



ACCC PRINCIPLES FOR 340B SUSTAINABILITY AND REFORM

BACKGROUND: ACCC members provide cancer care in private practices and hospitals, both academic and community-based; both for-profit and not-for-profit. Given the diversity of our membership, and the growing discussion around the need for reforms to the 340B Drug Pricing Program, ACCC is uniquely positioned to engage with policymakers in a dialogue about how to ensure sustainability and reform of this important program.

ACCC believes that to preserve the original intent of the 340B program, to continue to ensure that savings help oncology providers reach more underserved patients and provide more comprehensive services, and to modernize and ensure long-term viability of the program, the following steps should be taken:

- Congress should revise the 340B statute to give HRSA the general rulemaking authority and adequate funding it needs to appropriately regulate and oversee the program.
- Congress should revisit the metric used to determine eligibility of hospital covered entities for the 340B program to better reflect 1) the level of outpatient services provided by the hospital, which is relevant because the 340B program relates to covered outpatient drugs, and 2) the patient population that the hospital covered entity and its sites serve. For example, rather than the DSH adjustment, Congress should explore other proxies for eligibility, including patient insurance status in the outpatient setting.
- Congress should expand HRSA's authority to sanction covered entities that knowingly and repeatedly violate the rules of the program.
- Congress should create a path for all oncology providers, including independent physician practices, to participate in the 340B program, particularly those that are already providing care for underserved patients.
- HRSA should require transparency and public reporting from covered entities on the savings accrued from the program and how these savings are spent on services that benefit underserved patients.
- HRSA should seek stakeholder input to clarify the definition of "covered entity" to focus on programs treating patients in a reasonable catchment area.
- HRSA should seek stakeholder input to clarify the definition of eligible patient so that providers understand clearly which patients qualify for the program.
- HRSA should examine the impact contract pharmacies, pharmacy benefit managers, and other outside entities have on the 340B program.

Request: As Congress, the Health Resources & Services Administration (HRSA), and the Centers for Medicare & Medicaid Services (CMS) consider reforms to the 340B Drug Pricing Program, legislators should support policies that encourage and, at a minimum, do not discourage medical oncology providers from treating underserved populations. Any reforms to the 340B Program should address the above principles, not place an excessive burden on clinicians, be appropriately tested to safeguard against barriers to access, and focus on ensuring that existing resources are reaching those cancer programs willing to treat underserved populations.