340B Drug Pricing Program

July 18, 2018

The 340B Drug Pricing Program has been a hot topic in Congress lately. It seems like new legislation and/or Congressional hearings related to the 340B Program pop up almost daily. To keep 340B covered entities and others interested in the possible future course of the 340B Program apprised of these legislative activities, we reviewed the currently pending legislation related to the 340B Program and have briefly summarized each bill. There's no way of knowing at this time which, if any, of these proposed pieces of legislation will ultimately become law. Bricker & Eckler will continue to track 340B-related legislation and provide updates as warranted.

Below is a listing of proposed 340B Program-related legislation that the House of Representatives' Energy and Commerce Subcommittee on Health (Subcommittee) held hearings about in its "Opportunities to Improve the 340B Drug Pricing Program" on July 11, 2018 with a brief summary and a link to each proposed piece of legislation. For the pieces of proposed legislation that the American Hospital Association (AHA) took a position on in its written testimony submitted to the Subcommittee for the July 11, 2018 hearings, we have noted that position as well.

- H.R. 2889, Closing Loopholes for Orphan Drugs Act – This bill would limit the orphan drug exclusion to apply only when the orphan drug is transferred, prescribed, sold or used for the rare condition or disease for which such drug is designated. When that same drug is used to treat an illness other than the rare conditions for which the orphan drug designation was given, this bill would permit covered entities to purchase that drug under the 340B Drug Pricing Program. The AHA supports this bill.
- 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 – This bill would void the provisions of the 2018 Medicare OPPS Final Rule published on November 13, 2017 that would drastically reduce the Medicare payment for separately payable, non-pass-through drugs and biologicals under the 340B Program. The AHA supports this bill.

- H.R. 4710, 340B Protecting Access for the Underserved and Safety-Net Entities (340B PAUSE) Act – This bill, which the AHA opposes, would impose a two-year moratorium on new DSH covered entities and child sites and requires the OIG and GAO to submit reports to Congress on aspects of the 340B Program, including the level of charity care provided by DSH, cancer, and children's hospital covered entities, an analysis of the government contracts used by some DSH hospitals to qualify as covered entities including the amount of care those entities are obligated to provide to certain low-income individuals and how the term "low-income individuals" is defined in each contract. This bill would also require DSH, children's and cancer hospitals that are covered entities under the 340B Program to report certain data, to be published on the public HHS website in a searchable format, with respect to the main hospital and its child sites:
    - The number and percentage of individuals who are dispensed or administered 340B drugs, organized by type of insurance coverage
    - For each child site: the total costs incurred at each site and each site's charity care costs
    - The aggregate amount of gross reimbursement received by each covered entity (including its child sites) for drugs purchased under the 340B Program and the entity's aggregate acquisition cost for such drugs; and
    - The name of all third-party vendors or similar entities the covered entity contracts with to provide services associated with the 340B Program
- H.R. 5598, 340B Optimization Act – This bill would require certain DSH covered entities to report the low-income outpatient utilization rate of the hospital and its child sites. The AHA opposes this bill.
- H.R. 6071, Stretching Entity Resources for Vulnerable (SERV) Communities Act – This bill, which has the support of the AHA, would:
    - Prevent HHS from implementing the 2018 Medicare OPPS Final Rule published on November 13, 2017 that would drastically reduce the Medicare payment for separately payable, non-pass-through drugs and biologicals under the 340B Program and provide for payment for such drugs as if that final regulation did not apply;
    - Codify HRSA's definition of "patient" as set forth in its October 24, 1996 guidance;
    - Prohibit third-party payers from discriminating against covered entities or contract pharmacies with respect to reimbursement because of their participation in the 340B Program;
    - Expand eligibility for the 340B Program to programs funded by Community Mental Health Services Block Grants and Substance Abuse Prevention and Treatment Block Grants; and
    - Implement several measures aimed at drug manufacturer transparency and program integrity.
- H.R. 6240, To amend the Public Health Service Act to provide for certain user fees under the 340B drug discount program – This bill would require HHS to collect a user fee from certain 340B covered entities in an amount not to exceed 0.1 percent of the total amount paid in the prior year by the covered entity to manufacturers for the purchase of covered outpatient drugs. The proceeds from the user fee would be used to pay for program integrity and oversight functions. The AHA opposed this bill.
- 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 – This bill would require 340B covered entities that are DSH hospitals with emergency departments to become designated as sexual assault forensic evidence [SAFE]-ready facilities within 12 months of enactment of the law, and if they are not so designated within 12 months, they must inform sexual assault victims who come to their EDs for treatment relating to sexual assault that the hospital is not a SAFE-ready facility, provide the name and location of the closest SAFE-ready facility, offer to stabilize and then transfer the patient in an official vehicle, at no cost, to the closest SAFE-ready facility.
- H.R. __, Protecting Safety-Net 340B Hospitals Act – This discussion draft legislation would raise the eligibility threshold for hospitals that qualify for the 340B Program based on their Medicare DSH adjustment percentage from 11.75 percent to 18 percent. This proposed legislation would also increase the discount received by covered entities (excluding DSH hospitals

