Effective but very expensive drugs are forcing state Medicaid directors to make some tough decisions.

BY MICHAEL BOOTH

One of the deadliest infectious diseases in the nation now has a lifesaving cure. But the drug boasts a price as astounding as the medicine is miraculous. Millions of patients could benefit; yet if too many of them show up for treatment too fast, the cost would bust the budgets of straining Medicaid programs across the nation.

Hepatitis C. Around 3.5 million Americans have this troubling public health threat although half of them don’t know it. Without treatment, it eventually attacks the liver and can cause liver cancer and cirrhosis and require a liver transplant. Close to 20,000 people died from it in 2014, more than the total combined number of deaths from 60 other infectious diseases, including HIV, pneumococcal disease and tuberculosis.

But at around $50,000 currently per person, the cure is far from the reach of many. Courts have ruled the states have to offer the drug to everyone, with legal advocates finding enormous leverage in the federal government’s rule that states must pay for all treatments that are “medical necessities.”

A Tangled Tale

It’s a tangled tale involving every branch of government and private industry, one that the most inventive professor of ethics would be hard-pressed to think up. But this is no ivory tower imaginary scenario. The battle over hepatitis C is an all-too-real human problem—“and a math problem,” as one Medicaid expert puts it—sparking furious political, executive and legal skirmishes in several states.

Colorado is among the latest to experience this clash between patient advocates and Medicaid directors and their legislative leaders who must carefully steward tight state budgets. Delaware, Florida, New York, Washington and elsewhere also have had to wrestle with hepatitis C payment rules.

Michael Booth is a freelance writer from Denver.
“There are people falling through the cracks right now who really need help,” says Colorado Representative Joann Ginal (D). “We should be able to help everybody, but prices are going up and our budget is only so big…"

The agonizing choices for Medicaid departments promise only to pile up in coming months and years. Treatments are being developed for other debilitating conditions, such as muscular dystrophy and sickle cell anemia.

That’s good news for patients, says Matt Salo, leader of the National Association of Medicaid Directors. He calls it “a Renaissance for treatments of long-untreatable illnesses.”

The bad news, however, is the collective price tag. The new drugs are coming with potential retail prices between $300,000 and $500,000 for each patient’s treatment.

**Hep C Sets the Bar**

Nowhere do the numbers pile up faster than with hepatitis C. Colorado’s dilemma reached its height last year when the state Medicaid department said it couldn’t afford the hepatitis C cure if all 10,000 Medicaid clients testing positive for the virus sought treatment. The department told legislators it had already spent $26.6 million on the cure for 326 patients. Treating everyone would cost $1.14 billion more, the department says, a budget-busting amount in a state that currently supplements Medicaid’s federal funding with $2.6 billion of its own money.

Many people testing positive for hepatitis C have no symptoms for years. So Colorado, like some other states, sought to limit the expensive drug treatment to patients with more severe symptoms, like liver scarring, whose disease progression “score” has reached reached at least three, on a nationally accepted four-point scale of the disease.

That idea was not received well by patients, advocacy groups and many public health experts who decried the notion that limiting a drug with so much potential to cure disease could be considered a solution. They pointed out that patients can have debilitating fatigue, aches and other symptoms long before they reach level three.

“When I heard about the new drugs, little did I know they would only give them to the people in the worst shape,” says David Higginbotham, a Colorado plumber who has lived with hepatitis C for decades since acquiring it during a stint as a surgical technician. In fact, Higginbotham feels so passionate about this topic that he ran for a House seat last fall, but lost.

“The system is set up to ignore the problem until they go away. And they do go away—they die.”

Although Colorado Medicaid officials declined an interview, citing pending litigation, in past statements they have pointed to the extremely high price pharmaceutical companies place on the drugs as the roadblock.

### HEP-C

**BY THE NUMBERS**

1st

Hepatitis C’s place as the leading infectious killer in the U.S.

20,000

People killed by the disease in U.S. each year—more than 60 other infectious diseases combined.

