



American Society of Clinical Oncology

PRESIDENT

Douglas W. Blayney, MD

IMMEDIATE PAST PRESIDENT

Richard L. Schilsky, MD

PRESIDENT-ELECT

George W. Sledge, Jr., MD

TREASURER

Clifford Hudis, MD

CHIEF EXECUTIVE OFFICER

Allen S. Lichter, MD

DIRECTORS

Dean F. Bajorin, MD

Monica M. Bertagnolli, MD

Eduardo L. Cazap, MD

Susan L. Cohn, MD

Bruce E. Johnson, MD

Robert M. Langdon, Jr., MD

Robert S. Miller, MD

Kathleen I. Pritchard, MD

Deborah Schrag, MD, MPH

Lynn M. Schuchter, MD

Sandra M. Swain, MD

Joel Tepper, MD

Everett E. Vokes, MD

Peter P. Yu, MD

August 28, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1414-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1414-P Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates

Dear Acting Administrator Frizzera:

The American Society of Clinical Oncology (ASCO) appreciates the opportunity to submit these comments on the proposed changes to the Hospital Outpatient Prospective Payment System (HOPPS) for calendar year (CY) 2010 as published in the Federal Register (FR) on July 20, 2009 (“the proposed rule”). ASCO is the national organization representing over 27,000 physicians who specialize in the treatment of cancer. ASCO is committed to advancing policies that provide access to high-quality cancer care. We offer our comments on the HOPPS proposed rule with that mission in mind.

ASCO is concerned by the practical implications the proposals will have on access to cancer care. Policies of particular concern include the payment for separately paid drugs and biologicals at Average Sales Price (ASP) + 4%, the continued wholesale packaging of diagnostic radiopharmaceuticals and contrast agents, and the packaging for the first time of antiemetic agents.

As discussed in detail below, ASCO strongly advises CMS to set reimbursement for separately paid drugs and biologicals at ASP+ 6%. ASCO continues to disagree with the CMS decision to package all contrast agents and diagnostic radiopharmaceuticals. We believe that CMS should 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 or antiemetics, or other products that are part of anticancer chemotherapeutic regimens. Finally, we are supportive of the CMS proposal to reimburse for the use of therapeutic radiopharmaceuticals using ASP information.

In the balance of this letter, we describe our concerns more completely and address other matters of importance.

Payment for Specified Covered Outpatient Drugs and Other Separately Payable Drugs

ASP/ Pharmacy Overhead Costs

ASCO is highly concerned by CMS's proposal to maintain payment for separately payable drugs in the hospital outpatient setting at ASP+4%. For 2008, CMS used a transition mechanism to set payments at ASP+5%. For 2009, the agency paid for the acquisition, handling and associated pharmacy overhead costs of separately paid drugs and biologicals at ASP+4%. And for 2010, CMS is proposing to partially reallocate pharmacy overhead from packaged drugs to separately paid drugs. The reallocation results in payment for separately paid drugs and biologicals remaining at ASP +4%, an amount that will reflect both acquisition and overhead costs for these products. ASCO is concerned by this proposal as these ASP payment levels do not adequately cover the costs incurred by hospitals to acquire and handle drugs. Furthermore, the continued application of this policy reinforces a site of service differential between the hospital outpatient and the physician office¹ which could have implications for patient care and the site where beneficiaries receive such care.

The reimbursement level 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:² Large portions of pharmacy overhead costs are 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. ASCO is pleased that CMS is seeking to appropriately distribute payments for pharmacy overhead costs for both lower priced packaged drugs and more expensive separately payable drugs, but we are concerned that the amount of overhead being allocated to separately paid drugs continues to be inadequate.

While CMS's proposal to shift some of the pharmacy overhead from packaged to separately payable drugs is a step in the right direction, the current proposal would merely maintain the artificially low reimbursement rate CMS implemented for CY 2009. ASCO believes that CMS should shift a higher percentage of overhead dollars from packaged drugs to separately paid drugs. We note that the \$395 million pool that the agency is allocating represents only the overhead tied to HCPCS coded drugs with ASP data available. According to estimates by the Pharmacy Stakeholders group, HCPCS coded packaged drugs and packaged drugs without HCPCS codes represent an additional \$783 million in drug costs. We are concerned that the CMS proposal, focusing only on the pool of HCPCS coded drugs with ASPs doesn't address the full scope of the charge compression issue. At a minimum, we agree with the APC Advisory Committee that separately paid drugs and biologicals should be reimbursed at ASP+6%, in alignment with reimbursement levels in the physician office.

¹ Drugs provided in the physician office are reimbursed at ASP+6%.

² 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.

Packaging Drugs and Biologics

Antiemetic Products

ASCO does not support CMS's decision to package all 5-HT3 antiemetic drugs (*i.e.*, J1260, J1626, J2405, J2469, Q0166, Q0179, Q0180). CMS based this decision on the fact that 88 percent of all treatment days of 5-HT3 antiemetics, according to CY2008 HOPPS claims data, involved J2405. This particular antiemetic is the least costly of the seven available 5-HT3 antiemetic drugs, at approximately \$1 per day, and all but one of the available drugs are under the proposed \$65 per day packaging threshold. However, ASCO still fears that this proposed policy will affect a beneficiary's access to the particular antiemetic that is most effective as determined by the beneficiary and his or her physician. As CMS has acknowledged, chemotherapy is very difficult for many to tolerate, with debilitating side effects. It is important that patients undergoing chemotherapy be able to access the antiemetic that works best for them, and has the fewest side effects; packaging antiemetics could negatively affect that access.

