

March 1, 2013

Marilyn Tavenner, RN, BSN, MHA
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Submitted Electronically to AdvanceNotice2014@cms.hhs.gov

Re: Advance Notice/Call Letter for Medicare Advantage Plans for Calendar Year (CY) 2014

Dear Acting Administrator Tavenner:

The American Association for Cancer Research (AACR), American Society of Clinical Oncology (ASCO), the Association of American Cancer Institutes (AACI), the Association of Community Cancer Centers (ACCC), the National Coalition for Cancer Research (NCCR), the National Coalition for Cancer Survivorship (NCCS), National Comprehensive Cancer Network (NCCN), the Oncology Nursing Society (ONS), the Ovarian Cancer National Alliance (OCNA), and the Susan G. Komen for the Cure® are pleased to provide comments on the 2014 Advance Notice and Call Letter that the Centers for Medicare & Medicaid Services (CMS) has recently released. AACR, ASCO, AACI, ACCC, Komen, NCCR, NCCS, NCCN, OCNA, and ONS are among the world's leading organizations representing cancer patients and oncology care and research professionals. Information on our organizations is listed on the final page of our letter.

We urge CMS to correct a long-standing inequity in Medicare coverage by requiring in the final 2014 plan document that Medicare Advantage (MA) plans provide coverage for cancer clinical trials. As the policy currently stands, individuals in MA plans are required to relinquish their MA coverage and revert to standard fee-for-service (FFS) Medicare if they wish to participate in a clinical trial. Providing coverage as part of MA plans – which typically have lower copayments and out-of-pocket costs – rather than Medicare “paying on a fee-for-service basis” is important to the participants who enroll in these plans. MA enrollees typically chose these plans because they involve lower costs than FFS coverage and provide more comprehensive coverage. Cancer and other serious and life-threatening diseases have tremendous potential to result in high-cost health care services.

Our organizations are concerned that reverting to FFS coverage in order to participate in a clinical trial is confusing for MA enrollees and will likely result in a cost-differential – when comparing FFS and MA out-of-pocket costs. Most MA plans have lower cost-sharing for Medicare-covered services. Therefore, the out-of-pocket costs of participating in a clinical trial through FFS will likely be more than if the MA enrollee were participating on the trial through their MA coverage. MA enrollees, while participating in a clinical trial under the FFS reimbursement, are required to cover all deductibles, copays, and the 20% coinsurance for all charges associated with clinical trial care. CMS seemed to acknowledge this in its 2011 call letter when it stated that “MA organizations are responsible for reducing cost sharing for

clinical trials to the amount that their MA plan members would have for similar services provided by in-network providers.”

If over a decade of experience with the clinical trial National Coverage Decision is insufficient to “make statistically valid adjustments to MA capitation rates” (as CMS noted in the final 2012 call letter), our organizations are eager to help remedy this. Studies have demonstrated that the routine costs incurred from participation on clinical trials are not significantly greater than receiving standard care. We would be happy to work with CMS to gather the necessary data to change its policy. Perhaps we could do this through facilitating an analysis with the National Cancer Institute (NCI), which enrolls thousands of people on clinical trials each year at sites throughout the country through the Cooperative Groups, and now the National Clinical Trials Network (NCTN).

Without the cost-saving potential of MA coverage, the current policy could not only discourage MA enrollees from choosing clinical trials but also exacerbate health care disparities. This issue is of particular concern to us because of our eagerness to ensure participation of under-served populations on clinical trials, an issue that is also important to the National Institutes of Health and NCI. 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 and costs.

When CMS released the final 2012 MA call letter, it compared cost-sharing for MA enrollees with cost-sharing for Medigap enrollees. The comparison would have been more accurate if it compared MA and FFS out-of-pocket spending because this is the situation in which the current policy places MA enrollees. MA enrollees would likely have lower cost sharing if their MA plan, rather than FFS Medicare, covered their clinical trial. While MA plans are not required to have lower out-of-pocket costs, they typically do.

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, an initiative of the ACA. It also provides Medicare with the information it requires to determine the effectiveness of therapies in the Medicare-eligible population.

