SQUIRE PATTON BOGGS

House Panel Examines 340B Legislative Reforms

On Wednesday, July 11, 2018, House lawmakers again signaled their intent to reform the US Department of Health and Human Services (HHS), Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program (340B) during an Energy and Commerce (E&C) Subcommittee on Health hearing.

Since 2015, both E&C and the Senate Health, Education, Labor, and Pensions Committee (HELP) have conducted hearings to examine 340B. Additionally, E&C issued a January 2018 report that details potential congressional and agency actions to improve 340B administration.

The federal program, which permits covered entities that serve a certain threshold of low-income patients to purchase discounted outpatient drugs, still enjoys broad bipartisan support despite calls by some members of Congress and the Trump Administration to implement additional oversight. Covered entities include certain hospitals, as well as federally supported health centers and specialized clinics that meet defined criteria. Established in 1992, 340B has expanded to comprise nearly half of America's hospitals, many of which joined after the Affordable Care Act broadened eligibility.

Bipartisan consensus generally exists around refining 340B's intent, instituting well-defined eligibility rules for covered entities, and closing loopholes that may allow duplicate discounts through Medicaid's drug rebate program. However, Republicans tend to support measures that would slow or halt the enrollment of new covered entities in the program, as well as impose strict reporting requirements on how savings are spent for current participants.

During the hearing, lawmakers received feedback from 340B stakeholders on 15 bills, including eight discussion drafts. Additionally, they considered a recently released US Government Accountability Office (GAO) report that was requested by E&C and makes recommendations to ensure contract pharmacies are compliant with 340B regulations. A second E&C hearing to examine the reform proposals is slated for September. It remains unclear if HELP will propose similar reform legislation.

The following measures, as described by an E&C Majority memorandum, were discussed:

H.R. 2889, **Closing Loopholes for Orphan Drugs Act**, authored by Reps. Welch (D-VT) and Harper (R-MS) – The bill amends the Public Health Service Act to revise 340B, which currently requires drug manufacturers to discount orphan drugs (drugs for rare conditions) for certain entities covered by the program. The bill discounts orphan drugs that are not being used to treat rare conditions for all entities covered by the program.

H.R. 4392, **To provide that the provision of the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs final regulation relating to changes in the payment amount for certain drugs and biologicals purchased under the 340B drug discount program shall have no force or effect, and for other purposes**, authored by Reps. McKinley (R-WV), Thompson (D-CA), Johnson (R-OH), Kustoff (R-TN), Courtney (D-CT) and Castor (D-FL) – The bill nullifies the CY 2018 Medicare hospital outpatient reimbursement change that was finalized by HHS in a November 13, 2017 regulation. That final rule decreased reimbursement for outpatient drugs under Medicare that certain hospitals purchased under 340B – reducing the reimbursement from the average sales price (ASP) plus 6% to ASP minus 22.5%.

H.R. 4710, **340B PAUSE Act**, authored by Reps. Bucshon (R-IN) and Peters (D-CA) – The bill prohibits the registration of any new 340B covered entities into the program for two years, effective upon enactment. This moratorium includes Disproportionate Share Hospital (DSH) facilities and their potentially new child sites. To improve transparency, 14 months after the enactment of the bill covered entities shall begin to report on:

- Number and percentage of individuals dispensed 340B drugs
- Total cost incurred at each site
- Total charity care as defined by line S-10 on the Medicare cost report
- Aggregate amount of gross reimbursement
- Name of all 340B vendors who have entered into contractual arrangements with child sites (this information is already collected by HRSA on parent sites)

The bill also calls for a series of reports by the GAO, the HHS Office of Inspector General (OIG), and the Comptroller General about the level of charity care, an analysis of contracts between covered entities (parent and child sites) and vendors, and a comparison of 340B reimbursements to costs.

H.R. 5598, **340B Optimization Act**, authored by Reps. Carter (R-GA) and Collins (R-NY) – The bill requires certain DSH covered entities under 340B to submit reports to the Secretary of HHS on the low-income utilization rates of outpatient hospital services furnished by such entities, including both parent and child sites.

H.R. 6071, **Strengthening Entity Resources for Vulnerable Communities Act (SERV Act)**, authored by Rep. Matsui (D-CA) – The bill seeks to codify the 340B definition of a patient as described in the 1996 Federal Register. Under the bill, covered entities may not discriminate against a patient's choice of drugs received and pharmacies may not discriminate against covered entities in the reimbursement for drugs. The bill directs HHS to publish 340B ceiling prices – no later than 90 days from enactment – so that covered entities can verify that they are being charged the correct amount. If there is a discrepancy between the price paid by the covered entity and the 340B published ceiling price, then HRSA shall enforce civil monetary penalties on manufacturers in the amount of US$5,000 or 200% of the overcharged amount. The bill also requires parity in HRSA's audits of hospitals and pharmaceutical manufacturers, formalizes penny pricing and prevents HHS from making the Medicare hospital outpatient payment change as described in the November 2017 HHS regulation. Within one year of enactment, the bill requires GAO to report on HRSA's progress toward enacting these changes.

