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August 30, 2011

**By Electronic Submission**

Donald Berwick, MD

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Room 445-G

Hubert H. Humphrey Building

200 Independence Avenue, S.W.

Washington, D.C. 20201

**RE: CMS-1525-P Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates**

Dear Administrator Berwick:

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) 2012 as released to the public on July 1, 2011 and published in the Federal Register on July 18, 2011 (“the proposed rule”).

ASCO is the national organization representing nearly 30,000 physicians and other professionals specializing in cancer research, treatment, diagnosis and prevention. Our members are committed to conquering cancer by ensuring that all Americans – including all Medicare beneficiaries and Medicaid enrollees – have meaningful access to high-quality, evidence-based services for the prevention, diagnosis and treatment of cancer.

ASCO provides the following recommendations regarding the proposed rule:

- 1) **Performance Measures under the Hospital OQR Program.** CMS should expand the sets of oncology measures available for hospitals to use in satisfying requirements of the hospital outpatient quality reporting program (Hospital OQR Program). This could be accomplished by replicating the option available to physicians under the Physician Quality Reporting System (PQRS) to report measures groups through registries. To further this approach, CMS should adopt more robust and comprehensive sets of quality measures for oncology for use in all settings of cancer care under all CMS-

sponsored quality reporting programs. ASCO has extensive experience in developing and testing new quality measures and is uniquely positioned to assist in finalizing such sets of quality measures and specifications for oncology.

- 2) **The Quality Oncology Practice Initiative.** CMS should adopt harmonized policies that facilitate provider participation in the Quality Oncology Practice Initiative (QOPI). The proposed registry reporting option under the Hospital OQR Program is one important step in this direction. ASCO would welcome the opportunity to work with CMS on approaches to hospital quality reporting that would leverage the breadth, depth and widespread acceptance of the QOPI program.
- 3) **Safeguarding Beneficiary Access through Adequate Reimbursement for Prescription Drugs Used to Treat Cancer.** To ensure that Medicare beneficiaries have access to the most appropriate cancer treatment regimens, CMS should amend its proposal and ensure that separately payable prescription drugs used as part of cancer treatment regimens are reimbursed at no less than 106 percent of the average sales price.
- 4) **Packaging of Antiemetic and Other Drugs used in Anti-Cancer Regimens.** We urge CMS to protect patient access to antiemetic and other agents used in anti-cancer regimens by providing for separate, non-packaged reimbursement of these drugs in the hospital outpatient department setting.
- 5) **Protecting PPS-Exempt Cancer Hospitals.** ASCO supports CMS' efforts to try to ensure that PPS-exempt cancer hospitals receive adequate reimbursement under Medicare. CMS should undertake similar efforts to evaluate and provide adequate reimbursement for community-based oncology providers to protect the interests of Medicare beneficiaries with cancer.
- 6) **Physician Supervision.** If CMS finalizes its proposal to use the APC Advisory Panel to adjust the supervision requirements for services provided in the hospital outpatient department setting, then CMS should ensure that robust opportunities for notice and comment exist under this panel, and CMS should emphasize the importance of protecting patient safety. In particular, the new proposed process should not reverse the supervision requirements for chemotherapy administration. We continue to agree with CMS' prior determination that general supervision for chemotherapy administration is inadequate to protect the interests of individuals with cancer.
- 7) **Diagnostic Radiopharmaceuticals and Contrast Agents.** CMS should reverse its current policies and provide for separate payment of diagnostic radiopharmaceuticals and contrast agents.

A discussion of these recommendations follows below.

- 1. Performance Measures under the Hospital OQR Program. CMS should establish an option for hospitals to voluntarily report a more expansive set of quality measures in oncology under the Hospital OQR Program, such as by replicating the option available to physicians under the Physician Quality Reporting System (PQRS) to report measures groups through registries. CMS should adopt more robust and comprehensive sets of quality measures for oncology for use in all settings of cancer care under all CMS-sponsored quality reporting programs. ASCO has a robust quality measure development program that should serve as the primary source for aligned measures in oncology for all federal programs.***

The Hospital OQR Program currently has only a few measures that are relevant to oncology, and even with the addition of the cancer measures proposed for implementation in 2015, the Hospital OQR measures will remain woefully inadequate in the area of oncology.

