

States struggle to help patients navigate insurance hurdle known as 'step therapy'

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Cassidy Yermal, 32, began experiencing debilitating migraines when she was 17 years old. As a teenager growing up in northeastern Pennsylvania,

she saw numerous neurologists and tried a variety of medications before finding one that provided relief.

In 2022, her new insurer asked her to prove it.

Yermal now lives in Marlboro, Maryland, where she's a sales representative at a furniture store. She is married and receives [health care coverage](#) through her husband's employer. In 2022, their new insurer told Yermal that it wouldn't pay for her medication unless she tried several less expensive drugs first—or could prove that she already had.

"I was like, 'I don't know why they're asking for this documentation now. My other insurance company didn't ask for it,'" Yermal told Stateline. It was "really frustrating to me to have to dig up the kind of things that I knew didn't work."

Millions of Americans have experienced similar frustrations under protocols known as step [therapy](#), or fail-first policies. Insurance companies, and the pharmacy benefit management companies that handle prescriptions for them, often refuse to cover a specific drug until after the patient has tried cheaper alternatives. Insurers argue that step therapy—taking [drug treatment](#) one step a time—prevents wasteful spending by directing patients to less expensive, but still effective, treatments.

But patient advocacy groups and physicians say doctors, not insurers, are best qualified to know which drug or treatment is likely to be most effective. Delaying the implementation of that decision, they say, often harms patients.

At least 36 states—including Maryland, where Yermal lives—have laws that are supposed to limit insurers' use of step therapy. But most only

apply in certain cases, and enforcement has been spotty. Most important, states do not have the power to regulate the self-funded insurance policies that large employers typically offer to their workers—and 65% of Americans are covered that way.

Only Congress has the power to curb the use of step therapy in self-funded plans; a bill that would do just that is pending on Capitol Hill. In the meantime, legislatures in several states, including Illinois, Kentucky and New Mexico, this year approved measures designed to close loopholes in their step therapy laws and extend protections to more people. The Kentucky and New Mexico bills are now law.

The Illinois measure, which is awaiting the signature of Democratic Gov. JB Pritzker, is especially far-reaching: It would ban any insurers regulated by the state, including Medicaid, from using step therapy. But because states can't regulate self-funded insurers, many Illinois residents wouldn't be covered.

"Knowing that our hospitals have hundreds of employees on staff just to deal with the insurance companies really says something," Democratic state Rep. Anna Moeller, chief sponsor of the bill, told Stateline.

"Nobody should be turned away in the middle of a mental health crisis or spend months potentially failing on other drugs while the doctors know they won't work. No one should have to go through that."

Illinois Democratic state Sen. Laura Fine, another sponsor of the bill, acknowledged that forcing large insurance companies to abide by the ban would be a challenge.

"Our Department of Insurance is going to have to come in. This is where we are going to have to make rules. How do we make sure that these laws are being carried out as written?" she said.

Nevertheless, Fine said, the ban almost certainly would be a huge improvement over the current step therapy law in Illinois. That law is so weak, she said, that for most people subjected to step therapy rules, "you could complain about it, but there was nothing that could be done about it."

"Now, we're saying, 'No, this is not [allowed],'" Fine said. "And so, you can complain about it, and something can get done."

In Maryland, Yermal had to wait two months for her insurer to approve her preferred migraine medication, Emgality, which has no generic form and can cost more than \$700 for the once-a-month dose. During that time, she suffered pounding headaches; "it was hard to live my life, and it was hard to do basic things," she said.

She also said that taking medications that don't work can have long-lasting effects. More than a decade later, she said, she is still feeling the impact of her time on a migraine drug that didn't help her.

"I still can't think straight. I used to be a really fast learner and pick up on stuff really quickly," Yermal said. "I took that medication over 10 years ago and I still feel that I never recovered."

Increasing use

Insurers argue that by preventing excessive spending, step therapy yields savings for consumers in the form of lower insurance premiums and less expensive prescriptions for everyone on the plan.

James Swann, a spokesperson for AHIP, a trade group formerly known as America's Health Insurance Plans, said step therapy protects patients from potentially harmful or unnecessary care, and that legislation to restrict it "would lead to clinically inappropriate care and could raise

costs for all consumers and purchasers."

