

Why GAO Did This Study

DOD offers comprehensive health care coverage—pharmacy and medical benefits—to eligible beneficiaries through its TRICARE program. As part of its benefits package, TRICARE pays for compounded drugs. Traditionally, a drug is compounded through the process of mixing, combining, or altering ingredients, to create a customized drug tailored to the medical needs of an individual patient upon receipt of a prescription. Concerns exist about the safety and the rising costs of compounded drugs.

The National Defense Authorization Act for Fiscal Year 2014, mandated that GAO review TRICARE's payment for compounded drugs. For this report, GAO examined (1) the number and cost of compounded drugs paid for by TRICARE in fiscal year 2013, and (2) TRICARE's payment practices for compounded drugs and how they compare to other federal health care programs. GAO reviewed and analyzed TRICARE data on compounded drugs and reviewed, analyzed, and compared federal laws, regulations, and other documents pertaining to pharmacy and medical benefits under TRICARE, Medicare, and the VA health care system. GAO also interviewed program and contractor officials.

What GAO Recommends

GAO recommends that DOD align TRICARE's payment practices for compounded drugs with applicable regulations governing the TRICARE program. DOD concurred with GAO's recommendation and VA generally agreed with GAO's conclusions. HHS and VA provided technical comments that GAO incorporated as appropriate.

View [GAO-15-64](#). For more information, contact John E. Dicken at (202) 512-7114 or dickenj@gao.gov.

COMPOUNDED DRUGS

TRICARE's Payment Practices Should Be More Consistent with Regulations

What GAO Found

The Department of Defense's (DOD) TRICARE program paid for about 465,000 compounded drug prescriptions through its pharmacy benefit in fiscal year 2013; these prescriptions represented 0.3 percent of all prescription drugs paid for through TRICARE's pharmacy benefit in that year. Most of these compounded drug prescriptions were dispensed in retail pharmacies and to retirees and their family members. Compounded drug prescriptions paid for by TRICARE's pharmacy benefit cost \$259 million in fiscal year 2013—accounting for about 3 percent of the total cost of all prescription drugs paid for through TRICARE's pharmacy benefit—up from \$5 million in fiscal year 2004, and were largely driven by compounded drug prescriptions containing bulk drug substances. Bulk drug substances are typically raw powders that are generally not approved by the Food and Drug Administration (FDA)—the agency within the Department of Health and Human Services (HHS) responsible for assuring the safety and effectiveness of drugs and approving them for marketing in the United States. TRICARE could not identify compounded drug prescriptions paid for through its medical benefit, which pays for drugs administered to patients in outpatient or inpatient settings, because claim forms for outpatient and inpatient drugs lack specific billing codes.

TRICARE's payment practices for certain compounded drugs under its pharmacy and medical benefit are inconsistent with TRICARE regulations and are typically more generous than those of Medicare and the Department of Veterans Affairs (VA). Through its pharmacy benefit, TRICARE pays for compounded drugs that contain bulk drug substances in a manner that is inconsistent with its regulations, which stipulate that TRICARE is to pay for FDA-approved drugs only. In contrast, Medicare and VA have more restrictive payment practices for compounded drugs provided through their pharmacy benefits. By paying for compounded drugs containing bulk drug substances, TRICARE incurred additional costs. DOD officials told us that they are considering denying payment for compounded drugs that include bulk drug substances. TRICARE also pays for compounded drugs administered to patients through its medical benefit but does not determine whether these drugs contain bulk drug substances, in which case payment practices may be inconsistent with TRICARE's regulations. TRICARE's payment practices for these drugs are similar to Medicare's, but more generous than VA's.

Though compounded drugs represent a small share of TRICARE's overall drug costs, its costs for these drugs have risen significantly in recent years. Moreover, because most of these drugs contain bulk drug substances generally not approved by FDA, TRICARE's practice of paying for them is inconsistent with its regulations and results in added costs for the program.