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January 28, 2008

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

RE: File code CMS-1392-FC Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Dear Acting Administrator Weems:

The American Society of Clinical Oncology (ASCO) appreciates the opportunity to submit these comments on the Hospital Outpatient Prospective Payment System (OPPS) final rule for calendar year (CY) 2008 as published in the Federal Register (FR) on November 27, 2007. 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 and as part of this, pays particular attention to the effects Medicare payment systems have at the provider and beneficiary level. ASCO commends CMS for its work to create prospective payment policy and annually update the OPPS, but remains concerned by the practical implications certain final rule decisions (and the interaction of those policy decisions) will have on access to cancer care.

In this letter we limit our final rule comments to three main policy topics of concern, all of which could create potential access problems to important therapies:

1. Setting transitional payment for drugs and pharmacy overhead costs in the hospital outpatient setting at Average Sales Price (ASP) + 5% or lower while continuing to expand the use of packaging;
2. Proceeding with the policy to package all contrast agents and diagnostic radiopharmaceuticals, and CMS's desire to significantly increase the number of separately paid drugs and biologicals that are packaged in the future; and
3. Establishing payments for therapeutic radiopharmaceuticals, and their handling, based on mean unit cost, without resolving issues of charge compression.

As discussed in detail below, ASCO strongly advises CMS to maintain reimbursement for separately paid drugs and biologicals at ASP + 6%. ASCO also disagrees with the CMS decision to package all contrast agents and diagnostic radiopharmaceuticals. We believe that CMS should continue to pay separately for products in these categories with costs above a reasonable threshold. Furthermore, we continue to believe that packaging should never include antineoplastic agents and other products that are part of anticancer chemotherapeutic regimens. ASCO also respectfully requests CMS consider the unique aspects of therapeutic radiopharmaceuticals, revisit its payment policy decisions and establish 2008 payment rates that more appropriately reflect acquisition costs. With these recommendations we seek to assure continued access to important cancer care therapies.

2008 Annual Meeting
May 30-June 3, 2008
Chicago, Illinois

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Payment for Drugs and Pharmacy Overhead Costs in the Hospital Outpatient Setting

CMS's policy to provide a bundled payment for the acquisition costs of separately payable drugs and biologicals and the associated pharmacy overhead costs at a transitional rate of ASP + 5% in 2008, with potentially lower levels in future years is troubling and ill advised. ASCO urges CMS to accept the APC Panel's recommendation to maintain reimbursement for separately payable drugs at ASP + 6%. Moreover, ASCO believes that CMS should maintain reimbursement for separately payable drugs and biologicals at ASP + 6% until the issue of charge compression is sufficiently researched and resolved.

While ASCO understands the CMS decision to use ASP as the basis for reimbursement for separately paid drugs and biologicals, the agency's combined use of ASP with OPSS claims data has created a system that has nothing to do with the "average acquisition cost" that Congress intended be used to pay for separately paid drugs and biologicals. ASCO strongly disagrees with the agency's decision to determine the relative ASP percent using mean costs calculated from the OPSS claims data. If the agency lacks average acquisition cost information, it should use the statutory backup of ASP + 6%, or the average payment under the competitive acquisition program (CAP), where applicable.

Furthermore, providing a packaged payment for drugs and pharmacy overhead costs at the reduced ASP + 5% rate is inadequate to cover the costs incurred by hospitals to acquire and handle drugs. The Medicare Payment Advisory Commission (MedPAC) has found that pharmacies have overhead costs of more than 25% of their direct costs.¹ We do not believe these overhead amounts—particularly for complex chemotherapy products, many of which have special storage and handling requirements—are adequately captured in the CMS reimbursement methodology.

ASCO recognizes that ASP + 5% is a transition policy and is even more concerned by the possibility of additional decreases in the relative ASP percent in future years. As CMS outlines in the rule, the agency has two sources of data to set 2008 payment rates for non-pass through separately paid drugs and biologicals: 1) ASP data from the 4th quarter of 2006, and 2) mean and median costs derived from the CY 2006 hospital claims data. CMS analyzed both data sources to calculate "equivalent average ASP-based payment amounts" and found that using mean unit costs to set the payment rates for drugs and biologicals would be ASP + 3%.

While we appreciate that the agency has decided to use a transition period to keep payment rates at ASP + 5%, ASCO believes that the agency's findings in the final rule represent an unsustainable trend toward lower reimbursement that will threaten patient access to important therapies. ASCO therefore strongly advises CMS to reconsider its reimbursement methodology for separately paid drugs and biologicals.

ASCO believes that the problems caused by the CMS reimbursement methodology may be particularly acute for the higher cost products that are most likely subject to charge compression. Having acknowledged this phenomenon in the OPSS and in the inpatient setting, CMS should pay careful attention to the impact of charge compression on reimbursement for high cost therapies.

CMS must consider the drastic impact its reimbursement policy for drugs and biologicals will have on providers and patients alike, particularly when reimbursement does not cover acquisition costs and when

¹ Medicare Payment Advisory Commission, Report to the Congress: Issues in a Modernized Medicare Program (June 2005).



additional charges, such as pharmacy overhead costs are increasingly packaged. ASCO believes that reimbursement for drug acquisition cost in the hospital setting should remain at ASP + 6%.

