

340B UPDATE: HOSPITAL GROUPS FILE (...AND REFILE) 340B PROGRAM LITIGATION

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Health Care Alert

By: Richard P. Church, Macy L. Flinchum, Eric M. Matava

Regulation and reimbursement of drugs, particularly those purchased through the 340B Drug Discount Program (the "340B Program" or "340B"), continue to be dynamic issues of debate for federal policymakers. In response to recent program changes and ongoing regulatory debate, many hospital and other provider groups have sought to challenge the status quo through litigation. In particular, the three pending cases outlined below could have a significant impact on the 340B Program, including 340B pricing transparency, civil monetary penalties on drug manufacturers, and recent Medicare reimbursement cuts.

HOSPITAL GROUPS FILE LAWSUIT SEEKING 340B DRUG TRANSPARENCY RULE IMPLEMENTATION

On September 11, 2018, the American Hospital Association ("AHA"), the Association of American Medical Colleges ("AAMC"), America's Essential Hospitals ("AEH"), and 340B Health, along with several lead plaintiff hospitals, filed a complaint against the U.S. Department of Health and Human Services ("HHS") in the U.S. District Court for the District of Columbia asking the court to order HHS to implement regulations that would impose penalties for overcharging covered entities participating in the 340B Program and set a methodology for calculating 340B drug prices. [1]

The regulations, originally promulgated during the Obama administration, were designed to address drug pricing calculations and civil monetary penalties for drug manufacturers that knowingly and intentionally overcharge covered entities for 340B drugs. [2] The Trump administration has since delayed implementation of the rules several times. HHS most recently postponed the implementation of the rule until July 1, 2019, [3] to allow for "necessary time to consider more fully the substantial questions of fact, law, and policy identified by the Department during its review of the rule." The Health Resources and Services Administration also noted that it needs time to finalize additional rulemaking and that HHS is developing "new comprehensive policies to address the rising costs of prescription drugs . . . in government programs, such as Medicare Parts B & D, Medicaid, and the 340B discount drug program." [4]

In a joint press release following the filing of the complaint, the plaintiffs stated: "The continued success of the 340B program must rely on compliance by all parties, including drug manufacturers. . . . The final regulation provides important transparency for this vital program. Delaying implementation of that rule ultimately harms vulnerable patients and the teaching hospitals they rely on for care." [5]

The lawsuit argues that the administration's delay is arbitrary and capricious and violates the Administrative Procedure Act ("APA"). [6] The plaintiffs are requesting relief in the form of a declaratory judgment and an order directing HHS to make the rules effective within 30 days of judgment. [7]

PLAINTIFFS RE-FILE LAWSUIT CHALLENGING OPPTS REIMBURSEMENT CUT

On September 5, 2018, AHA, AAMC, AEH, and several lead plaintiff hospitals re-filed a lawsuit in the U.S. District Court for the District of Columbia challenging the authority of the Centers for Medicare & Medicaid Services ("CMS") to reduce payment for certain drugs under the 340B Program under the Medicare hospital Outpatient Prospective Payment System ("OPPS"). [8] The filing of the complaint came after the U.S. Court of Appeals for the District of Columbia upheld the reimbursement cut earlier this year on procedural grounds without ruling on the merits of the plaintiffs' case. [9]

As discussed in previous alerts (for additional background, please refer to our most recent alert on this topic), effective January 1, 2018, CMS cut OPPTS payments for 340B drugs by 28.5% — from the former rate of the drug's average sales price ("ASP") plus 6% to the current rate of ASP minus 22.5%.

The AHA and other trade organizations, along with several lead plaintiff hospitals, are continuing to challenge CMS's authority to implement the cut under the Social Security Act. In particular, the complaint argues that the 340B provisions of the CMS final rule implementing the OPPTS cut should be set aside as unlawful under the APA and exceeding the statutory authority granted to the Secretary of HHS. The complaint also notes that previous court rulings are no longer applicable given that hospitals have now filed claims that have gone through the Medicare appeals process. [10]

The complaint argues that the court should strike down the reimbursement cut, noting that it would be futile for the plaintiffs to seek further administrative remedies given that CMS has taken the position that there is no administrative review of 340B Program reimbursement disputes. [11] In addition to declaratory relief, the plaintiffs are requesting that the court order CMS to reimburse hospitals retroactively for the difference between the amount they were paid for under the lower rate and the amount they would have been paid in the absence of the cut.

ONCOLOGY GROUP CONTINUES TO ASSERT ITS POSITION AGAINST SEQUESTER CUTS FOR PART B DRUGS

Finally, the Community Oncology Alliance, Inc. ("COA") has filed suit in the U.S. District Court for the District of Columbia alleging that CMS lacked authority to apply reimbursement cuts under the Budget Control Act of 2011 to Medicare Part B drugs, reducing payment under the Medicare Physician Fee Schedule ("MPFS") from ASP plus 6% to ASP plus 4.3%. For details on the allegations and additional background, please see our prior alert. This litigation is likely to set key precedent for upcoming 340B Program litigation surrounding CMS's proposal to also reduce reimbursement to 340B Program-covered entities at non-excepted off-campus provider-based departments ("PBDs").