H.R. 6240, **Drug Discount Accountability Act**, authored by Reps. Carter (R-GA) and Collins (R-NY) – The bill directs HRSA to assess and collect user fees from covered entities. The Secretary of HHS will have 180 days to determine the fee amount and the amount shall not exceed 0.1% of the total paid during the previous year by a covered entity to manufacturers. User fees shall be used to finance the administration and oversight of the program. The Secretary of HHS is given direct authority to hire, at a minimum, 10 more full-time equivalent employees. Fees shall be collected upon certification or re-certification as appropriate. The bill also directs OIG to submit a report to Congress on the enactment and implementation of user fees.

H.R. 6273, **To amend the Public Health Service Act to ensure appropriate care by certain 340B covered entities for victims of sexual assault, and for other purposes**, authored by Reps. Walters (R-CA) and Walden (R-OR) – The bill applies only to 340B DSH hospitals that have an emergency department. Within one year of enactment, such hospitals must enact a plan to transfer victims of sexual assault to the nearest SAFE (Sexual Assault Forensic Examiner)-certified facility using official hospital transportation at no charge to the victim. Within two years of enactment, such hospitals must become SAFE-certified, meaning the entity employs or contracts with a SANE (Sexual Assault Nurse Examiner) program such that a SANE is available or on call 24 hours a day. HHS will publish a list of 340B SAFE-certified entities on the HHS website, and update such list annually.

H.R. _____, **To amend the Public Health Service Act to require under the 340B drug discount program reports by covered entities regarding certain information on savings to covered entities from discounted prices under the program and the relationship between such savings and charity care expenditures of such covered entities**, authored by Rep. Bucshon (R-IN) – The discussion draft requires covered entities to report to HRSA every 12 months on 340B total savings, total amount of revenue generated from the sale of 340B outpatient drugs, payer mix and total uncompensated costs (including charity care, net loss or income, bad debt and unreimbursed costs).

H.R. _____, **To amend the Public Health Service Act to allow the Secretary of Health and Human Services to prescribe regulations as necessary or appropriate to carry out the 340B drug discount program, and for other purposes**, authored by Rep. Mullin (R-OK) – The discussion draft gives HRSA the authority to enforce specific regulations regarding all aspects of the 340B program.

H.R. _____, **Protecting Safety-Net 340B Hospitals Act**, authored by Rep. Barton (R-TX) – The discussion draft increases the required DSH percentage from 11.75% to 18%. It also increases the 340B discount for all covered entity types, other than DSH hospitals and critical access hospitals, by 5%.

H.R. _____, **Bettering Operations and Oversight through Senate-Process Transparency (BOOST) 340B Act**, authored by Rep. Hudson (R-NC) – The discussion draft requires the administrator of 340B to be an Assistant Secretary and Senate-confirmed, with the goal of increasing the oversight of the program and accountability of the administrator.

H.R. _____, **To amend the Public Health Service Act to define the term patient for purposes of the 340B drug discount program**, authored by Rep. Collins (R-NY) – The discussion draft establishes a new definition of a patient for purposes of 340B. The draft requires HRSA to promulgate rulemaking on the new patient definition within 180 days.

H.R. _____, **To amend the Public Health Service Act to require the Secretary of Health and Human Services to conduct audits under the 340B drug discount program in accordance with generally accepted government auditing standards, and for other purposes**, authored by Rep. Burgess
(R-TX) – The discussion draft requires HRSA to perform audits utilizing auditing standards recognized by the Comptroller General of the US.

H.R. _____, **To amend the Public Health Service Act to require certain covered entities under the 340B drug discount program to establish certain fee amounts charged to certain low-income patients for 340B drugs**, authored by Rep. Burgess (R-TX) – The discussion draft prohibits 340B covered entities from charging low-income and uninsured patients the full price for 340B drugs. The discussion draft does not mandate a specific discount for covered entities for such patients, but states that certain covered entities must pass on a discount (at or below the 340B ceiling price) and that covered entities have documentation of this process.

H.R. _____, **To require the Secretary of Health and Human Services to implement the Government Accountability Office recommendations for the Health Resources and Services Administration relating to 340B contract pharmacies**, authored by Rep. Burgess (R-TX) – The discussion draft would mandate the Secretary of HHS to implement GAO recommendations for HRSA relating to 340B contract pharmacies.

For more information about the bill, please contact one of the lawyers listed in this publication.

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