

Stretching Entity Resources for Vulnerable (SERV) Communities Act

The 340B Drug Pricing Program was created in 1992 and has made it possible for hospitals and clinics serving large populations of low-income and/or uninsured patients to purchase outpatient prescription drugs at a discount, with no cost to taxpayers. Eligible hospitals and clinics that participate in the 340B Program administered by the Health Resources and Services Administration (HRSA) are called “covered entities”. Covered entities must recertify their eligibility each year and are subject to annual audits. The Affordable Care Act, recognizing the valuable work of covered entities, intentionally expanded 340B eligibility to include hospitals and clinics serving rural communities.

The SERV Communities Act clarifies the intent of the 340B Program, enhances program integrity, and expands the program to further address the opioid crisis:

Clarifies Program Intent:

- The 340B Program enables eligible hospitals and clinics to stretch scarce resources as far as possible by reaching more eligible patients and by providing more comprehensive services than would be available without the program.
- Savings generated to covered entities from the 340B drug discount can be utilized to provide direct drug discounts to individual patients, but that is not the sole purpose of the program. Congress intended savings to be used in a variety of ways by 340B covered entities to help vulnerable patients access quality medical care and to improve population health.
- Any efforts to link the definition of “patient” to 1) a given patient’s payor, whether it be public or private; or 2) to require that 340B covered entities direct all of their generated savings to the provision of direct drug discounts for patients, would undermine the legislative intent of the 340B Program.

The 340B Program ensures patients can access needed medications, but the Program is also needed to increase access to comprehensive services.

Enhances Program Integrity:

- Hospitals and clinics eligible for the 340B program meet strict program eligibility requirements and are audited periodically for program compliance. However, the same oversight has not been applied to drug manufacturers in the program. In fact, over the life of the program only 11 drug manufacturers have been audited. The bill seeks parity between covered entity and drug manufacturer audits in the program.
- The bill would require program integrity efforts that have not yet gone into effect:
 - HRSA has been required by law to create a website displaying manufacturer ceiling drug prices for covered outpatient drugs. However, this has never been done, making it impossible for covered entities to make precise calculations about savings.
 - HRSA has published rules for Civil Monetary Penalties (CMPs) for drug manufacturers found not in compliance with the program. However, these rules have never been implemented, leaving no accountability for manufacturers not in compliance with the program.

Combats the Opioid Epidemic:

- Extends 340B program eligibility to safety net providers that receive grant funding from the Substance Abuse and Mental Health Services Administration (SAMHSA) to provide substance use disorder and mental health services.
- Overturns implementation and enforcement of a provision of the FY 2018 Medicare Outpatient Prospective Payment System (OPPS) Rule, which, beginning on Jan. 1, 2018, cut 340B hospitals’ Medicare payment for Part B drugs by 28.5 percent, thereby undermining the hospitals’ capacity to expand underserved patients’ access to a broad range of medical services.