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August 31, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, D.C. 20201

RE: CMS-1504-P – Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates

Dear Administrator Berwick:

I am pleased to submit these comments on behalf of the American Society of Clinical Oncology (ASCO) in response to the recent notice of proposed rule making regarding the Medicare hospital outpatient prospective payment system (OPPS) for calendar year (CY) 2011 (75 Federal Register 46170, August 3, 2010).

ASCO is a national organization representing over 28,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis and prevention. ASCO members also are dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidenced-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans, including Medicare beneficiaries. We appreciate the opportunity to comment on the policies that CMS is proposing for 2011.

ASCO provides the following recommendations regarding the proposed rule:

- A. **Performance Measures under the HOP QDRP.** CMS should expedite efforts to address the lack of meaningful performance measures within the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) that reflect the day-to-day treatment of cancer patients. We urge CMS to work with ASCO and other relevant stakeholders to promote the adoption of the performance measures for outpatient cancer care used in the Quality Oncology Practice Initiative (QOPI).

- B. **Adequate Reimbursement for Prescription Drugs used to Treat Cancer.** CMS should finalize its proposal to reimburse for separately payable prescription drugs in the hospital outpatient department setting at 106 percent of the average sales price (ASP).

- C. **Antiemetic Products.** CMS should reinstate the policy in place prior to CY 2010 and protect access to the full scope of antiemetic products by providing separate (non-packaged) payment for all 5-HT3 antiemetic drugs.
- D. **Payments to Cancer Centers.** CMS should finalize the methodology it developed to ensure IPPS-exempt cancer hospitals receive adequate reimbursement.
- E. **Physician Supervision.** CMS should finalize its proposal to exclude all chemotherapy administration codes from the list of APCs that may be provided under general supervision.
- F. **Chemotherapy Administration Codes.** ASCO supports the ongoing use of the 5-level APC structure for drug administration codes in the hospital outpatient setting.
- G. **Diagnostic Radiopharmaceuticals and Contrast Agents.** CMS should reverse its current policies and provide for separate payment of diagnostic radiopharmaceuticals and contrast agents. ASCO supports the proposal to pay for such products under the pass-through system at 106 percent of the ASP.
- H. **Therapeutic Radiopharmaceuticals.** CMS should finalize its proposal to continue reimbursing for therapeutic radiopharmaceuticals using the “ASP +” methodology. For instances in which the ASP is not established, we urge CMS to set aside its proposal and instead reimburse on the basis of the hospital’s charges adjusted to cost.

These recommendations are discussed in greater detail below.

- A. Performance Measures under the HOP QDRP.** CMS should expedite efforts to address the lack of meaningful performance measures within the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) that reflect the day-to-day treatment of cancer patients. We urge CMS to work with ASCO and other relevant stakeholders to promote the adoption of the performance measures for outpatient cancer care used in the Quality Oncology Practice Initiative (QOPI).

CMS should expedite efforts to address the lack of meaningful performance measures within the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) that reflect the day-to-day treatment of cancer patients. The hospital outpatient department setting provides a significant amount of the outpatient cancer care throughout the United States, although CMS has not proposed any oncology-specific performance measures for the HOP QDRP to date.

We urge CMS to work with ASCO and other relevant stakeholders to promote adoption of the performance measures for outpatient cancer care used in the Quality Oncology Practice Initiative (QOPI). QOPI is a national, data-driven quality improvement program with participation from over 600 oncology practices in the outpatient setting throughout the United States. The

performance measures used in QOPI are scientifically based and well accepted in the oncology community.

