340B UPDATE: CMS PROPOSES TO REDUCE 340B DRUG REIMBURSEMENT; DRAFT EXECUTIVE ORDER COULD MEAN FURTHER CHANGES TO THE 340B PROGRAM

Date: 17 July 2017

Health Care Alert

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The Trump administration is considering significant changes relating to the 340B Drug Pricing Program ("340B Program"), which allows certain categories of safety net providers to access discounted pricing on covered outpatient drugs from manufacturers. In particular, the Centers for Medicare and Medicaid Services ("CMS") recently proposed as part of its Calendar Year 2018 update to the Outpatient Prospective Payment System ("OPPS") to reduce Medicare Part B drug reimbursement for 340B Program covered entities to the drug's average sales price ("ASP") minus 22.5%.[1] Moreover, an early draft of the Trump administration's proposed executive order ("EO") on drug pricing issues could result in new limitations on the 340B Program, potentially including new limits on contract pharmacy arrangements. Accordingly, hospitals, contract pharmacies, and other entities affected by the 340B Program should note that these changes may substantially impact the 340B Program as to both reimbursement and scope. As the administration considers these proposals, engagement with decision makers in Department of Health and Human Services is critical for stakeholders to shape the outcome of these new policies.

CMS PROPOSAL WOULD CUT OPPS REIMBURSEMENT FOR 340B DRUGS

As part of its Calendar Year 2018 OPPS proposed rule, released in pre-publication form on July 13, 2017, CMS proposed to apply an average discount of 22.5% of ASP for non-pass-through separately payable drugs purchased under the 340B Program. Discussing the proposal, CMS explains:

> Given the growth in the number of providers participating in the 340B program and recent trends in high and growing prices of several separately payable drugs administered under Medicare Part B to hospital outpatients, we believe it is timely to reexamine the appropriateness of continuing to pay the current OPPS methodology of ASP+6 percent to hospitals that have acquired those drugs under the 340B program at significantly discounted rates. This is especially important because of the inextricable link of the Medicare payment rate to the beneficiary cost-sharing amount. In addition, we are concerned about the rising prices of certain drugs and that Medicare beneficiaries, including low-income seniors, are resonsible [*sic*] for paying 20 percent of the Medicare payment rate for these drugs. We are concerned that the current payment methodology may lead to unnecessary utilization and potential overutilization of separately

> payable drugs.[2]

CMS further notes that its goal with the proposal is to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care."[3] CMS intends to implement the proposed rule by establishing a modifier, effective January 1, 2018, for hospitals to use with separately payable drugs under the OPPS that are *not* acquired under the 340B Program. In having hospitals identify which drugs were not acquired under the 340B Program, CMS presumes that separately payable drugs on OPPS claims submitted by 340B covered entities were purchased at 340B pricing.[4]

CMS also requested comments on several issues, including comments on the methodology and analysis used in the Medicare Payment Advisory Commission ("MedPAC") report that led to ASP minus 22.5% as the proposed payment rate,[5] whether CMS should adopt a different rate or phase in the new proposed rate over time, and whether it should require providers to identify their actual acquisition costs for each drug as a way for CMS to not rely on an aggregate rate across all 340B covered entities. Finally, CMS seeks comments on whether certain groups of hospitals (e.g., rural sole-community hospitals) or certain groups of drugs (e.g., hemophilia factor) should be excluded, as well as whether hospital-owned or affiliated ambulatory surgical centers have access to 340B drugs.

Public comments are due by September 11, 2017.

DRAFT EXECUTIVE ORDER COULD SIGNIFICANTLY ALTER THE 340B PROGRAM

The draft EO, although less specific than the payment reduction included in the OPPS proposed rule, could nevertheless have a far-reaching impact on the 340B Program moving forward. In particular, the draft EO calls for the Health Resources and Services Administration ("HRSA") to rescind or revise administrative actions that have allowed benefits under the 340B Program to accrue to populations and entities other than covered entities and their patients, raising the possibility that HRSA may attempt to limit the scope of the 340B Program.

It is unclear whether the 340B Program language will be included in the final version of President Trump's forthcoming EO;[6] nevertheless, the draft EO reflects ongoing efforts by policymakers to address the rising cost of prescription drugs. Major policy proposals so far have called for the federal government to negotiate directly the price of drugs covered by the Medicare program, accelerate the approval of generic drugs, require greater transparency from pharmacy benefit managers ("PBMs"), and allow Americans to import drugs from outside the United States.

In this regard, the draft EO, titled "Reducing the Cost of Medical Products and Enhancing American Biomedical Innovation," does not specifically include any of the proposals above but rather outlines a series of high-level directives involving various federal agencies within the Department of Health and Human Services (including HRSA, the Food and Drug Administration, and the Centers for Medicare and Medicaid Services), as well as the Internal Revenue Service ("IRS"), the Office of the U.S. Trade Representative, the Department of Commerce, the Federal Trade Commission, the Department of State, the Office of Management and Budget, and the Executive

Office of the President. These directives focus on issues such as value-based purchasing, reducing regulatory and administrative burdens that distort drug prices and slow commercialization, and international drug purchasing issues including price differentials between foreign governments and the United States, potential revisions to bilateral and multilateral trade agreements to promote competition in the global market, and potential violations of trade agreements. The draft EO also calls for the IRS to update rules relating to the high deductible health plan "preventive care safe harbor" — which allows a health plan to meet the definition of a high deductible health plan for federal tax purposes despite not having a deductible for preventive care — to ensure that plans without a deductible for medications that are intended to prevent chronic disease progression or complications can satisfy the safe harbor.