At the same time, hospitals and all other oncology providers are struggling under a growing list of administrative burdens, and we urge the agency to exercise caution when considering any expansion of the mandatory quality reporting requirements. We encourage, wherever possible, leveraging the most rigorous programs already in use by the provider community as a means of satisfying required quality reporting.

At least in the case of oncology, it is critical for a mature quality improvement program to rely on detailed, disease-specific measures. Quality measurement systems should be relevant and meaningful to the full spectrum of oncology care, and the available measure sets for oncology should be expansive enough to allow reporting by all oncologists, regardless of their professional focus. Cancer is a leading cause of morbidity and mortality for Medicare beneficiaries, but the existing and proposed Hospital OQR Program measures for oncology are extremely limited and do not reflect the scope of activity appropriate to the specialty.

The complexity and rapidly evolving nature of cancer care makes it especially important to promote a quality measurement system that can grow and evolve with our understanding of cancer. The more than 100 different diseases that comprise cancer require different health care strategies depending upon type, stage, co-morbidities and individual patient preferences. As a result, there is great value in quality improvement programs that include comprehensive sets of robust, evidence-based cancer measures. Our experience suggests that oncology providers place great value on participating in comprehensive quality reporting initiatives; they often do so voluntarily, investing the time and other resources required to participate in such efforts.

We urge CMS to guard against the impulse to minimize the number of measures, thereby restricting the menu of possible reporting opportunities and limiting our insight into outcomes in this complex field of care. We can and should encourage hospitals and other oncology providers to participate in quality improvement activities that involve a meaningful number of cancer-specific quality measures. This could be accomplished by replicating the option available to physicians under the Physician Quality Reporting System (PQRS) to report measures groups through registries in combination with the adoption of more robust and comprehensive sets of quality measures for oncology.

ASCO is uniquely positioned to assist policymakers in identifying and implementing additional evidence-based quality measures for oncology that are both actionable and relevant at the point of patient care. In the case of cancer, this effort should be based on sets of measures implemented in QOPI, which is a unique quality improvement system with an extensive collection of expert-developed and field-tested performance measures.

QOPI includes nearly 100 evidence-based performance measures, which are updated rapidly to reflect our evolving evidence base for cancer care. New performance measures are field-tested through QOPI and can be incorporated within months after publication of scientific evidence. These measures are derived from clinical guidelines and published standards, reflecting the consensus of cancer experts. A summary of the current measures used by QOPI is available at <http://qopi.asco.org/Methodology>.

ASCO can provide detailed recommendations in short order for expanding and updating the sets of quality measures for cancer care available under Medicare's quality reporting programs, including the Hospital OQR Program, the Physician Quality Reporting System (PQRS) and the new program for PPS-exempt cancer hospitals.

**2. The Quality Oncology Practice Initiative. *CMS should adopt harmonized policies that facilitate provider participation in the Quality Oncology Practice Initiative (QOPI). The proposed registry reporting option under the Hospital OQR Program is one important step in this direction. ASCO would welcome the opportunity to work with CMS on approaches to hospital quality reporting that would leverage the breadth, depth and widespread acceptance of the QOPI program.***

The challenges facing the oncology community are unique. QOPI's comprehensive set of quality measures can extend the reach of limited CMS resources to target a complex, high-priority disease area. The complexity associated with cancer care is difficult to capture in a system that is designed to work across all medical specialties or that otherwise operates under the inherent resource and time constraints imposed on CMS. By leveraging the investment already made in QOPI, CMS-sponsored quality initiatives can take full advantage of opportunities to address areas in oncology that are vulnerable to underuse, overuse and ineffective care.

