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August 30, 2011

By Electronic Submission

Donald Berwick, M.D.
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-1524-P – Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012

Dear Administrator Berwick:

I am pleased to submit these comments of behalf of the American Society of Clinical Oncology (ASCO) in response to the recent notice of proposed rulemaking regarding the Medicare Physician Fee Schedule (MPFS) for Calendar Year (CY) 2012, (76 Federal Register 42772, July 19, 2011). ASCO is the national organization representing nearly 30,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis and prevention. Our members also are dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidenced-based practices for 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 CY 2012.

ASCO provides the following recommendations regarding the proposed rule:

- A. Performance Measures under the PQRS.** CMS should establish opportunities for physicians to voluntarily report a more expansive set of quality measures for oncology under the Physician Quality Reporting System (PQRS) by adopting new oncology measures groups reported 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 policy makers in finalizing such sets of quality measures and specifications for oncology.

- B. The Quality Oncology Practice Initiative.** CMS should adopt harmonized policies under the PQRS that facilitate provider participation in the Quality Oncology Practice Initiative (QOPI). This will optimize the significant added value that arises for patients and the Medicare program when oncology providers participate in QOPI – and can do so in a way that satisfies parallel reporting required by CMS and other payers.
- C. Flawed PPIS Data.** CMS should abandon use of the American Medical Association’s (AMA) Physician Practice Information Survey (PPIS), which distorts the relative value system for oncologists. The small sample sizes and lack of precision in the AMA PPIS data have likely overstated the expenses for other specialties, exacerbating longstanding problems that oncology practices face in recouping fair and adequate reimbursement for expenses incurred in providing patient care.
- D. PE and Work Code Review Process.** As part of the code review process, ASCO urges CMS to address the inadequate compensation of oncologists for various services. Furthermore, ASCO believes that the timeline CMS has proposed for E/M review is overly aggressive given the time and labor that would be required to support review of the affected codes. We support, however, efforts to ensure that E/M codes fully reflect the effort involved in treating patients with chronic conditions, including cancer.
- E. Payment Issues for Part B Drugs and Biologicals.** ASCO supports the agency’s continued use of caution with regard to substituting Average Manufacturer Price (AMP) for Average Sales Price (ASP). We are concerned that the application of the AMP substitution authority is likely to increase the number of situations in which physicians, particularly those in small practices, are unable to acquire Part B drugs for less than the Part B reimbursement amount.
- F. Changes to the Electronic Prescribing Incentive Program.** ASCO commends CMS for making a number of improvements under the proposed rule for the electronic prescribing (eRx) program; however, CMS should further promote the adoption of electronic prescribing by creating an opportunity for eligible professionals who are not successful electronic prescribers in a given reporting period to reclaim reimbursement by becoming successful electronic prescribers during the period to which a payment adjustment is applied.
- G. Aligning EHR and eRx Incentive Programs.** CMS should finalize its proposal to expand the definition of a “qualified electronic prescribing system” to include certified EHR technologies, but CMS should make additional changes to minimize the remaining administrative burdens that oncologists and other eligible professionals will otherwise incur under Medicare’s electronic prescribing program.

H. MPPR. The proposed expansion to the Multiple Procedure Payment Reduction (MPPR) policy would result in inadequate reimbursement for imaging procedures subject to the expanded policy. We urge CMS to refrain from finalizing the proposed expansion.

I. Sustainable Growth Rate. ASCO continues to be concerned about the lack of a permanent fix to the sustainable growth rate formula, and we urge CMS to work with Congress to develop a permanent solution to this continuing issue.

These recommendations are discussed in greater detail below.

A. Performance Measures under the PQRS. *CMS should establish opportunities for physicians to voluntarily report a more expansive set of quality measures for oncology under the Physician Quality Reporting System (PQRS) by adopting new oncology measures groups reported 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 policy makers in finalizing such sets of quality measures and specifications for oncology.*

Community-based oncology practices and 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 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 PQRS measures are extremely limited and do not reflect the scope of activity appropriate to the specialty.

ASCO strongly supports the addition of several performance measures in the proposed rule related to oncology. These measures are “Image Confirmation of Successful Excision of Image-Localized Breast Lesion,” “Radical Prostatectomy Pathology Reporting,” “Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients,” “Preoperative Diagnosis of Breast Cancer,” “Sentinel Lymph Node Biopsy for Invasive Breast Cancer,” “Biopsy Follow-up” and measures from the new radiology measures group. Even with the addition of these measures, however, the number of cancer-specific quality measures under PQRS remains inadequate.

