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August 27, 2008

Kerry N. Weems, Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW.  
Washington, DC 20201

Re: CMS-1403-P – Proposed Revisions to Payment Policies Under the Medicare Physician Fee Schedule and Other Revisions to Medicare Part B for 2009

Dear Acting Administrator Weems:

The American Society of Clinical Oncology (ASCO) is submitting these comments in response to the proposed changes in the Medicare physician fee schedule and related policies for 2009 that were published in the Federal Register on July 7, 2008. ASCO is the leading national organization representing physicians who specialize in the treatment of cancer, and our members are very interested in the proposed changes.

Our comments can be briefly summarized as follows:

- ASCO supports CMS's proposed changes in the practice expense relative values for certain chemotherapy services.
- CMS should continue the current payment for pre-administration services related to intravenous immune globulin. Normal market conditions do not yet exist.
- ASCO supports CMS's proposal to continue the current threshold for deviating from use of average sales price as the basis for drug payments.
- CMS should avoid applying payment penalties for so-called preventable conditions to situations involving cancer patients. Conditions that might be preventable in patients with other diseases may not be preventable in cancer patients.
- The standards applicable to independent diagnostic testing facilities should not be extended to physician offices.

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- The current policy on the effective date of physician enrollment in Medicare should be retained.
- The anti-markup rules for diagnostic services should not be extended beyond their current scope. Both of CMS's proposed approaches would interfere with the current methods of delivering cancer care, which are legitimate and do not lead to overutilization of diagnostic services as the proposal assumes.

### **RUC Practice Expense Recommendations**

The American Medical Association's Relative Value Update Committee ("RUC") recommended revising the practice expense relative values for a number of codes including 96440 (chemotherapy administration requiring thoracentesis), 96445 (chemotherapy administration requiring peritoneocentesis), 96450 (chemotherapy administration requiring spinal puncture), and 96542 (subarachnoid or intraventricular chemotherapy injection via subcutaneous reservoir). CMS is proposing to accept the RUC's recommendations. ASCO supports CMS's proposal.

### **Intravenous Immune Globulin (IVIG)**

Medicare currently makes an additional payment when IVIG is administered to account for pre-administration services incurred in locating sources of IVIG. CMS is proposing to discontinue this payment for IVIG, since it believes that the market conditions for IVIG have improved.

ASCO opposes this proposal and requests that the payment for pre-administration services be continued in 2009. Oncologists continue to experience considerable difficulties in obtaining IVIG and in obtaining it at a price covered by the Medicare payment amount. IVIG vendors often cannot provide a consistent supply and patients must be switched from one brand of IVIG to another as supply conditions change. Many cancer patients are still being referred to hospitals for IVIG because of cost and availability issues. In short, the market conditions for IVIG are still not normal, and we urge CMS to retain the payment for IVIG pre-administration services.

### **Alternative to ASP-Based Payment Methodology**

Under the Medicare statute, CMS may substitute a different payment methodology for ASP+6% if the average manufacturer price or the widely available market price for the drug exceeds ASP by more than a specified threshold percentage. CMS is proposing to maintain that threshold percentage at 5%, which is the current amount. ASCO supports this proposal.

### **Non-Payment for Preventable Conditions**

Medicare recently adopted a policy of not paying hospitals for preventable conditions acquired during a hospital stay. CMS states in the notice on the physician fee schedule that the same principle could be applied in other settings, including physician practices. 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.

### **Standards for Providing Diagnostic Services in Physician Offices**

Medicare rules establish standards for independent diagnostic testing facilities (“IDTFs”). In the notice, CMS states its concern that entities furnishing diagnostic services are enrolling as physician practices to avoid the standards for IDTFs, and CMS is therefore proposing to require physicians who furnish diagnostic services to enroll in Medicare as an IDTF and comply with most of the IDTF standards by September 30, 2009. CMS is also seeking comment on whether the requirements should be limited to certain types of diagnostic procedures.

ASCO urges CMS to address its concern about entities avoiding the IDTF rules in some other manner. Oncologists’ offices often have diagnostic testing equipment, including advanced imaging equipment such as CT and PET/CT scanners, that are essential in diagnosing and monitoring cancer patients. Oncologists’ offices should not be subject to extensive and burdensome regulations based on a concern that they may be disguised IDTFs. ASCO suggests that CMS identify characteristics of entities that are not true physician practices, but instead are really IDTFs, and limit the application of the IDTF rules to such entities.

A particular concern is the prohibition in the IDTF regulations against the entity’s leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization or sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization. Especially in rural areas, oncology practices may band together to provide CT or PET/CT scanning services in a common facility. This service to patients should not be prohibited by application of the IDTF rules.

### **Billing for Services Furnished Prior to Medicare Enrollment**

Currently, physicians and nonphysician practitioners (“NPPs”) can bill for services furnished to Medicare patients prior to the date that the Medicare program officially accepted their enrollment. CMS states that it is concerned about its current policy, since physicians may not have been in compliance with Medicare requirements prior to their enrollment. CMS is proposing two alternative approaches to deal with this issue.

Under the first approach, physicians and NPPs could not bill for services furnished to Medicare patients prior to the date on which the Medicare contractor approved their enrollment. Under the second approach, physicians and NPPs who are enrolled in Medicare could retroactively bill for services after the date on which they submitted the enrollment application to Medicare.

ASCO opposes this change in the Medicare rules and urges that CMS maintain its current policy. When a new oncologist joins a practice, it often takes considerable time to complete and submit the CMS enrollment form. Under both approaches suggested by CMS, the oncologist could not bill for treating Medicare patients during this period. Under the more severe approach, the oncologist could not bill until CMS processes the application, which takes many weeks.