Swann also suggested that insurers have a holistic perspective on the health care system that even doctors lack.

But Dr. Jack Resneck, former president of the American Medical Association, rejected that idea.

"I would make an argument that physicians who have gone to medical school and have the patient's entire medical record can help keep patients way more safe," Resneck said. "[Insurers] are often recommending things to me that are frankly unsafe."

He added, "Is it true that we have seen some drug prices go up astronomically? Absolutely. The solution is to fix drug pricing. It's not to tell patients that the drug they've been on that's been great for them is one they can't be on anymore."

Recent research suggests that the use of step therapy by insurance companies and pharmacy benefit managers is increasing—and that it is often divorced from [clinical evidence](#).

In a study published earlier this year in the journal *Health Affairs*, researchers looked at about 10 years' worth of Medicare Part D plan data and found that insurers increasingly imposed restrictions on patient access to medications. They did so through step therapy, requiring doctors to get insurers' permission before prescribing a drug, or by excluding drugs from coverage.

The percentage of drugs restricted by the policies increased from 32% in 2011 to 44% in 2020.

"While plans justify the use of these tools as a means to control costs,

restricting access to an increasing number of drugs raises concerns that these policies may adversely affect patients' health," Geoffrey Joyce, chair of the Department of Pharmaceutical and Health Economics at the University of Southern California and an author of the study said in an interview.

A study published in *Health Affairs* in 2021 found that 17 of the largest commercial health plans applied step therapy policies about 40% of the time for treatments related to 10 diseases.

The researchers found that there was wide variation among the companies' use of step therapy, and that the policies' requirements often departed from clinical guidelines. The protocols were more rigid than clinical guidelines at least half the time for patients with hepatitis C, multiple sclerosis and psoriatic arthritis. For psoriasis, the step therapy protocols were stricter more than 99% of the time.

James Chambers, an associate professor at the Tufts Medical Center Institute for Clinical Research and Health Policy Studies and an author of the study, told Stateline that the inconsistency "maybe raises a red flag about how these protocols were developed and for what reason."

"From experience, we see very different step therapy protocols across plans for the same drugs for the same uses," Chambers said. "It's not just subtle differences, but impactful differences for patients."

Current laws limited

The loopholes in existing state laws—and the fact that the laws don't apply to people with the most common form of insurance—frustrate patient advocacy groups. Dozens of them have been involved in lobbying for tougher state rules and the stalled federal bill.

"We have a ton of inflammatory arthritis and autoimmune patients in our network. And this population typically has to undergo step therapy, which causes major delays in treatment," said Zoe Rothblatt, director of community outreach at the Global Healthy Living Foundation, which advocates for patients with chronic diseases such as migraines, arthritis, osteoporosis and psoriasis.

"Patients can spend a lot of time—months—in pain, not able to work," Rothblatt said. "They could have disease progression."

Joyce said it won't be easy to further restrict the use of step therapy, either at the state or the federal level. He noted the country is spending more than \$4 trillion annually on health care, and "the reason it's so hard to change things is because that money is somebody's income—whether it's yours, or a doctor's or a pharma company's."

And the health care companies, he said, don't want reform.

"They all fight it tooth and nail, and they all have lobbyists in Washington fighting for their interests," he said.

Kaye Pestaina, vice president and director of patient and consumer protections at KFF, a health research organization, said innovative approaches to regulating insurance companies are more likely to occur on the state level, and that civil lawsuits are a powerful enforcement tool.

"States are really where the action is on health care. Changes and reforms depend on the state," Pestaina told Stateline. "The state law says how much the civil penalty is, what the circumstances are, when a government investigates, what makes something a violation and what doesn't."

Fine, the Illinois senator, said the measure set to be signed by the

governor is evidence of a growing legislative appetite to regulate insurers, a change that is shifting state government.

"I feel our Department of Insurance now is very consumer-focused," Fine told Stateline. "For a long, long time, everything was sort of slanted towards industry. And now, you know, the scale is kind of changing. And we're slanting towards, 'How is this helping the consumer?'"

Yermal, meanwhile, says she's doing fine now, although she still suffers from some headaches. She's happy she can at least get the medication she needs to deal with them, she said.

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