

## **VA to outsource care for 180,000 vets with hepatitis C**

USA TODAY NETWORK Dennis Wagner, The Arizona Republic

PHOENIX – The Department of Veterans Affairs is moving to outsource care nationwide for up to 180,000 veterans who have hepatitis C, a serious blood and liver condition treated with expensive new drugs that are costing the government billions of dollars.

The VA has spent weeks developing a controversial transition as patient loads have surged and funding has run out. Those efforts were not disclosed until records were released last week to The Arizona Republic.

Instructions on how to carry out the program show that the sickest veterans generally will get top priority for treatment. However, patients who have less than a year to live or who suffer "severe irreversible cognitive impairment" will not be eligible for treatment.

That provision, and the mass shifting of patients, drew immediate criticism from veterans advocates.

Tom Berger, executive director of a health council established by Vietnam Veterans of America, ripped the VA for launching a "faulty plan" and blasted the idea of medical teams deciding which patients will be denied antiviral remedies.

"They've set up what I would call, in Sarah Palin's words, 'death panels.' ... Maybe rationalization panels is a better term," Berger said.

The maneuver also caused a furor among experts inside the Veterans Health Administration, some of whom disassociated themselves from the plan and warned about ethical compromises. According to emails obtained by The Republic, about 200 specialists sent a letter in April to Secretary Robert McDonald expressing their "dismay at this unacceptable development."

"To halt hepatitis C treatment at VHA facilities now would be unconscionable," they wrote. "We can and must end the epidemic. Once we have treated every veteran with hepatitis C, the costs will go away. ... Give us the ammunition, and we will win this war."

### **HCV funds run out**

The transition plan for so-called HCV patients was developed in a working group chaired by Kenneth Berkowitz, acting executive director of VHA's National Center for Ethics in Health Care. In an April email, he told colleagues they needed to develop an "ethical framework" in

anticipation of a complete depletion of funds for drugs. "A fair and transparent plan that can be consistently applied is better than having no plan," he wrote.

The shift to private providers through the VA's Choice Plan enables the VHA to pay for HCV with bailout money from the Veterans Access, Choice and Accountability Act, a \$16.3 billion funding and reform measure passed last year. About \$10 billion of that money was earmarked for private care, but the Choice Plan has been so lightly used that it remains untapped. The money was intended to ease the backlog of veteran appointments for health care.

Emails show Dr. David Ross, the VA's director of HIV, HCV and public-health pathogens programs, resigned from the working group. "I cannot in good conscience continue to work on a plan for rationing care to veterans," he wrote.

In a separate email to top VA officials, Ross wrote, "There is no doubt in my mind that exclusively relying on Choice, rather than seeking supplemental funding, will be a disaster for patients, providers and VA."

VHA administrators concede they implemented the plan without a cost-benefit analysis or studies of provider availability and patient impacts. Records indicate only eight HCV veterans received antiviral therapy through the Choice Program from August 2014 through May 31, while more than 16,000 were getting treatment in VA medical centers.

The VA had set aside nearly \$700 million this year for HCV antiviral drugs. In documents and a written statement, department officials confirmed soaring patient loads and medication expenses have nearly wiped out that budget with several months to go in the federal fiscal year that ends Sept. 30. That's an estimated \$400million shortfall with more dramatic costs expected, beginning in October.

In an official statement on the hepatitis dilemma, VHA officials said they remain "committed to ensuring America's veterans have access to the health care and benefits they have earned and deserve." They stressed that "no patients on current therapy will be stopped," but declined to clarify how many patients are being moved to private providers or how many will not be eligible for cure.

### **Treatment demand soars**

Hepatitis C is a blood-borne virus that attacks the liver. According to the Centers for Disease Control and Prevention, about 3 million Americans are infected, though many have not been diagnosed. The virus is most commonly transmitted through hypodermic needles shared by narcotic-drug users, and before blood-screening improved in 1992, it spread dramatically via transfusions. It also may be transmitted by sexual contact.

The disease is considered epidemic among Vietnam-era veterans due to transfusions and blood contact in combat or training. More than 60% test positive, while one in 10 veterans overall has the infection — a rate five times higher than the general population. Last year, about 3,000 veterans died in VA care as a result of HCV infection, according to internal records.

Hepatitis C patients are treated with a breakthrough medication, sofosbuvir, approved in late 2013 under the brand names Sovaldi and later as Harvoni. In combination with other drugs, sofosbuvir cures the HCV infection in about nine of 10 patients while reducing risks of cirrhosis and liver cancer.

However, the pills reportedly cost about \$1,000 each retail, or \$600 per dose to the VA at a discount. A typical treatment regimen of 12 to 24 weeks costs \$50,000 to \$100,000. The price tag to serve VA patients could exceed \$10 billion.

Records show the VA has cured nearly as many HCV patients in the past 15 months as during the previous 15 years. Healed patients not only mean fewer deaths but reduced medical costs over the long haul.

In the short term, however, success has spawned a six-fold increase in demand for treatment by veterans, creating a huge funding gap.

The drug is so critical to care, and the expense so high, that Sen. Bernie Sanders, I-Vt., former chairman of the Senate Committee on Veterans Affairs and a Democratic presidential candidate, during a recent hearing urged the VA secretary to break the patent due to the manufacturer's "excessive profits."

Sovaldi and Harvoni are manufactured by Gilead Sciences Inc., which made \$22.8 billion on antiviral sales during 2014, according to the California company's annual earnings report.

In a statement, Gilead said high prices reflect the "innovation of the medicines" and are comparable to other antiviral drugs. The statement emphasized that Gilead offers discount rates for government health programs and assistance for patients in financial need.

### **Choice Program**

During a hearing last month of the Senate Committee on Veterans' Affairs, Deputy VA Secretary Sloan Gibson pleaded with lawmakers for "additional flexibility" to use Choice Program funds to pay for the hepatitis remedy.

There was no official action by Congress. But, a week later, on May 21, Undersecretary for Health James Tuchschiidt issued national orders to begin shifting HCV patients out of VA care "effective immediately."

Instructions accompanying that internal directive stressed the process should be "ongoing and transparent," but it was not publicized outside the agency.

Patients already receiving the antiviral therapy in veterans' facilities will continue. The remainder will be contacted by their VA doctors, told of the Choice Program and evaluated to determine whether they meet eligibility for treatment.

Decisions on who will be first in line for treatment, and who will be denied the cure, are to be made by teams at Veterans Integrated Service Networks, regional offices also known as VISNs.

The VA has set up a priority system to determine which patients get the HCV cure first, and which are not eligible. Veterans already receiving antiviral drugs are the No.1 priority, followed by those with severe conditions such as cirrhosis of the liver, compromised immune systems or B-cell lymphoma.

Patients with a prognosis of living less than 12 months will not be eligible for the drugs. Veterans in a vegetative state or with advanced dementia also are excluded, along with those who have hepatitis C strains resistant to antiviral therapy.

The instructions note that, "based on the principles of equity and human dignity," ineligible patients "should be provided all other appropriate medical care and support."