

March 7, 2014

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

Submitted Electronically to AdvanceNotice2015@cms.hhs.gov

Re: Advance Notice/Call Letter for Medicare Advantage Plans for Calendar Year (CY) 2015

Dear Administrator Tavenner:

The Alzheimer's Foundation of America (AFA), American Academy of Neurology® (AAN), American Association for Cancer Research (AACR), American Brain Coalition (ABC), the American Cancer Society Cancer Action Network (ACS CAN), American College of Cardiology (ACC), the American Heart Association/American Stroke Association (AHA/ASA), American Society of Clinical Oncology (ASCO), the Association of American Cancer Institutes (AACI), the Association of Community Cancer Centers (ACCC), the Brain Injury Association of America (BIAA), the National Coalition for Cancer Research (NCCR), the National Coalition for Cancer Survivorship (NCCS), National Comprehensive Cancer Network (NCCN), the National Multiple Sclerosis Society (NMSS), the National Stroke Association (NSA), the Oncology Nursing Society (ONS), the Ovarian Cancer National Alliance (OCNA), the Parkinson's Action Network (PAN), and Susan G. Komen® (Komen) are pleased to provide comments on the 2015 Advance Notice and Call Letter that the Centers for Medicare & Medicaid Services (CMS) has recently released. AFA, AAN, AACR, ABC, ACS CAN, ACC, AHA/ASA, ASCO, AACI, ACCC, BIAA, Komen, NCCR, NCCS, NCCN, NMSS, NSA, OCNA, PAN, and ONS are among the world's leading organizations representing people impacted by serious or life-threatening diseases and specialty providers 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 2015 call letter that Medicare Advantage (MA) plans provide coverage for 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. Treatments for serious or life-threatening diseases can be very costly for the patients involved, regardless of whether the patient participates in a clinical trial. Preserving MA plan coverage is very important.

Our organizations are concerned with the requirement that MA enrollees revert to FFS coverage to participate in a clinical trial. The policy is confusing, may deter MA enrollees from participating in clinical trials, and will likely result in a cost-differential for MA enrollees – when comparing FFS and MA out-of-pocket costs. Most MA plans have lower cost-sharing for Medicare-covered services, and MA enrollees

often do not have supplemental coverage. 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 remedy this. Studies have demonstrated that the routine costs incurred from participation in 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 Institutes of Health (NIH), which enrolls thousands of people on clinical trials each year at sites throughout the country, including the cancer cooperative groups, and now the National Cancer Institute’s (NCI) 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 access and participation of under-served populations in clinical trials, an issue that is also important to the NIH, NCI and the Food and Drug Administration (FDA). 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. Congress recently indicated its views on the importance of ensuring appropriate representation of under-served populations in clinical trials as part of the FDA Safety and Improvement Act of 2012 (FDASIA). FDASIA explicitly requires the FDA to develop a plan to improve its efforts at communicating available clinical trial data on subpopulations in order to improve the quality of care provided to individuals from such groups. If such individuals are discouraged from participating in clinical trials for cost reasons, there will be little to no data available upon therapy approval, making it more difficult for physicians to appropriately assess the therapeutic value of new drugs and devices once they are available.

For many serious or life-threatening diseases, 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 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.

We sincerely hope that CMS will change its policy in the final 2015 call letter to require that MA plans cover the cost of clinical trials. This would be the most efficient and effective way to accomplish the important goal of increasing the participation of Medicare beneficiaries in clinical trials.

If CMS decides to continue its policy in 2015 of requiring MA beneficiaries to relinquish their MA coverage and revert to a FFS Medicare plan, we urge the Agency to adopt the recommendations described above as soon as possible.