$84,000

The original cost of a 12-week course of Sovaldi, one of the first Hep-C drugs with a 90% cure rate

24.3%

Medicaid’s rate of spending increase on drugs in 2014 (Medicare’s increase was 16.9%; private health insurance, 11.3%)

25%

The increase in Medicaid spending on prescription drugs (2013–2014) due to higher use

75%

The increase in Medicaid spending on prescription drugs due to increases in price

Sources: The Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services
The Miracle Comes With a Price

The current impasse in various states began when the federal Food and Drug Administration approved Gilead Science Inc.’s drug Sovaldi in 2013. The previous standard treatment for active hepatitis C patients was a year’s worth of interferon injections with excruciating side effects.

With a 90 percent cure rate and few side effects, Sovaldi appeared to many patients to be the miracle they had hoped for. But at about $1,000 a pill, it came with a cost: $84,000 per patient for the full 12-week course of treatment.

Gilead has since added the drug Harvoni, and other drugmakers are coming to market with similarly effective treatments. The variety and competition have helped Medicaid departments negotiate a lower price.

Why So Much?

The patents owned by drug companies give them a monopoly on their formulas and the legal authority to charge whatever they want to. They argue that it’s an expensive, tedious process to get a drug approved in the United States. Drug companies invest roughly 15 percent of their revenues back into research and development. Limiting that revenue has the consequence of limiting new investments in research, they argue.

Gilead’s position is that the price of its drugs to cure hepatitis C is a good deal for states overall, as the long-term costs for treating hepatitis C patients plummet after they are cured.

The company’s executives say states benefit from a Medicaid-mandated discount for the drugs, and state officials can negotiate deeper discounts if they agree to extending the drugs to more patients through their formularies.

Despair Over Disparities

Patient advocates denounce government limits that they argue exacerbate current health disparities between those who will receive the new treatments because they have Medicare or private insurance and those who will have to wait until they are sick enough to receive treatments because they are on Medicaid.

Advocates, some of whom acknowledge they receive funding from the same drug companies that would benefit from expanded state purchases, joined their voices with the American Civil Liberties Union and other groups demanding an alternative to the limitations.

“Our contention is that the professionally accepted clinical standard of care is to treat chronic hepatitis C with these modern curative medications, regardless of how far the disease has progressed,” says Mark Silverstein, legal director for the Colorado ACLU.

The ACLU threatened to take Colorado to court unless the standard was changed to allow treatment for all diagnosed Medicaid patients. In response, Colorado Medicaid announced it would lower the criteria for treatment to those patients diagnosed at level two or above. Advocates welcomed that step but said it was not enough, and cited states that have opened treatment to all.

Last fall, the ACLU followed through with its threat and filed a federal class-action lawsuit against the state’s Medicaid program for failing to allow treatment for all diagnosed Medicaid patients and thus violating the federal rule requiring coverage of any treatment deemed “medically necessary.” The overwhelming number of public health doctors who support full treatment proves the medical necessity of the hepatitis C drugs, Silverstein says.

The Budget Is No Reason

“When a Medicaid agency wants to rely on its budget as a reason for not providing medical care, it’s problematic legally,” Silverstein says.

It’s also bad public health and fiscal policy, patient advocates contend. Curing hepatitis C in more patients means fewer people transmitting the deadly and costly disease to others.

Untreated hepatitis C not only leads to eventual liver disease, but it can complicate diabetes, lymphoma and arthritis, among other conditions, says Nancy Steinfurth,
director of Colorado’s patient advocacy group Liver Health Connection.

“There are a lot of diseases made worse by hepatitis C that Medicaid is already paying for,” Steinfurth says. A study commissioned by her group—which receives drug company backing—showed that Medicaid departments save money in the second year after treating those in level two of the disease as well.

**Repeat Offenders**

Medicaid directors and their professional advisory boards are wrestling with other ethical issues regarding hepatitis C, says Salo, with the Medicaid directors association. The new class of drugs may constitute an effective cure, but they do not protect or immunize patients, especially against their own risky behavior.

Injection drug users, for example, frequently relapse, risking reinfection with hepatitis C from shared needles. Moreover, Salo says, some prescribers are reluctant to authorize a $50,000 course of drugs without some kind of supervision ensuring the patient sticks to the regimen and takes them correctly.

“Are you going to mail someone a bottle of pills that’s worth $20,000 and hope they take them right?” Salo asks. “Are you going to pay for someone who is reinfected, and how many times?”

