

340B PROGRAM OPPS PAYMENT REDUCTIONS AND LEGISLATIVE LIMITATION PROPOSALS: WHAT'S SMOKE AND WHAT'S FIRE?

On July 25, the Centers for Medicare & Medicaid Services ("CMS") issued its 2019 Outpatient Prospective Payment System ("OPPS") Proposed Rule ("OPPS Proposed Rule"). As anticipated based on public comments made by Department of Health and Human Services ("HHS") Secretary Alex Azar, CMS is proposing to expand application of reduced payment for discounted drugs purchased under the 340B drug discount program ("340B" or "340B Program"). If finalized, this expansion would mean reduced Medicare reimbursement for 340B drugs (ASP-22.5 percent rather than ASP+6 percent) would apply to "non-excepted" off-campus provider-based departments (each a "PBD") paid at a reduced rate (40 paid of APCs). Currently, these non-excepted PBDs are able to purchase 340B drugs and be reimbursed at ASP+6 percent.^[1] Needless to say, this represents a significant impact for 340B participating "Covered Entities." This is especially true for those Covered Entities that have not budgeted for this reduced reimbursement or may have invested or committed significant capital in expanding facilities given that the OPPS Proposed Rule does not discuss any kind of "under-development" or pre-existing facility exception.

More, as the health care reform debate moves beyond repeal and replace and toward seeking value and efficiency, the 340B Program now finds itself at the center of a legislative debate in Washington, D.C. regarding the best way to address rising prescription drug prices. This focus, sharpened by statements made by the president, has resulted in various legislative proposals that could have further material impacts on 340B Program operation.

Other 340B Program pending developments include:

- Final Rule Delay – 340B Ceiling Prices and Civil Monetary Penalties
- CMS Litigation – 340B Program Hospital Payment Cuts

Read together, 340B Covered Entities should carefully review the OPPS Proposed Rule and submit comments detailing its impact. More, Covered Entities should monitor legislative activity and involve their advocacy team members to ensure legislators understand the purpose of the program and the negative community impact any potential 340B Program limitations could cause.

Below, we detail the Medicare Part B 340B drug payment and discuss the likely implementation challenges for providers who rely on the 340B Program savings to serve their patient populations. We also detail pending 340B Program litigation and discuss common themes we have been seeing in the proposed 340B Program legislation. Ultimately, strong advocacy efforts will be necessary to convince CMS to reverse the OPPS Proposed Rule 340B Program changes. Additionally, Covered Entities should begin developing contingency plans in the event these changes are finalized.

I. PAYMENT REDUCTIONS AND RESTRICTIONS FOR OFF-CAMPUS PROVIDER-BASED LOCATIONS

As mentioned previously, beginning January 1, 2018, Medicare pays an adjusted amount of the average sales price ("ASP") minus 22.5 percent for certain separately payable drugs or biologicals. These include those drugs acquired through the 340B Program by a hospital paid under the OPPS that is not excepted from the payment adjustment policy. Rural sole community hospitals ("SCHs"), children's hospitals and PPS-exempt cancer hospitals were excepted from the 340B payment adjustment. Critical access hospitals ("CAHs") were also not included since they are not paid under the OPPS. **For CY 2019, CMS is now proposing to extend the Medicare Part B payment reduction to all 340B-acquired drugs furnished by non-excepted (established after November 2, 2015) off-campus PBDs.** Currently, non-excepted PBDs are only subject to reduced payment (40 percent of APCs). "Excepted" PBDs currently are not subject to payment reductions but are paid at ASP – 22.5 percent for 340B drugs.

While CMS hinted at these changes in its CY 2018 OPPS Final Rule and Secretary Azar has made similar public comments, this official Proposed Rule makes a large scale sub-regulatory 340B Program payment reduction relatively likely to occur. Advocacy efforts should focus on not only complete reversal of these changes but also on the fact that no grandfather provisions were discussed. If finalized without regard to pre-existing or "under-development" status, these payment reductions could materially and negatively impact budget assumptions and disrupt care. At a minimum, CMS should consider its history of allowing for appropriate budgeting and planning processes in order to

minimize patient care disruptions.