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, the presence of 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 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 for this complex field of care. We can and should encourage oncology providers to participate in quality improvement activities that involve a meaningful number of cancer-specific quality measures. This could be accomplished by establishing the option for physicians to report under multiple new groups of cancer-focused measures through registries under the PQRS.

ASCO is uniquely positioned to assist policymakers in identifying and implementing additional evidence-based quality measures and measures groups 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. Currently, approximately 20 to 25 percent of community-based oncology practices already participate in QOPI.

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 PQRS, the Hospital OQR Program and the new program for PPS-exempt cancer hospitals.

B. The Quality Oncology Practice Initiative. CMS should adopt harmonized policies under the PQRS that facilitate provider participation in the Quality Oncology Practice Initiative (QOPI). This will optimize the significant added value that arises for patients and the Medicare program when oncology providers participate in QOPI – and can do so in a way that satisfies parallel reporting required by CMS and other payers.

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.

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.

C. Flawed PPIS Data. *CMS should abandon use of the American Medical Association's (AMA) Physician Practice Information Survey (PPIS), which distorts the relative value system for oncologists. The small sample sizes and lack of precision in the AMA PPIS data have likely overstated the expenses for other specialties, exacerbating longstanding problems that oncology practices face in recouping fair and adequate reimbursement for expenses incurred in providing patient care.*

We continue to strongly object to the use of the AMA's PPIS data and to phasing these data into the calculation of the practice expense (PE) relative value units (RVUs) under Medicare Part B. ASCO supports CMS' continued use of the Gallup data for calculating practice expenses for medical oncologists. However, we are concerned that use of the AMA PPIS data for other specialties distorts the relative value system for oncologists. We urge CMS to reverse its policy of using the AMA PPIS data for the calculation of PE RVUs under the Medicare Part B physician fee schedule.

As we have stated in the past, collecting data on multiple specialties simultaneously does not ensure the validity of the data if the sample sizes for the individual specialties are too small. Although the precision of the PEs per hour for all physicians generated by the AMA PPIS data may provide a reliable result, it is the PEs per hour for each individual specialty that are critical to assigning relative values to particular codes. The rationale that CMS used in accepting these data was far from clear. We strongly disagree with this approach.

Because of fundamental statistical shortcomings in the data from the AMA PPIS, the data from this survey should not be used to establish PE values. We urge CMS to reverse its policy initiated in CY 2010 of using the AMA PPIS data to establish PE relative values for medical specialties under the Medicare physician fee schedule.

D. PE and Work Code Review Process. *As part of the code review process, ASCO urges CMS to address the inadequate compensation of oncologists for various services. Furthermore, ASCO believes that the timeline CMS has proposed for E/M review is overly aggressive given the time and labor that would be required to support review of the affected codes. We support, however, efforts to ensure that E/M codes fully reflect the effort involved in treating patients with chronic conditions, including cancer.*

Oncologists are undercompensated for their cognitive work, care coordination and treatment planning under the current Medicare physician fee schedule. We urge CMS to address these inadequacies as part of the overarching efforts by CMS to review the practice expense (PE) and work relative value units (RVUs) assigned to specific codes. As discussed elsewhere in these comments, the provision of oncology care is unique in many ways, and the cognitive work, care coordination and treatment planning services provided in oncology warrant new, distinct codes.

CMS has identified a code for further review that is commonly used in the treatment of individuals with cancer – HCPCS code 96413 (*Chemo, IV Infusion, 1 Hr*). This code currently is undervalued. We ask that CMS work with ASCO and other stakeholders to make fair and adequate increases to the RVUs assigned to this code.

In addition, ASCO is concerned about the timeframe that CMS has proposed for review of the E/M codes. We appreciate that CMS has proposed that only half of the E/M codes, listed in Table 6 of the proposed rule, need to be reviewed by July of 2012. However, review and survey of these E/M codes would be tremendously labor and time intensive. In addition, we note that many of the codes were quite recently reviewed. Performing another review with a similar methodology, given the constraints of the RBRVS system, is unlikely to produce any significant changes in RVUs.

However, ASCO would be supportive of any review process that would revalue E/M codes in such a way that the new values would reflect the work that is necessary to provide care coordination and management of Medicare beneficiaries with cancer. Therefore, ASCO would support a review of the E/M codes that would take into consideration and attempt to reflect all of the important services that oncologists provide to their patients.

