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August 31, 2009

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1413-P – Proposed Policies Under the Medicare Physician Fee Schedule and Other Revisions to Part B for CY 2010

Dear Ms. Frizzera:

These comments are submitted by the American Society of Clinical Oncology (“ASCO”) in response to the proposed changes in the Medicare physician fee schedule that were published in the Federal Register on July 13, 2009.

ASCO is a 27,000 member national organization, representing physicians and other healthcare professionals involved in cancer treatment, diagnosis, prevention and research. ASCO members also conduct research leading to improved patient outcomes. We are committed to ensuring that evidence-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 this proposed policy.

Our principal comments can be briefly summarized as follows:

Practice expense relative value units. CMS should not implement its proposal to revise the practice expense relative value units based on data from the American Medical Association’s Physician Practice Information Survey (“AMA PPIS”). As we discuss below, the study is sufficiently flawed as to not be credible. Furthermore, since practice expenses associated with chemotherapy administration have increased in recent years, application of the 20 percent cuts proposed by CMS for these services are extremely problematic. The gap between our estimates of actual expenses and the reimbursement rates resulting from the proposed cuts will result in practices to shut down or discontinuing critical services. As a result, implementation of the proposed rule would have

significant adverse impacts on beneficiary access to medically necessary cancer treatments.

Furthermore, oncology-specific problems with AMA survey data arose with the Socioeconomic Monitoring Survey (“SMS”) for 1995-99, as demonstrated for medical oncology based on a supplemental survey conducted in 2002 by an independent organization (the Gallup Organization) using the same survey instrument as the AMA’s surveys. Congress addressed this oncology-specific inaccuracy in the Medicare Modernization Act with a provision that still governs this area. As a result, if CMS uses the AMA PPI survey for rate setting in 2010, CMS should not apply the AMA PPIS data to medical oncology. Instead, for 2010 rate setting, CMS should continue to base the practice expense relative value units for medical oncology on the more accurate Gallup Organization survey, as required under the clear intent and plain meaning of Section 1848(c)(2)(H) of the Social Security Act. To use the Gallup survey data for medical oncology in tandem with the AMA PPIS data for other specialties, CMS must update the Gallup survey data by the Medicare Economic Index (MEI) plus a percentage reflecting the additional average increases in expenses (in addition to MEI) that are unique to these services. In the future, ASCO is prepared to work with CMS and other policy makers to explore ways to implement a new survey for medical oncology that replicates the response rates and accuracy of the Gallup survey. These issues are discussed in greater detail below.

Malpractice relative value units. CMS should not reduce the malpractice relative value units assigned to the chemotherapy administration codes as proposed. The proposed methodology assumes that the malpractice risk associated with any particular procedure corresponds to the amount of physician work included in the code for the procedure. The methodology therefore assigns little malpractice risk to the drug administration codes because they include little or no physician work relative value units. ASCO believes that this approach fails to account for the malpractice risk associated with cancer chemotherapy and that the methodology should be revised so that the malpractice risks to oncologists related to chemotherapy administration are properly recognized in the payments for those codes even though they have only minimal physician work relative value units.

Sustainable growth rate. ASCO supports removing physician-administered drugs from the sustainable growth rate methodology, both prospectively and retroactively.

Consultations. ASCO opposes the proposal to eliminate the consultation codes. The rationale stated by CMS for their deletion does not withstand analysis, and their elimination would disadvantage physicians, like most oncologists, who must provide significant additional documentation for a consultation. Additional payment should be made for this additional work. If CMS nevertheless consolidates the consultation and office visit codes, ASCO opposes re-assigning half of the relative value units now in the consultation codes to established patient visits, since that reallocation would disadvantage physicians who currently furnish a large number of consultations.

These issues are discussed in greater detail below.

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CMS Should Not Implement the Proposed Revisions to the Practice Expense RVUs

The indirect costs reflected in the practice expense relative value units (“RVUs”) of the physician fee schedule are based on information about physicians’ practice expenses obtained through surveys of a sample of physicians. For most physician specialties, the practice expenses are based on the American Medical Association’s Socioeconomic Monitoring Survey (“SMS”) for 1995-99. For medical oncology, the practice expenses are based on a supplemental survey conducted in 2002 by an independent organization (the Gallup Organization) using the same survey instrument as the AMA’s surveys. Since the surveys were conducted in various years, the data from the surveys are inflation-adjusted to make them comparable.

