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340B IN 2017 AND BEYOND: WHAT COVERED ENTITIES AND CONTRACT PHARMACIES NEED TO KNOW

Just over half a year into the new administration, significant developments have occurred that may permanently alter the landscape of the 340B drug discount program ("340B Program"), developments so significant that the mainstream news media has started to take notice.[1] As 340B Program participating "Covered Entities" and their contract pharmacy partners work to develop their 2018 budgets and business plans, we continue to field questions related to the current and future availability of continued (or even reduced) 340B Program savings. This article aims to summarize key 340B Program developments and also to estimate their potential impact on Covered Entities and contract pharmacies working to make available vital safety net services.

Among a myriad of other issues that indirectly affect 340B Program savings, we discuss below the following key developments that directly and indirectly impact 340B Program participation.

- A proposed 27 percent cut to Outpatient Prospective Payment System ("OPPS") reimbursement for drugs purchased using a 340B Program discount detailed in the Centers for Medicare & Medicaid Services' ("CMS's") OPPS proposed rule published on July 20, 2017;
- A significant proposed cut to Medicare Physician Fee Schedule ("MPFS") reimbursement for services provided in new off-campus provider-based departments detailed in CMS's proposed rule published on July 13, 2017;
- The implementation actual acquisition cost ("AAC") reimbursement by all state Medicaid agencies for drugs purchased using a 340B Program discount under CMS's final rule published in February 2016;
- Congressional focus on and hearings related to 340B Program oversight;
- Continued efforts to implement new 340B Program legislation limiting 340B Program savings; and
- Executive branch focus on 340B Program savings as a key factor leading to rising drug costs.

CMS PROPOSES A MAJOR (27 PERCENT) REDUCTION TO OPPS PASS-THROUGH PAYMENTS FOR DRUGS PURCHASED AT 340B PRICES

On July 20, 2017, CMS formally published its annual proposed rule addressing various updates to the Hospital Outpatient Prospective Payment System ("OPPS Proposed Rule"). Among other changes, the OPPS Proposed Rule details a proposal that, if finalized, would reduce OPPS reimbursement rates for 340B-eligible drugs that cost over $120 by almost 27 percent.

Though this change would represent a significant payment reduction for provider-based departments that are on-campus or operating prior to November 2, 2015 ("Grandfathered Provider-Based Departments"), it likely will not impact non-Grandfathered Provider-Based Departments since these facilities are paid under the MPFS rather than the OPPS. Similarly, critical access hospitals would not be affected by this proposed change since their drug reimbursement is based on a reasonable cost methodology (101 percent of reasonable costs). The proposed changes would also not impact certain children's and freestanding cancer hospitals. Of course, non-Grandfathered Provider-Based Departments are subject to other potential payment reductions under the MPFS as discussed in greater detail below.

For Covered Entity locations affected by the OPPS proposed change, drugs administered to patients in the hospital outpatient department setting are either included or packaged in the associated procedure's Medicare Ambulatory Payment Classification ("APC") payment (if at or below the "packaging threshold" dollar amount) or paid separately on a "non-pass through" basis at the rate of average sales price ("ASP") plus 6 percent (if above the "packaging threshold" dollar amount).[2] For federal fiscal year ("FFY") 2018, the packaging threshold is $120. For FFY 2017, the packaging threshold is $110. Under the CMS proposal, separately payable drugs over the $120 threshold would be paid at a significantly reduced ASP minus 22.5 percent, or a total reduction of approximately 26.9 percent in OPPS non-packaged drug reimbursement. Stated more simply, if finalized, the proposed reimbursement reduction from 106 percent of ASP to 77.5 percent of ASP could have a significant impact on 340B Covered Entities relying on 340B savings to enable access to care to underserved populations.

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CMS attempts to justify these cuts by citing Medicare Payment Advisory Commission ("MedPAC") findings that the average minimum discount that 340B-eligible hospitals received for drugs purchased within the program was at least 22.5 percent of ASP. CMS also states that "Medicare expenditures on Part B drugs are rising due to underlying factors such as growth of the 340B Program, higher price drugs, or price increases for drugs." Among other issues, this analysis fails to recognize the fact that lower 340B prices are reflected as lower costs on hospital cost reports, which is data that is ultimately used to calculate OPPS payment increases from year to year. As a result, these OPPS proposed rule changes would, in a sense, allow CMS to double count the 340B Program benefit in the form of both lower costs reported by hospitals and lower pass-through drug payments.