E. Payment issues for Part B Drugs and Biologicals. ASCO supports CMS' continued caution with regard to substituting Average Manufacturer Price (AMP) for Average Sales Price (ASP). We are concerned that the application of the AMP substitution authority is likely to increase the number of situations in which physicians, particularly those in small practices, are unable to acquire Part B drugs for less than the Part B reimbursement amount.

The Medicare Modernization Act (MMA) provided CMS with the authority to substitute 103 percent of AMP for 106 percent of ASP in situations where ASP exceeded AMP by a discretionary threshold (which the agency has maintained at 5 percent). CMS has thus far declined to exercise this authority, and we support CMS' caution in implementing this policy.

Differences between AMP and ASP can be based on temporary market fluctuations, and such fluctuations may not be reflected in the marketplaces applicable to all physician practices. ASCO continues to be concerned about this policy and any other policy that could expand the number of situations in which Medicare reimbursement for Part B drugs is not sufficient to cover physician acquisition cost. As we have noted in the past, many physician practices are unable to purchase a number of oncology drugs at 106 percent of ASP, so any policy that further lowers the payment levels for oncology drugs risks triggering further exacerbations to the access issues faced by Medicare beneficiaries seeking to obtain chemotherapy.

In addition, we urge CMS to delay implementation of any price substitutions until recent changes to AMP are fully implemented and the potential impacts on access to cancer drugs can be studied and understood. The statutory changes to AMP have not been fully implemented, and AMP information has not yet been released to the public. Therefore, the impact these changes will have, particularly in the event that price substitutions are implemented in Part B, cannot be known. ASCO continues to believe that it would be premature for CMS to implement price substitutions based on AMP.¹

F. Changes to the Electronic Prescribing Incentive Program. ASCO commends CMS for making a number of improvements under the proposed rule for the electronic prescribing (eRx) program; however, CMS should further promote the adoption of electronic prescribing by creating an opportunity for eligible professionals who are not successful electronic prescribers in a given reporting period to reclaim reimbursement by becoming successful electronic prescribers during the period to which a payment adjustment is applied.

ASCO supports a number of changes CMS proposes to make to the electronic prescribing incentive program. In particular, we support CMS' proposal that, for purposes of avoiding the CY 2013 and CY 2014 payment adjustments, eligible professionals would be able to report the electronic prescribing measure's numerator for any Medicare Part B service under the physician

¹ In addition, as the agency acknowledges, up-to-date Widely Available Market Price (WAMP) information is similarly not available. Therefore, implementation of price substitution based on WAMP would be similarly inappropriate.

fee schedule provided during a reporting period, regardless of whether the code for such service appears in the measure's denominator. This revision recognizes the important fact that some oncologists and other eligible professionals may generate prescriptions during encounters that are not included in the measure's denominator.

We also would like to highlight our support for CMS' proposal to continue permitting eligible professionals to use registries and EHR technology for reporting on their use of qualified electronic prescribing systems. Retaining these reporting options will provide important flexibility for eligible professionals while promoting these useful technologies.

Finally, while we support CMS' proposal of adding 6-month reporting periods for avoiding the CY 2013 and CY 2014 payment adjustments, the proposed reporting periods remain insufficient. Just as CMS has done for many years with regard to incentive payments, we urge CMS to enable oncologists and other eligible professionals to avoid payment adjustments based on reasonably contemporaneous data. CMS could opt to begin by applying the payment adjustment to all eligible professionals who do not become successful electronic prescribers during prior applicable reporting periods and who do not qualify for hardship exemptions. Then, at the end of the year to which an adjustment is applied, CMS could refund the monies deducted from claims to those eligible professionals who became successful electronic prescribers during the year in question. It would be fair and simple for CMS to distribute these refunds by using the system CMS has established for awarding eRx bonus payments. More importantly, such a revision would encourage the broadest possible participation in the electronic prescribing program. We urge CMS to make this important refinement.

G. Aligning EHR and eRx Incentive Programs. *CMS should finalize its proposal to expand the definition of a "qualified electronic prescribing system" to include certified EHR technologies, but CMS should make additional changes to minimize the remaining administrative burdens that oncologists and other eligible professionals will otherwise incur under Medicare's electronic prescribing program.*

We wish to commend CMS for its efforts under this proposed rule to promote the use of electronic prescribing and to lessen the administrative burdens for oncologists and other health care professionals who adopt electronic prescribing. Aligning the electronic prescribing program and electronic health record (EHR) program requirements is an important step toward reducing wasteful spending and duplicative work. ASCO therefore strongly supports CMS' proposal to expand the definition of a "qualified electronic prescribing system" in the electronic prescribing measure to include certified EHR technology for reporting periods in CY 2012 and CY 2013.

