340B Health System Coalition Legislative Proposal

The 340B Program – which was established more than three decades ago – is vital for the millions of patients who rely on the myriad of services hospitals are able to provide because of this program's structure. Over the years, Congress has made various and important adjustments to the program. However, the 340B Program is now in need of additional balanced reforms to ensure its viability and purpose.

The 340B Program was established "to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (H.R. Rep. 102-384, Pt. 2 (1992)). Hospitals, in particular disproportionate share hospitals, were the original beneficiaries of the legislation. Over time, Congress expanded the definition of a covered entity to include other types of providers, such as critical access hospitals, that also care for lower income patients who depend on public health programs to cover their cost of care. The changes made by Congress have gone far to expand the provision of care to the poor and underserved in our nation.

The following represents reforms to the 340B Program we believe collectively will bring fairness and stability while continuing our ability to stretch resources to provide critical care and programing to our patients in need. We ask Congress to support this package of reforms in its entirety.

1. **End Pharmacy Benefit Manager (PBM) Discriminatory Practices Towards 340B Entities**.

    - Over the past decade, PBMs have instituted practices that target 340B entities to ensure that PBMs benefit from the discount intended for the entities or are able to maintain the PBM's negotiated rebates from pharmaceutical manufacturers.
    - PBMs are implementing a policy referred to as "white bagging" where a physician-administered drug is purchased by the patient from the PBM-owned specialty pharmacy and then sent to the provider for administration. "White-bagging" requires that the drug no longer be dispensed by the hospital-owned pharmacy, but instead be sent from separate pharmacies, usually owned by the PBM, to the provider. The practice should be banned and only allowed at the request of the provider. This PBM business practice causes three major problems negatively impacting patients:
        - The cost of the drug is usually higher for the patient with no available discount from the covered entity (the health care provider). Additionally, drugs are not sent unless (or until) the patient has paid in full, while hospitals will dispense and administer the drug regardless of the patient's ability to pay.
        - Many infusion drugs – especially for cancer – are created specifically for the individual patient (depending on blood tests up to 24 hours prior to the administration of the drug). When a drug is "white bagged" it is sent days, sometimes weeks, before the appointment. These drugs are no longer targeted to the patient and are not as effective so must be wasted. The hospital must then, using its own supply, prepare the drug for the patient and take the loss on the sale.

        - PBM specialty pharmacies are not governed by the same rules and regulations as hospitals and health-systems pharmacies. They are not subject to the same statutory requirements that hospital and health systems' pharmacies must comply with regarding the medical supply chain. This raises serious patient safety issues. To help assure patient safety, we must dispense all drugs in accordance with all requirements throughout the supply chain.
    - When the drug is dispensed through the 340B provider pharmacy, the PBM is often paying the provider pharmacy less than the retail rate. This violates the intent of the program. PBMs must allow the purchase of the drug from any pharmacy at the same payment rate, regardless of site of dispensing.
    - PBMs have been using direct and indirect remuneration fees (DIR) for many years that allow them to apply their own plan performance measures as a way to assess fees on pharmacies dispensing covered Part D drugs. This "loophole" for PBMs is often arbitrary and unknown until payment to the dispensing pharmacy and/or assessed retroactively. The fees create losses in revenue that, at times, may surpass the acquisition cost of the drug itself. While PBMs state that DIRs are a pay for performance measure, many times it is applied across all purchases and adjusted based on performance. PBMs should be transparent on DIR fees, especially for 340B purchases, and be required to publicly report on the fees instituted on 340B entities.

2. **Define 'Contract Pharmacy' in the 340B Statute and Give Limited Regulatory Authority to HRSA to Create and Monitor Contract Pharmacy Agreements.**

    - The term "contract pharmacy" was created in a government guidance document, which has limited legal authority. As such, many pharmaceutical manufacturers believe that HHS does not have the authority to mandate usage of contract pharmacies or to impose penalties on pharmaceutical manufacturers when they limit or cut off access because contract pharmacies are not defined in either statute or regulations. To remove this ambiguity, "contract pharmacy" must be defined in statute so that 340B providers can continue to contract with area and specialty pharmacies to improve access and increase patient choice, thereby advancing the original intent of the program.
    - While most independent pharmacies – especially specialty pharmacies – negotiate terms of contracts with 340B providers, many large, nationwide pharmacy chains do not. This often results in predatory practices that can limit the intent of the 340B Program.

