



March 4, 2011

Deondra Moseley
Centers for Medicare & Medicaid Services
7500 Security Boulevard
C1-13-07
Baltimore, Maryland 21244

Submitted Electronically to AdvanceNotice2012@cms.hhs.gov

Re: Advance Notice/Call Letter for Medicare Advantage Plans for Calendar Year (CY) 2012

Dear Ms. Moseley:

The American Society of Clinical Oncology (ASCO), the Association of American Cancer Institutes (AACI), the Association of Community Cancer Centers (ACCC), the National Comprehensive Cancer Network (NCCN) and the Oncology Nursing Society (ONS) are pleased to provide comments on the 2012 Advance Notice and Call Letter that the Centers for Medicare & Medicaid Services (CMS) has recently released. ASCO, AACI, ACCC, NCCN and ONS are five of the world's leading professional and scientific organizations representing oncology care professionals. ASCO represents nearly 30,000 physicians and health care professionals involved in cancer clinical care and research from all oncology disciplines and subspecialties. AACI comprises 95 leading cancer research centers in the U.S., including National Cancer Institute (NCI)-designated centers and academic-based cancer research programs that receive NCI support. ACCC affiliates with nearly 17,000 cancer care professionals from approximately 900 hospitals and more than 1,200 private practices. NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers. ONS is a professional organization of over 35,000 registered nurses and other healthcare providers dedicated to oncology nursing.

In the 2011 Advance Notice, CMS addressed a long-standing inequity in the Clinical Trial Policy for Medicare Advantage (MA) enrollees. 2011 MA plans are required to reimburse enrollees for the difference between fee-for-service cost sharing incurred for clinical trial items and services and the MA plan's in-network cost sharing for the same category of service. This change is very important, however, it places a significant burden on MA enrollees to provide paperwork to document their out-of-pocket costs associated with their trial participation. For example, in the experience of the Ohio State University – James Cancer Hospital and Solove Research Institute, twenty-one percent of the patients who declined going on a trial did so because of the financial concerns associated with MA plan benefit.

We urge CMS to revisit this issue in the final 2012 plan document by requiring MA plans to directly cover the routine costs associated with clinical trial participation. The Clinical Trial Policy has been in place for over a decade, and MA plans should be required to provide coverage for clinical trial services in the same way as other Medicare-covered services. It was understandable that CMS would provide fee-for-service coverage when the policy went into effect in September 2000 because it was implemented in the midst of an existing contract year. However, it is not clear why CMS has not subsequently required plans to comply with the policy. Several studies have demonstrated that the routine costs incurred from participation on clinical trials are not significantly greater than receiving standard care. If CMS believes that adjustments to MA plan payment rates are necessary, a decade of experience under the Clinical Trial Policy should provide sufficient claims data to demonstrate any difference in costs.

Many Medicare beneficiaries, especially those with limited resources, enroll in MA plans because of the lower out-of-pocket spending and additional services provided. While the 2011 plan requirements ensure that trial participants will be reimbursed for the higher out-of-pocket costs of fee-for-service coverage, they place a financial burden on the MA enrollee to cover the costs upfront and to provide documentation to the MA plan of costs incurred. CMS commented in the 2011 plan document that “MA enrollee participation in and access to clinical trial services outweighs the plans’ concern for heightened administrative burden.” We could not agree more and hope that CMS would address the burden it is placing on MA enrollees by requiring MA plans to cover clinical trials costs directly.

For many types of cancers, existing therapies approved by the Food and Drug Administration (FDA) are not sufficient, meaning that clinical trials may offer the best hope for treatment for many cancer patients. In addition, improved participation on clinical trials – particularly among the Medicare-eligible population – leads to a stronger evidence base on the comparative effectiveness of various therapies. It also provides Medicare with the information it requires to determine the effectiveness of therapies in the Medicare-eligible population.

This issue is of particular concern to ASCO, AACI, ACCC, NCCN and ONS because of our eagerness to ensure participation of under-served populations on clinical trials. The elderly and those with lower incomes are notoriously under-represented on clinical trials. When having discussions with these patients about participating on a clinical trial, they are very concerned about the impact that participation will have on their insurance coverage. While the 2011 policy helps us ensure MA enrollees that they will not experience higher out-of-pocket costs, it nonetheless requires a lot of explanation about why they are reverting to fee-for-service coverage and what type of documentation they will have to provide. All of this comes at a time when cancer patients are making difficult decisions and should not be burdened by additional administrative and paperwork hassles.

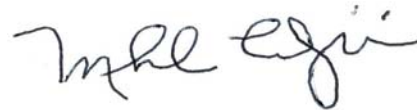
Because of these concerns, ASCO, AACI, ACCC, NCCN and ONS urge CMS to change its policy and require MA plans to provide coverage for clinical trials in the same way as other Medicare-covered benefits. As CMS noted in the final 2011 plan document “Clinical trial services are covered under FFS Medicare and MAOs must cover all Medicare services as in-network services – see section 1852(a)(1)(A) of the Social Security Act.” With this recognition, it is difficult to understand the justification for Medicare continuing to require MA enrollees to revert to fee-for-service coverage when they enroll on a clinical trial. We would be happy to work with CMS on behalf of providers to help ensure smooth implementation and address any concerns that plans may have. We strongly believe that MA enrollees should be taken out of the middle of this process.

Thank you for your attention to this important issue.

Sincerely,



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