In the July 13 notice, CMS has proposed to use a survey conducted by the AMA in 2007-08, called the Physician Practice Information Survey (“AMA PPIS”), in place of both the AMA’s SMS data and the supplemental surveys conducted by several specialties. ASCO strongly opposes this proposal.

- **Use of the AMA PPIS Data Would Adversely Affect Cancer Treatment**

Medicare payments for chemotherapy administration services would decline by over 20% if CMS uses the AMA PPIS data as proposed. Combined with the decreases effected by the previous change in methodology for calculating the “direct” portion of the practice expense relative value units, the proposed payment amounts for the principal infusion codes would be more than 30% below what they were in 2006. The continued viability of office-based cancer chemotherapy is significantly threatened if cuts of this magnitude are implemented.

As is well-known, the Medicare Modernization Act of 2003 radically revised the payment structure for oncology services. Payments for drugs administered in the office were sharply reduced by lowering payments to 106% of the manufacturer’s average sales price; it should be noted that the 80% of 106% of the average sales price that Medicare pays is actually 84.4% of ASP, and that many patients have no secondary insurance. This reduction in reimbursement by CMS highlighted the need for Medicare to provide accurate and fair reimbursement for chemotherapy administration. To partially offset this reduction in drug payment levels, the Act required CMS to substantially increase the payments for drug administration services by using the supplemental survey of practice expenses that the Gallup Organization conducted on behalf of ASCO. In addition, the Act provided for an additional transitional payment amount, and CMS, on its own initiative, implemented a demonstration project that included further chemotherapy-related payments. These multiple congressional and administrative provisions allowed oncology practices to continue furnishing office-based chemotherapy despite the major reduction in payments for drugs.

The current payment system for oncology services is still not satisfactory. As a result of the variability of market prices and of prices available to particular physician practices, combined with the narrow margin implicit in payments only 6% higher than the manufacturer’s average sales price (which does not consider the wholesaler’s markup), many oncologists pay prices for some drugs that are greater than the Medicare payment amount. These out-of-pocket losses are evidence of a defective payment system. A system is not sustainable in which oncologists routinely lose money in treating Medicare cancer patients, especially given that

medical oncologists in the physician office setting provide critical access points to oncology care throughout rural and urban communities in the United States.

Especially in light of the defects inherent in the current payment structure, a 20%-plus reduction in payments for chemotherapy administration services as proposed (over 30% for infusion services considering other recent reductions) would be a serious mistake that could have adverse consequences to the treatment of Medicare patients. More than 60% of cancer diagnoses occur in Medicare-eligible individuals, and this proportion is projected to increase to 70% in the near future. At the same time, a 30% shortage of oncologists is developing. Significant reductions in Medicare reimbursement for oncology services will seriously aggravate the difficulties of continuing a viable healthcare delivery system to treat Medicare patients with cancer.

The impact analysis in the notice reflects an estimate that the sharp reductions in chemotherapy administration payments to oncologists would be offset to some extent by increases in payments for evaluation and management ("E&M") services. This partial mitigation does not alleviate our serious concern about the reduced payments for chemotherapy administration. Office-based oncologists have the option of referring patients to hospitals for their chemotherapy services while continuing to provide only E&M services in their offices and cannot be expected to incur major losses in providing chemotherapy services simply because Medicare would in the future be making more adequate payments for E&M services.

Although each oncology practice faces its own financial situation, many oncology practices would have financial difficulty coping with a payment reduction of this extraordinary magnitude. Some practices may discontinue furnishing chemotherapy in their offices in general or to certain patients, and some oncologists will retire early. If enough physicians in a geographic area cease administering in-office chemotherapy, these patients will have to go elsewhere for their chemotherapy treatments—likely to a hospital setting. At some point, the burden on hospitals providing this service will be overwhelming, and they simply will not be able to absorb additional patients. These are serious potential consequences that CMS should not bring about by using the flawed AMA PPIS data.

- **The AMA PPIS Data Do Not Meet Reasonable Standards for Validity**

Although the AMA PPIS data are recent, that does not make the data more reliable than the existing combination of data from the AMA SMS and the supplemental surveys.

The weakness of the AMA PPIS survey is evident by comparing it to Gallup Organization's supplemental survey. The AMA PPIS received results from 135 oncologists and obtained usable data from only 50. By contrast, the Gallup Organization's supplemental survey received results from 999 respondents and usable data from 245.

