Title: **Coverage of Routine Costs in Clinical Trials by Medicare Advantage Organizations**

Sponsors: **New England Delegation**
The Maryland State Medical Society (MedChi)
American College of Radiation Oncology (ACRO)
American Society for Radiation Oncology (ASTRO)
American Society of Clinical Oncology (ASCO)
Association of University Radiologists (AUR)

Whereas, our AMA is a powerful advocate for clinical research;

Whereas, our AMA believes it is an inherent obligation of managed care organizations to invest in broad-based clinical research (AMA policy H-460.930);

Whereas, our AMA advocates that the Centers for Medicare and Medicaid Services (CMS) regulate Medicare Advantage Plans to assure the same treatment and authorization guidelines are followed for both fee-for-service Medicare and Medicare Advantage patients (AMA policy D-285.959);

Whereas, our AMA supports that Medicare Advantage plans, at a minimum, must provide enrollees with coverage for all Part A and Part B original Medicare services, if the enrollee is entitled to benefits under both parts (AMA policy H-330.878);

Whereas, in contrast, current Medicare policy states, "For clinical trials covered under the Clinical Trials National Coverage Determination 310.1, **original** Medicare covers the routine costs of qualifying clinical trials for all Medicare enrollees, including those enrolled in MA [Medicare Advantage] plans… [Emphasis added.]" (Medicare Managed Care Manual, Chapter 4, Section 10.7.1);

Whereas, current Medicare policy only holds that the Medicare Advantage Organization (MAO) is responsible for paying the enrollee the cost-sharing portion that was incurred with the original Medicare coverage for qualified clinical trial items (paragraph 3 of Section 10.7.1);

Whereas, for the enrollee to receive reimbursement from the MAO for this cost-sharing portion, current Medicare policy states, "To be eligible for reimbursement, an enrollee must notify their plan that the enrollee received a qualified clinical trial service and provide documentation of the cost-sharing incurred, as a provider bill" (paragraph 4 of section 10.7.1);

Whereas, this means that a Medicare Advantage enrollee who enters a qualified clinical trial is obligated to pay the cost-sharing portion of their standard-of-care services, and then to seek reimbursement from the MAO, even though the enrollee would otherwise never have been billed by the MAO for such standard services, including the cost-sharing portion;

Whereas, the cost-sharing portion of standard services for patients enrolling on clinical trials (trials that address critical questions in oncology, heart disease, and a host of other serious conditions) can amount to **tens of thousands of dollars** across months of treatment for a **single** patient;

Whereas, these policies annually affect many thousands of patients enrolling on large-scale clinical trials (including many funded by NIH and its individual Institutes);

Whereas, these policies punish public-spirited patients who enter clinical trials that will provide future generations with better medical treatments and improved health outcomes, even though that individual has no rational expectation of benefit, given the clinical equipoise inherent in a clinical trial;

Whereas, these policies create a profound financial disincentive for patients to enter clinical trials, who thereby incur many thousands of dollars in liabilities in exchange only for the promise of potential future reimbursement, making trial enrollment very unattractive;

Whereas, most Medicare Advantage patients will not enroll in clinical trials if they are informed of these financial liabilities;

Whereas, such policies effectively provide the MAO these sums free-of-charge for many months, even though the MAO ultimately will be liable to pay these sums – in short, a "loan" from the enrollee to the MAO;

Whereas, a recent inquiry across member organizations of the Association of American Cancer Institutes (AACI) identified numerous institutions across the country that reported increasing difficulties with billing and reimbursement for their MAO patients;

Whereas, at least one of these institutions (namely, Dartmouth Cancer Center) has incurred significant costs to employ additional financial services staff to advise and support patients who are wrestling with these payment difficulties, a fact that vividly demonstrates the needs of these vulnerable, public-spirited patients and the demands on institutions attempting to support them;

Whereas, such individual institutional interventions can only serve as temporary stopgaps and cannot serve as long-term solutions to this issue, inasmuch as they create unsustainable costs at the single institutional level and would engender massive expenditures if implemented across larger systems and disease types; therefore be it

RESOLVED That our AMA advocate that CMS require that Medicare Advantage Organizations (MAOs) pay for routine costs for services that are provided as part of clinical trials covered under the Clinical Trials National Coverage Determination 310.1, just as the MAO would have been required to do so had the patient not enrolled in the qualified clinical trial.