

Opioid Settlement Hinders Patients' Access to a Wide Array of Drugs

An agreement between attorneys general and major drug distributors increased scrutiny on medications for A.D.H.D., addiction, anxiety and pain.

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Nearly a year after a sweeping opioid settlement imposed new requirements on the companies that provide medications to pharmacies, patients across the United States are having difficulty obtaining drugs to treat many conditions, including anxiety, attention deficit hyperactivity disorder and addiction.

The \$21 billion settlement, which was brokered between the three largest American pharmaceutical distributors and the attorneys general of 46 states, was designed in part to correct practices that had flooded the country with prescription painkillers, contributing to the nation's opioid crisis. Distributors are placing stricter limits on drug supplies to individual pharmacies and heavily scrutinizing their dispensing activity.

But the oversight is not limited to opioids: It applies to an array of drugs known as controlled substances that have the potential to be addictive or habit-forming, such as muscle relaxants or medications like Xanax, used to treat anxiety and panic disorders.

As a result, tens of thousands of drug orders have been canceled, disrupting the flow of medication nationwide as the distributors — powerful but little-known wholesalers — navigate the line between implementing safeguards and making necessary drugs available.

Ilisa Bernstein, chief executive of the American Pharmacists Association, said that the controls, which took effect in July, had created "havoc" for some pharmacies.

"They have patients coming in to get medication, and they can't have it," Ms. Bernstein said. "It's disrupting patient care."

The distributors use algorithms that cap the quantities of controlled substances a pharmacy can sell in a month. Before the settlement, pharmacists said, they could explain to a distributor the reason for a surge in demand and still receive medications past their limits. Now the caps appear to be more rigid: Drugs are cut off with no advance notice or rapid recourse. As a condition of the settlement, distributors cannot tell pharmacies what the thresholds are.

Distributors are also monitoring orders that appear to mirror the practices of pill mills that blanketed the country with opioids, including the dispensing of certain combinations of drugs — such as opioids and sedatives — or filling orders for people who live far away. Attorneys general who led the settlement talks had accused distributors of asking few questions and profiting heavily as they shipped billions of deadly pills to communities devastated by overdoses.

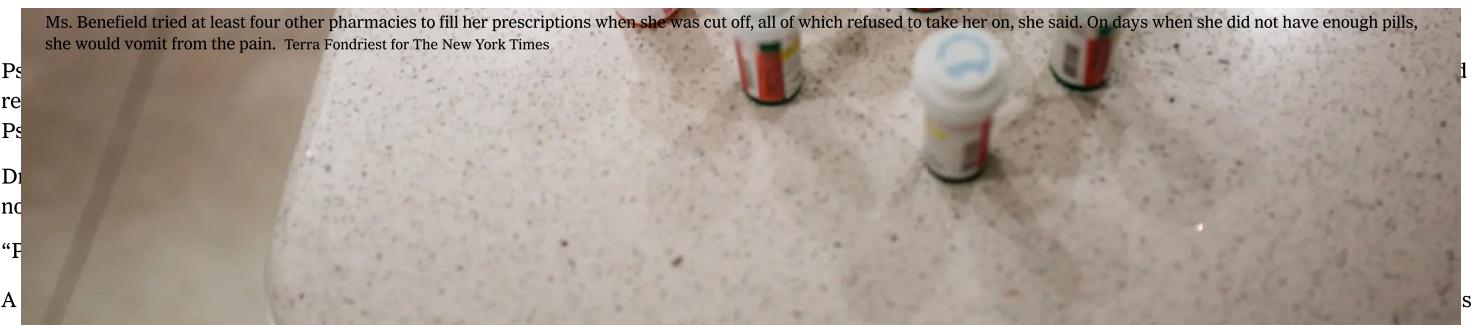
But some doctors said that legitimate prescriptions were being caught in the dragnet, while pharmacists said they were declining to dispense some medications for fear of setting off triggers.

Distributors can investigate and resolve red flags if they are satisfied by a pharmacy's explanation, but they can also stop supplying them with controlled drugs altogether.

Swept up in the scrutiny are college students far from home trying to fill their Adderall prescriptions, patients in rural areas where it is customary to drive long distances for medical care, and hospice providers that rely on local pharmacies for controlled substances instead of on a specialized supplier that would be exempt from the limits, The Times found.

Restrictions on controlled substances had already been ratcheted up for years, as concerns about abuse grew during the opioid epidemic. More recently, shortages of some drugs, such as Adderall, which is used to treat A.D.H.D., made those medications hard to get. The settlement with distributors appears to have tightened supplies even more.





Ms. Benefield tried at least four other pharmacies to fill her prescriptions when she was cut off, all of which refused to take her on, she said. On days when she did not have enough pills, she would vomit from the pain. Terra Fondriest for The New York Times

The effort to hold companies responsible for their role in the opioid crisis is continuing: In December, federal prosecutors accused AmerisourceBergen of systematically failing to flag suspicious orders, saying the distributor could face billions more in penalties. In response, AmerisourceBergen accused federal officials of shifting the burden of policing pharmacies to private companies.