We do not wish to disregard the importance of the positive changes proposed by CMS. Nonetheless, in addition to aligning the definition of qualified technology under the EHR and electronic prescribing programs, CMS should also align the reporting processes for these programs. This is necessary to remove unnecessary administrative burdens from oncologists and other eligible professionals.

To achieve meaningful use under the EHR incentive program, eligible professionals must demonstrate that “more than 40 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.”² In almost all circumstances, meeting this requirement under the EHR program involves a higher rate of electronic prescribing than is required by the eRx program. Therefore, CMS should not subject any eligible professional who demonstrates meaningful use under the EHR incentive program to the eRx payment adjustment. Once an eligible professional has demonstrated meaningful use under the EHR incentive program, he or she should not have to use any additional reporting mechanism, submit any additional code or satisfy any additional measure in order to avoid the eRx payment adjustment.

H. MPPR Expansion. *The proposed expansion to the Multiple Procedure Payment Reduction (MPPR) policy would result in inadequate reimbursement for imaging procedures subject to the expanded policy. We urge CMS to refrain from finalizing the proposed expansion.*

CMS has proposed to expand the 50% MPPR policy currently applied to the technical component (TC) of advanced imaging services to the professional component (PC) of these same imaging services. The advanced imaging services that will be subject to the MPPR PC policy include computer tomography (CT), magnetic resonance imaging (MRI), and ultrasound (US).

ASCO objects to the implementation of this policy. We do not agree with CMS’s justification that there are “expected efficiencies in furnishing multiple services in the same session due to duplication of physician work—primarily in the pre- and post-service periods, with smaller efficiencies in the intra-service period.”³ There may be efficiencies within modalities or across contiguous body areas, but any such efficiencies would be lost when performing imaging services across modalities or across non-contiguous body parts. We also note that in 2011, CMS expanded the MPPR policy to apply to imaging services regardless of imaging family and regardless of the contiguous body region. In doing so, CMS has already cut the payments for these imaging services. Further cuts may reduce patient access to care.

CMS currently applies the MPPR to the TC of advanced imaging services, defined for this purpose by CMS as CT, MRI and US. The TC portion of payment (including the TC portion of a global code) is reduced by 50% for the second and subsequent services performed in the same session. To justify the proposal to expand this policy to the PC portion of services, CMS cited the provisions of section 3134(a) of the Affordable Care Act (ACA), granting CMS the authority to “identify, review, and adjust the relative values of potential misvalued services under the Physician Fee Schedule.”⁴ However, the agency has not provided sufficient data in support of its proposed expansion of the MPPR.

CMS also indicated that further expansion of the MPPR to all imaging services and diagnostic tests is under consideration for sometime in the future. Further payment cuts to these valuable

² 42 CFR 495.6(d)(4)

³ Federal Register, Vol. 76, No. 138. Tuesday, July 19, 2011, pg. 42812.

⁴ Federal Register, Vol. 76, No. 138. Tuesday, July 19, 2011, pg. 42812.

services could potentially reduce beneficiary access to care, and we urge extreme caution if CMS considers further expansion of the MPPR.

Based on these concerns, ASCO urges CMS to abandon its proposed expansion of the MPPR, especially in the absence of adequate data in support of such significant cuts to payments for imaging services.

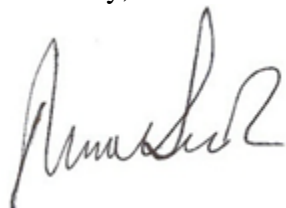
I. Sustainable Growth Rate. *ASCO continues to be concerned about the lack of a permanent fix to the sustainable growth rate formula, and we urge CMS to work with Congress to develop a permanent solution to this continuing issue.*

As payment cuts continue to loom over physicians, we are deeply concerned that an increasing number of physicians will feel forced into opting out of participation in the Medicare program. This would have a significant adverse impact on access to health care services for Medicare beneficiaries. We urge CMS to work with Congress to develop and implement a permanent solution to the SGR problem that will maintain payment rates for physicians and provide stability to the Medicare program.

* * * *

Thank you for the opportunity to submit comments 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, or quality improvement programs in oncology. Please contact Karen Hagerty, M.D. at 571.483.1614 or 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 "L".

Michael P. Link, MD
ASCO President