Legislators and executive branches around the nation also have to account for hepatitis C costs in their prison systems, where Medicaid can’t be used to cover state prisoners. That means states pick up the full tab rather than split costs with the federal government. Pennsylvania says in a court filing that treating thousands of inmates with hepatitis C would cost $600 million and “effectively cripple the department” budget, according to The Wall Street Journal.

**States Weigh In**

When drug prices jump by huge amounts for no apparent reason, it’s not hard to understand why lawmakers are taking note. They are starting to demand more transparency from drug companies on what their true research and production costs are for certain expensive treatments.

“What good is making a drug if a person who really needs it can’t afford it?” Colorado’s Ginal asks.

The Affordable Care Act requires transparency in the costs from hospitals and insurance companies but not from drug companies.

Vermont lawmakers passed the nation’s first law to bring more transparency into drug pricing in early 2016. It requires drug-makers to justify why an increase in price is needed for certain medications each year. Another dozen or so states considered similar legislation in 2016, and it looks like 2017 will be similar.

Tennessee Representative Cameron Sexton (R) says his state is using a pilot program agreement with the federal Centers for Medicare & Medicaid Services to make some payments based on patient outcomes, not just on budget targets.

“One of the limitations of government is that it only looks at the cost for today, and very rarely looks at the savings over time,” Sexton says. “We’re trying to change that philosophy in our pilot program. So you hold PhRMA (Pharmaceutical Research and
“One of the limitations of government is that it only looks at the cost for today, and very rarely looks at the savings over time.”

Representative Cameron Sexton, Tennessee

Manufacturers of America) or the individual company accountable for the results they say they’re going to achieve.”

In the example of hepatitis C, Sexton says, if the drug seller claims the product will reduce hospitalization and other costs down the road, in exchange for a $50,000 drug cost, then the state should modernize its technology and accounting to be able to measure that outcome. “Did you really see the benefits you were told there would be? If you are not seeing that, then there’s no longer any need for the state to use that product,” Sexton says.

Not Forgetting the Future

Hepatitis C has upended the calculations of Medicaid directors because it’s much more common than other conditions that have high-priced cures or treatments, Salo says. Hemophilia can cost $1 million a year to treat and manage, but it’s extremely rare. The condition that worries health leaders most as baby boomers age is Alzheimer’s, with several drug companies pursuing treatments that are likely to prove enormously expensive, Salo says.

Drug companies are already shifting the talk about Alzheimer’s away from how much it will cost them to produce new drugs to how much it will cost the state or caregivers to treat and care for patients in a nursing home, Salo says. If those price tags come in at $75,000 a year for a drug that millions of baby boomers will want to take as soon as they near 55, “that’s unsustainable,” Salo says.

With hepatitis C drugs and other pending high-price treatments, Salo says states will not be able to solve the cost problem on their own. The federal government will either have to come in as a financial partner to pay a higher share of treatments it has deemed medically necessary, or it will have to use its aggregate negotiating power to lower prices.

A Hopeful Sign

Gilead executives say the states’ crises in hepatitis C costs are already showing signs of diminishing because of the effectiveness of the cure. The total number of hepatitis C infections nationwide is starting to drop, as are the prices of new effective treatment regimens, says Coy Stout, Gilead vice president of managed markets.

For many, that trend can’t come too soon. Representative Robert Bancroft (R), a cosponsor of the Vermont legislation, describes the situation this way: “Drug costs are like a rubber band that keeps stretching and stretching. Eventually it’s going to break.”

The ABCs of Hepatitis

Three different viruses cause the three kinds of hepatitis. All produce similar symptoms: fever, headache, malaise, anorexia, nausea, vomiting, diarrhea and abdominal pain. But all are transmitted differently, according to the Centers for Disease Control and Prevention. Their effects on the liver vary as well. There are vaccines to prevent A and B, but not C.

A is acquired primarily through close personal contact with an infected person and during food-borne outbreaks. Hepatitis A appears only as an acute infection and does not become chronic. People with hepatitis A usually improve without treatment.

B is transmitted by exposure to the blood or body fluids of an infected person through sexual contact, childbirth, unscreened blood transfusion or unsafe injections.

C is transmitted primarily from injection-drug use, needle stick injuries and inadequate infection control in health-care settings.

Source: Centers for Disease Control and Prevention

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Representative Robert Bancroft, Vermont

Up and Up

Annual expenditures on prescription drugs between 2007 and 2014

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Source: Centers for Disease Control and Prevention