HEALTH CAPITAL Topics
Volume 11
Issue 8
August 2018
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340B's Uphill Legal Battle for Hospital Associations

As discussed in the December 2017 *Health Capital Topics* article entitled, "*Massive Cuts Made to 340B Prescription Drug Discount Program*," the 2018 Hospital *Outpatient Prospective Payment System* (OPPS) final rule cut Medicare Part B and state Medicaid payments under the *340B Drug Discount Program* (340B Program) by an estimated $1.6 billion.[1] These cuts faced fierce opposition prior to their January 2018 implementation, and several hospital groups, including the *American Hospital Association* (AHA), *Association of American Medical Colleges* (AAMC), and *America's Essential Hospitals* (AEH), filed legal action to block these cuts from taking effect.[2] On July 17, 2018, the D.C. Circuit Court of Appeals, affirming the decision of the District Court, dismissed the lawsuit for failure to satisfy the presentment requirement for judicial review;[3] the hospital group plaintiffs plan to refile the suit in hopes of obtaining a binding decision by the end of 2018.[4]

The 340B Program was created by Congress in 1992 in an effort to provide the vulnerable and uninsured with access to prescription medications at safety-net facilities, i.e., those serving a high number of the vulnerable or uninsured patient population (termed "*covered entities*").[5] In 1994, the *Health Resources and Services Administration* (HRSA) released guidance allowing the off-campus outpatient sites of 340B hospitals to be included as covered entities, and in 1996, HRSA released guidance that allowed covered entities without an on-site pharmacy to contract with one off-site pharmacy.[6] In 2010, HRSA released guidance allowing all covered entities to have an unlimited number of contract pharmacies, and with the passage of the *Patient Protection and Affordable Care Act* (ACA) that same year, 340B eligibility was extended to: (1) critical access hospitals; (2) sole community hospitals; (3) rural referral centers; and, (4) cancer centers.[7] When enacted, the 340B Program required pharmaceutical manufacturers to enter into *pharmaceutical pricing agreements* (PPA) with the *Department of Health and Human Services* (HHS) to ensure discounts for hospitals and clinics serving the most vulnerable patient populations.[8] In 2016, the median amount of uncompensated care provided by hospitals participating in the 340B Program was higher than their non-340B counterparts; between 2011 and 2016, the number of hospitals participating in the 340B Program increased by more than 60%, largely due to the ACA broadening program eligibility.[9]

The ACA eligibility expansion led to the 2014 statement by Kathleen Sebelius (then Secretary of HHS), during testimony before the Senate Finance Committee, that the 340B Program "*has expanded beyond its bounds*" (i.e., the number of 340B Program participants had increased to an unsustainable amount).[10] Further, according to the *Government Accountability Office* (GAO), the number of unique contract pharmacies in 2010 was 1,300, but by 2017, that number had jumped up to 18,700, a more than 1,300% increase.[11] The HHS *Office of Inspector General* (OIG) believes that these "*contract pharmacy arrangements complicate efforts to prevent diversion and duplicate discounts*," both of which would (allegedly) be in violation of 340B Program requirements.[12] Hospital lobbyists have argued that the 340B Program is vital to safety-net providers serving low-income populations, while drugmakers have differing opinions on the program's scope and reach.[13]

In July 2017, the *Centers for Medicare and Medicaid* (CMS) proposed changes to the 2018 OPPS that significantly impacted the 340B Program.[14] As discussed in the August 2018 *Health Capital Topics* article, "*CMS Continued Payment System Overhaul: OPPS Proposed Rule*," the finalized 2018 OPPS covered outpatient drugs and biologicals at a rate of the drug's *average sales price* (ASP) *minus* 22.5%, compared to the original payment system rate, i.e., ASP *plus* 4.3%; this resulted in both large payment reductions to the 340B Program and significantly higher drug expenditures for those hospitals participating in the program.[15]

The 2018 OPPS proposed rule was finalized on November 13, 2017, and on the same day, AHA, AAMC, and AEH filed the aforementioned lawsuit against HHS in the D.C. District Court, in an effort to prevent the 340B payment cuts from taking effect.[16] These hospital associations argued that the HHS Secretary lacked authority to establish an average-price metric, and that a 30% payment reduction cannot qualify as a mere "*payment adjustment*."[17] HHS stated that these 340B payment reductions were justified based on developments in the market and the program's overexpansion;[18] ultimately, the District Court dismissed the case for lack of subject-matter jurisdiction, specifically for the associations' failure to present claims for reimbursement to the HHS Secretary, as required for judicial review under Medicare.[19] The hospital associations appealed the case to the D.C. Circuit Court

