

# Summary

## WHY WE DID THIS STUDY

Compounded drugs are customized medications that meet specific needs of individual patients and are produced in response to a licensed practitioner's prescription. Compounded drugs that are contaminated pose a severe threat to public health and safety. An outbreak of fungal meningitis and other fungal infections in late 2012 was linked to contaminated injectable compounded drugs. As of October 2013, the Centers for Disease Control and Prevention had reported over 700 cases linked to this outbreak. Although certain compounded drugs can be eligible for coverage under Medicare Part B, Medicare does not pay for compounded drugs when the Food and Drug Administration determines that an entity is producing compounded drugs in violation of the Federal Food, Drug, and Cosmetic Act (the Act). In light of the 2012 outbreak and increased scrutiny of compounded drugs, we sought to determine the extent to which Part B paid for compounded drugs and to examine Medicare Administrative Contractors' (MAC) policies and procedures for reviewing and processing claims for compounded drugs.

## HOW WE DID THIS STUDY

We surveyed CMS staff and Part B MACs to assess their oversight of Medicare claims for compounded drugs. We asked CMS and MACs whether they track the number of claims and the amount paid for compounded drugs and to describe their policies and procedures for reviewing and processing claims for compounded drugs.

## WHAT WE FOUND

We found that neither CMS nor MACs tracked the number of claims for compounded drugs under Part B or the corresponding amounts paid, and that Part B claims do not contain information that can be used to systematically identify claims for compounded drugs. We also found that claims for compounded drugs do not identify the compounding pharmacy; however, this information may be included in documentation kept by the provider. Finally, we found that most MACs manually reviewed Part B claims containing "not otherwise classified" codes, which can represent compounded drugs, to determine payment amounts.

## WHAT WE RECOMMEND

The inability to track claims for compounded drugs and identify the compounding pharmacies that produce these drugs prevents CMS and MACs from taking steps to stop payments for compounded drugs that are produced in violation of the Act. Therefore, we recommend that CMS (1) establish a method to identify Part B claims for compounded drugs, (2) explore the possibility of requiring providers to identify on the Part B claim the pharmacy that produced the compounded drug, and (3) explore the possibility of conducting descriptive analyses of Part B claims for compounded drugs. CMS concurred with the first recommendation, did not concur with the second, and conditionally concurred with the third.