If CMS decides to continue its policy of requiring MA beneficiaries to relinquish their MA coverage and revert to a FFS Medicare plan, we would encourage the agency to include in the final call letter the language from the 2011 call letter that specifies that “MA organizations are responsible for reducing cost sharing for clinical trials to the amount that their MA plan members would have for similar services provided by in-network providers.” This language is not included in the draft 2014 call letter. CMS could also require that MA plans notify their enrollees that this assistance is available as part of the notice that the enrollee has to revert to FFS coverage for the clinical trial.

We would be happy to work with CMS to help ensure smooth implementation and address any concerns that plans may have. We strongly believe that MA enrollees should be given clear coverage for clinical trial services – the same as other Medicare-covered services – through their MA plan.

Thank you for your attention to this important issue. If you have any questions, please contact Suanna Bruinooge, Director of Research Policy for ASCO at suanna.bruinooge@asco.org.

Sincerely,

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American Association for Cancer Research (AACR)

The AACR, representing 34,000 laboratory, translational, and clinical researchers; other health care professionals; and cancer survivors and patient advocates, is the world's oldest and largest scientific organization focused on every aspect of high-quality, innovative cancer research.

American Society of Clinical Oncology (ASCO)

ASCO is the world's leading professional organization representing physicians who care for people with cancer. With more than 30,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. In addition, ASCO promotes and provides for lifelong learning for oncology professionals; cancer research; an improved environment for oncology practice; access to quality cancer care; a global network of oncology expertise; and educated and informed cancer patients.

Association of American Cancer Institutes (AACI)

The Association of American Cancer Institutes comprises 95 leading cancer research centers in the United States. AACI's membership roster includes National Cancer Institute-designated centers and academic-based cancer research programs that receive NCI support.

Association of Community Cancer Centers (ACCC)

The Association of Community Cancer Centers (ACCC) promotes the entire continuum of quality cancer care for our patients and our communities. Since 1974, ACCC has been helping oncology professionals adapt to the complex changes of delivering quality cancer care while responding to regulatory and legislative changes. ACCC's core purpose is to be the leading education and advocacy organization for the cancer team. Nearly 19,000 cancer care professionals from approximately 900 hospitals and more than 1,200 private practices are affiliated with ACCC.

National Coalition for Cancer Research (NCCR)

The National Coalition for Cancer Research (NCCR) is comprised of 23 nonprofit national cancer organizations. Its membership includes cancer researchers; nurses and physicians; cancer centers and specialized research institutions representing cancer patients, survivors and their families. The mission of NCCR is to transform public policy to enable every individual to participate in, and benefit from, cancer research.

National Coalition for Cancer Survivorship (NCCS)

The National Coalition for Cancer Survivorship (NCCS) is a 26-year-old cancer advocacy organization dedicated to assuring quality cancer care to all from the time of diagnosis through treatment and post-treatment survivorship. NCCS relies on the available scientific evidence, informed by patient experience, to improve the quality of cancer care, reform the cancer care delivery and payment systems, and enhance patient involvement in treatment decision-making.

National Comprehensive Cancer Network (NCCN)

NCCN is a not-for-profit alliance of 21 of the world's leading cancer centers. The primary goal of all NCCN initiatives is to improve the quality, effectiveness, and efficiency of oncology practice so patients can live better lives.

Oncology Nursing Society (ONS)

The Oncology Nursing Society (ONS) is a professional organization of over 35,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing.

Ovarian Cancer National Alliance

The Ovarian Cancer National Alliance is the foremost advocate for women with ovarian cancer in the United States. To advance the interests of women with ovarian cancer, the organization advocates at a national level for increases in research funding for the development of an early detection test, improved health care practices, and life-saving treatment protocols. The Ovarian Cancer National Alliance educates health care professionals and raises public awareness of the risks and symptoms of ovarian cancer. The Ovarian Cancer National Alliance is a 501 (c) (3) organization established in 1997.

Susan G. Komen for the Cure®

Susan G. Komen for the Cure®, launched in 1982, is the boldest community fueling the best science and making the biggest impact in the fight against breast cancer. Komen has invested more than \$2.2 billion to fulfill our promise, working to end breast cancer in the U.S. and throughout the world through ground-breaking research, community health outreach, advocacy and programs in more than 30 countries.