In discussing the rationale for its proposal, CMS also expressed concerns over increased drug spending at 340B-eligible hospitals compared to non-340B hospitals, though it did not address the amount of under-compensated and uncompensated care provided by what are, by definition, hospitals that provide care to underserved populations.

To implement this reduced payment model, CMS proposes that 340B Covered Entities would submit a claims modifier in the event a drug is not purchased using a 340B Program discount. CMS did not address the fact that many 340B Covered Entity hospitals have elected to exclude Medicaid fee-for-service claims from 340B eligibility in part due to the complexities and costs associated with identifying 340B-eligible drugs and their acquisition costs. CMS similarly neglected to consider that while the 340B Program allows Medicaid fee-for-service claims to be excluded from 340B Program participation and purchased using a Group Purchasing Organization account, no such exception exists for Medicare claims. Neither did CMS acknowledge the significant administrative costs associated with 340B Program implementation, including significant audit, software and staffing outlays. As a result, by effectively requiring 340B AAC pass-through for Medicare claims, CMS is requiring affected 340B Covered Entities to take a loss on non-packaged OPPS drugs without an alternative option that is available for Medicaid fee-for-service claims that are addressed in the underlying statutes.

The challenges noted above ultimately beg the question: is this CMS proposal permitted under applicable law? Though CMS affirmatively argues that it has statutory authority under the Social Security Act to implement these targeted payment reductions, they do not clearly address whether they are utilizing "relevant characteristics," as is arguably required under the statute. In addition, CMS is requesting comments on whether it should apply all or part of the savings generated by this payment reduction to increase payments for specific services paid under the OPPS, or under Part B generally, rather than simply increasing the OPPS conversion factor. In one view, CMS does not have the statutory authority to take savings from a program under the authority of an entirely different federal agency (in this case the Health Resources and Services Administration ("HRSA")) and redistribute those savings from one cohort of providers explicitly authorized by Congress to receive those savings to an entirely different class of provider based on factors not contemplated by Congress. More, this change could be viewed by some as a circumvention of congressional public policy goals that made the 340B Program available explicitly to non-profit and government safety net providers.

Whether or not these issues are enough to convince CMS to rescind its proposed 340B payment reduction is unclear. Since it is distinctly possible that this proposal or something very similar is finalized by CMS, potentially affected Covered Entities should work with their finance department staff to estimate the impact based on a recent sample period. This analysis should review claims to estimate the total number of units billed for those HCPCS codes that will be affected by the proposed 340B payment reduction. The total value of the listed payment rate would then be reduced by 26.9 percent.

We would also encourage Covered Entities to consider what may happen to new off-campus provider-based departments that are not subject to OPPS payments. Since these facilities are paid under the same ASP plus six percent methodology, it is possible that CMS could look to implement the same reduced non-pass through reimbursement methodology. We note that this was not addressed in the 2018 MPFS proposed rule (again, discussed further below).

CMS is soliciting comments on various aspects of the OPPS Proposed Rule, including whether and how the savings could be channeled to hospitals that treat large shares of lower income and uninsured patients in addition to the exact amount of the payment reduction and if the reduction should be phased in over a period of time. Given its significance, we strongly encourage all affected Covered Entities to both submit comments on the OPPS Proposed Rule before the **September 11, 2017** deadline and to similarly involve their advocacy teams to educate their representatives on the potential impact to safety net populations.

PROPOSED PAYMENT CUTS FOR NEW OFF-CAMPUS PROVIDER-BASED DEPARTMENTS

As most hospital Covered Entities know, provider-based status is a prerequisite for 340B eligibility and is still available for new facilities.

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However, new off-campus provider-based departments established after November 1, 2015 are no longer paid under the OPPS. Instead, they are now paid at a reduced rate under new MPFS provisions.

While the 340B reimbursement reductions discussed above likely do not apply to services provided in these new off-campus provider-based departments, the new 2018 MPFS proposed rule published by CMS on July 13, 2017 proposes to reduce the payment rate, again, for these "new" off-campus provider-based hospital departments by changing its conversion factor applied to OPPS payments from 50 percent to 25 percent of the OPPS APC amount. A more detailed discussion of this proposed change can be found in our article, available here.

As such, in addition to non-pass-through drug reimbursement reductions, 340B Covered Entities should also consider the impact of these MPFS payment reductions when planning for their 2018 budgets.

MEDICAID FEE-FOR-SERVICE ACTUAL ACQUISITION COST BILLING REQUIREMENTS

On February 1, 2016, CMS published a Final Rule[3] addressing national requirements for Medicaid state plans governing fee-for-service ingredient cost reimbursement for drugs purchased using a 340B discount. This rule requires state Medicaid programs to implement state plan amendments (or "SPAs") that cap ingredient cost reimbursement for 340B drugs at AAC. A professional dispensing fee must still be paid, though that dispensing fee must reasonably approximate the cost of the services provided.