3. **The Health Resources Services Administration (HRSA) has no authority over what may be included in contracts between 340B providers and pharmacies.**

    - Legislation should give HRSA limited – very targeted – regulatory authority to create and define rules to govern contract pharmacies to ensure the intent of the 340B Program is maintained.

4. **Require Transparency of Community Benefits, Charity Care and Estimated Annual Savings by 340B Entities.**

    - 340B entities are eager to tell their stories of how they utilize the savings created through the Program. To that end, 340B providers should be required to provide public reports to HRSA on how they are using their 340B savings to "stretch scarce Federal dollars needed for programs for vulnerable patients," during the annual 340B recertification process (created by amendments in the Affordable Care Act). These reports would include the following additional information:
        - The net aggregate of the savings (in good faith) that the covered entities have acquired under the 340B Program. This amount will be calculated at the parent level and will include all activities at off-campus outpatient sites as if they are one entity for the purposes of this requirement.
        - A report of "community benefits" funds as is currently reported in Schedule H of IRS 990 form of the reporting year, to include, but not be limited to, community benefits (including patient assistance programs), charity care, Medicaid/Medicare shortfalls, and bad debt. For public entities that do not file a 990 Schedule H, a comparable report at the Secretary's discretion, determined in coordination with stakeholders, will be allowed to include the same items reported on Schedule H of the IRS 990 form.

5. **Definition of a 340B Patient.**

    - A 340B patient is any person who receives services from a 340B entity. All legislative history clearly points to Congressional intent for all patients of the entity to be considered 340B patients, with the covered entity retaining the savings "to enable [covered] entities to stretch Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."
    - To remove potential confusion, it is important to define a "patient" of the 340B Program in statute. A 340B patient is "any person who was provided a documented encounter or communication with a health care professional at a 340B entity within the time period for prescribed medication in accordance with state and federal laws."

6. **Create an Appeals Process for 340B Entities**.

    - Currently following an HRSA audit, 340B providers have no appeal rights, merely an opportunity to refute the finding within 30 days of the audit. All audit decisions are then deemed final. This is a major program oversight. The statute should be updated to require HRSA to develop an appeals process for audits of covered entities.

7. **Establish an Independent National Clearinghouse for 340B Claims Data**.

    - Creating a government sanctioned National 340B Clearinghouse would provide the necessary data protections, as well as create a simplified, automated process for 340B providers.
    - To maintain 340B contract pharmacy prices, many pharmaceutical manufacturers require 340B providers to provide claims data to them. The manufacturer audit programs

currently being used are not monitored or authorized by the federal government, leaving openings for patient-specific data to be vulnerable to disclosure.

- State Medicaid programs require 340B entities to place additional claims identifiers, known as modifiers, to drugs purchased at the 340B price. This is intended to stop "duplicate discounts" under Medicaid programs. Nearly every state uses different modifiers, leading to a time-consuming process when entities see patients from multiple states.
- The statute should require electronic records to be sent to a centralized National 340B Clearinghouse maintained by HRSA. The data could then be available to government entities.
  - Individual states would have the ability to obtain necessary information from the Clearinghouse to prevent Medicaid duplicate discounts.
  - Medicaid modifiers would be eliminated and prohibited because the relevant information would be available through the Clearinghouse.
  - To ensure data protection, non-governmental entities would only have access to completely de-identified data, showing the name of the drug, the purchase price, and the payment reimbursement.

8. **Pharmaceutical Manufactures Should be Audited at the Same Rate as Covered Entities.**

- HRSA - or their contracted auditors - regularly audit 340B entities to ensure that they are adhering to the law in their 340B purchases. Pharmaceutical manufacturers must be held to the same standard of the law and be audited at the same rate annually as covered entities.

It is time to ensure the security of the American health care safety net by establishing new policies to strengthen the 340B Program. Enacting these compromise policy reforms will add certainty to the 340B Program structure so that it continues to support health care for the poor and under-served for years to come.