and CAHs) under the 340B Program by 5 percent. The AHA opposes this proposed legislation.

- H.R. __, Bettering Operations and Oversight through Senate-process Transparency (BOOST) in 340B Act – This proposed draft legislation would create a position known as the Administrator for the 340B Drug Discount Program within HRSA, who would be a Presidential appointee, and require the transfer of all functions previously delegated to the HRSA Administrator to the 340B Drug Discount Program Administrator.
- H.R. __, To amend the Public Health Service Act to define the term patient for purposes of the 340B drug discount program – This proposed draft legislation would define the term "patient" as it applies to DSH hospitals and CAHs participating in the 340B Drug Discount Program more narrowly than HRSA guidance currently defines the term (including by excluding patients who receive infusion services only) and would codify HRSA's definition of "patient" as set forth in its October 24, 1996 guidance for other types of covered entities. The AHA opposes this proposed legislation.
- H.R. __, To require the Secretary of Health and Human Services to implement the Government Accountability Office recommendations – This proposed draft legislation would require HHS to implement all of the recommendations made by the GAO in its June 2018 report, "Drug Discount Program Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement." The AHA did not take a position for or against this proposed legislation but recommended that the GAO recommendations should "review carefully any measure that adds administrative and regulatory burden with a focus on whether and to what extent the measure actually helps expand access to care for vulnerable populations."
- H.R. __, To amend the Public Health Service Act to require under the 340B drug discount program reports by covered entities – This proposed draft legislation, which the AHA opposes, would require that certain covered entities (DSH hospitals, children's hospitals, cancer hospitals, CAHs, rural referral centers and sole community hospitals) report certain information:
    - An estimate of the aggregate savings and aggregate revenue on drug purchased as a result of being a covered entity;
    - The covered entity's payor mix; and
    - The aggregate unreimbursed costs and uncompensated costs of the covered entity.
- H.R. __, To amend the Public Health Service Act to require the Secretary of Health and Human Services to conduct audits – This proposed draft legislation would require that the audits conducted by HRSA be performed in accordance with generally accepted government auditing standards. The AHA does not oppose this proposal but noted that HRSA should make greater effort to audit drug manufacturers.
- H.R. __, To amend the Public Health Service Act to require certain covered entities under the 340B drug discount program – This proposed draft legislation would limit the amount that DSH hospitals, children's hospitals, and cancer hospitals can charge "targeted low-income patients" (defined as low-income individuals who do not have coverage under an insurance plan that meets ACA requirements) for covered outpatient drugs. The AHA opposes this draft legislation, not in theory, but because operationally it is not workable since hospitals do not collect information on patients unless they are applying for financial assistance.
- H.R. __, To amend the Public Health Service Act to allow the Secretary of Health and Human Services to prescribe regulation – This draft legislation would allow HHS to promulgate regulations for the 340B Program. The AHA opposes this proposed legislation, noting that HRSA already has sufficient authority to safeguard the 340B Program.

Meanwhile, in a private meeting with Republican House lawmakers on July 12, 2018, HHS Secretary Alex Azar mentioned the idea of standardizing the 340B drug discounts at 20 percent of the list price, which is significantly lower than the typical 40 to 60 percent discount that 340B hospitals currently receive.

Prior to that meeting, in a speech to 340B Health, a trade association of 340B-participating hospitals, on July 9, 2018, Secretary Azar mentioned that the White House 2019 budget proposal would give HHS broader regulatory authority over the 340B Drug Pricing Program. Secretary Azar stated that the budget "proposes broad regulatory authority to help HHS ensure the 340B benefits reach the intended recipients and proposes new funding to support more oversight activities." He also noted that "Covered entities that are responsibly investing their 340B savings have nothing to fear from such measures."

Authors