The large difference in the number of usable surveys directly affects the validity of the results. During the time that CMS accepted supplemental surveys, CMS imposed a precision requirement that survey data had to meet. A supplemental survey was accepted only if its results demonstrated a 90% confidence interval with a range of plus or minus 10% of the mean (that is,

1.645 times the standard error of the mean, divided by the mean, should be equal to or less than 10% of the mean). 65 Fed. Reg. 65376, 65383 (Nov. 1, 2000).

CMS determined that the ASCO supplemental survey met that requirement – it had a 9.8% precision for practice expenses per hour and a 10.1% precision for total practice expenses. By contrast, CMS has stated that the oncology data on practice expenses per hour in the AMA PPIS has only a 14% precision – a level that would have caused CMS to reject the data as unreliable under the standards that it applied in determining whether to accept data from supplemental surveys.

Moreover, while the small sample size for oncologists in the AMA PPIS has caused their practice expenses to be understated, the small sample sizes and consequent lack of precision for other specialties may have caused their practice expenses to be overestimated, thereby further reducing the relative values attributed to oncology services.

In the July 13 notice, CMS asserts that application of the precision criteria to the PPIS is not necessary because the AMA PPIS was a “contemporaneous, consistently collected, and comprehensive multispecialty survey,” whereas the supplemental surveys were specific to an individual specialty (74 Fed. Reg. at 33531). This rationale does not make sense, and we do not agree with it. Simply collecting data on multiple specialties at the same time does not ensure the validity of the data if the sample sizes for each specialty are too small. While the precision of the PPIS results for practice expenses per hour for “all physicians” is listed by CMS as 4%, and thus might well be accurate, it is the practice expenses per hour for each specialty that are critical in assigning relative values to particular codes. Because of the statistical shortcomings of the AMA PPIS, CMS should not use this data for medical oncology.

- **Use of the AMA PPIS Data to Determine the Practice Expenses of Oncologists Would Violate the Intent and Plain Meaning of the Medicare Modernization Act**

Section 1848(c)(2)(H) of the Social Security Act, which was added by the Medicare Modernization Act (“MMA”), requires CMS to use a specified supplemental survey to determine the practice expense relative values or medical oncology. The statute describes that survey as one that was submitted to CMS as of January 1, 2003, covers practice expenses for oncology drug administration services, and meets the criteria established by CMS for acceptance of supplemental surveys. This provision describes the supplemental survey of oncologists’ practice expenses sponsored by ASCO and conducted by the Gallup Organization.

The statute specifies that data from the Gallup survey is to be used “[i]n establishing the physician fee schedule . . . with respect to payments for services furnished on or after January 1, 2004. . . .” Nothing in the statute permits CMS to cease using the Gallup survey data because the AMA has conducted a new survey. Indeed, the AMA PPIS has the same flaws that existed in the prior AMA survey, and Congress addressed this issue under the MMA. The small number of surveyed oncologists in the AMA survey from the 1990s was the major factor in triggering the need for the Gallup Organization’s supplemental survey for medical oncology.

CMS should not use the AMA PPIS data to revise the practice expense RVUs. If CMS nevertheless uses the AMA PPIS data, CMS is legally required to continue using data from the

Gallup Organization’s supplemental survey instead of data on oncologists’ practice expenses determined in the AMA PPIS. The Gallup Organization’s supplemental survey data would, of course, need to be updated to be consistent with the AMA PPIS data from later years. The AMA PPIS data indicate a greater increase in practice expenses than the Medicare Economic Index would have predicted. Accordingly, updating the Gallup Organization’s supplemental survey data by the increase in the MEI would appear to understate oncologists’ practice expenses, and a more appropriate measure should be used. CMS should update the Gallup Organization’s survey data by the MEI plus a percentage reflecting the additional average increase in expenses (in addition to the MEI) that are unique to these services.

Although CMS is legally bound to use the Gallup Organization’s survey data in 2010 and beyond, we recognize that CMS may have interest in developing a method for surveying the practice expenses for medical oncology in the future. As a result, ASCO is prepared to work with CMS and other policy makers in the future to explore ways to implement a new survey for medical oncology that replicates the response rates and accuracy of the Gallup survey.

In closing on this issue, we want to emphasize that there are compelling policy concerns that provide sufficient reasons for CMS to refrain from using the AMA PPIS data. These concerns, which are described above, include the significant adverse effects the proposed rule would likely have on Medicare beneficiaries with cancer. There are serious flaws in AMA PPIS, especially in the area of medical oncology.

