization; however, a similar incentive exists throughout the Part B program.

[1] 82 Fed. Reg. 33558 (July 20, 2017).
[2] MedPAC, May 2015 Report to the Congress: Overview of the 340B Drug Pricing Program.
[3] *Id.*

Pew commends the Centers for Medicare & Medicaid Services (CMS) for thoroughly reviewing programs that affect federal spending on pharmaceuticals, including the 340B program. As the largest purchaser of drugs in the US, Medicare policies can have a significant effect on drug expenditures in the US. However, we wish to highlight three considerations:

- CMS proposes to offset any reduced 340B drug spending by equivalent increases in payments to hospitals. Therefore, as noted in the proposed rule, this rule change would not reduce federal health expenditures.
- In response to this change, hospitals could alter their drug purchasing in a way that limits reductions in drug spending.
- The rule, as written, creates incentives that could shift patients to 340B hospitals from other sites of care.

Cost-Neutral Aspect of the Proposed Rule

This proposal will not reduce Medicare spending, as any savings would be redistributed from 340B hospitals to all Medicare providers through slight increases in payment for non-drug expenditures.[4] As discussed below, some potential savings from reduced 340B drug reimbursement could also accrue to drug manufacturers rather than to the Medicare program.

Potential Unintended Consequences of Reduced Drug Payments to 340B Hospitals

Currently, Medicare Part B pays all providers, including 340B hospitals, for physician-administered covered outpatient drugs at Average Sales Price (ASP) plus 6 percent.[5] The Medicare Payment Advisory Commission (MedPAC) estimates that 340B hospitals receive, on average, a minimum discount of 22.5 percent of the ASP for drugs paid by Part B;[6] the proposed rule notes that discounts may be greater due to voluntary supplemental discounts offered by manufacturers through the Prime Vendor Program.[7]

CMS has proposed to reduce payment to hospitals for drugs purchased under the 340B program from ASP plus 6 percent to ASP minus 22.5 percent, in order to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs."[8] Along with reducing Medicare drug spending at 340B hospitals, this change would reduce beneficiary spending because co-insurance would be calculated from the reduced payment.

However, two potential unintended consequences of this proposal should be considered:

1) 340B hospitals may choose to purchase new drugs at the list price instead of the discounted 340B price

Under the proposal, 340B hospitals would be paid under Medicare Part B at Average Sales Price (ASP) minus 22.5 percent instead of the current payment of ASP plus 6 percent.[9] This may incentivize 340B

[4] 82 Fed. Reg. 33712.
[5] Currently less an additional reduction imposed through budget sequestration.
[6] *Supra* note 2.
[7] 82 Fed. Reg. 33632.
[8] *Id*.
[9] 82 Fed. Reg. 33634.

hospitals to purchase new drugs at the list price rather than the 340B price, as hospital revenue will be greater under this purchasing model. Because Medicare is only proposing to reduce payment in cases where a 340B hospital purchases the drug at the 340B price,[10] 340B hospitals are incentivized to pick and choose which drugs they buy at the 340B price based upon the anticipated difference between their costs and the Medicare payment for each drug. For this analysis, we estimated 340B hospital revenue for sole-source brand-name drugs, comparing those drugs with a 340B price set only by the base discount percentage (23.1 percent) and those drugs with a further discounted 340B price due to the inflation penalty. Assuming no voluntary sub-ceiling manufacturer discounts, 340B hospitals would receive greater revenue under the proposal when purchasing drugs not subject to a substantial inflation penalty at full price rather than the 340B price.

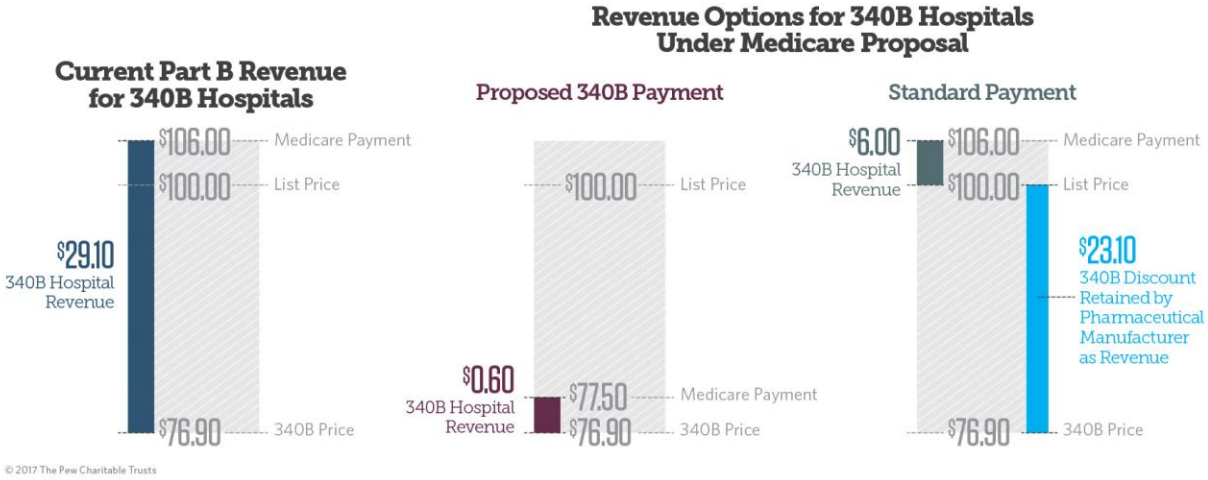
For example, for a hypothetical drug with a list price of $100, a hospital purchasing through the 340B program would pay $76.90, but under this proposal would be paid only $77.50, resulting in hospital income of $0.60.[11] In contrast, that same hospital purchasing the drug at the list price of $100.00 would be paid at $106.00, resulting in hospital income of $6.00. In this scenario, no savings accrue either to the 340B hospital or to Medicare, and the manufacturer receives a higher payment from 340B hospitals than under the status quo (see figure).