QOPI has gained the trust and confidence of the oncology community. There is widespread recognition of the value that QOPI provides in promoting high-quality, high-value oncology care. For example, funding from Susan G. Komen for the Cure has made a critical difference in the trajectory of QOPI development and implementation. The National Cancer Institute has been an active participant and has brought the majority of National Community Cancer Center Program participants into QOPI. In addition, a growing group of private health insurance companies are adopting incentives for QOPI participation. An increasing number of scientific publications have explored the QOPI program.

There remains an acute need for QOPI to pursue solutions to the challenges facing oncology, and there is ongoing work to strengthen its programs. Harmonizing national reporting and recognition programs with QOPI will better enable oncology providers to examine, improve and advance the quality of care for their patients. We urge CMS and other stakeholders to consider

policies that will harmonize national quality reporting and improvement programs with QOPI and facilitate participation in QOPI.

**3. Safeguarding Beneficiary Access through Adequate Reimbursement for Prescription Drugs Used to Treat Cancer. *To ensure that Medicare beneficiaries have access to the most appropriate cancer treatment regimens, CMS should amend its proposal and ensure that separately payable prescription drugs used as part of cancer treatment regimens are reimbursed at no less than 106 percent of the average sales price.***

The adequacy of the payment rates adopted by Medicare in the hospital outpatient department setting is critically important for ensuring that Medicare beneficiaries with cancer have meaningful access to the most appropriate prescription drugs to treat their cancers, including anti-cancer and supportive care agents. ASCO remains concerned about the effects of the CMS methodology for reimbursement of separately paid drugs and biologicals.

Although we support CMS' decision to reallocate some pharmacy overhead from packaged drugs and biologicals to separately paid therapies, the amount of this allocation is still inadequate. We urge CMS to establish payment for drugs and biologicals at no less than 106 percent of the average sales price (ASP) using its statutory authority to do so in the absence of appropriate data on the average acquisition cost for drugs and biologicals. Alternatively, CMS should allocate enough overhead to separately paid drugs and biologicals to ensure payment of at least 106 percent of ASP. As we have stated previously, ASCO believes that even this amount might not adequately cover the costs incurred by hospitals to acquire and handle drugs and biologicals used to treat cancer.

The reimbursement level CMS has chosen is tied to claims data that various analysts have shown to be influenced by charge compression<sup>1</sup> with large portions of pharmacy overhead costs being packaged into underlying Ambulatory Payment Classifications (APCs). As a result, CMS' mean cost findings for higher cost drugs that are separately reimbursed have historically been dramatically understated. ASCO commends CMS for its efforts 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.

Similarly, although ASCO supports CMS' decision to update the overhead allocation amount to account for inflation, this is mainly a check on the erosion in the overhead percentage that is inherent in the agency's methodology. A stable reimbursement level at 106 percent of ASP would be preferable to the continued uncertainty caused by CMS's current methodology.

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<sup>1</sup> 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.

**4. Packaging of Antiemetic and Other Drugs used in Anti-Cancer Regimens. *We urge CMS to protect patient access to antiemetic and other agents used in anti-cancer regimens by providing for separate, non-packaged reimbursement of these drugs in the hospital outpatient department setting.***

As CMS has acknowledged in the past, chemotherapy is very difficult for many individuals with cancer to tolerate and is often accompanied by debilitating side effects. It is vital that patients undergoing chemotherapy be able to access the antiemetic products that work best for them, and our experience suggests that packaging antiemetics has adverse impacts on this access. In prior years, CMS has recognized that packaging antiemetic drugs could lead to predictable and undesirable barriers to access for 5-HT3 antiemetic drugs used as part of an anti-cancer treatment regimen. We strongly agree with this concern, and we urge CMS to reinstate its prior policy of providing separate payment for all 5-HT3 antiemetic products.

We have similar concerns regarding the subset of other cancer drugs (including both anti-cancer agents and supportive care drugs) that fall below the packaging threshold. The current policy creates perverse financial incentives against the use of drugs that fall below the packaging threshold, even when these drugs are the most appropriate clinical alternative for individuals with cancer. Moreover, a number of observers have noted that perceived inadequacies in reimbursement for packaged cancer drugs may be contributing to the drug shortage problems that are plaguing the cancer community. We believe that CMS should refrain from packaging any drugs used in anti-cancer regimens, and we urge CMS to work with ASCO to find alternative solutions that provide adequate safeguards to protect beneficiary access to these important therapies.