ASCO has developed and continues to operate QOPI, which is the obvious vehicle for promoting use of quality improvement programs in the oncology community, including participation in HOP QDRP. The wide acceptance of QOPI by oncology providers is based on their confidence in ASCO's understanding of both the scientific and operational aspects of providing oncology care. Over the past several years, ASCO has invested heavily in advancing the science and practice of oncology—and in assuring the highest quality of care for every patient. Here are just a few of the programs that shape the contours of QOPI and its content:

- Two respected journals: Journal of Clinical Oncology and the Journal of Oncology Practice
- Rigorous evidence based guidelines
- Education programs, including self guided instruction through ASCO University
- Patient information website, Cancer.Net

ASCO has developed scores of consensus-based measures that are specific to the operation of modern oncology practices. These measures are based on the leading scientific developments and clinical guidelines in oncology and are validated through field-testing in oncology practices throughout the United States. For the fall of 2010, QOPI will collect data from hundreds of participating oncology practices on more than 80 clinically relevant performance measures.

We would welcome the opportunity to meet with CMS staff regarding these important issues. In the interim, a summary of the current measures used under QOPI is posted on the following web page: <http://qopi.asco.org/Methodology>.

B. Adequate Reimbursement for Prescription Drugs used to Treat Cancer. CMS should finalize its proposal to reimburse for separately payable prescription drugs in the hospital outpatient department setting at 106 percent of the average sales price (ASP).

The adequacy of the payment rates adopted by Medicare in the hospital outpatient setting are important for ensuring that Medicare beneficiaries have meaningful access to the full range of prescription drugs, including anti-cancer and supportive care agents. We urge CMS to finalize its proposal to reimburse for separately payable prescription drugs in the hospital outpatient department setting at 106 percent of ASP.

We also ask that CMS stabilize the payment rates for prescription drugs in this setting at no less than the level proposed for CY 2011 (106 percent of ASP) for the indefinite future. We understand the complexity of allocating pharmacy overhead to establish adequate payment levels and urge the Agency to exercise its discretion to ensure the reimbursement level does not fall below 106 percent of ASP, both for CY 2011 and in future years.

C. Antiemetic Products. CMS should reinstate the policy in place prior to CY 2010 and protect access to the full scope of antiemetic products by providing separate (non-packaged) payment for all 5-HT3 antiemetic drugs.

In prior years, CMS has acknowledged the concern that packaging antiemetic drugs could lead to predictable and undesirable barriers to access for 5-HT3 antiemetic drugs used as part of an anticancer treatment regimen. We strongly agree with this concern. CMS should reinstate its policy to provide for separate payment for all 5-HT3 antiemetic products, regardless of whether the daily packaging threshold is exceeded for a particular product.

Packaging antiemetic products runs the risk of impairing access to the specific antiemetic that may be most effective for the individual. Chemotherapy is often very difficult for cancer patients to tolerate and responses to treatment of side effects can vary widely across individuals. It is critical to preserve meaningful access to therapies best suited to the individual patient's circumstance. It is virtually impossible for CMS to monitor the impacts on individuals by looking at aggregate data, and there appears to be little if anything to be gained from eliminating the safeguard that CMS has applied for many years.

We have similar concerns about the subset of other cancer drugs (including anticancer agents and supportive care drugs) that also fall below the packaging threshold. Packaging could create perverse financial incentives that inhibit access to the handful of oncology drugs that fall under the threshold. Given the array of clinical and patient-specific parameters involved in treating cancer patients, oncology drugs are not an appropriate class for packaging.

We urge CMS to work with ASCO to find alternative solutions that provide safeguards to protect access to drugs used to treat cancer that may fall under the packaging threshold.

D. Payments to Cancer Centers. CMS should finalize its methodology to ensure IPPS-exempt cancer hospitals receive adequate reimbursement.

Under the health care reform legislation enacted earlier this year, Congress required CMS to examine whether the costs incurred by IPPS-exempt cancer hospitals exceed the costs incurred by other hospitals under the hospital outpatient prospective payment system. Congress instructed CMS to make payment adjustments where appropriate.

ASCO supports this effort to ensure these hospitals receive fair and adequate reimbursement. We believe that the methodology CMS has developed reflects a careful and appropriate response to the mandate from Congress.

