



American Hospital
Association

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December 23, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1404-FC, Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; (Vol. 73, No. 139), November 18, 2008.

Dear Mr. Weems:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 38,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to provide additional comments on the outpatient drug payment issues raised in the Centers for Medicare & Medicaid Services' (CMS) 2009 outpatient prospective payment system (PPS) final rule.

In the final rule, CMS notes that, given stakeholders' comments about increasing hospital participation in the Federal 340B drug discount program and the significantly reduced drug acquisition costs that result, it is considering using its equitable adjustment authority to adjust outpatient PPS payments to hospitals for separately payable drugs based on hospitals' participation in the 340B program. This would result in different drug payment levels for the two classes of hospitals: 340B participating and 340B non-participating hospitals. The final rule describes stakeholder comments related to an analysis by Christopher Hogan of Direct Research using 2007 claims data. Based on his analysis of drug costs for hospitals with and without 340B status, hospitals participating in the 340B program had outpatient drug costs equal to the average sales price (ASP) minus 1.1 percent, while 340B non-participating hospitals had outpatient drug costs equal to the ASP plus 7.6 percent. CMS requested comments on this approach and seeks input on a number of specific related issues.

The AHA strongly opposes any approach that would pay hospitals differentially based on their participation in the 340B program. The program was created specifically to help safety-net hospitals and to improve access to care for the poor and uninsured. The program requires drug manufacturers who agreed to participate in the Medicaid Drug Rebate Program to provide



deep discounts for drugs and biologics to qualified public and non-profit disproportionate share hospitals and other covered entities that serve these vulnerable populations. The 340B program was created to provide much needed financial assistance to safety-net hospitals. It was not intended to penalize 340B participating hospitals or other providers by making lower payments under the Medicare program. To do so would undermine Congress' intent by effectively removing the subsidy from these safety-net hospitals.

To pay these hospitals at a lower rate under Medicare for separately paid drugs, as CMS notes it is considering, would impose a further hardship on these already struggling safety-net hospitals. While the average Medicare outpatient margin for all hospitals in 2006 was a dismal negative 11.9 percent, the margin for the 808 340B participating hospitals was an even lower negative 14.9 percent. The situation is not expected to improve. The ripple effects of the financial crisis, a rise in unemployment with more uninsured and the loss of job-based health care coverage has impacted hospitals' ability to continue to serve their communities. In these difficult financial times, all hospitals, especially these safety-net hospitals, are struggling to operate and to continue serving their communities.

In addition, we believe that CMS' current methodology, which has resulted in the 2009 payment rate of ASP plus 4 percent for separately payable drugs, is flawed and, unless corrected, will continue to lead to payment rates that are inadequate to cover hospitals' acquisition and pharmacy overhead costs. In comments on the proposed rule, we noted that CMS' methodology has resulted in rates that consistently fall far below those calculated by other studies attempting to estimate these costs, including studies by the General Accounting Office, the Medicare Payment Advisory Commission and CMS' own contractor, RTI. We also discussed a study by the Moran Group, on behalf of Centacor Inc., that found that CMS' methodology consistently underestimates the costs of separately paid drugs and overestimates the costs of packaged drugs. This finding suggests that, if CMS continues to use its current methodology to calculate drug payments, the rate that CMS calculates for separately payable drugs will continue to decline, conceivably to levels that fall below the ASP. This result is unsustainable and clearly inconsistent with the intent of Congress.

The AHA recommends that CMS exclude the cost of 340B drugs from 340B participating hospital-reported data used in setting the ASP-based Medicare reimbursement for separately payable drugs. That is, the only data that should be used in setting Medicare rates for separately payable outpatient drugs is 340B non-participating hospital drug data and 340B participating hospital data for drugs not covered under the 340B program. We understand that CMS may be able to obtain information on which hospitals participate in the 340B program and which drugs are available under the 340B program. CMS could crosswalk the National Drug Codes (NDCs) to the HCPCS codes used in the Medicare outpatient PPS system. Another option that we support, which is simpler to implement, is to exclude all claims data from 340 participating hospitals from CMS rate-setting for drugs. Using one of these two approaches makes sense, especially given that drug sales under the 340B program are excluded by law from the ASP calculation (unlike other discounts and/or rebates). The resulting payment rates for drugs should be applied to all hospitals, regardless of their participation in the 340B program. In order to

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maintain the budget neutrality of the outpatient PPS, CMS could institute a reduction in payments across all ambulatory payment classifications.

Thank you again for the opportunity to comment. If you have any questions, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President