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August 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: File code CMS-1404-P Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates

Dear Acting Administrator Weems:

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 (OPPS) for calendar year (CY) 2009 as published in the Federal Register (FR) on July 18, 2008 ("the proposed 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 and accordingly offers comments on the OPPS proposed rule, and we offer these comments with that mission in mind.

ASCO commends CMS for its work to create prospective payment policy and annually update the OPPS, but remains concerned by the practical implications certain proposed and subsequently final rule decisions (and the interaction of those policy decisions) 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) plus 4% and the continued wholesale packaging of diagnostic radiopharmaceuticals and contrast agents. In other areas, such as the payment for drug administration services, CMS has made some improvements but further work is needed.

As discussed in detail below, ASCO strongly advises CMS to set reimbursement for separately paid drugs and biological at ASP + 6%. ASCO continues to disagree with the CMS decision to package all

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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 anticancerchemotherapeutic regimens.

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 further reduce payments for separately payable drugs in the hospital outpatient setting. For 2008, CMS used a transition mechanism to set payments at ASP+5%. For 2009, the agency is proposing to pay for the acquisition, handling and associated pharmacy overhead costs of separately paid drugs and biologicals at ASP+4%. 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 of service 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 compression²—with large portions of pharmacy overhead costs being packaged into underlying 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. However, we are concerned that the solutions that the agency has adopted will not have an impact on hospital payment rates in the near future.

While CMS's proposal to break the standard drug cost center into two: 1) drugs with high overhead cost charged to patients, and 2) drugs with low overhead cost charged to patients could eventually result in more accurate measurement of drug acquisition and overhead costs, this proposal will not have an impact on the artificially low reimbursement rate CMS has proposed for CY 2009. While we agree that improved and more precise cost reporting is the best way to enhance OPSS rate setting methodologies, such improvements must be balanced with the practical implications for hospitals, and we have heard that hospitals and the organizations that represent them believe that the proposed cost reporting changes would be unduly onerous.

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.

Various stakeholders have proposed other solutions, including the proposal of the pharmacy stakeholders group that the agency discusses in the proposed rule. 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 for adoption in CY 2009. At a minimum, we believe that separately paid drugs and biologics should be reimbursed at ASP+6%, in alignment with the reimbursement in the physician office.

RTI recommendations

As CMS continues to evaluate pharmacy acquisition and overhead issues, ASCO encourages the agency to continue exploring RTI's recommendations in addressing these issues. For example, we believe that correcting hospitals' misclassification of non-standard cost centers on the Medicare cost reports may prove to have a positive impact on oncology related services and particularly drug administration procedures. It is important that hospitals with oncology departments are accurately represented on cost reports and that correct and applicable Cost-to-Charge Ratios (CCRs) are calculated for these departments. RTI found that hospitals may code many of their oncology related costs in non-standard lines on cost reports. Given this, the contractor recommended ways to decrease the number of instances where a hospital matches oncology revenue codes to a more general hospital department with lower CCRs. ASCO supports CMS's continued investigation into this matter and the RTI recommendation.

Likewise, we believe that continued evaluation of the RTI recommendation to expand and revise the detailed revenue code crosswalk used to map OPPS claim chargers to provider-specific cost report CCRs could also result in more accurate reimbursement for oncology related procedures. Efforts to ensure that chemotherapy charges are accurately mapped to the correct hospital department CCRs are important; however we again caution that such initiatives must not overly burden hospital administrative staff.

In all, patient access to cancer care is the most important consideration and we urge CMS to carefully consider such implications as the agency moves to address the relevant and important issues of pharmacy overhead costs, charge compression and cost reports. ASCO will continue to evaluate these matters and communicate with CMS accordingly.

Packaging Drugs and Biologics

Anti-Emetic Products

ASCO applauds CMS's proposal to continue exempting the oral and injectable forms of 5HT3 anti-emetic products from packaging, thereby making separate payment for all of the 5HT3 anti-emetic products (*i.e.*, J1260, J1626, J2405, J2469, Q0166, Q0179, Q0180) regardless of the continued \$60 packaging threshold policy. As CMS states, "chemotherapy is very difficult for many patients to tolerate, as the side effects are often debilitating" and "in order for Medicare beneficiaries to achieve the maximum therapeutic benefit from chemotherapy and other therapies with side effects of nausea and vomiting, anti-emetic use is often an integral part of the treatment regimen."³ ASCO strongly supports CMS's continued belief that Medicare payment rules should

³ 42 CFR Parts 410 and 419 page 275 (display copy).

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.”³

Anti-Cancer Chemotherapy Drugs

Similar to CMS’s position on anti-emetic products, the therapeutic effectiveness of anti-neoplastic drugs, and the extent to which they cause debilitating side effects and/or 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 physician(s) involved, the type and stage of the cancer in question, patient characteristics/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 anti-neoplastic agents would fall under the \$60 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. Similar to its policy on anti-emetics, ASCO strongly encourages CMS to use its discretion and refrain from further packaging any anti-neoplastic 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.

