Principles for Ensuring the 340B Program Benefits Patients and True Safety-Net Providers

The 340B Drug Pricing Program (340B program) is well-intentioned but evolution of our health care system over three decades has exposed flaws in the way the program is structured. Below is a comprehensive set of principles designed to work together to ensure the 340B program is put on a sustainable path for the future and benefits patients and true safety-net providers, including rural hospitals. These principles would require changes applicable to all stakeholders in the program.*

The Alliance to Save America’s 340B Program (ASAP 340B) supports an approach that includes all the policy areas outlined below, with statutory changes that codify both contract pharmacy arrangements and critical changes necessary to curb abuse and better tailor the program to benefit safety-net providers and their patients. We urge policymakers to focus on all of these principles as they consider changes to realign the 340B program.

1. **Make 340B a true safety-net program for patients.**

   The 340B program is intended to help support safety-net providers serving low-income and vulnerable patients. The program should be structured to enable true safety-net providers to help low-income and other vulnerable patients access more affordable medicines and health care services.

2. **Ensure 340B prescriptions are offered to patients at a discount.**

   Covered entities in the 340B program should increase access to affordable medicines for the patients that need help the most. Hospitals participating in the program should have a sliding fee scale for medicines that, at a minimum, applies to uninsured patients and patients with incomes under 200% of the federal poverty level with private insurance. Grantees should provide support for access to medicines that is consistent with the scope of their grant that qualifies them for the 340B program and at least as generous as any sliding fee scale requirements for other medical care.

3. **Update the 340B patient definition with strong safeguards.**

   The current definition of a “patient” of a covered entity, which determines whether a prescription is eligible for a 340B discount, is overly broad and needs to be updated to protect the integrity of the program and ensure it is serving vulnerable populations. The definition also needs strong safeguards and objective standards. For example, to be considered a “patient” of a covered entity, an individual should be required to have periodic in-person visits with a provider employed or contracted by the covered entity and the covered entity should be required to maintain a consistent responsibility for care of such individual. Additionally, prescription eligibility for a 340B discount should reflect a direct connection between the patient’s medical condition and the services being provided or managed (through permitted referrals) by the covered entity.

4. **Establish clear criteria for 340B contract pharmacy arrangements to improve access.**

   As part of broader 340B program changes described here, contract pharmacy arrangements, which are not currently binding on manufacturers, should be permitted for: 1) covered entities located in a medically underserved area or an area serving a medically underserved population, or 2) grantees providing care to a specific population, such as patients with HIV or chronic illness, for qualified prescriptions provided within the scope of the grantee’s 340B-qualifying Department of Health and Human Services (HHS) grant. In general, contract pharmacies also should be located near the covered entity, should have to provide the same patient affordability assistance for 340B prescriptions that is provided at the covered entity, and should be required, as a condition of program participation, to take certain steps to prevent diversion and duplicate discounts.

5. **Prevent middlemen and for-profit entities from profiting off the 340B program.**

   The savings generated from the 340B program are intended to support safety-net providers and vulnerable patients and should not be diverted for private benefit or other purposes not closely tied to a covered entity’s safety-net mission. Protections are needed to prevent for-profit companies, like pharmacy benefit managers, from siphoning off 340B savings intended to help patients by reducing reimbursement for 340B-qualifying prescriptions. Additionally, fees that pharmacies and other for-profit third parties charge for 340B-related services should be limited to ensure covered entities and the patients they serve receive most of the savings associated with the program.
Critical to improving the 340B program is the creation of additional accountability requirements to ensure eligible hospitals are supporting underserved communities as true safety-net providers. 340B hospitals should have policies that increase access to affordable health services, and their participation in the 340B program should be conditioned on them not engaging in aggressive debt collection practices that penalize the most at risk communities. New hospital eligibility criteria should be added to existing requirements to ensure the program is supporting true safety-net hospitals, including quantitative metrics that appropriately identify hospitals treating a disproportionately large share of low-income patients on an outpatient basis. Current eligibility requirements should be maintained for rural hospitals, specifically critical access hospitals and sole community hospitals, and eligibility should be updated so critical access hospitals that convert to the new rural emergency hospital designation do not lose 340B eligibility.

Hospitals’ use of lax 340B program guidance to expand to offsite clinics, known as child sites, requires reform and government oversight. Strong eligibility standards for these child sites are needed that include provisions to prevent abuse of the program’s intent. For example, each child site should be required to meet the same or analogous eligibility criteria as the 340B hospital it is associated with, comply with standards to ensure it is an integral part of the hospital, and have the same sliding fee scale requirement to ensure the program is reaching the intended populations. Additionally, child sites should be required to provide a meaningful range of clinically relevant services beyond dispensing, infusing or otherwise providing prescriptions. Similarly, the eligibility criteria for subgrantees should be revisited to ensure they are accomplishing their intended purpose.

To facilitate verification of 340B claim eligibility, the 340B program needs a neutral, independent clearinghouse capable of receiving Medicare, Medicaid, and commercial claims data. Establishing a national clearinghouse will strengthen program integrity and create transparency for manufacturers to monitor compliance. This neutral clearinghouse is a step toward building accountability and coordination for covered entities without increasing administrative burdens for safety-net providers. Data provided to a clearinghouse would be deidentified and subject to safeguards that prohibit use for marketing or other unauthorized purposes.

In general, covered entities should be required to report to HHS basic information about their involvement in the 340B program, including the total acquisition cost and reimbursement for 340B discounted medicines and the total amount spent to reduce out-of-pocket costs for patients receiving 340B discounted medicines. The state or local government contracts that are the basis for certain private non-profit hospitals’ program eligibility should also be publicly available.

Targeted rulemaking authority should be granted to the relevant HHS agencies to the extent needed to implement specific legislative provisions. Additional and improved program integrity measures to help enforce program requirements and legislative reforms should be included. The 340B program is governed exclusively by federal law. The provisions of the 340B statute, and the regulations issued thereunder, shall supersede any state or local law, regulation or other provision relating to or that could otherwise affect the 340B program.

*This includes covered entities, which include certain hospitals that generally provide care to low-income and other vulnerable patients, and certain community providers, referred to as federal grantees, that receive HHS grants to provide health care services to vulnerable populations; hospital off-site clinics, known as child sites, and subgrantees that are associated with other larger grantees in the program; biopharmaceutical manufacturers; and pharmacies that have arrangements with covered entities.