

Legislative and Regulatory History Of THE EVOLUTION OF 340B PROGRAM



1992

The 340B program was created by Congress to help vulnerable or uninsured patients access prescription medicines at safety net facilities. These “covered entities” are considered to serve a high number of uninsured or vulnerable patients.

1994

Health Resources and Services Administration (HRSA) guidance allows 340B hospitals to include off-campus outpatient sites, called child sites, in the 340B program. These child sites are outpatient clinics owned by the hospital.

1996

HRSA guidance allows covered entities without an on-site pharmacy to contract with one off-site pharmacy. HRSA also finalizes the definition of “patient” in guidance. This guidance is later criticized as being overly vague by the Government Accountability Office and the Department of Health and Human Services Office of the Inspector General.

2005

In December, the House Energy and Commerce Subcommittee on Oversight and Investigations held the first hearing on the program since its creation.

2010

HRSA released guidance allowing all covered entities to have an unlimited number of contract pharmacies, including for-profit chain drug stores. And with the passage of the Affordable Care Act, 340B eligibility is extended to critical access hospitals, sole community hospitals, rural referral centers and cancer centers.

2014

In April, Kathleen Sebelius, then-Secretary of the Department of Health and Human Services, testified before the Senate Finance Committee regarding the President’s Fiscal Year 2015 Health Care Proposals. Regarding 340B, she stated “it has expanded beyond its bounds.”

2015

In March, the House Energy and Commerce Subcommittee on Health held the second hearing on the 340B program. In August, HRSA proposed megaguidance that would have clarified the 1996 definition of “patient.” This megaguidance was later withdrawn.

2017

The House Energy and Commerce Subcommittee on Oversight & Investigations held two hearings on the 340B program, one in July and one in October. In July, the Administration proposed changes to the Hospital Outpatient Prospective Payment System that impact 340B.