Now What Happens To 340B?

November 6, 2020

To: 340B Health System Coalition

From: Devon Seibert-Bailey, Senior Vice President
Paul Lee, Senior Partner

Re: 340B Policy Update

As the election neared, there was new activity surrounding the 340B program, this memo provides updates on these activities as well as a forecast for the next year now that we have some election results.

Pharmaceutical Manufacturer Contract Pharmacy Policies

Novartis scaled back its earlier plan to restrict 340B discounts on drugs accessed through contract pharmacies after stakeholders complained. Click here for Novartis' new contract pharmacy policy. The drug maker's updated 340B contract pharmacy policy does not affect Ryan White clinics, community health centers and other federal grantees, and Novartis will honor contract pharmacy arrangements within a 40-mile radius of a 340B hospital.

Astra Zeneca, Eli Lilly, and Sanofi (in the case of 340B entities that did not provide data that was requested) cut off 340B pricing for contract pharmacies. It is also important to note that some entities have reported that Astra Zeneca and Sanofi has also cut off all pricing from even in-house hospital pharmacies. Please be sure to check all pharmacy prices, even in-house in ensure you are getting the discounts as required by law.

Industry Response –

- PhRMA-funded AIR340B released a report that discusses "negative impact that continued growth in the contract pharmacy program is having," click here. They are advertising this report heavily in media widely read across Washington.
- The National Association of Community Health Centers filed a lawsuit against HHS to compel the department "to implement a long-delayed dispute resolution process that would allow health centers to act against drug companies that are violating the 340B statute and have abruptly stopped shipping discounted drugs to health centers' contracted pharmacies." Click here for the 30-page lawsuit. Click here for the press release from NACHC.
- Ryan White Clinics for 340B Access and two 340B grantee clinics filed a law suit to protect 340B entities' longstanding right to dispense their drugs through contract pharmacies under the federal 340B drug pricing program as mandated by statute and regulation. Click here for the lawsuit. Click here for the additional details.

Congressional Response –

- Iowa's Senators Finance Chair Chuck Grassley (R) Sen. Joni Ernst's (R) met with "top officials" at HHS to share hospitals' concerns about drug manufacturers unilaterally ending or imposing conditions on 340B pricing for their products. Grassley (R) tweeted, "Rural providers rely on these drug discounts and there's concern about drug companies cutting back discounts especially during a pandemic. Iowa Hospitals are very concerned because they use $$ 2serve low income ppl." Click here for the tweet.
- House Energy and Commerce Committee Republican Leader Greg Walden (R-OR) and Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) are calling for stakeholders to provide feedback on the 340B drug pricing program and how to "modernize" the program. In the request for input on how to improve the program, Walden and Alexander stated, "...it is clear changes are long overdue." Comments and recommendations to be submitted by October 30th to the following email addresses: 340B@help.senate.gov and 340B@mail.house.gov. To read the notice, click here.
- A bipartisan group of 28 U.S. Senators sent a letter to HHS Secretary Alex Azar urging him "To ensure pharmaceutical manufacturers continue to comply with the 340B statute and provide discounts to safety-net providers, we call on HRSA to take appropriate, prompt enforcement action to address violations of the Public Health Service Act." Click here for the final letter.
- 243 House members sent a letter to HHS Secretary Azar urging action against the manufacturers who are taking actions to cut contract pharmacy arrangements. Click here for their letter.
- 22 Democratic senators sent a letter to the association representing drug manufacturers, PhRMA, saying "many of your member companies are taking retaliatory actions against FQHCs and other nonprofit health care providers that utilize legally permissible channels, such as contract pharmacies, to dispense 340B drugs. This coercive behavior is ultimately most harmful to patients and should be reversed." Click here for the letter.
- Other individual letters from other senators have also been sent to the HHS Secretary. For example, Senator Joe Manchin (D-WV) sent this letter yesterday. Click here.

HHS Response –

HRSA sent a letter to Eli Lilly regarding its recent actions impacting contract pharmacies. Although HRSA says it "has yet to make a final determination as to any potential action," it outlined four concerns. Click here for the HRSA letter. An HHS official told Strategic Health Care that the letter would provide a good indication of where HHS is positioning itself on the issue.

State Response –

Connecticut's Attorney General William Tong sent letters to Eli Lilly and Co., AstraZeneca, Sanofi, Novartis, and Merck demanding they cease recent unilateral actions restricting access to 340B pricing for drugs dispensed by contract pharmacies or cease unreasonable demands for contract pharmacy claims data. Tong said in all the letters that the manufacturers' actions "would directly undermine" the 340B program. Click here for the press release.