Although we have referenced a “work around” in which CMS might use the AMA PPIS for other specialties and use the Gallup survey for oncology, simply substituting the Gallup Organization’s supplemental survey data for the oncology portion of the AMA PPIS is still a partially flawed approach. Because the sample sizes for virtually every specialty in the AMA PPIS were inadequate, the practice expenses for other specialties likely overstate their true practice expenses, resulting in decreased payments to oncologists and other specialties whose expenses are understated in the AMA PPIS. Consequently, CMS should not use the AMA PPIS at all and should develop an alternative, methodologically sound method for assigning practice expense RVUs to codes. ASCO would be pleased to work with CMS in such efforts.

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ASCO Opposes the Proposed Revisions to the Malpractice Relative Value Units

CMS is proposing to revise the malpractice RVUs assigned to codes based on new data and revisions to the methodology. The principal chemotherapy administration codes currently have malpractice relative values of 0.06 to 0.08, but under the proposal those relative values would decline to 0.01. ASCO opposes these changes.

As described in the July 13 notice, CMS assigns malpractice RVUs to particular CPT codes based on the number of physician work RVUs assigned to the code. The implicit assumption is that the degree of malpractice risk associated with any particular service correlates with the amount of physician work involved.

While that may be a useful general assumption, it results in insufficient malpractice RVUs being assigned to the chemotherapy administration codes. These codes have only a small physician work component, representing physician supervision of the procedures, but they obviously present a significant risk of malpractice liability to the physician if the services are not furnished correctly. In addition to potential problems at the site of administration, such as drug extravasation, cancer chemotherapy presents the risk of serious side effects and, in some cases, even anaphylaxis. The assignment of a de minimis .01 malpractice RVU to each chemotherapy administration service on the ground that very little physician work is recognized in the code fails to capture accurately the relative malpractice risk involved.

In the July 13 notice, CMS discusses the similar issue of codes, such as injections, that have no physician work value assigned (74 Fed. Reg. at 33542). CMS states that since injections are normally furnished by non-physician practitioners (NPPs), “it is appropriate for the malpractice RVUs assigned to [technical components] to be based on the malpractice costs of the NPP . . . not the professional liability of the physician.”¹

ASCO does not agree that the malpractice risk of procedures like injections that have no physician work value, or chemotherapy administration services that have a minimal physician work value, should ignore the professional liability of the physician. Physicians will be held responsible for malpractice in the delivery of chemotherapy drugs in their offices, and the payment amounts for those services should reflect that fact. CMS should adopt an appropriate proxy measure to fully account for the physician malpractice risk involved and to result in assignment of an appropriate level of malpractice RVUs to the drug administration codes.

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ASCO Supports Removing Physician-Administered Drugs from the SGR

CMS estimates that, under the sustainable growth rate (“SGR”) methodology in the Medicare statute, the conversion factor for 2010 will be reduced by 21.5% compared to 2009 unless Congress enacts overriding legislation. CMS also estimates reductions of 5% to 6.5% in the conversion factor for each of the several succeeding years under the current law and administrative policies.

CMS notes that it currently includes physician-administered drugs in the SGR methodology although it is not required to do so. In the notice, CMS proposes to exclude physician-administered drugs from the SGR methodology both prospectively and retroactively to the SGR’s base year. CMS states that this change would not reduce the projected 21.5% reduction in the conversion factor for 2010 but that it would reduce the number of subsequent years in which there would be reduction in the conversion factor.

ASCO strongly supports this proposed change in the SGR methodology. Many Part B drugs included in the calculation of the SGR are used in the treatment of cancer patients. Their inclusion in SGR’s target expenditures for all physician services is inappropriate because

¹ Drug injections and infusions in oncology offices are ordinarily administered by registered nurses, including oncology certified nurses, not NPPs (e.g., nurse practitioners and physician assistants).

physicians do not have control over the prices of drugs or, in general, which drugs are appropriately used for treatment of diseases such as cancer. Therefore, drugs should be removed from the SGR calculation both prospectively and retroactively.

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ASCO Opposes Eliminating Payment for the Consultation Codes

In the notice, CMS reviews the long-standing issue of when a consultation code can be billed, particularly in light of ambiguous language regarding transfer of care and the differences between the CPT guidance and Medicare policy. CMS is proposing to eliminate payment for all consultation codes (except telehealth consultation G-codes) effective January 1, 2010. The revision would be made in a budget-neutral manner by redistributing the relative value units from the consultation codes to the codes for new and established patient visits and initial hospital and initial nursing facility visits.

ASCO opposes this change. ASCO agrees that there is long-standing confusion about when it is appropriate to bill a consultation as opposed to a new patient visit, especially with respect to the issue of transfer of care. This confusion is, however, not a rationale for eliminating the consultation codes altogether. Instead, CMS should clarify them.