Even prior to this rule, multiple states had already adopted SPAs requiring AAC reimbursement for 340B drugs.[4] Going forward, though, all states will eventually require AAC pass-through for 340B drugs.

CMS indicated that it believes moving to AAC will serve the dual aims of improving beneficiary access to covered outpatient drugs while complying with statutory requirements governing drug ingredient cost reimbursement. What is more likely, though, is that 340B Covered Entities will "carve out" 340B drugs from their program to avoid the costs associated with 340B Program administrative burdens (including AAC tracking and submission).

To combat this flight from 340B Program participation, many states (e.g., Illinois) are requiring that 340B Covered Entities purchase 340B drugs for Medicaid fee-for-service beneficiaries if they are eligible to do so since, in many cases, the 340B Program savings are more beneficial to the state than the drug rebates they receive for non-340B drugs.

Given this regulatory change, Covered Entities should verify their states' Medicaid billing and reporting requirements under the 340B Program. Ensuring compliance with the requirements for submitting claims is necessary to avoid overpayments implicating federal False Claims Act risks.

PREREQUISITE TO LEGISLATIVE CHANGE? CONGRESSIONAL SUBCOMMITTEE HOLDS HEARINGS ON 340B PROGRAM OVERSIGHT

On July 18, 2017, the House Subcommittee on Oversight and Investigations within the Committee on Energy and Commerce ("Subcommittee") held a hearing entitled "Examining HRSA's Oversight of the 340B Drug Pricing Program." Representatives from HRSA's Office of Pharmacy Affairs ("OPA"), Department of Health and Human Services ("DHHS") Inspector General's office and Government Accountability Office ("GAO") testified about the 340B Program and made recommendations about areas needing improvement. In calling for the hearing, Subcommittee Chairman Tim Murphy (R-PA) expressed concern about a lack of sufficient 340B Program oversight, citing statements by the GAO and the near quadrupling number of Covered Entities within the past ten years. It also followed a June letter sent to HRSA from Rep. Murphy and Committee Chairman Greg Walden (R-OR) requesting information about provider audits and hospitals' use of 340B Program savings. To that end, Subcommittee Ranking Member Diana DeGette (D-CO) suggested holding another hearing for hospitals to discuss how savings are used.

Generally, there was bipartisan agreement about the importance of the 340B Program, and many members made positive statements about the 340B Program and 340B hospitals. However, there were also some comments that highlighted disagreements within the Subcommittee members. Some members expressed concern about the growth of the program, while others forcefully rejected proposed regulations to decrease 340B hospitals' Medicare Part B drug reimbursement.

Bipartisan comments pointed to the lack of statutory requirements governing the use of 340B savings. Members also expressed concerns about the perceived lack of 340B Program oversight. It was no surprise, therefore, that bipartisan comments indicated support for giving HRSA wider latitude in outlining compliance rules and ensuring program integrity. Particularly, the members discussed granting HRSA the authority to regulate a new patient definition, manufacturer pricing and distribution and nondiscrimination guidance for manufacturers in

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cases where drug distribution is restricted.

While the tangible results of this congressional committee hearing remain unclear, it suggests an increased appetite in Washington for implementing statutory changes to the 340B Program that will likely negatively impact the availability of 340B discounts for Covered Entities. Again, these developments argue for continued and increased involvement of Covered Entity advocacy team members.

LOOMING 340B LEGISLATION IN AN UNCERTAIN POLITICAL CLIMATE

The executive branch has also formally weighed in on the 340B Program by requesting new legislation related to the 340B Program in its 2018 budget proposal to Congress. This budget proposal, which signals the administration's policy priorities, notably contained specific language about the 340B Program. This language includes a call from the administration for new legislation that limits how Covered Entities can use the benefits they receive from 340B discounts, which would be a significant departure from the current state of the 340B Program. In its statement on May 23, 2017, HRSA's Congressional Budget Justification stated that DHHS "will work with Congress to develop a legislative proposal to improve 340B Program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations."

This scrutiny aligns with recent comments by legislators related to draft 340B Program legislation that was recently circulated on a non-public basis. In May 2017, while speaking at a summit for the Alliance for Integrity and Reform of 340B ("AIR 340B"), Rep. Chris Collins (R-NY) announced plans to introduce legislation to restructure the 340B Program.