Kalderos Proposal to Pay 340B Rebates in Lieu of Discounts

Prescription drug information technology company Kalderos launched a platform called 340B Pay on Sept. 8th "to facilitate 340B discounts via a rebate," several drug manufacturers are adopting the platform. To learn more about the Kalderos platform, click here.

The AHA has voiced concerns that the 340B Pay system would turn the 340B program from a discount program into a rebate program sending a letter on October 30th to the HRSA's urging the agency to order drug manufacturers and Kalderos to immediately halt their conversion of the 340B program to a back-end rebate program, click here.

CMS Proposed Additional Cuts

Once again in the CMS outpatient rule, the agency proposed additional cuts to payments for 340B drugs ASP minus 28.7 percent. On July 31, 2020, the US Court of Appeals for the District of Columbia Circuit held that CMS does have authority under the Social Security Act to reduce Medicare payment rates for 340B-eligible drugs reimbursed under the OPPS. For 2021 CMS is proposing to further revise payments by using 2018 and 2019 drug acquisition cost data from the Hospital Acquisition Cost Survey for 340B-Acquired Specified Covered Drugs to establish payment for CY 2021 and beyond. As a result, CMS is proposing to pay for 340B purchased drugs at ASP minus 34.7 percent with an add-on of 6 percent for a new proposed rate change of ASP minus 28.7 percent. It should be noted, providers will be unable to calculate themselves CMS payment formulation because 340B survey data is not publicly available. The proposed does note that CMS may delay the agency's proposed 2021 policy, i.e., CMS solicited comments to continue the current policy of ASP minus 22.5 percent. The final rule is expected in the first two weeks of November.

In a 2-1 decision, the US Court of Appeals for the DC Circuit reversed the lower court's ruling and upheld the 340B payment cuts arising from the 2018 and 2019 OPPS rules. The Court held that the agency's interpretation of its adjustment authority was reasonable and not directly foreclosed by statute. "At a minimum, the statute does not clearly preclude HHS from adjusting the SCOD [specified covered outpatient drugs] rate in a focused manner to address problems with reimbursement rates applicable only to certain types of hospitals." Click here for the court decision.

Legislation

Offices in both the House and Senate have expressed interest in drafting legislation to "shore-up" the 340B program and protect it for the future. We are working with them to create bills that would work to our advantage and not include harmful policies. While we are developing it from the draft that we had put together in the previous Congress, there will be changes – it will not be a carbon copy. We look to you for policies that you would like to see in the legislation such as a defined appeals process, or some limited regulatory authority for HRSA to define things like contract pharmacies.

Senior GOP members of Congress requested 340B stakeholders for input to make the program better. To read the notice, click here.

Sen. Mike Braun (R-IN) introduced the Fair Care Act of 2020 (S. 4796, click here) on Oct. 5, 2020, and includes a section that would require 340B disproportionate share, children's, and free-standing cancer hospitals to report data from their main and child sites on patient insurance status, charity care costs, and aggregate acquisition costs and reimbursements for 340B drugs. The reporting requirements would take effect 14 months after enactment and require HRSA to make the hospitals' patient insurance status, charity care cost, and contract information publicly available on 340B OPAIS. As this Congress is ending, we expect this bill to be reintroduced in the new 117th Congress in January.

Forecast for Coming Year Post-Election

Currently, the most likely post-election scenario is a President Biden, a narrowly-GOP controlled Senate, slimmer-Democratic controlled House. Under this divided government scenario, 340B is likely to see changes.

Under a Democratic Administration, providers of 340B are likely to receive more favorable treatment, while tighter controls will be placed on manufacturers, we may even see a reversal of some kind on the 340B cuts by a Biden Administration. We will certainly have a more sympathetic ear at HHS, HRSA, and CMS on 340B issues.

The Committees of jurisdiction in both the House and Senate have stated that they would like to perform some oversight of the program in late spring/early summer –

- We can expect to see more pressure from Senators such as Braun (R-IN) and Cassidy (R-LA) on the HELP Committee to move legislation that would increase reporting and transparency into the program. There are Democrat Senators who expressed interest in a more hospital-friendly policy with some transparency that is "doable" for hospitals and would place requirements on manufacturers, they would like to offer a compromise 340B policy.
- The Energy and Commerce Committee leadership has stated that they need to perform oversight into the program first and then may entertain some policy changes that would be helpful to the program. Democrats are less like to push for anything other than restoring the program plus things such as an appeals process and stronger rules for manufacturers.