**5. Protecting PPS-Exempt Cancer Hospitals. *ASCO supports CMS' efforts to try to ensure that PPS-exempt cancer hospitals receive adequate reimbursement under Medicare. CMS should undertake similar efforts to evaluate and provide adequate reimbursement for community-based oncology providers to protect the interests of Medicare beneficiaries with cancer.***

The Patient Protection and Affordable Care Act required the Secretary to study whether the costs incurred by PPS-exempt cancer hospitals exceeded the costs of other hospitals under the hospital outpatient department prospective payment system and to make payment adjustments where appropriate.

ASCO supports efforts to ensure that these cancer hospitals receive appropriate payments that reflect their costs. Building off of this initiative, we urge CMS to undertake similar efforts under its existing authority to ensure that reimbursement under Medicare Part B is adequate for all cancer providers. The vast majority of cancer services in the United States are provided in community-based settings of care. Ensuring adequate reimbursement in community-based settings is critically important so that all Medicare beneficiaries have access to high-quality, high-value care throughout the United States.

- 6. Physician Supervision. *If CMS finalizes its proposal to use the APC Advisory Panel to adjust the supervision requirements for services provided in the hospital outpatient department setting, then CMS should ensure that robust opportunities for notice and comment exist under this panel, and CMS should emphasize the importance of protecting patient safety. In particular, the new proposed process should not reverse the supervision requirements for chemotherapy administration. We continue to agree with CMS' prior determination that general supervision for chemotherapy administration is inadequate to protect the interests of individuals with cancer.***

If CMS finalizes its proposal to use the APC Advisory Panel to adjust the supervision requirements for services provided in the hospital outpatient department setting, then CMS should ensure that robust opportunities for notice and comment exist under the proposed process, and CMS should emphasize the importance of protecting patient safety.

In particular, the new proposed process should not be used to reverse the supervision requirements for chemotherapy administration. We continue to agree with CMS' prior determination that general supervision for chemotherapy administration is inadequate to protect the interests of individuals with cancer. The administration of anti-cancer 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.

General supervision remains inadequate to protect the interests of individuals with cancer. This is consistent with the safety standards developed and published by ASCO and the Oncology Nursing Society in 2009.<sup>2</sup>

- 7. Diagnostic Radiopharmaceuticals and Contrast Agents. *CMS should reverse its current policies and provide for separate payment of diagnostic radiopharmaceuticals and contrast agents.***

With regard to the CMS proposal to continue packaging all diagnostic radiopharmaceuticals, ASCO continues to believe that, because of the large variation in underlying costs for these products, this policy remains inappropriate. Separate payment should be made according to the general packaging policy for drugs and biologicals. However, ASCO continues to support the proposal to provide pass-through payments for qualifying diagnostic radiopharmaceuticals and contrast agents on the basis of 106 percent of ASP, parallel with payments in the physician office.

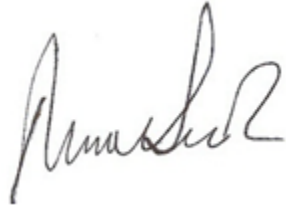
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<sup>2</sup> Jacobson JO, Polovich M, McNiff KK, LeFebvre KB, Cummings C, Galioto M, Bonelli KR, McCorkle MR. American Society of Clinical Oncology / Oncology Nursing Society Chemotherapy Administration Safety Standards. Journal of Clinical Oncology. 2009;27:5469-5475.

Thank you for the opportunity to comment on this proposed rule. We urge you to follow up with us if we can answer any questions or provide any information relating to prevention, diagnosis, treatment, research and quality improvement programs in oncology. Please contact Karen Hagerty, M.D. at 571.483.1614 or [Karen.Hagerty@asco.org](mailto:Karen.Hagerty@asco.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Michael P. Link". The signature is fluid and cursive, with a large initial "M" and a stylized "L".

Michael P. Link, MD  
ASCO President