



DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Center for Medicaid and State Operations
7500 Security Boulevard
Baltimore, MD 21244-1850

October 30, 2000

Dear State Medicaid Director:

The purpose of this letter is advise you of a National Coverage Decision (NCD) for Medicare payment for routine patient care costs and costs due to medical complications associated with participation in clinical trials. Clinical trials are research studies that evaluate the safety and effectiveness of medical care. Previously, Medicare has not generally paid for items or services related to clinical trials because of their experimental nature. Information on the NCD and Medicare implementing instructions are available on the Internet at: <http://www.hcfa.gov/quality/8d.htm>.

In keeping with the President's directive on June 7, 2000, the NCD defines the routine costs of clinical trials and identifies the clinical trials for which payment for such routine costs should be made by Medicare. For Medicare/Medicaid dual eligible beneficiaries, several things must be taken into account: 1) the type of dual eligible; 2) whether the State Medicaid agency covers categorical services that might be included in a clinical trial; and 3) the amount of Medicare payment for the routine patient care costs.

For Qualified Medicare Beneficiaries (QMBs), States are required to pay Medicare cost-sharing expenses for services covered under Medicare, without regard to whether or not the services are covered under the Medicaid State plan. States have flexibility, however, to establish the payment rates or amounts for the Medicare cost-sharing in the Medicaid State plan, both for Medicare services covered by Medicaid and not covered by Medicaid. Medicaid must pay, at least, amounts based on the Medicaid payment rate specified in the Medicaid State plan. At most, Medicaid pays full Medicare cost-sharing. States that do not specify such rates must pay full Medicare cost-sharing.

For other Medicare/Medicaid dual eligible beneficiaries, Medicaid is liable only for Medicaid services covered in the Medicaid State plan. State Medicaid agencies may already cover services provided in a clinical trial, as long as other pertinent Federal requirements are met (e.g., the services are medically necessary, provided by a qualified provider, etc.). To the extent routine costs for clinical trials are covered in the Medicaid State plan, Medicare is now a liable third party payer that the State must take into consideration before Medicaid pays for the costs.

Questions on Medicaid policy in this area can be directed to Robert Nakielny at (410) 786-4466 or by E-mail at Rnakielny@hcfa.gov.

Sincerely,

/s/

Timothy M. Westmoreland

Director

cc:

All HCFA Regional Administrators All HCFA Associate Regional Administrators for Medicaid and State Operations Lee Partridge, Director, Health Policy Unit - American Public Human Services Association Joy Wilson, Director, Health Committee - National Conference of State Legislatures Matt Salo, Director of Health Legislation - National Governors' Association