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December 29, 2008

Kerry Weems, Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20201

*Via Courier*

**RE: CMS-1404-FC Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates**

Dear Administrator Weems:

The American Society of Clinical Oncology (ASCO) appreciates the opportunity to submit these comments on the changes to the Hospital Outpatient Prospective Payment System (OPPS) that the Centers for Medicare and Medicaid Services (CMS) implemented for calendar year (CY) 2009 in its final rule with comment period published in the Federal Register (FR) on November 18, 2008 (“the final rule”). ASCO is the national organization representing physicians who specialize in the treatment of cancer. ASCO is committed to advancing policies that provide access to high-quality cancer care; we offer these comments with that mission in mind.

As with our comments on the proposed rule for OPPS payments that CMS published last summer<sup>1</sup>, ASCO believes that the methodology that the agency continues to advance for the reimbursement of separately paid drugs and biologicals is a threat to patient access to important medicines, particularly in the area of oncology. ASCO is also concerned about the implication in the final rule that CMS would consider cutting reimbursement to 340B hospitals if it adopted the sensible recommendation advanced by many stakeholders to remove these hospitals – which receive statutorily preferred pricing for drugs and biological – from the data used to set the payment rate for these therapies.

In this comment letter, we address the CMS request for input on its suggestion to cut reimbursement for 340B hospitals and reiterate a number of our serious concerns about policies the agency has adopted for 2009. Specifically:

<sup>1</sup> CMS-1404-P Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates (July 18, 2008).

- ASCO supports efforts to ensure that CMS is accurately calculating the ASP markup percentage, but does not believe that lowering reimbursement for Disproportionate Share Hospitals (DSH hospitals) and other entities receiving the 340B discounts would be appropriate. The 340B program was designed to aid these hospitals in serving needy Americans and these hospitals should not be penalized for receiving the 340B discount.
- The CMS payment methodology for separately paid drugs and biologicals does not adequately capture hospital costs in acquiring and handling these products—particularly in the case of higher cost products. Since drugs and biologicals used to treat cancer tend to be higher cost, ASCO is particularly concerned that further reduction in the payment rates for these products may negatively affect cancer patients and their access to needed medications.
- ASCO believes that expanded packaging of drugs and biologicals, particularly those products used to treat cancer patients, is inappropriate.

We look forward to working with the agency to continue to improve the care that cancer patients receive under the Medicare program.

### **CMS Payment Methodology for Drugs and Biologicals is Inaccurate and is Particularly Inappropriate for Cancer Therapies**

As we stated in our comments on the proposed rule, ASCO is quite concerned that access to higher cost products—which include many chemotherapy products—will be limited by the Agency’s continued reduction in the reimbursement rates for these products. We are disappointed that CMS is moving forward with its policy that may eventually result in reimbursement levels of Average Sales Price (ASP) plus 2% or lower. The reimbursement mechanism CMS has chosen is based on the agency’s claims data which its contractor RTI and other analysts have shown to be influenced by charge compression<sup>2</sup>—with large portions of pharmacy overhead costs being packaged into underlying Ambulatory Payment Classifications (APCs). As a result, the agency’s mean cost findings for higher cost drugs that are separately reimbursed are understated.

This methodology has a disproportionate impact on therapies used to treat cancer. Because these products tend to be higher cost, they are more susceptible to charge compression. The continuing downward trend in reimbursement for drugs and biologicals in the OPSS is a significant concern for ASCO and its members.

Various stakeholders have proposed other solutions, including the pharmacy stakeholders group’s proposal, currently under examination by the Agency. ASCO believes that the stakeholder proposal—which provides the Agency with mechanisms to more appropriately pay for separately paid drugs in a budget neutral manner—should be evaluated as soon as possible.

### **CMS Should not Cut Reimbursement to 340B Hospitals**

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<sup>2</sup> Charge compression exists when significant variation in mark-up occurs within a hospital department (or group of departments), such that the cost-to-charge ratio used in rate setting results in payment rates that overpay for high mark-up items and underpay for low mark-up items. Charge compression is recognized as a problem in rate setting for drugs, devices and certain procedures.

Various commenters suggested that the CMS methodology to determine reimbursement for separately paid drugs and biologicals inappropriately includes data from so-called 340B hospitals. In response, CMS raised a series of questions about the 340B program and, most troublingly, whether payments to 340B hospitals should be reduced because of the discounts these hospitals receive.

340B participants include DSH hospitals and other entities that serve poor, uninsured, and underserved patients. These entities receive significant discounts that were intended by Congress to allow 340B participants to provide care for more beneficiaries. ASCO agrees that including data from these hospitals in the payment methodology for separately paid drugs and biologicals understates average hospital costs for these products. However, it would be inappropriate and counterproductive to penalize these hospitals because of a poorly designed payment methodology.

### **CMS should not Expand the Packaging of Drugs and Biologicals Used to Treat Cancer Patients**

In addition to our concerns about the level of reimbursement for separately paid drugs and biologicals, ASCO remains concerned that expanded packaging of cancer products could curtail the flexibility of oncologists in choosing the best regimens for particular Medicare patients. Because of the carefully tailored drug regimens used in cancer care, ASCO believes that oncologists must retain flexibility in choosing the particular clinically appropriate therapies needed for particular situations. ASCO strongly supports CMS's continued belief that Medicare payment rules should not impede access to particular anti-emetics—but believes that this principle should also be applied to chemotherapy products in general.

Similarly, ASCO continues to believe that the CMS decision to package diagnostic radiopharmaceuticals and contrast agents is inappropriate. There is a wide variation in the costs of these products, which counsels for the application of the typical packaging threshold with separate payment for higher cost products.

### **Intravenous Immune Globulin (IVIG) Preadministration-Related Services**

As stated in our comments on the proposed rule, ASCO continues to oppose CMS's decision to package payment for HCPCS code G0332 (services for intravenous infusion of immunoglobulin prior administration) for CY 2009. Insufficient access to IVIG remains a concern that is exacerbated by inadequate Medicare reimbursement. Separate payment for IVIG preadministration-related services is appropriate, necessary and important to assure continuity and stability in the IVIG marketplace.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, flowing style.

Joseph S. Bailes, MD  
Chair, ASCO Government Relations Council