



Medicare: Today's Issue

June 4, 2004

BETTER BENEFITS – MORE CHOICES

*Good News about the Medicare Prescription Drug, Improvement
and Modernization Act of 2003!*

Medicare to Pay for Unclassified, FDA-Approved Drugs Administered in Outpatient Departments

- ❖ In an effort to **ensure that Medicare beneficiaries have prompt access to the latest drugs used in conjunction with a covered hospital outpatient service**, the Centers for Medicare & Medicaid Services (CMS) **issued instructions** telling the contractors that process claims under the hospital outpatient prospective payment system (OPPS) **how to pay for new drugs that have been approved by the Food and Drug Administration, but have not yet been assigned a product-specific HCPCS billing code.**
- ❖ The instructions, **which implement a provision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), authorize payment for drugs and biologicals administered on or after January 1, 2004.**

"With the authority granted us by the MMA, **we are closing the gap between FDA approval and Medicare payment for new drugs,**" said CMS administrator Mark B. McClellan, M.D., Ph.D.

- ❖ The instructions create a new code – C9399, Unclassified drug or biological - for hospitals to use when billing Medicare for approved drugs that have not yet been assigned billing codes and that have not been determined to be eligible for special OPPS pass-through payments. The payment rate for the drug will be set at 95 percent of the average wholesale price (AWP), as determined by the Medicare contractor. **As with all other outpatient drugs, Medicare will pay 80 percent of the payment rate, and the beneficiary will be responsible for a 20 percent copayment.**
- ❖ Previously, hospitals did not receive separate payment for drugs newly approved by FDA for which a HCPCS code was not assigned, although in some instances, the hospitals may have qualified for outlier payments.
- ❖ For drugs approved by the FDA after January 1, 2004 that are determined to be eligible for pass-through status, CMS will assign a product-specific C-code and payment classification under the Ambulatory Payment Classifications (APCs) that serve as the basis for Medicare payments under the OPPS.
- ❖ **Contractors have until July 6 to make the needed changes to their claims processing systems to begin paying for drugs and biologicals newly approved by the FDA for which a HCPCS billing code has not been assigned.** Hospitals may bill for these drugs and biologicals retroactively to January 1, 2004.