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Sommario/riassunto	Increasingly over the past five years, uncertainty about reimbursement for routine patient care has been suspected as contributing to problems enrolling people in clinical trials. Clinical trial investigators cannot guarantee that Medicare will pay for the care required, and they must disclose this uncertainty to potential participants during the informed consent process. Since Medicare does not routinely "preauthorize" care (as do many commercial insurers) the uncertainty cannot be dispelled in advance. Thus, patients considering whether to

enter trials must assume that they may have to pay bills that Medicare rejects simply because they have enrolled in the trial. This report recommends an explicit policy for reimbursement of routine patient care costs in clinical trials. It further recommends that HCFA provide additional support for selected clinical trials, and that the government support the establishment of a national clinical trials registry. These policies (1) should assure that beneficiaries would not be denied coverage merely because they have volunteered to participate in a clinical trial; and (2) would not impose excessive administrative burdens on HCFA, its fiscal intermediaries and carriers, or investigators, providers, or participants in clinical trials. Explicit rules would have the added benefit of increasing the uniformity of reimbursement decisions made by Medicare fiscal intermediaries and carriers in different parts of the country. Greater uniformity would, in turn, decrease the uncertainty about reimbursement when providers and patients embark on a clinical trial.