

## Why GAO Did This Study

Drug compounding is a process whereby a pharmacist mixes or alters ingredients to create a drug tailored to the medical needs of an individual patient. Compounded drugs make up 1 to 3 percent of the \$300 billion domestic prescription drug market. Compounded drugs and some of their ingredients are not approved by FDA. Members of Congress have questioned whether federal health care programs' payment practices create incentives for providers to prescribe these drugs.

GAO was asked to examine public programs' and private health insurers' payment practices for compounded drugs. GAO examined (1) Medicare's, Medicaid's, and private health insurers' payment practices for compounded drugs and (2) the extent to which these payment practices for compounded drugs affect their use. GAO reviewed the payment policies of CMS, the five largest state Medicaid programs, five of the largest insurers that offer both Medicare and Medicaid managed care plans as well as private plans, and the two largest Medicare Part D-only sponsors. GAO also interviewed officials from these entities and from provider associations.

## What GAO Recommends

GAO recommends that CMS clarify its Medicare Part B payment policy to either allow or restrict payment for compounded drugs containing bulk drug substances and align payment practices with this policy. HHS disagreed with this recommendation, stating that the Part B payment policy does not depend on drug ingredients. GAO maintains that the policy needs clarification.

View [GAO-15-85](#). For more information, contact John Dicken at (202) 512-7114 or [dickenj@gao.gov](mailto:dickenj@gao.gov).

## COMPOUNDED DRUGS

### Payment Practices Vary across Public Programs and Private Insurers, and Medicare Part B Policy Should Be Clarified

## What GAO Found

Medicare, Medicaid, and private health insurers have varying payment practices for compounded drugs, depending upon whether compounded drugs and their ingredients can be identified on health insurance claims, and Medicare's Part B payment policy for these drugs is unclear.

- For drugs dispensed in pharmacy settings, claims contain sufficient information for public programs and private insurers to identify compounded drugs and their ingredients. These programs and plans use claims information to determine whether compounded drug ingredients are products approved by the Food and Drug Administration (FDA) or are bulk drug substances—usually raw powders—that are generally not approved by FDA. Two of the five insurers and one of the two Medicare Part D-only sponsors we spoke with generally do not pay for these substances in their Medicare Part D plans. Four of the five state Medicaid programs and three of the five insurers offering private health plans we spoke with generally do not pay for ingredients that are bulk drug substances in their respective plans.
- For drugs administered in outpatient physician office settings, claims lack information to identify compounded drugs because there are no specific billing codes for most of these drugs. Therefore, Medicare, most state Medicaid programs, and most private health insurers pay for these compounded drugs. Some public programs and private health insurers conduct further claims reviews for compounded drugs billed under nonspecific codes, including obtaining information that can be used to determine FDA-approval status of compounded drug ingredients, and make payment decisions based on this information.
- Additionally, the Centers for Medicare & Medicaid Services (CMS)—the agency within the Department of Health and Human Services (HHS) responsible for administering the Medicare program—has a national payment policy for compounded drugs under Medicare Part B, but this policy is unclear. The policy generally states that drugs must be FDA-approved to be paid for under Medicare. Payment may be available for compounded drugs, but the policy does not stipulate whether payment is available for ingredients that are bulk drug substances, which are generally not FDA-approved. CMS contractors who process Part B claims do not collect information on the FDA-approval status of drug ingredients and, therefore, may be paying for ingredients that are not FDA-approved products. Thus, it is uncertain whether Medicare payments are inconsistent with Part B policy.

Payment practices of public programs and private health insurers may affect the use of compounded drugs when specific payment exclusions exist, such as those for bulk drug substances; however, other factors also affect the use of compounded drugs. For example, insurers that restrict payment for compounded drugs dispensed in pharmacy settings in their private health plans to only ingredients that are FDA-approved products saw significant decreases in both the number of claims and the amount of payments for these drugs after they implemented these restrictions. Individual patient need, such as the need for custom dosages, and drug shortages also affect the use of compounded drugs.