BACKGROUND

The draft EO, which was published on June 23, 2017,[7] states as follows as it relates to the 340B Program:

> The Secretary of Health and Human Services shall ensure that resources provided by the program established by Section 340B of the Public Health Service Act are directed in such a way they primarily benefit the lower income or otherwise vulnerable Americans for which the program was intended, including by rescinding or revising regulatory or other administrative actions that have allowed benefits of the program to accrue to other populations or entities other than the safety net healthcare providers that the program was intended to strengthen.

In this regard, the 340B Program is intended to allow covered entities (i.e., safety net providers who receive discounts on covered outpatient drugs through the 340B Program) to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[8] The 340B Program has grown significantly since its enactment, partially as a result of Congress adding new categories of eligible covered entities through the Patient Protection and Affordable Care Act[9] but also through developments such as the emergence of contract pharmacy arrangements, which are not specifically identified in the 340B Program statute but which HRSA has permitted through guidance.[10] Critics of the 340B Program, responding to this rapid growth, have argued that the benefit of the 340B Program should not accrue to entities such as contract pharmacies and PBMs, but instead should be used exclusively for the covered entities described in the statute and their indigent patients.

POTENTIAL IMPACT

Although the Trump administration has not yet confirmed the contents of the draft EO, its broad language suggests that HRSA could take steps in the months ahead that would impact the 340B Program as it exists today. This could include changing its guidance on contract pharmacies (*e.g.*, by imposing caps on the number of contract pharmacy locations and arrangements a covered entity may have). The draft EO also could be read to allow HRSA to impose limits on prices that covered entities charge to indigent patients for 340B drugs. Similarly, discussion draft legislation reportedly under development by Rep. Chris Collins (R-NY), a member of the House Energy & Commerce Committee, would require covered entities to establish a sliding fee schedule for providing 340B drugs to low-income individuals and those without minimum essential coverage. Under Rep. Collins' draft

bill, the Secretary would be required to issue regulations defining "low-income individual," providing a methodology for establishing the sliding fee schedule, and protecting data confidentiality.[11]

With that said, HRSA also could use the draft EO's directives to declare, for example, that contract pharmacy fees must be in line with fair market value or that PBMs should not be permitted to implement two-tier 340B pricing models in which the PBM reimburses one rate to 340B covered entities and a higher rate to non-340B covered entities, thereby capturing part or all of the 340B discount. Notably, Rep. Collins' discussion draft also calls for capping contract pharmacy fees at fair market value.

Any such action must be consistent with HRSA's existing regulatory authority in order to withstand scrutiny if challenged in court.[12] Nonetheless, if the draft EO is finalized in the form that is currently available, it suggests that the administration is open to policy changes to the 340B Program through administrative action beyond what was included in the President's Fiscal Year 2018 budget request to Congress. In this regard, President Trump's budget request generally called for funding of provider education and compliance efforts through HRSA, but otherwise asked Congress to grant broader regulatory authority to HRSA and impose limits on the 340B Program through statute. (See here for our prior alert on this topic.)

340B Stakeholders should continue to monitor the draft EO and other 340B Program-related developments from Congress and the administration.

Notes:

[1] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, p. 306, https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-14883.pdf.

[2] *Id.* at 304-05.

[3] *Id.* at 305.

[4] *Id.* at 306.

[5] *See* MedPAC, Report to Congress: Overview of the 340B Drug Pricing Program vii (2015), http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0 (". . . we estimated that, on average, hospitals in the 340B program receive a minimum discount of 22.5 percent of the average sales price for drugs paid under the outpatient prospective payment system.").

[6] *See* Virgil Dickson, Modern Healthcare, *Trump May Be Backing Off from Plan to Scale Down 340B*, July 12, 2017, http://www.modernhealthcare.com/article/20170712/NEWS/170719964/trump-may-be-backing-off-from-plan-to-scale-down-340b.

[7] Sarah Karlin-Smith, POLITICO Pro Health Care, *Drug Pricing Executive Order is Pharma-Friendly*, June 23, 2017, https://www.politicopro.com/health-care/story/2017/06/draft-drug-pricing-executive-order-is-pharma-friendly-158760.

[8] H.R. Rept. No. 102-384 (Pt. 2), at 12 (1992).

[9] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 7101(a), 124 Stat. 119, 821–22 (codified as amended at 42 U.S.C. § 256b(a)(4)(M)–(O)).

[10] *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010), https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf (describing 340B Program requirements between covered entities and contract pharmacies).

[11] Although Rep. Collins' office has stated the draft legislation published online is not current, at a minimum it reflects how Rep. Collins' staff was approaching this issue recently. *See* Brett Norman et al., *Republican Pushing Changes to 340B*, POLITICO Prescription Pulse, May 30, 2017, http://www.politico.com/tipsheets/prescription-pulse/2017/05/30/gottlieb-signals-priorities-for-fda-including-drug-pricing-220567.

[12] Litigation related to the 340B Program's orphan drug exclusion has clarified that HRSA has limited authority to regulate the 340B Program. In *Pharm. Research and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 43 F. Supp. 3d 28 (2014), the U.S. District Court for the District of Columbia concluded that HRSA has rulemaking under the 340B Program in just three areas: (i) establishing an administrative dispute resolution process; (ii) issuing of drug ceiling price methodologies; and (iii) imposing civil monetary sanctions against manufacturers. Accordingly, the court struck down HRSA's orphan drug regulation as outside the authority granted under the 340B Program statute. After HRSA reissued substantially the same regulation as "interpretive guidance," the court ruled against HRSA again, stating that the interpretive rule amounted to a final agency action that was inconsistent with the statute. Pharm. Research and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs., 138 F. Supp. 3d 31 (2015). As a result of these rulings, HRSA may be reluctant to take steps that could invite challenges in court without a specific grant of authority by Congress.

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