In justifying its proposal for extending the Part B Reduction, CMS stated that it “believe[s] the proposed payment policy would better reflect the resources and acquisition costs that nonexcepted off-campus [provider-based departments] incur for these drugs and biologicals.” CMS also stated that such changes will allow “Medicare beneficiaries (and the Medicare program) to pay less when hospitals participating in the 340B Program furnish drugs that are purchased under the 340B Program to Medicare beneficiaries.” Of course, while the Part B reduction will enable the Medicare program and certain beneficiaries to pay less for claims for 340B drugs, the projected savings will be applied in a budget neutral manner to fund the aggregate Medicare market basket update. This will result in the 340B savings being indirectly used to support both drug and non-drug items and services provided by 340B and non-OPPS hospitals alike, including those provided by for-profit hospitals. More, there will be no aggregate beneficiary benefit.

CMS’s proposed extension of the Part B payment reduction will be especially challenging for Covered Entities if implemented in conjunction with the prohibition on expansion of service lines for excepted off-campus provider-based departments discussed in the OPPS Proposed Rule. Generally, CMS is proposing to prohibit expansion of provider-based services at excepted PBDs beyond certain pre-existing categories of services not provided between November 1, 2014 and November 1, 2015. CMS would pay such services pursuant to the Physician Fee Schedule (“PFS”) by reimbursing those services at 40 percent of APC payment rates. Covered Entities that operate off-campus PBDs will therefore need to carefully consider how or if they will expand their service lines. Any Covered Entity seeking to expand service lines via off-campus PBDs will need to analyze the implications of the Proposed Rule on their operations. We discuss the provider-based implications of the Proposed Rule in depth in another recent [article](#).

Fortunately, as with the original Part B reduction applicable to main campus and excepted PBD Covered Entity locations, this proposed expansion of the Part B payment reduction will not apply to CAHs, rural SCHs, PPS-exempt cancer hospitals or children’s hospitals. This proposed expansion will likewise not apply to drugs with pass-through payment status, vaccines or drugs that are not 340B-eligible “Covered Outpatient Drugs.”

These proposed changes will present significant challenges for Covered Entities (and any other providers) that operate off-campus PBDs. Given the financial stakes at play, affected Covered Entities should submit comments to CMS explaining their opposition to these changes. These comments should address how enhanced 340B Program benefits and provider-based reimbursement enable such Covered Entities to provide a broad range of high quality health care services to their patients, including the most poor and vulnerable patient populations. Covered Entities will need to clearly explain and demonstrate the vital nature of OPPS payments to the continued operation of many off-campus provider-based sites, particularly those located in underserved communities. We also believe that there are regulatory arguments that can be reiterated. **Comments on this Proposed Rule are due no later than 5 PM EST on September 24, 2018 and may be submitted electronically [here](#).**

Further, affected Covered Entities should work closely with their Advocacy teams to contact their local legislators to emphasize the detrimental impact of these proposed regulatory changes on the Covered Entities’ ability to provide health care services to underserved members of the Covered Entities’ communities.

II. PROPOSED LEGISLATION AFFECTING 340B PROGRAMS

As discussed above, the 340B Program is the subject of numerous pieces of proposed legislation. While some of this legislation seeks to impose more stringent requirements on 340B Program participation and utilization, other legislation seeks to offset the recent Part B Reduction and enable Covered Entities to realize greater 340B Program benefits. While reading the tea leaves of Washington politics is never an exact art, most political insiders believe that the passage of any 340B-specific legislation is unlikely in the near future. Nonetheless, the various (and often conflicting) pieces of pending legislation contain some common themes and trends, including:

- Cease the enforcement of the Medicare Part B Reduction;
- Establish a moratorium on the registration of certain new 340B hospitals and child sites (generally DSHs);
- Mandate increased reporting requirements for Covered Entities, particularly regarding how such Covered Entities are utilizing the benefits from the 340B Program;
- Amend and narrow the “eligible patient” definition, thereby decreasing the number of patients that may qualify for 340B Program

benefits; and

- Provide HRSA OPA with increased oversight authority of 340B Program participants – particularly Covered Entities.

Ultimately, despite the unlikely passage of any 340B-specific legislation, there is no time like the present for increased and proactive advocacy efforts. Especially in light of CMS's ongoing reductions to Part B payment for 340B drugs, robust legislative advocacy is necessary to defend and clarify the important benefits that providers – and their patients – obtain from the 340B Program.