In the interim, the Agency should include the following requirements within the final 2015 call letter:

- 1. Promote Transparency by Requiring MA Plans to Notify Enrollees and Providers of Cost-Sharing Assistance** – The Medicare Managed Care Manual notes that “MA plans pay the enrollee the difference between Original Medicare cost-sharing incurred for qualified clinical trial items and services and the MA plan’s in-network cost-sharing for the same category of items and services. This cost-sharing reduction requirement applies to all qualifying clinical trials. MAOs cannot choose the clinical trials or clinical trial items and services to which this policy applies. The MAO owes this difference even if the member has not yet paid the clinical trial provider. Additionally, the member’s in-network cost-sharing portion must also be included in the plan’s out-of-pocket maximum calculation.”

We appreciate that this provides clarity to the MA plan about its obligations. There is currently no requirement, however, that the MA plan provide notice to enrollees and providers about this requirement. Under the current scenario, a patient or provider could submit a claim to the MA plan, be notified that the claim must be submitted to the Medicare contractor, and not be told that the MA plan is required to provide cost-sharing assistance. Greater transparency in the form of meaningful notification – including what information the enrollee or provider should provide to document the patient’s cost sharing responsibility – will help ensure that enrollees can make informed decisions about whether to participate in clinical trials and receive the full Medicare benefits that should be provided through their MA plan.

- 2. Promote Transparency by Requiring Medicare Contractor Notification of Cost-Sharing Assistance** – Medicare contractors should also provide notice to all MA enrollees, or providers who submit claims on their behalf, that the MA plan is required to cover the difference in cost sharing for clinical trials. This will again ensure full notification to enrollees and providers and clarify the documentation that should be provided.

Without the requirement that MA plans and Medicare contractors notify Medicare participants and providers of this assistance, enrollees may not be aware that they are eligible to receive payment from the MA plan for the difference in cost-sharing and therefore may be left with excess costs.

- 3. Promote Transparency by Clarifying the Medicare Clinical Trials Brochure** – We urge CMS to update its own “Medicare and Clinical Research Studies” brochure (www.medicare.gov/Pubs/pdf/02226.pdf) to clarify that MA enrollees are eligible to receive “the difference between Original Medicare cost-sharing and the MA plan’s in-network cost-sharing for the same category of items and services” (as is stated in the Medicare Managed Care Manual). While the brochure mentions that MA plans cannot “keep you from joining a clinical research study,” it should also inform Medicare beneficiaries that the MA plan is required to provide cost-sharing assistance.

- 4. Minimize Administrative Burdens by Requiring MA Plans and Medicare Contractors to Streamline Process and Timeline for Obtaining Cost-Sharing Assistance** – We urge CMS to require both MA Plans and Medicare Contractors to streamline the administrative steps and timeline for MA enrollees to obtain cost-sharing assistance for clinical trials. The system of moving MA enrollees to traditional Medicare and requiring MA plans to reimburse part of the patient’s out-of-pocket costs is confusing and difficult to describe. The Agency should take every precaution to ensure that administrative burdens on Medicare patients are eliminated or at least minimized. In many instances, clinical trials provide individual patients with the best clinical alternative, and needless administrative burdens should not interfere with patient access to such therapies. Ultimately, the best and simplest way to streamline the process is to require that the MA plan provide direct coverage for the clinical trial – without the enrollees reverting to traditional Medicare.

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,

Alzheimer's Foundation of America
 American Academy of Neurology®
 American Association for Cancer Research
 American Brain Coalition
 American Cancer Society Cancer Action Network
 American College of Cardiology
 American Heart Association/American Stroke Association
 American Society of Clinical Oncology
 Association of American Cancer Institutes
 Association of Community Cancer Centers
 Brain Injury Association of America
 National Coalition for Cancer Research
 National Coalition for Cancer Survivorship
 National Comprehensive Cancer Network
 National Multiple Sclerosis Society
 National Stroke Association
 Oncology Nursing Society
 Ovarian Cancer National Alliance
 Parkinson’s Action Network
 Susan G. Komen®

Alzheimer's Foundation of America

The Alzheimer's Foundation of America is a national nonprofit organization that unites more than 1,600 member organizations nationwide with the goal of providing optimal care and services to individuals confronting dementia, and to their caregivers and families. Its services include a toll-free hot line staffed by licensed social workers, educational materials, a free quarterly magazine for caregivers, and professional training.

