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December 29, 2009

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

RE: CMS-1414-FC Medicare Program: 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 changes implemented in the Hospital Outpatient Prospective Payment System (HOPPS) for calendar year (CY) 2010 as published in the Federal Register (FR) on November 20, 2009 (“the Final 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 Final Rule with that mission in mind.

ASCO wishes to reiterate its strong concerns about the effects of the policies CMS has finalized on access to cancer care. We remain very concerned about the payment level for separately paid drugs and biologicals of 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 continues to believe that CMS should set reimbursement for separately paid drugs and biologicals at ASP + 6% for 2010 and future years. We 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 strongly that antineoplastic agents, antiemetics, and other products that are part of anticancer chemotherapeutic regimens should not be packaged. Consequently, we are quite disappointed that CMS has abandoned its longstanding policy to ensure patient

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access to the most appropriate antiemetic therapy by paying separately for antiemetic products. However, 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 continues to be troubled by the CMS finalized payment for separately payable drugs in the hospital outpatient setting at ASP + 4%. While we agree with the agency's decision to reallocate pharmacy overhead from packaged drugs to separately paid drugs to address the effects of charge compression, we do not believe that CMS is reallocating enough overhead to produce an adequate payment rate. CMS is allocating only enough overhead to maintain a previously inadequate payment rate that is intended to cover both the acquisition and overhead of separately paid products. ASCO does not believe that this ASP payment level covers 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 department and the physician office¹ which could have implications for patient care and the site where beneficiaries receive such care. Thus, ASCO believes that while CMS's proposal to shift some of the pharmacy overhead from packaged to separately payable drugs is a step in the right direction, merely maintaining the artificially low reimbursement rate CMS implemented for CY 2009 in 2010 could exacerbate patient access issues.

In the Final Rule, CMS implemented a policy of reallocating overhead not only from packaged drugs with ASPs and HCPCS codes, but also—on a limited basis—from drug lines without HCPCS codes. ASCO supports this decision in principle—since it could be used to better mitigate charge compression issues. However, we find it curious, that instead of allocating overhead from these non-coded claims in the same proportion as other claims—which would have resulted in a payment rate of ASP + 7%, the agency chose a minimal number that had the effect of maintaining the artificially low payment rate of ASP + 4%. ASCO continues to 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.

Packaging Drugs and Biologics

Antiemetic Products

Prior to the current rulemaking, CMS had for several years maintained a policy of exempting 5-HT3 antiemetic drugs from the packaging threshold, choosing instead to maintain separate

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

payment for these therapies which are integral to the supportive care of cancer patients. ASCO has always supported this policy and has argued that it should be extended to other therapies in anticancer chemotherapeutic regimens. Consequently, ASCO is very disappointed that CMS has finalized its decision to package all the 5-HT3 antiemetic drugs (*i.e.*, J1260, J1626, J2405, J2469, Q0166, Q0179, Q0180). While we understand that the majority of patients are using an inexpensive therapy, we believe that patients attempting to tolerate chemotherapy should have full access to the antiemetic therapies that their oncologists believe are most appropriate. ASCO has strong fears that the CMS policy to package payment for antiemetic therapies will affect beneficiary access to some antiemetics. As CMS has acknowledged, chemotherapy is very difficult for many to tolerate, and it can be accompanied by extremely debilitating side effects. ASCO believes that it is vital that patients undergoing chemotherapy be able to access the antiemetic that works best for them, and we disagree with the CMS decision, as it may limit patient access to these important therapies.

Anti-Cancer Chemotherapy Drugs

Similar to our position on the 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 medical journals. Given the array of clinical and patient specific parameters involved in treating cancer patients, these drugs should not be packaged 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 decision to package antiemetics and to use its discretion to refrain from further packaging of any antineoplastic drugs 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 chemotherapy or supportive care products with per day costs above the \$65 packaging threshold.

Diagnostic Radiopharmaceuticals and Contrast Agents

With regard to the CMS decision to continue packaging all diagnostic radiopharmaceuticals, ASCO still 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 continues to support the decision 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 continues to support 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. ASCO will be monitoring therapeutic radiopharmaceutical payment policies—and the implementation of ASP-based payments—in the future. We were somewhat troubled by the very tight deadline for manufacturers to begin voluntary reporting of ASP for radiopharmaceuticals, and we are hopeful that CMS is continuing to work closely with manufacturers to make the reporting process as smooth as possible in the future.

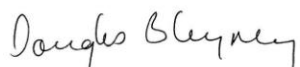
Quality Reporting Requirements

ASCO continues to support CMS's interest in establishing new quality reporting measures related to cancer. In order to ensure that oncology quality measures are meaningful, we once again 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 under the HOPPS and in future rulemakings. 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 the Final Rule.

Sincerely,



Douglas W. Blayney, MD
President