CMS also asserts in the July 13 notice that there is now little difference between a consultation and a new patient visit because the only difference is the requirement for a written report from the consultant to the referring physician, which CMS says is no longer a “major defining aspect of consultation services” because CMS has eased the level of formality for the report (74 Fed. Reg. at 33552-53). Although the documentation requirements have been reduced for consultations in hospital emergency departments and in settings that use a unified medical record, such as academic medical departments and large multi-specialty group practices, in the usual office setting Medicare still requires a consultation report in the form of a “separate document communicated to the requesting physician” (Medicare Claims Processing Manual, Ch. 12, § 30.6.10.F). Thus, in most cases, including most situations in which oncologists provide consultations, there is substantial additional work involved in a consultation compared to a new patient visit. ASCO opposes the effective elimination of payment for that additional work as proposed in the July 13 notice.

If CMS nevertheless eliminates payment for the consultation codes, ASCO strongly opposes the proposed redistribution of the relative value units in the office setting. As stated in a document posted on the CMS website, 50% of the RVUs for the outpatient consultation codes would be redistributed to new patient visits and 50% to established patient visits. No rationale is provided in the document for this reallocation.

We do not see any basis for redistributing 50% of the RVUs from the consultation codes to established patient visits. Generally, a physician would bill for a consultation only for a new patient. Since a patient is considered an established patient if the patient has received any professional service from a physician in the consultant’s group in the previous three years, there may be circumstances when a physician is asked to provide a consultation with respect to a patient who would be considered an established patient. But those situations are relatively rare,

and, ASCO believes, would be far less than 50% of all consultations. Reassigning 50% of the consultation code RVUs to established patient visits appears to disadvantage physicians who perform numerous consultations and to favor physicians who furnish few consultations. Any reallocation of RVUs from consultation to visit codes should be designed, to the extent feasible, to maintain the current level of RVUs billed by consulting physicians.

In the case of hospital admissions, CMS proposes that a new modifier would be created to identify the admitting physician. This change would permit both the admitting physician and a specialty physician to bill an initial hospital visit on the same day, which is not permitted under current Medicare policy. ASCO supports this proposal.

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ASCO Supports the Proposed Rules Concerning the Authorized Compendia and Coverage of Off-Label Uses

The Medicare statute requires that any compendium recognized by CMS as authoritative for purposes of Medicare coverage must have a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests, effective January 1, 2010. To implement the requirement for a publicly transparent process, CMS is proposing that the compendium must post the materials used in its evaluation process on its website.

CMS is also proposing that the compendia would be required to publish the names of the individuals who have substantively participated in the development of compendia recommendations, along with transcripts of meetings and records of votes. The compendia would need to have a process to disclose the financial and non-financial conflicts of individuals involved in making recommendations, as well as their immediate family members. CMS states that the four compendia have already adopted conflicts disclosure policies similar to its proposal.

ASCO supports these proposals. The compendia are very important for Medicare coverage of cancer treatments, and we support steps to make their procedures more transparent and free from conflicts of interest.

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Comments on the Proposals Regarding the Competitive Acquisition Program

CMS notes that the Competitive Acquisition Program for drugs (“CAP”) was put on hold for 2009 because of contractual issues with the bidders. In the notice, CMS is proposing various changes in the CAP.

In general, oncologists and other physicians have not found the CAP to be a useful method for obtaining drugs for their Medicare patients. One of CMS’s proposed changes has the potential to make the CAP more attractive, although the explanation in the notice is not sufficient to allow a full evaluation. CMS is proposing to allow physicians to maintain small quantities of the CAP vendor’s drugs on its premises. This would be permitted only if the physician uses an


electronic drug inventory management device. The CAP vendor would electronically authorize access to its drugs in response to a physician's order for a specific patient. ASCO believes that it is conceivable that a method of operating the CAP along these lines could eliminate much of the administrative burden associated with CAP participation, but, as noted, there is insufficient detail for us to evaluate the proposal.

CMS's proposed changes in the CAP do not address one of the major concerns that oncologists have with the CAP, namely the ability of the CAP vendor to cut off access to a patient's chemotherapy drugs mid-therapy if the patient does not pay the coinsurance in a timely manner. CMS needs to resolve this issue in order to remove one of the obstacles to greater use of the CAP.

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Thank you for the opportunity to submit comments on the proposal.

Sincerely,



Douglas W. Blayney, MD
ASCO President