Increased Packaging of Drug and Biological Therapies

ASCO disagrees with the CMS decision to package all contrast agents and diagnostic radiopharmaceuticals. We believe that CMS should continue to pay separately for products in these categories with costs above a reasonable threshold. More importantly, we believe that the agency's stated desire to significantly increase the number of separately paid drugs and biologicals that are packaged in the future is misguided and could cause serious problems for cancer patients.

While we understand that the nature of a prospective payment system dictates packaging many services into payment groups, separate payment for chemotherapy products is an appropriate means to ensure that oncologists have access to the full range of available options in designing chemotherapy treatment. Because of difficulties in tolerating cancer treatments, CMS has stated in the past that Medicare payment rules should not "impede a beneficiary's access to the particular anti-emetic that is most effective for him or her as determined by the beneficiary and his or her physician." ASCO believes that this logic holds true for cancer therapies also—and reiterates its comment that chemotherapy products should be separately paid under the OPPS. Given the array of clinical and patient specific parameters involved in treating cancer patients, these drugs would not serve as an appropriate class of products to package under Medicare payment rules.

Cancer chemotherapy treatment is neither ancillary nor supportive, and accordingly the packaging concept should not apply to this class of drugs. The CMS payment methodology for reimbursement of packaged drugs and biologicals, relying on data that can be two years old or more, is particularly ill-designed for the rapidly changing landscape of oncology.

Payment for Therapeutic Radiopharmaceuticals

While ASCO is pleased that CMS will continue to make separate payment for therapeutic radiopharmaceuticals, the society is greatly concerned by CMS's decision to base 2008 payment rates on mean unit costs using 2006 hospital claims data. This policy will be detrimental to monoclonal antibody therapies as it inappropriately separates out components of the FDA-approved treatment regimens and ultimately sets prospective reimbursement at a rate drastically below acquisition costs. Given the unique aspects of these FDA-approved therapeutic regimens, the limited patient populations which they target, and the lack of other therapeutically equivalent products available on the market, ASCO urges CMS to reconsider its decision and make some concessions to more appropriately align reimbursement with cost while also helping to ensure continued access to these novel therapeutic radiopharmaceuticals.

This new classification and methodology is particularly problematic for radioimmunotherapies such as monoclonal antibodies. By using a mean unit cost calculation to set payment for all therapeutic radiopharmaceuticals, even after applying a trimming methodology, expensive items are negatively penalized by averaging and reimbursement is set far below actual acquisition costs. Further, for expensive therapies such as Bexxar®, CMS has segmented integral components of the therapeutic regimen and only provided separate reimbursement for one aspect of the overall protocol.

For example, a dosimetric dose of I-131 Tositumomab is used as part of the Bexxar regimen to assist treating physicians in calculating the subsequent therapeutic dose for the patient. CMS has classified this



dose as a diagnostic radiopharmaceutical. As a result of this “diagnostic” classification, CMS packages the item into payment for the nuclear medicine procedure performed once the I-131 dose is administered. CMS has only categorized the therapeutic dose of I-131 as separately payable and thus does not accurately capture the full breadth of the treatment regimen when calculating mean unit costs. The dosimetric dose of I-131 plays a unique role in the Bexxar therapeutic regime and must be considered when calculating separate payment for these novel radiopharmaceutical therapies.

With either the prior reasonable cost method or the newly implemented policy to reimburse separately payable therapeutic radiopharmaceuticals based on mean unit costs the issue of charge compression is a real and valid concern. The phenomenon of charge compression leads to excessively low reimbursement for very expensive items such as therapeutic radiopharmaceuticals. ASCO encourages CMS to continue to investigate this issue and identify viable solutions to eliminate instances where the CMS cost-finding methodology misestimates the relative costs of medical procedures and items furnished in hospital departments.

Given the complexities associated with the use of claims data to set reimbursement rates for expensive therapeutic radiopharmaceuticals, ASCO appreciates CMS’s request for comments on how radiopharmaceutical cost data, such as ASP, could be used in rate setting in the future. ASCO encourages the agency to engage all stakeholders in these discussions. ASCO strongly supports an open and transparent decision making process and requests that, should such data ever be collected and incorporated into the methodology, it be applied and released in a publically available fashion.

Finally, ASCO is concerned that the CMS payment methodology for therapeutic radiopharmaceuticals does not appropriately capture necessary overhead costs despite CMS’s belief that hospitals submitted charges representative of their acquisition and associated handling costs based on prior CMS billing guidance. Therapeutic radiopharmaceuticals are further unique as there are compounding costs associated with their preparation. These costs should also be reflected in the prospectively set reimbursement rate. From a practical perspective, hospital billing behavior varies widely and in the instance of therapeutic radiopharmaceuticals, likely does not reflect the full breadth of costs associated with these therapies. This is evidenced in part by the large difference between CMS’s calculated mean unit costs and actual acquisition expenses for monoclonal antibody therapies.

Given the importance of these therapies to the beneficiaries that need them, ASCO asks that CMS reconsider its payment decisions for radiopharmaceutical therapies such as Bexxar and establish reimbursement levels that more accurately reflect acquisition costs.

In Conclusion

ASCO remains available to assist CMS on these or other issues that arise during the rule making process. We look forward to continued discussion with CMS and are available to answer any questions the agency might have. Thank you for the opportunity to comment on this final rule.

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, Government Relations Council