Proposed Use of Single and Multiple Procedure Claims: Inclusion of add-on codes for drug administration to the CY 2009 Bypass list

ASCO is pleased by CMS’s proposal 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 2009 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 2009 and beyond.

CMS did not, however, include code 90768 (Ther/diag concurrent inf) on the bypass list for CY 2009. 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 2009.

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 2009 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 2009.

Proposed Coding and Payment for Drug Administration Services: 5-level APC structure for CY 2009

ASCO agrees that it is appropriate to streamline drug administration Ambulatory Payment Classifications (APCs) to better assure clinical and resource homogeneity of the APC groups and eliminate 2 times rule violations. ASCO, however, encourages CMS to proceed cautiously and consider how to best design the new APCs for drug administration to not only reflect similar resource utilization but to carefully evaluate the grouping of services from a systematic clinical perspective. ASCO is concerned that intermingling of vastly different drug administration services (e.g., chemotherapy vs. immunization/immunotherapy vs. therapeutic/prophylactic/diagnostic therapy drug administration) under the same APCs creates an amalgamated classification system that is inconsistent with CPT coding and medical practice. As CMS considers the restructuring of drug administration APCs, ASCO suggests that CMS seek a more clinically coherent classification system.

ASCO supports comprehensive use of the full range of drug administration CPT codes developed in 2006 and is pleased that complete hospital claims data for these services, combined with an increased number of single claims resulting from the proposed bypass policy, is now available for CMS to use in rate setting. ASCO, however, agrees with the APC panel recommendation that CMS should inform its proposals with more data as it becomes available and provide a crosswalk analysis of that data. While on balance it appears that the proposed 5-level APC structure will not overly harm hospital reimbursement for drug administration services, we do note that at the CPT level, reimbursement for certain services may drop by as much as 28% because of the remapping to different APCs. We understand that this is a natural consequence of restructuring, but will closely monitor and evaluate any potential negative impact on hospitals or patient care.

Under the existing drug administration APC structure there were a number of 2 times rules violations, and we agree with CMS that it is important to eliminate those situations where appropriate. We do note however, that under the proposed 5-level APC structure, it appears that one 2 times rule violation remains. CPT code 90779 (ther/prop/diag inj/inf proc) falls under APC 0436 with a payment rate of \$25.03. The median for this code in 2007 claims is \$77.07, with 1399 single claims identified. Given this, it seems that under CMS's proposed restructuring, this procedure might be more appropriately placed in APC 0438.

As CMS considers the restructuring of drug administration APCs, ASCO encourages the agency to base its proposals on additional data and clinical input to better obtain improved homogeneity. It is consistent with OPSS methodology to consider APC structures based on median costs, however clinical judgment and rationale should be applied when structuring the drug administration APCs to reflect greater clinical coherence. This will help assure that chemotherapy payment rates are consistent with the cost of chemotherapy procedures and

thereby better protect beneficiary access to cancer care in the hospital outpatient setting. ASCO is ready and available to assist CMS by providing informed medical expertise, clinical judgment and analysis of these issues.

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.

Therapeutic Radiopharmaceuticals

ASCO supports provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) which extend the requirement to make payments for therapeutic radiopharmaceuticals based on charges reduced to cost through January 1, 2010.

Intravenous Immune Globulin (IVIG) Preadministration-Related Services

ASCO does not support CMS's proposal to package payment for HCPCS code G0332 (services for intravenous infusion of immunoglobulin prior administration) for CY 2009. ASCO continues to understand from the medical community that 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.

Imaging

ASCO is concerned that the proposed single session imaging APCs for CT, MR, and ultrasound modalities may provide incentives for hospitals to limit the number of diagnostic imaging tests performed in a single session since the payment levels for these composite APCs most closely approximate payment for two tests on the same date of service. We understand that more than 20% of CT and MR single session APCs in the 2007 claims released with the proposed rule, include three or more procedures on the same date of service. While we understand CMS's intent to achieve efficiencies for multiple imaging sessions, we caution CMS to explore the potential for incenting behavior that imposes additional visits and decreased efficiency for patients and hospitals. We recommend delaying implementation of single session imaging composite APCs to appropriately evaluate the incentives and potential implications they create.

Non-Payment for Preventable Conditions

Medicare recently adopted a policy of not paying hospitals for preventable conditions acquired during an inpatient hospital stay. CMS states in this notice that the same principle could be applied in other settings including the hospital outpatient department. CMS is not proposing any changes at this time but is soliciting comment on the issue.

ASCO urges CMS to avoid applying this policy to conditions involving cancer patients. Cancer patients, who often have compromised immune systems, may have side effects of their treatments that are unavoidable but might be considerable preventable in patients with other types of health problems. For example, neutropenic fever, infusion line infections, and sepsis can occur in cancer

patients through no fault of the healthcare providers involved. Any Medicare policies related to so-called preventable conditions should take the special situation of cancer patients into account.

Quality Reporting Requirements

We 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.

Thank you for the opportunity to comment on this proposed 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, ASCO Government Relations Council