[10] Specifically, the proposal states that 340B hospitals will be paid at the reduced rate "unless the hospital identifies that the drug was not purchased under the 340B program" (82 Fed. Reg. 33634).

[11] Calculations based on the assumption that Average Manufacturer Price (AMP) and ASP are the same as the Wholesale Acquisition Cost (WAC) (commonly called the "list price") for sole-source brand-name drugs. This is consistent with the MedPAC analysis relied on in the Proposed Rule (82 Fed. Reg. 33634), which used ASP as a proxy for AMP. *See* MedPAC, May 2015 Report to the Congress: Overview of the 340B Drug Pricing Program, Appendix A. CMS uses WAC in place of AMP and ASP for pricing calculations on new drugs that do not yet have the sales data to generate AMP and ASP. *See* 42 U.S.C. § 1395w–3a(c)(4) ("Payment methodology in cases where average sales price during first quarter of sales is unavailable"); 82 Fed. Reg. 1210, 1218 ("The methodology set forth in this final rule for the estimated 340B ceiling price is WAC minus the appropriate rebate percentage.") (Modifying 42 C.F.R. §10.10, Effective Oct. 1, 2017). Other reports further demonstrate that AMP and ASP closely track both each other and invoice price for sole-source brand name drugs. *See*, *e.g.*, Department of Health and Human Services Office of the Inspector General (HHS OIG), Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices (A-06-11-00002) (2011) (finding that AMP is, on average, within one percent of a drug's invoice price for sole-source brand-name drugs). *See also* HHS OIG, Comparing Average Sales Prices and Average Manufacturer Prices for Medicare Part B Drugs: An Overview of 2012 (OEI-03-13-00570) (2014) (finding that 92% of the 472 Part B drugs assessed had an ASP no greater than 5% of AMP). *Note* The 2015 MedPAC report relied on the 2011 HHS OIG report to justify using ASP and AMP as relative proxies.

Potential Revenue Impact of Medicare's Proposed Payment Reduction to 340B Hospitals

Medicare's proposal to reduce payments to 340B hospitals would decrease 340B hospital revenue. Under this proposal, for some drugs, 340B hospitals would receive greater revenue by purchasing the drug at the list price instead of the discounted 340B price, receiving the standard Medicare payment instead of the proposed reduced Medicare payment. In these situations, manufacturers would retain the 340B discount as revenue.



When the list price of a drug increases more than the rate of inflation, manufacturers are required to provide additional discounts to 340B purchasers. Under this circumstance, the incentive to purchase drugs through 340B would be maintained when the inflation penalty produces greater revenue than the standard 6 percent revenue.[12] The inflation penalty can substantially affect a manufacturer's revenue, creating an incentive to set high initial list prices and then offer discounts and rebates to insurers that are excluded from AMP and ASP calculations.[13] For the six drugs with the highest Part B spending in 2015,[14] 340B hospitals would likely choose to purchase three (Eylea, Lucentis, and Avastin) at the list price instead of the 340B price because of limited price increases;[15] under this purchasing change, the manufacturer would retain the 340B discount and Medicare would continue to pay the hospital at the standard rate of ASP plus 6 percent. Together, these three drugs accounted for over $4 billion in Medicare Part B spending in

[12] The inflation penalty will only lead to higher revenue when a manufacturer has taken cumulative price increases at least 5.4 percent greater than cumulative inflation (5.4 percent additional inflation discount, plus 0.6 percent income under the reduced reimbursement (23.1 percent - 22.5 percent)). For an explanation of the calculation methodology for the inflation penalty (referred to as the "additional rebate calculation"), *See* Centers for Medicare & Medicaid Services, Unit Rebate Amount (URA) Calculation for Single Source or Innovator Multiple Source Drugs (available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/ura-for-s-or-i.pdf).

