

Analysis of the Health Care Financing Administration's (HCFA's) Modifications of Coverage of Routine Services Associated with Clinical Trials.

Changes from current policies:

Except for allowing for payment for Medicare covered services for patients in the treatment arm of a clinical trial, there are essentially no changes from current HCFA policies.

HCFA has, for many years, paid for any complications or follow-up care required as a result of non-covered services, such as treatment that was furnished as part of a clinical trial, following the patient's discharge from the hospital stay in which the non-covered services were furnished.

For at least three years, HCFA has agreed to pay for patients in the control arm of a clinical trial all Medicare-covered services furnished them as part of a clinical trial.

HCFA has, since 1995, covered some clinical trials for devices furnished under an Investigational Device Exemption (IDE) which the Food and Drug Administration (FDA) classifies as a Category B IDE.

Comparison of payment policy under this provision to payment under a Category B IDE:

For medical devices, payment under this provision is less liberal than that offered under HCFA's Category B process.

Under the Category B IDE process, HCFA contractors will pay for all covered services, including the costs of the device that do not exceed the amounts paid for similar devices that are FDA approved or cleared.

Under this provision, the costs of the investigational device and most investigational drugs are excluded from the payment. Only the routine medical and hospital costs for otherwise covered services are covered. This would, however, be an advantage for a Category A device, since the routine patient care would be paid, which is not now the case. (NOTE: HCFA will have to change the regulations regarding payment for patients with Category A devices).

Comparison to other clinical trial coverage:

The one area where this provision does offer a substantial liberalization of current coverage and payment policies is the treatment Investigational New Drugs (INDs). Such trials are among those deemed qualified, effective September 19, 2000.

Specific Qualifications

There are several qualifications to this provision that limit its scope and impact.

First, the trial must evaluate an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage. Thus, trials dealing with preventive services, which are generally excluded from coverage by the law, would not be covered by this provision.

Second, the trial must have a therapeutic intent. Trials conducted to test toxicity or disease pathology are not covered by this provision. Thus, Phase I and most Phase II trials would be excluded from coverage under this provision.

Third, in cases where the trial is designed to test therapeutic interventions, it must enroll patients with diagnosed disease, rather than healthy volunteers. Only tests of diagnostic interventions may enroll healthy patients in order to have a control group.

Fourth, items and services furnished solely for data collection needs of the trial are not covered and paid. Examples would be weekly blood tests, monthly CT scans, or other services, usually diagnostic, which are needed solely for data collection, rather than patient care and medical intervention.

General impact:

While not as far-reaching as its press releases may have indicated, this change does offer several advantages over previous coverage and payment policies.

First and foremost, it clarifies what HCFA's policies are in this area. Since the existing HCFA policies in this area were often misunderstood or misinterpreted, this should be helpful.

Second, it does offer a more liberal coverage of Treatment INDs, which will probably have the greatest immediate impact.

Third, it does offer payment of routine patient care costs for trials involving Category A IDE devices, which is a liberalization of previous policy.

Cautions:

These provisions will not be completely effective anytime soon. HCFA must revise several regulations as well as write new ones involving payment and coding, which, historically, have taken months to finalize.

Second, while some clinical trials with certain sponsorship are deemed covered, the development of the necessary requirements for self-certified trials will probably involve a good deal of time and controversy. Although publication of the criteria for self-certification is expected soon, the development of the necessary forms, reports and other details will probably take at least a year to complete. (OMB approval of forms generally takes one year.)

Thus, it could take two to three years for this provision to be fully and completed implemented.

Prepared by: *Ron Milhorn, LLC*