American Academy of Neurology®

The American Academy of Neurology (AAN) is the premier national medical specialty society for neurology representing more than 26,000 neurologists and clinical neuroscience professionals, and is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system such as multiple sclerosis, Alzheimer's disease, stroke, Parkinson's disease, epilepsy, migraine and brain injury.

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 Brain Coalition (ABC)

The American Brain Coalition is a non-profit organization comprised of over 85 of the United States' leading professional neurological, psychological, and psychiatric associations and patient organizations. Together, ABC seeks to advance the understanding of the functions of the brain, and to reduce the burden of brain disorders through public advocacy.

American Cancer Society Cancer Action Network (ACS CAN)

The American Cancer Society Cancer Action Network (ACS CAN), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

American College of Cardiology (ACC)

The College is a 47,000 member nonprofit medical society comprised of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care.

American Heart Association/American Stroke Association (AHA/ASA)

The AHA is the nation's oldest and largest voluntary health organization dedicated to fighting heart disease and stroke. Our mission is to build healthier lives by preventing, treating and defeating these diseases – two of America's leading killers. We fund cutting-edge research, conduct lifesaving public and professional educational programs and advocate to protect public health. To learn more or join us in helping all Americans, call 1-800-AHA-USA1 or visit www.heart.org.

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 (AACI) 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. The Association is dedicated to reducing the burden of cancer by enhancing the impact of the nation's leading academic cancer centers.

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.

Brain Injury Association of America (BIAA)

The Brain Injury Association of America (BIAA) is the country's oldest and largest nationwide brain injury advocacy organization, founded in 1980 by individuals and family who wanted to improve the quality of life for their family members and patients who had sustained brain injuries. The mission is to advance brain injury prevention, research, treatment and education and to improve the quality of life for all people affected by brain injury. The Association is dedicated to increasing access to quality health care and raising awareness and understanding of brain injury. With a network of state affiliates, local chapters and support groups, BIAA is the voice of brain injury.

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 cancer patient advocacy organization dedicated to assuring quality cancer care for 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.

AFA, AAN, AACR, ABC, ACS CAN, ACC, AHA/ASA, ASCO, AACI, ACCC, BIAA, Komen, NCCR, NCCS, NCCN, NMSS, NSA, OCNA, ONS, PAN Comments 2015 Draft Advance Notice/Call Letter

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.

National Multiple Sclerosis Society

The National MS Society is a collective of passionate individuals who want to do something about MS now—to move together toward a world free of multiple sclerosis. The Society helps each person address the challenges of living with MS through its 50-state network of chapters. The Society funds cutting-edge research, drives change through advocacy, facilitates professional education, and provides programs and services that help people with MS and their families move their lives forward.

National Stroke Association (NSA)

National Stroke Association's mission is to reduce the incidence and impact of stroke by developing compelling education and programs focused on prevention, treatment, rehabilitation and support for all impacted by stroke.

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.

Parkinson's Action Network (PAN)

The Parkinson's Action Network (PAN) is the unified voice of the Parkinson's community advocating for better treatments and a cure. In partnership with other Parkinson's organizations and its powerful grassroots network, PAN educates the public and government leaders on better policies for research and an improved quality of life for people living with Parkinson's.

Susan G. Komen®

Susan G. Komen is the world's largest breast cancer organization, funding more breast cancer research than any other nonprofit while providing real-time help to those facing the disease. Since its founding in 1982, Komen has funded more than \$800 million in research and provided \$1.7 billion in funding to screening, education, treatment and psychosocial support programs serving millions of people in more than 30 countries worldwide. Komen was founded by Nancy G. Brinker, who promised her sister, Susan G. Komen, that she would end the disease that claimed Suzy's life. Visit komen.org or call 1-877 GO KOMEN. Connect with us on [Facebook](#) and [Twitter](#).