Among other changes, Rep. Collins' proposed legislation would narrow the 340B Program's patient definition, limit new 340B Program hospital enrollment until Congress establishes charity care eligibility thresholds, place new limits and requirements on 340B Program contract pharmacies, require sliding fee schedules in certain circumstances and expand HRSA oversight over the 340B Program. The bill would also create reporting requirements for hospitals related to 340B Program funding similar to requirements for 340B Program grantees.

If passed, the proposed legislation would materially restructure the 340B Program, which Rep. Collins labeled a driver of rising drug costs. While such a bill is likely to draw support from the pharmaceutical and manufacturing industry, significant concerns expressed by 340B Covered Entities (and the representatives/senators representing those 340B Covered Entities) suggest the bill is unlikely to proceed in its current form. Nonetheless, 340B Covered Entities and their advocacy teams should be working to proactively address this issue and highlight the importance of the 340B Program to their local communities, with their representatives.

DRAFT EXECUTIVE ORDER PROPOSES TO RESCIND OR REVISE RULES RELATED TO 340B

A draft presidential executive order on pharmaceutical policy, leaked to the *New York Times* in mid-June, highlights some other areas of the 340B Program rules and regulations that may be the focus of future change. Although the order is light on specifics as it relates to the 340B Program, the draft order indicates plans by the administration to direct DHHS to rescind or revise rules that "have allowed benefits of the [340B] program to accrue to other populations or entities other than the safety net healthcare providers that the program was intended to strengthen."

The text of the proposed order also directed the Secretary of HHS to ensure that resources provided by the 340B Program are "…directed in such a way they primarily benefit the lower income or otherwise vulnerable Americans for which the program was intended…." This language appears to contemplate the role of for-profit contract pharmacies and provides insight into potential areas where 340B Program savings are most at-risk.

In response to this draft order, 29 members of Congress signed and sent a letter on June 23, 2017 urging the president to avoid "pursuing policies that disproportionately benefit the prescription drug industry" and encouraging the president to prioritize high drug costs faced by patients. The letter expresses concerns about the draft executive order and its effect of scaling back of the 340B Program, which could impact hospitals, clinics and low-income patients.

The executive order was expected to have been released in June, but it is now unknown if or when the administration will promulgate a final version of this order. At this point, it would be speculative to consider how DHHS may implement this potential executive order, but 340B Program stakeholders should closely watch any developments related to this executive order and, again, ensure that advocacy team members continue to work to educate their representatives regarding the benefit of the 340B Program for safety net populations.

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PRACTICAL TAKEAWAYS

Despite the uncertain political climate and inconsistent messaging, one fact is clear: the 340B Program's current state is likely to change. While the exact scope of any proposed changes remains nebulous, there are recurring themes of increased oversight of the utilization of 340B Program savings, restricting contract pharmacy arrangements and generally limiting the scope of the 340B Program. These 340B Program risks must also be considered in conjunction with CMS's changes (and proposed changes) to provider-based reimbursement. When considered together, the HRSA OPA and CMS changes discussed above suggest that 340B Covered Entities should carefully consider the impact of all Medicare and Medicaid reimbursement and 340B Program final and proposed changes before moving forward with any strategic initiatives.

While some stakeholders may have breathed a sigh of relief over the withdrawal of the 340B Program Omnibus Guidance, also known as the "Mega-Guidance," both the legislative and executive branches continue to appear interested in advancing the regulation and oversight of the 340B Program. Stakeholders in the 340B Program should continue monitoring actions by Congress and HRSA as budgets and policies affecting the 340B Program develop.

Given the potentially material changes to the 340B Program, and the fluid political situation, it is now more important than ever for stakeholders to contact their federal representatives to make their opinions heard. 340B Program stakeholders should also remain vigilant in commenting on any proposed rules pertaining to the 340B Program.

If you would like additional information about these developments and their potential impact on the 340B Program, please contact:

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[1] https://www.marketplace.org/2017/08/08/health-care/seniors-are-paying-200-million-more-drugs-they-need-says-federal-government.

[2] Due to federal budget sequestration, like other Medicare services, this rate is reduced by 1.6 percent through 2024, resulting in actual pass-through drug reimbursement of ASP + 4.3 percent.

[3] Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170 (February 1, 2016). Effective April 1, 2016.

[4] These states include Virginia, the District of Columbia, North Dakota, Rhode Island and Kansas. *See*: 12 Va. Admin. Code § 30-80-40 (2016), 29-Public Welfare D.C. Code Mun. Regs. § 27 (2017), North Dakota State Plan Amendment ND-16-0011, Rhode Island State Plan Amendment RI-17-004 and Kansas State Plan Amendment KS-17-00.

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