Covering Costly HCV Tx: Who Makes that Call?

Medicaid budgets face 'Death Star Senario

by Shannon Firth

Washington Correspondent, MedPage Today

WASHINGTON -- Forcing U.S. states to cover pricey treatments for people with the hepatitis C virus (HCV) would cause the Medicaid budget to "explode," according to a Medicaid representative.

The Medicaid budget, which must be balanced each year, could find itself in a "Death Star scenario," said Matt Salo, executive director National Association of Medicaid Directors (NAMD), making a *Star Wars* reference. "You don't want us to blow up your home planet -- well, which planet would you like us to blow up? You spend an additional 5% of your program each year, which 5% do you want to cut? Who do you want to not cover because we're spending all this money here?"

NAMD is a nonprofit that represents Medicaid directors in all 50 states.

The current poster children for high-cost specialty drugs are HCV drugs, according to a briefing on affordable drugs at the Bipartisan Policy Center here. One example is Sovaldi (sofosbuvir) from Gilead, which costs $84,000 for a 12-week course of treatment.

Gerard Anderson PhD, of the John Hopkins University Bloomberg School of Public Health in Baltimore, noted that in 2014, only 4% of people in the U.S. who had HCV were getting the "curative" treatment.

In November 2015, the Centers for Medicare & Medicaid Services (CMS) issued a letter assuring Medicaid beneficiaries access to hepatitis C medications. The letter stated:

"CMS is concerned that some states are restricting access to [direct-acting antiviral drugs or DAA] HCV drugs contrary to the statutory requirements in section 1927 of the [Social Securities] Act by imposing conditions for coverage that may unreasonably restrict access to these drugs. ... While states have the discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes ... the effect of such limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections."

But Salo told *MedPage Today* that "CMS has traditionally given states broad latitude in order to set the criteria for the drugs that it covers. ... This is a departure from that."

Salo argued that the CMS letter put an unreasonable and unfair burden on states, and opened them up to lawsuits from beneficiaries. While pharmaceutical companies also received letters from the agency pressuring them to reduce the cost of their high-cost treatment, "there's zero leverage on that side," he said.

In addition to posing a financial challenge, Salo said the coverage might not be providing the value that CMS intends. While in clinical trials, these HCG drugs demonstrated a "super-high" curative rate, he said, but study participants are "predisposed to be compliant," and they generally aren't active abusers of alcohol or drugs.

"That's not the real world; that's not the Medicaid world," Salo said. "One of my members said, 'Look, we are taking someone who has no money, potentially no home, might have an IV drug use problem. We're handing them a bottle of pills [to treat HCV] that might cost as much as a boat every month for 3 months. Does anyone see what might go wrong here?'"

He also said he's frustrated when he hears members of the Veterans Administration admonishing Medicaid program directors for being "irresponsible" by not offering

coverage, when the VA can request more for its budget and get it approved. "We can't do that," he said.

Regarding access to HCV drugs, Salo said, "every state has a procedure in place to make sure that those who need it the most get it."

One possible strategy for making this value judgment is to use a liver fibrosis score. These scores will show a range of disease from 0-4. A HCV patient rated 0 has no symptoms, and a patient rated 4 needs a liver transplant. All states are covering patients starting in the 2-3 range, he noted.

Because Medicaid is required to offer coverage for all FDA approved drugs, and because of the warning letter CMS sent state directors, beneficiaries without any symptoms could potentially sue their states for not providing coverage, he argued.

Salo acknowledged in an email that solutions lie with Congress.
In 2014, NAMD sent a letter to Congress suggesting possible strategies for lowering the price of HCV treatment, including the following:

- Asking Congress to "exert downward pricing" on Sovaldi and companies with similar specialty drugs
- Federal purchase of the supply chain and discounted distribution to states
- Creating enhanced federal match rates for "curative" specialty drugs
- Introducing risk corridors or reinsurance based around subsidized state spending that surpasses federal projections of costs or coverage

NAMD also sent a more recent letter to the Senate Finance committee in March asking Congress to revisit the issue. "Something's got to be done," Salo said.