Consistent with the 2018 payment change for drugs paid under the OPPTS, CMS proposed in its recent OPPTS Proposed Rule for Calendar Year ("CY") 2019 to further reduce payment for certain 340B drugs furnished in non-

excepted PBDs from ASP plus 6% to ASP minus 22.5%. [12] Beginning in CY 2018, PBDs that were not furnishing services prior to November 2, 2015, are considered "non-excepted" and subject to site-neutral payment pursuant to Section 603 of the Bipartisan Budget Act of 2015. The lower rate of ASP minus 22.5% that applies to grandfathered PBDs has not yet applied to non-excepted PBDs under the site-neutral rule because items and services furnished by such PBDs are no longer reimbursed under the OPPIs and are instead reimbursed under the MPFS. The COA litigation raises a number of issues related to CMS's ability to alter statutory reimbursement formulas that will likely be relevant to 340B Program reimbursement cuts for non-excepted PBDs if CMS finalizes its proposal. The final rule is expected later this year.

Currently, in the COA litigation, defendants Secretary Alexander Azar, HHS, and Mick Mulvaney, Office of Management and Budget, filed a motion on August 3, 2018, to dismiss for lack of subject matter jurisdiction, stating that plaintiff's claims are precluded from judicial review under the Medicare Modernization Act and the Medicare Act, along with other sovereign immunity and standing arguments. [13] Subsequently, COA filed a brief in opposition to this motion to dismiss on September 7, 2018, refuting the government's arguments and requesting the court grant jurisdiction under the Balanced Budget and Emergency Deficit Control Act of 1985. [14] To date, a hearing on the merits of the case has not been set, and the government has until October 23, 2018, to submit a reply brief in support of their prior motion to dismiss.

NEXT STEPS

As demonstrated above, 340B Program reimbursement and regulation remain at the forefront of issues affecting 340B Program stakeholders. K&L Gates' Health Care practice regularly assists clients in planning, assessing, and responding to commercial, state, and federal reimbursement program changes impacting 340B Program-covered entities. We will continue to closely monitor developments in 340B Program changes and ongoing litigation related to the same. Looking ahead, stakeholders should assess their compliance with existing 340B Program requirements and related Medicare, Medicaid, and commercial 340B billing requirements and continue to plan for future changes to the 340B Program that could result from the litigation discussed above, additional regulatory action, or potential legislation from Congress.

Notes:

[1] *Am. Hosp. Ass'n v. Dept. of Health & Human Servs.*, No. 1:18-cv-02112 (D.D.C. Sept. 11, 2018), <https://www.aamc.org/download/492198/data/hospitalassociationscomplaintagainsthhsseeking340bpricetranspar.pdf>.

[2] 82 Fed. Reg. 1,210 (Jan. 5, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf>.

[3] 83 Fed. Reg. 25,943 (June 5, 2018), <https://www.gpo.gov/fdsys/pkg/FR-2018-06-05/pdf/2018-12103.pdf>.

[4] 83 Fed. Reg. 20,008 (May 7, 2018), <https://www.gpo.gov/fdsys/pkg/FR-2018-05-07/pdf/2018-09711.pdf>.

[5] Press Release, Ass'n of Am. Med. Colls., Hospital Groups File Lawsuit to Shine Needed Light on Drug Company Pricing and Overcharging (Sept. 11, 2018), <https://news.aamc.org/press-releases/article/hospital-groups-file-lawsuit-shine-needed-light-dr/>.

[6] *Am. Hosp. Ass'n v. Dept. of Health & Human Servs.*, *supra* n. 1.

[7] *Id.*

[8] Am. Hosp. Ass'n v. Azar, No. 1:18-cv-02084 (D.D.C. Sept. 5, 2018), <https://www.aha.org/system/files/2018-09/180905-complaint-340b-refiling-suit.pdf>.

[9] Am. Hosp. Ass'n v. Azar, No. 18-5004 (D.C. Cir., July 17, 2018).

[10] In a statement released immediately following the filing of the complaint, AHA stated: "Having filed claims that have progressed through the appeals process, the hospital plaintiffs have now addressed the court's procedural concern, and with the hospital associations, have refiled the lawsuit asking for expedited relief." Press Release, Am. Hosp. Ass'n, Hospital Groups Continue Fight, Refile Lawsuit to Reverse Cuts for 340b Hospitals (Sept. 5, 2018), <https://www.aha.org/press-releases/2018-09-05-hospital-groups-continue-fight-refile-lawsuit-reverse-cuts-340b-hospitals>.

[11] Am. Hosp. Ass'n v. Azar, *supra* n. 8.

[12] 83 Fed. Reg. 37,046, 37,143 (July 31, 2018), <https://www.gpo.gov/fdsys/pkg/FR-2018-07-31/pdf/2018-15958.pdf>.

[13] See Memorandum of Points and Authorities in Support of Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction, Cmty. Oncology Alliance in Cmty. Oncology Alliance v. Mulvaney, 1:18-cv-01256 (D.D.C. filed Aug. 3, 2018).

[14] See Plaintiff's Brief in Opposition to Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction, Cmty. Oncology Alliance in Cmty. Oncology Alliance v. Mulvaney, 1:18-cv-01256 (D. D.C. filed Sept. 7, 2018).

KEY CONTACTS



RICHARD P. CHURCH
PARTNER
RESEARCH TRIANGLE PARK, CHICAGO
+1.919.466.1187
RICHARD.CHURCH@KLGATES.COM



MACY L. FLINCHUM
ASSOCIATE
RESEARCH TRIANGLE PARK
+1.919.466.1259
MACY.FLINCHUM@KLGATES.COM

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