AmerisourceBergen has warned pharmacies on its website to expect more orders to be flagged by the company's monitoring system, saying they would be "automatically canceled and reported."

In a statement, the company said it was seeking guidance from government agencies on how to prevent the misuse of "these drugs without interfering with good-faith clinical decisions made by doctors."

The other distributors in the settlement, Cardinal Health and McKesson, did not respond to requests for comment.

Although the tighter restrictions have been in place for months, the government has offered little remedy for patients.

Two trade groups — the National Community Pharmacists Association and the National Association of Boards of Pharmacy — said they had contacted the Drug Enforcement Administration about problems with access to controlled substances. The D.E.A. declined to comment, but in January the agency issued guidance saying distributors were responsible for setting limits.

A spokeswoman for the North Carolina attorney general's office, a lead negotiator of the settlement, said there was no effort underway to change the agreement, and the offices of three other state attorneys general did not respond to requests for comment.

Still, this year lawmakers in Arkansas introduced a bill that would limit distributors' power to cut off controlled substances to pharmacies.

The country's two largest pharmacy chains, Walgreens and CVS Health, declined to comment about the settlement's effect on their stores.

But data provided by five states showed that, since last summer, tens of thousands of pharmacy deliveries had been halted because of suspicious orders, including hitting the monthly cap. Distributors report each of these to the D.E.A. and, in most cases, state regulators.

Illinois has received 3,300 suspicious order reports since September, a spokeswoman for the attorney general's office said. (The state has about 2,400 pharmacies that dispense controlled substances.) The Texas attorney general's office said it had received 5,000 such reports since June. Michigan has received more than 10,000 reports since the settlement took effect, although a spokeswoman said some might be duplicates.

How those numbers compare to previous years is not clear. Several states said they had begun to receive data only after the settlement. The D.E.A. and distributors declined to comment on how many orders had been reported in recent months.

While some pharmacists have scrambled to get backup supplies, and some doctors have spent hours on the phone to help patients over the new hurdles, many other patients have been left empty-handed.

Charity Benefield, 42, was in the middle of radiation treatments for cancer in Northwest Arkansas and was facing a series of surgeries when AmerisourceBergen blocked her pharmacy from buying controlled drugs in November. Ms. Benefield tried to find another local pharmacy to fill her prescriptions for pain and anxiety. At least four refused, she said.

On days when she did not have enough pills, she would vomit from the pain. Ultimately, her oncologist called an Oklahoma City chain pharmacy that agreed to fill her prescriptions — at a location 90 minutes from her home.

AmerisourceBergen had cut off her usual pharmacy, Super Sav Drug, over a series of what were deemed red flags. The pharmacy's owner, Mark Manes, sought a court order to allow him to continue dispensing controlled substances but was initially denied after failing to prove that he had suffered irreparable harm: He had lost only about 15 percent of his business.

Still, the federal judge overseeing the case wrote in an opinion last month that AmerisourceBergen had displayed "bureaucratic rigidity" while the pharmacy had used sound judgment.



Mark Manes, owner of Super Sav Drug, Ms. Benefield's pharmacy, sought a court order to continue to prescribe controlled substances but lost an initial bid. Terra Foundation for The New York Times

While pharmacists can request increases to their controlled-drug limits, distributors must thoroughly vet each request, which can be a lengthy process. A pharmacist in Washington State, who did not want to be identified as having potent pain drugs on hand, said his morphine supply had been cut off before the end of a month, nearly preventing him from fulfilling a large contract with a local hospice. He found another source for that order, but six weeks after asking his distributor to increase his threshold, he still has not received an answer.

"There's not an independent pharmacy I've talked to that hasn't had a problem with not getting medication shipped because they hit some threshold and they don't know about it," said Jenny Arnold, chief executive of the Washington State Pharmacy Association.

The constraints also appear to be interfering with attempts to help people with addiction. The settlement singles out as a red flag some dispensing of buprenorphine, which is routinely used to treat opioid use disorder. The drug helps blunt symptoms of withdrawal and cravings for opioids, and is considered a key tool in fighting addiction.

Wesley Hickman, who owns a pharmacy in Leland, N.C., said he receives a call about every two hours from someone looking for buprenorphine. He hits his limit on the drug each month and has to turn patients away, including some who come to him after the local CVS or Walgreens runs out. (Although Dr. Hickman's pharmacy uses a smaller distributor that is not part of the settlement, the company has also enacted restrictions.) He noted that southeastern North Carolina has disproportionately high rates of opioid overdoses.

The tightened limits come as Congress seeks to broaden access to buprenorphine. Last year, lawmakers authorized more doctors to prescribe the drug to keep people from buying opioids on the street, where the risk of overdose from fentanyl remains high.

"I am turning people away," Dr. Hickman said. "It feels horrible."