[13] T. Horn and S. Dickson., Modernizing And Strengthening Existing Laws To Control Drug Costs, Health Affairs Blog, March 31, 2017 (available at: http://healthaffairs.org/blog/2017/03/31/modernizing-and-strengthening-existing-laws-to-control-drug-costs/) (discussing incentives to offer rebates rather than up front discounts).

[14] Medicare Drug Spending Dashboard 2015 (available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/2015-Medicare-Drug-Spending/medicare-drug-spending-dashboard-2015-data.html).

[15] Eylea and Lucentis have not taken list price increases since introduction. Avastin has taken annual price increases no greater than 4.5 percent, limiting the impact of the inflation penalty. AnalySource data, July 24, 2017.

2015.[16] New drugs would not be subject to any inflation penalty, encouraging 340B hospitals to buy new drugs at the list price instead of the discounted price. MedPAC has previously expressed concern that providers may choose higher-cost drugs to receive a larger payment even when cheaper drugs are available;[17] this proposal may create similar incentives that could drive drug selection for non-clinical reasons.

The rationale for the 22.5 percent reduction outlined in the proposed rule includes an assumption that 340B entities receive an average 10 percent additional savings by purchasing drugs through the Prime Vendor Program (PVP),[18] a group that negotiates for voluntary manufacturer supplemental discounts for all 340B covered entities. These supplemental discounts are voluntarily provided by manufacturers, similar to supplemental Medicaid rebates, and can be revoked at any time. More importantly, the 10 percent estimated savings is an average across all covered drugs, including drugs that would be paid under the Medicare Part D, not Part B, program. In 2012, 72 drugs accounted for 90 percent of Medicare Part B costs;[19] even if each of these drugs were included in the PVP, they would account for only 2 percent of the 3,557 drugs included in the PVP. In educational materials, the PVP states that the formulary only covers "one or two products within therapeutic drug class," suggesting that participants only receive sub-ceiling prices on a subset of drugs.[20] Because there is no public information on the average discount on Part B drugs under the PVP, the estimated 10 percent average additional savings across all 3,557 drugs should not underpin a proposal to reduce every Part B drug's payment.

2.) Medicare patients seeking lower cost-sharing may shift their care to 340B hospitals and away from other providers.

Currently, Medicare patient cost-sharing for Part B drugs is 20 percent of the total payment to the provider. Under this proposal, patients will have substantially lower out-of-pocket costs at 340B hospitals, because the co-insurance is calculated on a lower base amount (ASP minus 22.5 percent in 340B hospitals vs ASP plus 6 percent in non-340B hospitals, resulting in a 27 percent lower co-insurance payment). Consideration should be given to the possibility that beneficiaries will change their provider to take advantage of lower cost-sharing payments.

Reducing the cost-sharing payments at 340B hospitals may give these providers a competitive advantage over other providers who are prohibited from offering reduced cost-sharing payments, even if they could afford to do so. According to the HHS OIG, the Anti-Kickback Statute prohibits providers from offering reduced or waived cost-sharing payments because "[w]hen providers, practitioners or suppliers forgive

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[16] *Supra* note 14.
[17] MedPAC, June 2016 Report to Congress: Medicare and the Healthcare Delivery System ("Financial considerations may also play a role in providers' choice of drugs. Concern has been expressed by some researchers and stakeholders that the 6 percent add-on to ASP creates an incentive to use higher priced drugs when cheaper therapeutic alternatives are available.") (internal citations omitted) (pg. 127).
[18] 82 Fed. Reg. 33632. The Proposed Rule cites the Fiscal Year 2017 Budget Justification from the Health Resources and Services Administration for this figure. However, the Budget Justification does not provide the methodology by which the estimate was created, nor does it discuss how the discounts may vary across the 3,557 drugs covered by the PVP.
[19] HHS OIG, Comparing Average Sales Prices and Average Manufacturer Prices for Medicare Part B Drugs: An Overview of 2012 (OEI-03-13-00570) (2014) (pg. 2).
[20] 340B Prime Vendor Program Fundamentals (September 2016) (available at https://www.hhs.gov/opa/sites/default/files/340b-prime-vendor-programs-slides.pdf).

financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them."[21]

We appreciate the opportunity to comment on this Proposed Rule and encourage a robust analysis of the proposal's impact on beneficiaries and providers before implementation. Should you have any further questions, please contact me by phone at 202-540-6392 or via email at acoukell@pewtrusts.org.

Sincerely,

Allan Coukell, BScPharm

Senior Director, Health Programs
The Pew Charitable Trusts

[21] The Anti-Kickback Statute prohibits the offer or payment of "any remuneration" for the purchase of a good or service "for which payment may be made in whole or in part under a Federal health care program." The Civil Monetary Penalties Law, which creates civil penalties for violations of the Anti-Kickback Statute, defines prohibited remuneration to include "the waiver of coinsurance and deductible amounts (or any part thereof)." (42 U.S.C. 1320a–7a(i)(6)).