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of Appeals, and on May 4, 2018, the AHA, alongside 34 state and regional hospital associations, asserted during oral arguments that they satisfied the presentment requirement by filing comments opposing the new OPPS rule during the informal rulemaking process.[20] But on July 17, 2018, the Court of Appeals affirmed the District Court's ruling and dismissed the case on the same subject-matter jurisdiction grounds.[21]

CMS Administrator, Seema Verma, stated, "*The court's ruling is a big win for patients, who this year alone are expected to save $320 million in out-of-pocket expenses for medicines in their doctors' offices....[t]his policy is providing relief every day from the rising costs of drugs, a top priority for President Trump*."[22] The hospital associations released a statement shortly after the ruling expressing their disappointment over the courts "*once again fail[ing] to rule on the merits of [the] case*."[23] The associations also stated that they plan to continue their fight to reverse these "*unwarranted*" 340B payment cuts and protect access for patients; they expect to refile "*promptly*" in district court.[24]

The straining effects of the 340B payment cuts have been further exacerbated in the 2019 OPPS proposed rule, by extending these cuts to drugs provided in non-excepted off-campus *hospital outpatient provider-based departments* (HOPDs) (i.e., a hospital-affiliated provider-based facility located off of the hospital's main campus).[25] On July 25, 2018, AHA released a condemnatory statement in regards to the proposal to expand the 340B cuts to a significant number of additional HOPDs and life-saving drugs. AHA stated, "*…like the previous cuts…[this proposal] requires no federal contributions…but instead relies on discounts required of drug companies, [which] exceed[s] CMS's statutory authority and remain subject to legal challenge*."[26]

Despite CMS cuts to the program through OPPS rulemaking, Congress is seeking information on how to improve upon the 340B Program. On August 1, 2018, the Energy and Commerce Committee of the U.S. House of Representatives sent letters to nine 340B contract pharmacy participants, seeking information related to their 340B Program participation.[27] These letters were sent in response to a June 2018 GAO report that found weaknesses in contract pharmacies' compliance with 340B Program requirements.[28]

Because prescription drug affordability is such a prevalent and predominant problem in the U.S. healthcare industry, it is debatable as to whether making significant cuts to the 340B Program is the most effective way to address it. The AHA asserts that the 340B Program represents a very small portion of national drug expenditures, and 340B Health states that the 340B presence in the overall drug market "*cannot plausibly be causing manufacturers to increase drug prices*."[29] According to HRSA data, in 2016, the 340B Program accounted for only 3.6% of the total U.S. drug market.[30] Time will tell if the current administration's efforts to lower drug prices will actually increase access and affordability for the patient, or if drug manufacturers will remain the sole market beneficiaries in the pharmaceutical industry.

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3 *Ibid*. The *presentment requirement* is one of the two preconditions required by 42 U.S.C. § 405(g) for obtaining judicial review of covered Medicare claims – the plaintiff must have "*presented*" the claim to the Secretary because without presentment "*there can be no 'decision' of any type*" – also required by § 405(g). *See* "American Hospital Association, et al. v. Alex Michael Azar, HHS" Case No. 1:17-cv-02447 (D.C. July 17, 2018), Appeal from the United States District Court for the District of Columbia, p. 6.

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17 *Ibid*.

18 Revenue Cycle Advisor, April 2, 2018.

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25 For more information, see "CMS Continued Payment System Overhaul: OPPS Proposed Rule" Health Capital Consultants, Vol. 11, Issue 8 (August 2018). "CMS Targets Off-Campus Provider-Based Departments in 2019 OPPS Proposed Rule" Polsinelli, July 2018, https://sites-polsinelli.vuturevx.com/33/977/july-2018/upd0718eri.asp?sid=16fc9a05-9e5f-48f3-832d-6605cbc599aa (Accessed 7/31/18). "Non-excepted" off-campus HOPDs are HOPDs that are not allowed to bill under OPPS in accordance with the Bipartisan Budget Act of 2015 (BBA).

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