

Massive Cuts Made to 340B Prescription Drug Discount Program

On November 1, 2017, the *Centers for Medicare and Medicaid Services* (CMS) published a final rule cutting Medicare Part B and state Medicaid payments under the *340B Drug Discount Program* (340B Program) by an estimated \$1.6 billion in 2018.¹ To illustrate the payment reduction, a drug with an average sales price of \$1,000 is currently reimbursed at \$1,060, but would be reduced to \$775 under the final rule.² The 340B Program was originally passed in 1992 as a way to decrease the cost of pharmaceuticals reimbursed to hospitals under Medicare Part B and state Medicaid programs by requiring pharmaceutical companies to give rebates to hospitals and clinics with a high volume of low-income patients.³ Since its passage, the 340B Program has been expanded three times, most recently by the *2010 Patient Protection and Affordable Care Act* (ACA).⁴ In 2015, approximately 40 percent of U.S. hospitals purchased pharmaceuticals through the 340B Program.⁵ Moreover, these hospitals provided 60 percent of uncompensated care in the U.S.⁶ This final rule, cutting 340B reimbursement, came after a 2015 *Government Accountability Office* (GAO) report entitled, “*Medicare Part B Drugs – Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*” (2015 GAO Report)⁷ was published and the House Energy and Commerce Committee held recent hearings.⁸ CMS reasoned among other things, that the 2015 GAO Report indicated that 340B hospitals were being incentivized to increase Medicare revenue by prescribing both a *greater number* of drugs and *more expensive* drugs.⁹ CMS further acknowledged concerns of advisory panels such as the Hospital Outpatient Payment Panel,¹⁰ but decided to finalize the proposed rule against their recommendation.¹¹ Additionally, providers have expressed concerns that this change would force some hospitals, especially safety-net and rural hospitals, to close and block patient access to lifesaving care for patients with serious illnesses like cancer.¹²

Much of the controversy surrounding the 340B Program emanates from the fact that the 340B Program does not include any restrictions regarding how hospitals can use the revenue generated through the program. This appears to be CMS’s main concern after the 2015 GAO Report suggested that 340B hospitals were incentivized to

increase revenues through prescription drugs.¹³ *Pharmaceutical Research and Manufacturers of America* (PhRMA), a pharmaceutical company trade association, is an advocate for these changes to the 340B Program and has employed an advertising campaign geared toward changing this program specifically.¹⁴ Further, PhRMA alleged that the criteria to become a “*covered entity*,” i.e. a 340B Program participant, are too lax and agreed with CMS that providers exploit the program by using the revenue to supplement profits instead of providing care to patients.¹⁵

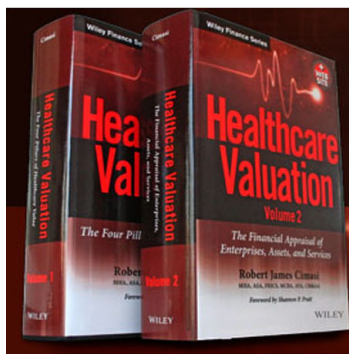
Opponents of the final rule argue that 340B “*covered entities*” provide a necessary service to communities through large-scale indigent care, and if 340B Program funding is cut, these populations will not be able to receive proper care.¹⁶ The final rule faces strong opposition by trade associations such as: the *American Hospital Association* (AHA); *America’s Essential Hospitals*; and, the *Association of American Medical Colleges*, which filed a lawsuit arguing that CMS violated the *Administrative Practices Act*.¹⁷ This argument is supported by the 2015 GAO Report (on which CMS relied to make its decision), which stated that CMS did not have statutory authority to reduce hospitals’ reimbursement for 340B drugs.¹⁸ The *Office of Inspector General* (OIG) estimated that, in 2015, providers experienced an average savings of 33.6 percent of the average sales price.¹⁹ These savings are likely a primary reason PhRMA opposed the reimbursement structure of the 340B Program.

The final rule is set to take effect January 1, 2018, but CMS is accepting comments on the rule through December 31, 2017.²⁰ Additionally, bipartisan legislation (H.R. 4392)²¹ has been introduced that would reverse these payment cuts.²² Further, because this payment reduction is budget neutral, the savings from the reduction of 340B Program payments (estimated \$1.6 billion) would be reallocated among all hospitals reimbursed under the OPPIs.²³ If neither the pending legislation nor the pending litigation produce a result before January 1, 2018, providers may experience the immediate effects of decreased 340B Program reimbursement.

1 “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs” 42 C.F.R. § 414, 416, 419 (November 13,

2017); “CMS Issues Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System and Quality Reporting Programs Changes for 2018 (CMS-1678-FC)”

- Centers for Medicare and Medicaid Services, Press Release, November 1, 2017, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-01.html> (Accessed 12/1/17).
- 2 “Legislation, Lawsuit Cloud Future of 340B Program Payment Rate Reduction” By Adam Rogers et al., Jones Day Publications, December 2017, <http://www.jonesday.com/legislation-lawsuit-cloud-future-of-340b-program-payment-rate-reductions-12-01-2017/> (Accessed 12/1/17).
- 3 “Heated and Deep-Pocket Battle Erupts Over 340B Drug Discount Program” By Sarah Tribble, November 28, 2017, <https://khn.org/news/heated-and-deep-pocketed-battle-erupts-over-340b-drug-discount-program/> (Accessed 12/1/17).
- 4 *Ibid.*
- 5 “Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals” United States Government Accountability Office, June 2015, <https://www.gao.gov/assets/680/670676.pdf> (Accessed 12/1/17), p. 1.
- 6 “Hospital Groups to Sue CMS over \$1.6 Billion cut to 340B Program” By Virgil Dickson, November 1, 2017, <http://www.modernhealthcare.com/article/20171101/NEWS/171109982> (Accessed 12/1/17).
- 7 US GAO, June 2015.
- 8 “Examining HRSA’s Oversight of the 340B Drug Pricing Program” House of Representatives, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, July 18, 2017, <https://energycommerce.house.gov/hearings/examining-hrsas-oversight-340b-drug-pricing-program-2/> (Accessed 12/11/17); Adam Rogers et al., December 2017.
- 9 Adam Rogers et al., December 2017.
- 10 The Hospital Outpatient Payment Panel consists of 15 members, including employees of hospitals, health systems, or other Medicare providers. This panel’s purpose is to advise CMS on issues such as ambulatory payment classifications, CPT codes, payment for drugs, and other services in the hospital outpatient setting. “Advisory Panel on Hospital Outpatient Payment” Centers for Medicare & Medicaid Services, November 28, 2017, <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html> (Accessed 12/7/17).
- 11 Adam Rogers et al., December 2017.
- 12 Sarah Tribble, November 28, 2017.
- 13 US GAO, June 2015.
- 14 Sarah Tribble, November 28, 2017.
- 15 *Ibid.*
- 16 Adam Rogers et al., December 2017.
- 17 *Ibid*; Sarah Tribble, November 28, 2017.
- 18 US GAO, June 2015, p. 30.
- 19 Adam Rogers et al., December 2017.
- 20 42 C.F.R. § 414, 416, 419 (November 13, 2017)
- 21 For more information, see: “A Bill To provide that the provision of the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs final regulation relating to changes in the payment amount for certain drugs and biologicals purchased under the 340B drug discount program shall have no force or effect, and for other purposes.” H.R. 4392, 115th Cong. § 1 (November 14, 2017).
- 22 Adam Rogers et al., December 2017.
- 23 *Ibid.*




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