



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

JUL - 7 2004

JUL 16 2004

The Honorable Charlie Norwood
House of Representatives
Washington, DC 20515

Dear Mr. Norwood:

Thank you for your letters regarding the rates under the new Medicare payment methodology for drugs beginning with 2005, as required in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

The statute requires manufacturers to submit manufacturer's average sales price (MASP) data to the Centers for Medicare & Medicaid Services (CMS) quarterly. The first submission covered the January to March 2004 quarter and was submitted on April 30, 2004. The manufacturer's submission of MASP data for the January to March 2004 quarter is the first "dry run" in calculating MASPs. These data will not be used in determining the revised payment rates for 2005. There will be another dry run for the April to June quarter.

The statute also requires that CMS update drug payment rates quarterly, based on the most recent MASP data from manufacturers. Actual Medicare payment for drugs for the first quarter of 2005 will be based on MASP data for the third quarter of 2004. Medicare's payment for drugs for the second quarter of 2005 will be based on MASP data for the fourth quarter of 2004.

The statute specifies formulas to calculate the average sales price (ASP) upon which, Medicare payment is based for specific drugs using the MASP data submitted by manufacturers. There is an enormous amount of data that was received from manufacturers; roughly data on 10,000 National Drug Codes that we are cross walking to the approximately 600 5-digit codes we use for payment. As with any new payment system, there were some data submission issues the first time around, e.g., unreadable disks, unreadable formats, etc. We are working on these issues with manufacturers to make sure they properly submit accurate data.

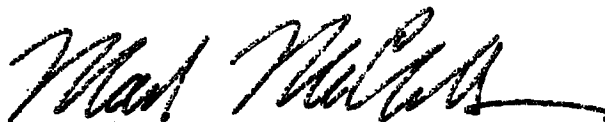
We understand the interest in these data. We are in the process of calculating "hypothetical" MASPs based on the first dry run, as well as assuring that the submissions from manufacturers are accurate. We are simultaneously working on impact analyses assuming that these data are illustrative of 2005 payment rates.

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We plan to implement the MASP changes as part of the Medicare physician fee schedule notice of proposed rulemaking to be published in the *Federal Register* in the near future, which will be available for public comment.

The CMS is fully committed to ensuring access to cancer treatment.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark B. McClellan", with a long horizontal flourish extending to the right.

Mark B. McClellan, M.D., Ph.D.