III. FINAL RULE DELAY - 340B CEILING PRICES AND CIVIL MONETARY PENALTIES

On June 5, 2018, HHS issued its decision to postpone the January 2017 Drug Pricing Program final rule ("Ceiling Price Rule"). That Final Rule would set new ceiling prices for the 340B Program, to July 1, 2019. Ceiling prices are the statutorily set maximum amount that a manufacturer can charge a Covered Entity for the purchase of 340B Covered Outpatient Drugs. The Ceiling Price Rule would apply to all drug manufacturers that must offer discounts under the 340B Program, establishing a process to calculate the ceiling price for drugs purchased under the program and civil monetary penalties for manufacturers that charge in excess of those ceiling prices. This represents the fifth postponement of the Final Rule which had originally had a March 2017 implementation date. This is clearly important to Covered Entities that have long been frustrated by the inability to confirm access to 340B pricing for 340B covered outpatient drugs.

Whether the Final Rule will be finalized is unclear since HHS questioned the regulation's statutory basis. In publishing its decision to delay the Final Rule, HHS noted that it needed more time to consider additional rulemaking, stating that the delay would "allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for any additional rulemaking."

This Final Rule has encountered significant pushback from pharmaceutical manufacturers, who wish to maintain confidentiality surrounding what they perceive as their proprietary ceiling prices. Of course, 340B Covered Entities and their advocacy groups continue to push for the implementation of the Final Rule in an effort to obtain increased 340B Program transparency and recourse against uncooperative manufacturers. Taking into account the larger picture, the delay of the Ceiling Price Rule, in conjunction with the proposed expanded Part B Reduction, signals an approach that imposes additional burdens on Covered Entities, while minimizing manufacturers' 340B Program responsibilities.

IV. CMS LITIGATION - 340B PROGRAM HOSPITAL PAYMENT CUTS

In response to the Part B Reduction implemented in the final OPPS rule for CY 2018, several large health care associations including the American Hospital Association and American Association of Medical Colleges, hospitals and health systems ("Group") filed a lawsuit on November 13, 2017 against HHS to invalidate the Part B Reduction.

After a series of filings and appeals, on July 17, 2018, a panel of three judges from the D.C. Circuit Court affirmed the lower court's decision and unanimously dismissed the Group's appeal from the U.S. District Court. The D.C. Circuit Court found that the Group had filed the lawsuit prematurely. In its decision, the D.C. Circuit Court stated that when the Group filed its lawsuit, it had not yet challenged the new reimbursement regulation based on a specific administrative claim for payment. Because the OPPS final rule that included the reduction had not become effective yet when the Group filed, and as a result, the D.C. Circuit Court determined that Group failed to fulfill the legal prerequisites for judicial review.

Since the decision dismissed the lawsuit on procedural grounds, the D.C. Circuit Court did not address the substantive merits of the Group's claims. The Group stated that it would take action to challenge the D.C. Circuit Court's decision, and it is therefore likely this litigation will continue. We continue to believe that a reasonable statutory argument exists for challenging the CMS Part B 340B payment reductions.

V. PRACTICAL TAKEAWAYS AND RECOMMENDATIONS

The time for action is now for all Covered Entities potentially affected by the recent proposed and actual changes to the 340B Program. Most urgently, such Covered Entities should **submit comments to CMS explaining their opposition to the Proposed Rule prior to 5 PM EST on September 24, 2018**. Covered Entities should also work with their advocacy teams and local legislators on a parallel track to shed light on the value brought by their continued participation in the 340B Program and advocate for the policy changes that would most benefit their patients. Sustained efforts to demonstrate the effectiveness of the 340B Program for low income populations and the savings generated by the 340B Program may assist policymakers in formulating successful policies and advocating for protections rather than payment cuts. Stakeholders should seek opportunities to explain the benefits that they provide to patients through the health and pharmaceutical services provided.

Covered Entities also should plan for the worst if the proposed 340B payment cuts are finalized. This includes modeling the reimbursement impact and preparing budgets, proformas and strategic plans reflective of various scenarios. These include the OPPS Proposed Rule being finalized as-is, the Proposed Rule being reversed or CMS adopting a grandfather rule for pre-existing PBDs.

For pharmaceutical manufacturers, pharmacy benefit managers, pharmacies and other providers that facilitate the drug supply chain, careful consideration in the design, implementation and evaluation of drug-related contracts, programs and policies is vital in this environment. Stakeholders should continue monitoring developments, including legislation, agency regulations and judicial decisions and should be prepared to respond with explanations and documentation.

We will continue to monitor developments in all of these areas.

If you have any questions or would like additional information about this topic, please contact:

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[1] We discussed this payment reduction at length in [a series of recent articles](#).