Many oncology practices have little additional capacity and need new oncologists to serve their patients, but the supply of physicians becoming oncologists is quite limited. This proposal would be a disservice to Medicare cancer patients who would be unable to take advantage of oncologists who have newly joined a practice, as well as being an unnecessary burden on practices that would have to juggle patient and physician schedules until a new oncologist becomes entitled to bill Medicare patients. The current procedure of allowing retroactive billing for services furnished to Medicare patients better serves the interests of the Medicare program and its beneficiaries, as well as physicians.

### **Anti-Markup Rule**

Last year CMS adopted new rules prohibiting physicians from charging Medicare more than the cost of diagnostic services that were either (a) purchased or (b) furnished by an employee or contractor at a site different from the office of the billing physician. The rule applies to both the professional and technical components of diagnostic services. Subsequently, CMS delayed implementation of part of the rule. As the rule went into effect on January 1, 2008, it applied only to purchased tests and to anatomic pathology diagnostic tests furnished in a different building than the location of the billing physician.

CMS is now proposing two alternative approaches. Under the first approach, the anti-markup provision would apply only to diagnostic services performed or supervised by a physician who does not “share a practice” with the billing physician. A physician who is employed by or contracts with more than one practice would not be considered to share the practice, and therefore diagnostic tests furnished or supervised by that physician would be subject to the anti-markup rule. Alternatively, CMS is proposing to continue the current site-related approach. The current rules would be modified, however, to clarify what is the same office location. In general, the anti-markup rule would not apply if the diagnostic service is furnished in the same building as substantially the full range of services furnished by the practice.

ASCO opposes both of these approaches because both would conflict with legitimate methods by which oncologists furnish diagnostic services to their patients. The first approach would obstruct the common practice of using part-time radiologists to interpret PET/CT scans and other imaging. Oncology practices may furnish the technical component of the service with their own employees but rely on a part-time radiologist, who is also employed by or contracts with other practices, to read the images. Under current rules, the oncology practice can bill a global fee for both the technical and professional components, but under the proposal, the professional component would apparently be subject to the anti-markup rule. The use of a part-time radiologist in this situation would not somehow encourage overutilization, which is CMS’s underlying concern, and the anti-markup rule should therefore not apply.

CMS’s alternative approach of requiring the diagnostic services to be furnished in the same building as other services of the practice would also interfere with efficient care of cancer patients. Many oncology practices that provide PET/CT and other advanced diagnostic services have located those services in a separate building. Oncology practices at any given location usually consist of only a few physicians and are often located in a medical building, but the practice may have multiple locations across a wide geography. In those situations, it has often

been more practical to locate the scanner in a building reasonably accessible to multiple practice locations than to attempt to place it in a medical office building in which a few oncologists and an infusion suite are located. That the scanner is located in a separate building does not in any way support an inference that the diagnostic services furnished are not an integral part of the practice, as the CMS proposal assumes. To allow the continuation of practice structures that successfully deliver care to cancer patients, diagnostic services furnished by an oncology practice in a building separate from the locations of its clinics and drug administration services should not be subject to the anti-markup rule.

### **Physician Quality Reporting Initiative (PQRI)**

ASCO supports the addition of cancer quality measures to the PQRI program for 2009. Specifically, we support the following measures included in the proposed rule: Cancer Care: Medical and Radiation Oncology – Plan of Care for Pain; Cancer Care: Pain Intensity Quantified and Cancer Care: Radiation Dose Limits to Normal Tissues.

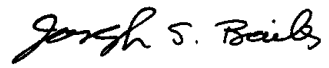
As co-chairs of the ASTRO/ASCO/AMA PCPI oncology work group, we were disappointed that two of the group's measures were not included in the proposed 2009 PQRI measures list: Cancer Care: Cancer Stage Documented and Radiation Oncology: Treatment Summary Documented and Communicated. These measures have now been endorsed by the National Quality Forum. We urge CMS to consider inclusion of these measures in the PQRI program.

We are pleased that the PQRI methodology is moving toward registry-based reporting and measure groupings, as these may promote more comprehensive and valid data. ASCO agrees that reporting measure groups can provide a more comprehensive assessment of the quality of patient care; however, the definition of a measure group must be sufficiently flexible to allow for the development and implementation of meaningful measure sets. Clear and clinically meaningful denominator groupings, rather than exact matched denominators, will meet this need. For instance, a measure with a more widely applicable denominator (e.g., chemotherapy planning) could be limited to a more specific denominator for a measure group (e.g., a breast cancer grouping, including the chemotherapy planning measure applied only to breast cancer patients). Such an approach will allow for integration of existing measures into measure groups and promote their use. Reporting PQRI data via registries is preferable to claims-based reporting, in terms of data validity and administrative burden, and ASCO urges CMS to continue to work toward registry-based reporting solutions.

Finally, ASCO urges CMS to exercise caution in moving toward public reporting of PQRI participation, and especially public reporting of PQRI data. We suggest additional external evaluation of PQRI program before public reporting of participation. The PQRI methodology and measures should undergo additional testing before performance data is considered for public reporting. CMS can avoid recreating mistakes made by others in the past, when public release of data led to adverse incentives for physicians and misunderstanding and confusion among patients.

Thank you for the opportunity to comment on the proposals.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive style with a large initial 'J'.

Joseph S. Bailes, MD  
Chair, ASCO Government Relations Council