Anti-Cancer Chemotherapy Drugs

Similar to our position on packaging of antiemetics, ASCO feels compelled to reiterate that the therapeutic effectiveness of antineoplastic drugs, and the extent to which they cause debilitating side effects and potential interactions, is patient-specific and dependent upon the type, dose and schedule of the cancer chemotherapy regimen undertaken. A patient's course of cytotoxic therapy (either as monotherapy or as a combination of drugs) is based on the medical decision-making of the physicians involved, the type and stage of the cancer in question, patient characteristics and preferences, and scientific evidence in the medical journals. 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. While ASCO recognizes that there currently are instances where certain antineoplastic agents would fall under the \$65 threshold and thus be packaged, as we have stated in the past, we do not support application of this concept to anti-cancer chemotherapy drugs, particularly if expanded on a wider scale.

ASCO will continue to monitor CMS's packaging rules, and is available to work with CMS as the agency considers how to increase packaging in the future. ASCO strongly encourages CMS to reverse its proposal to package antiemetics and use its discretion and refrain from further packaging any antineoplastic drugs in future rule makings to protect beneficiary access to high quality care and advances in cancer treatment. We further believe that this policy should extend to those products typically used in chemotherapy supportive care regimens. At a minimum, CMS should not attempt to package supportive care products with per day costs above the \$65 packaging threshold.

Proposed Use of Single and Multiple Procedure Claims: Inclusion of add-on codes for drug administration to the CY 2010 Bypass list

ASCO is pleased by CMS's proposal to continue to include Current Procedural Terminology (CPT) add-on codes for drug administration services (e.g., subsequent hour of infusion, subsequent drug in a sequence) on the CY 2010 bypass list and appreciates CMS's recognition that the standard bypass code criteria should not be applied to these services. This

is important as chemotherapy and supportive care regimens increasingly entail administration of multiple drugs in the same treatment sessions, and claims for these procedures should be used in rate setting. Amending the bypass code list to include drug administration codes as a class of bypass codes will treat these procedures as single claims and increase the amount of data used for rate setting in 2010 and beyond.

Similar to last year, however, CMS did not include code 90768 (Ther/diag concurrent inf) on the bypass list for CY 2010. ASCO continues to believe that including this code on the bypass list, rather than packaging it, is an appropriate option that is consistent with treatment of other add-on and additional hour codes that are already bypassed and thus treated as single claims. Therefore, ASCO recommends that CMS include concurrent infusion code 90768 on the bypass list for CY 2010.

As ASCO has recommended in comments on past proposed rules, inclusion of add-on drug administration codes (e.g., 90767, 90775, 96411, 96417) on the bypass list allows for a greater number of available claims to calculate APC weights which will likely result in more accurate payments. ASCO supports CMS's 2010 proposal to include these codes on the bypass list and also suggests that CMS add code 90768 to the list of codes that are bypassed in 2010.

Proposed Coding and Payment for Drug Administration Services: 5-level APC structure for CY 2010

ASCO supports the continued use of the 5-level APC structure for payment of drug administration services and would urge CMS to be cautious when considering any changes to the assignment of CPT codes within this structure.

Diagnostic Radiopharmaceuticals and Contrast Agents

With regard to the CMS proposal to continue packaging all diagnostic radiopharmaceuticals, ASCO believes that because of the large variation in underlying costs for these products, this wholesale packaging remains inappropriate. Separate payment should be made according to the general packaging policy for drugs and biologicals.

However, ASCO supports the proposal to provide pass-through payments for qualifying diagnostic radiopharmaceuticals and contrast agents on the basis of ASP+6%, parallel with payments in the physician office.

Therapeutic Radiopharmaceuticals

As with diagnostic radiopharmaceuticals with pass-through status, ASCO supports the proposal to reimburse therapeutic radiopharmaceuticals based on ASP. We understand that there is no statutory requirement for radiopharmaceutical manufacturers to report ASP information, and that calculating reimbursement levels for radiopharmaceuticals can be complicated by the unique re-constitution and handling requirements of these products. Where ASP information is not available, ASCO believes that the agency should use its discretion and continue to follow the current statutory directive to pay on the basis of hospital-specific reasonable cost findings even beyond the expiration of the statutory requirement.

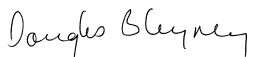
Quality Reporting Requirements

ASCO continues to support CMS' interest in establishing new quality reporting measures related to cancer. In order to ensure that oncology quality measures are meaningful, we encourage CMS to work with ASCO to identify appropriate measures and develop measure specifications and reporting requirements.

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 proposed rule.

Sincerely,

A handwritten signature in cursive script that reads "Douglas Blayney".

Douglas W. Blayney, M.D.
ASCO President