

because veterans would still be hurt by a partial government shut-

federal agencies.  
In particular, he mentioned the

including the temporary closure of VA regional offices to the public

programs in any shut-down program shutdown.

against it. □

# DoD policy on compounded meds still unresolved

By Patricia Kime  
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As the year draws to a close, thousands of Tricare beneficiaries still don't know whether their medications will be covered by the military health program after Jan. 24.

The medications are compounds — drugs formulated by pharmacists to meet individual patients' needs, often to alter a dose, change a delivery method (from a pill to a liquid, for example) or eliminate an ingredient not tolerated by the patient.

In July, Tricare announced it would no longer cover prescriptions that contained ingredients not approved by the Food and Drug Administration. Tricare's pharmacy benefit manager, Express Scripts, sent letters to 45,000 beneficiaries who would be affected by the change.

A month later, the Defense Department announced it had delayed the decision while it evaluated its policies on compounded medicines.

Air Force wife Susan Reynolds,

mother of a special needs child, said her son requires a dye-free medication. Her family didn't receive a letter from Express Scripts, but she is under the impression her son's prescriptions would not be covered, based on speaking with her pharmacist and on her own research on the FDA website.

"I don't have many available options when it comes to medications for him," Reynolds said. "If it's made with red dye and he needs to have it made dye-free, then we'll just have to suck it up and pay out of pocket."

## Concerns for patient safety

Tricare officials say the military system decided to stop covering compounded medications that included bulk chemicals and bulk powders not approved by the FDA out of concern for patient safety as well as legal restrictions on paying for prescriptions containing unapproved ingredients.

The decision followed an outbreak last year of fungal meningitis that killed 64 people and

sickened 751 — an illness they contracted after receiving contaminated steroid injections mixed at a compounding pharmacy in Framingham, Mass.

That tragedy sparked intense scrutiny of the industry and prompted Congress to consider legislation giving the FDA more power to regulate these companies.

But the increased scrutiny has left many patients confused and compounding pharmacists scrambling to promote their industry.

Rob Gussenhoven is chief science officer at DermaTran, a company that makes prescription pain creams for patients, including 2,000 Tricare prescriptions.

He said there has been much misinformation about the proposed Tricare change, and the industry is trying to clear up misunderstandings.

"A lot of people think there are going to be onerous restrictions," Gussenhoven said. "There aren't. This is not a wholesale ban. The confusion created was created, people thought there was a limitation on compounding, but what [Tricare] really wants us to do is use the proper dosage forms in listing the active pharmaceutical ingredients."

Retired Coast Guard Chief Petty Officer Jack Bishop, 75, of Grand Bay, Ala., uses a DermaTran product for arthritis pain. He had been prescribed Tramadol, a synthetic opioid analog, to be taken every six hours as needed for pain.

But by using the compounded pain cream and following an exercise regimen, he ends up taking a pain pill not more than once a week.

Bishop said if Tricare stops paying for his product, he'll consider whether he can afford the out-of-pocket expense. But he is worried that he'll end up taking more potentially addictive pain medications.

"When I use this salve, the pain relief is almost immediate. Within an hour or two, I can exercise normally and am pain free. But I've heard that these compounded medications are pretty expensive, so I don't know if I can afford it," he said.

According to Gussenhoven, a 120 gram supply of DermaTran averages \$800.

DermaTran recently hired a company to conduct a survey of its products and determined that 58 percent of patients found relief within 24 hours of using them.

## The wrong time?

Gussenhoven said given the military's concerns about prescription pain medications, now is the wrong time to restrict access to compounded medications.

"We're looking for alternatives to what the Institute of Medicine calls the 'conundrum of opiates.' In addition to overdoses and deaths, opioids can ... magnify pain over time and disrupt the neuroendocrine system, limiting the ability

for people to recover, reducing testosterone production, magnifying pain and depression and leading to suicide ideation," Gussenhoven said.

The Senate on Nov. 12 approved legislation that would give the FDA stronger regulatory power over compounding pharmacies. The legislation also would establish a voluntary system for industry oversight.

Tricare officials said they are continuing to evaluate the issue, but no decision has been made. A spokesman for Express Scripts said, however, that the beneficiaries who received letters are the ones most likely to be affected.

"Compound drugs are complex," said Thom Gross, senior manager of communications for Express Scripts. "Some compounds are mixtures of FDA approved ingredients. For example, when a pharmacist mixes two FDA-approved creams together, those would not have been impacted. Others are mixtures of non-FDA approved bulk powders and chemicals."

In 2012, about 500,000 compound claims were submitted to Tricare at a cost to the government of \$330 million.

Reynolds said she hopes Tricare will listen to affected patients as officials make a decision.

"It's very frustrating to know that I will have to file appeals to Tricare" to get medications for her son, she said.

"And they could still say no." □