



Policy Brief

March 9, 2018



What's Happening with the 340B Program?

The 340B Drug Discount program continues to attract the attention of policy makers. That's because many believe that the program has grown very fast and without appropriate oversight. This has sparked a variety of efforts, including those outlined below.

- The Senate Health Education Labor and Pensions (HELP) Committee announced that it will hold an oversight hearing on the 340B program in early spring.
- The House Energy & Commerce Committee will also consider changes to the 340B program in the spring. Among the bills to be considered is the [340B Protecting Access for the Underserved and Safety-net Entities \(PAUSE\) Act](#), which would freeze hospital enrollment in the program for two years.
- Senator Charles Grassley (R-IA) introduced legislation, [Ensuring the Value of 340B \(S. 2435\)](#), which would require hospitals to disclose acquisition costs for 340B drugs and reimbursement for those drugs from *all* payers.
- The recently proposed [President's Budget](#) includes a plan to impose user fees on 340B providers to help pay for oversight of the program. The fees are projected to raise \$16 million a year.
- The President's Council of Economic Advisers released a [report](#) noting concerns about the program. The report recommends “more precise eligibility criteria” and the creation of “a single agency to set prices at which the eligible providers can buy drugs.”

But it's not all bad news. There are efforts occurring simultaneously in support of the program.

- Congressman David McKinley's (R-WV) bill, which would stop the 28.5% Medicare payment cut for 340B drugs (H.R. 4392), continues to gain co-sponsors. Co-sponsor count is currently at 189.
- A federal appeals court has agreed to fast-track a lawsuit filed by the American Hospital Association (AHA) to reverse the 28.5% payment cut to the 340B program.



Efforts to Address the Opioid Crisis Continue at Full Speed

There has been a flurry of activity around America's opioid epidemic, which was declared a national public health emergency last year. With over two million Americans directly impacted by opioid use disorder, here's what you need to know about the federal and state-level efforts to address the crisis.

The Battle Plan: White House Opioid Summit Recap

On March 1st, the Trump Administration convened physicians, cabinet members and community representatives for the White House Opioid Summit. Led by the Surgeon General, the White House [unveiled its plan](#) to simultaneously attack the epidemic on three fronts: reducing demand, controlling illicit supply and expanding treatment.

- **Reduce demand:** The Department of Health and Human Services plans to [prioritize alternative pain-management research](#), pledging over \$750 million in funding. The Administration also hopes to provide increased resources for first responders to opioid crisis events.
- **Control supply:** Cracking down on illegal supply streams of opioids will be done via joint ventures with law enforcement, including the Department of Justice's new Joint Criminal Opioid Darknet Enforcement team (J-CODE). The goal is to stop the online sale of opioids and [prosecuting producers](#) of illicit fentanyl.
- **Expand treatment:** Addressing the need for comprehensive addiction treatment will include increasing the availability of recovery and rehabilitation services, delegating increased funding for [opioid-specific grant programs](#) and promoting communication between providers and patients' families. The Administration also voiced approval for injectable opioid overdose medications and cross-sector innovative partnerships.

Congress and States Join the War on Opioids

In addition to the White House, we are seeing efforts by Congress and state legislatures to address the opioid crisis. Some of these efforts align with [recommendations](#) outlined by the President's Commission on Combating Drug Addiction and the Opioid Crisis. Here's what you should know about these efforts.



U.S. Congress

- The Senate Health Committee recently held a [hearing](#) to examine the role of technology in preventing and treating addiction, as well as [another hearing](#) on state programs that combat the opioid crisis.
- The House Energy and Commerce Committee is working on [a legislative package](#) to combat the epidemic with the goal of getting it to the House floor by Memorial Day.
- A bipartisan group of Senators introduced [legislation](#) that limits opioid prescribing to three day and dedicates \$1billion fund evidence-based prevention, enforcement, treatment, and recovery programs that address the opioid crisis.

State Legislatures



- **29 states** have proposed or passed legislation that places limits on the number of opioids clinicians can prescribe.
- **24 states** have proposed or passed legislation that requires additional opioid specific training for providers.
- **32 states** have passed or have pending legislation encouraging access to opioid antagonists or overdose reversal drugs like Naloxone.
- **19 states** have passed or have pending legislation regarding the licensing and regulation of Pain Management Clinics.
- **34 states** have passed or have pending legislation that outline requirements for the use of Prescription Drug Monitoring Programs or electronic databases that track prescriptions of controlled substances.
- **39 states** have incorporated efforts that addresses the opioid crisis including: task forces, opioid education in schools, prescription take-back programs, abuse-deterrent opioids, awareness efforts and even a proposed tax on opioid use.

State level data found [here](#).

A Look at the Federal Register



The Food and Drug Administration (FDA) is seeking comments on a [proposed rule](#) to improve the safe use of opioids. The goal is to curb overprescriptions, limit misuse and abuse, and decrease the occurrence of new addictions. Comments are due on March 16, 2018.

The FDA is also accepting comments on creative ways to improve opioid packaging. Scott Gottlieb, the Commissioner of the FDA, stated that the Agency is looking for innovative tools and strategies to address the public health crisis of opioid addiction. Comments are due on March 16, 2018.

In Other News...

[Kentucky Looking To Tax Opioid Prescriptions](#) – STAT

[Justice Dept. Backs Lawsuit Against Opioid Makers](#) – The New York Times

[The Price They Pay: Americans Living with High-Cost Drugs](#) – ProPublica/The New York Times

[Efforts to Reduce Adult Opioid Use Have Not Reduced Pediatric Ingestions](#) – American Academy of Pediatrics

[Google Sister-Company, Verily Plots a Move to the Health Insurance Industry](#) – NBC News