E. Physician Supervision. CMS should finalize its proposal to exclude all chemotherapy administration codes from the list of APCs that may be provided under general supervision.

The administration of anticancer drug regimens is complex and carries a significant risk of harm to the patient. ASCO has a long history of working to promote patient safety in the context of chemotherapy administration. Robust standards and appropriate oversight are integral to the safe administration of chemotherapy in oncology. The challenges faced in providing chemotherapy continue to grow with the introduction of new antineoplastic agents and supportive care drugs.

We agree with CMS that general supervision is inadequate to protect the interests of individuals with cancer. This is consistent with the recent safety standards developed and published by ASCO and the Oncology Nursing Society (Jacobson JO, Polovich M, McNiff KK, LeFebvre KB, Cummings C, Galieto M, Bonelli KR, McCorkle MR. American Society of Clinical Oncology / Oncology Nursing Society Chemotherapy Administration Safety Standards. J Clin Onc. 2009;27:5469-5475).

ASCO would be pleased to address any questions from CMS that may arise now or in the future regarding safety issues in oncology care.

F. Chemotherapy Administration Codes. ASCO supports the ongoing use of the 5-level APC structure for drug administration codes in the hospital outpatient setting.

The existing 5-level APC structure for the drug administration codes is working well, and ASCO urges CMS to keep this structure in place. As a result, we support the approach taken in the proposed rule.

ASCO urges CMS to be very cautious if the Agency considers making changes to the assignment of CPT codes within this framework in the future, and we request that CMS consult with ASCO before considering any changes to the APC structure or the CPT assignments within this framework.

G. Diagnostic Radiopharmaceuticals and Contrast Agents. CMS should reverse its current policies and provide for separate payment of diagnostic radiopharmaceuticals and contrast agents. ASCO supports the proposal to pay for such products under the pass-through system at 106 percent of the ASP.

ASCO disagrees with CMS' proposal to continue packaging diagnostic radiopharmaceuticals and contrast agents. We are concerned that packaging these products regardless of cost could result in perverse incentives that may interfere with access to care. Because of the large variation in the underlying costs for these products, the current policy is not appropriate. To promote fair and adequate reimbursement, CMS should provide separate payment according to the general policies used for packaging drugs and biologicals.

ASCO supports CMS' proposal to pay for diagnostic radiopharmaceuticals and contrast agents under the pass-through system at 106 percent of the ASP.

H. Therapeutic Radiopharmaceuticals. CMS should finalize its proposal to continue reimbursing for therapeutic radiopharmaceuticals using the “ASP +” methodology. For instances in which the ASP is not established, we urge CMS to set aside its proposal and instead reimburse on the basis of the hospital’s charges adjusted to cost.

ASCO supports the CMS proposal to reimburse for therapeutic radiopharmaceuticals under the “ASP +” methodology for a patient ready dose. This would equate to 106 percent of ASP under the current proposed rule.

However, we oppose adoption of this proposal for reimbursement of therapeutic radiopharmaceuticals that do not have an assigned ASP value. CMS proposes to rely upon the mean unit cost data from hospital claims data. We are concerned that these amounts are inadequate to promote meaningful access to therapeutic radiopharmaceuticals for individuals with cancer. Instead, we urge the Agency to base reimbursement on the hospital’s charges adjusted to cost. This is the methodology used as recently as CY 2009 for all therapeutic radiopharmaceuticals. Hospitals are familiar with the “charges adjusted to cost” payment methodology, and this approach is less likely to result in undesirable barriers in access to care.

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Thank you for the opportunity to submit comments on this proposed rule. If you have any questions or would like to request assistance from ASCO on any issues involving the Medicare and Medicaid programs, please contact Karen Hagerty, M.D. at 571.483.1614 or Karen.Hagerty@asco.org.

Sincerely,



George W. Sledge, Jr., MD
ASCO President