Make Clinical Research Top Priority

by Sue Prophet, RHIA, CCS, CHC

Whenever biomedical or behavioral research is conducted and supported by government agencies, it's critical to comply with federal regulations designed to protect human subjects. For compliance officers, this means understanding and constantly monitoring a number of federal laws, regulations, and guidelines pertaining to clinical research.

Governmental authorities have been monitoring compliance related to clinical research for a number of reasons. The Office of the Inspector General (OIG) has issued several reports related to clinical research, citing problems with the protection of human subjects by institutional review boards (IRB), controls over testing of investigational devices, and the FDA's oversight of clinical investigators. The OIG identified problems with the accounting and tracking of investigational devices and the local oversight by IRBs, including the informed consent process.1

The OIG noted that IRBs' limited efforts in conducting continuing reviews of active research is a serious national issue because it compromises their protection of human subjects. This makes it difficult to identify and address situations where unacceptable risks emerge, research results prove to be too favorable to continue, or protocols stray beyond approved limits. It also inhibits IRBs' capacity to ensure that subjects understand the risks they may incur in the research process.2

What's more, well-publicized cases of adverse outcomes in gene transfer trials have raised the public's awareness of the risks that can be associated with clinical research. The recognition of the need to strengthen human subject projections prompted the announcement of several new government initiatives in May 2000 to improve the safety of human research subjects, further strengthen government oversight of clinical research—including gene transfer research—and reinforce researchers' responsibility to follow federal guidelines.

The Department of Health and Human Services (HHS) will pursue legislation to enable the FDA to levy civil monetary penalties for violations of informed consent and other important research practices. They are seeking penalties up to $250,000 per clinical investigator and up to $1 million per research institution. HHS is also undertaking an aggressive effort to improve the education and training of clinical investigators, IRB members, and associated IRB and institutional staff. This education will include research bioethics training and human subject research training.

The National Institutes of Health (NIH) and the FDA will issue specific guidance on informed consent, clarifying that research institutions and sponsors are expected to audit records for evidence of compliance with informed consent requirements. For particularly risky or complex clinical trials, IRBs will be expected to take additional measures, such as third-party observation of the informed consent process. The guidance will also reassert the obligation of investigators to reconfirm informed consent of participants upon the occurrence of any significant trial-related event that may affect a subject's willingness to participate in the trial.

NIH will require investigators conducting smaller-scale early clinical trials (phase I and II) to submit clinical trial monitoring plans to the NIH at the time of grant application; investigators are expected to share these plans with IRBs. Additional guidance on conflicts of interest will be issued to clarify NIH regulations, which apply to all NIH-funded research. HHS will hold public discussions to find new ways to manage conflicts of interest so that research subjects are appropriately informed and to ensure that research results are analyzed and presented objectively.

New Policy Authorizes Reimbursement for Services

Effective for items and services furnished on or after September 19, 2000, Medicare began to cover the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in clinical trials. This policy creates new compliance risks for organizations participating in clinical research, because of the complexity of the rules regarding what Medicare will pay for as part of a clinical trial.

In recognition of the new compliance challenges, the OIG identified Medicare payments for clinical trials as a project in its 2002 Work Plan. As part of this initiative, the OIG will determine whether Medicare payments associated with clinical trials were made in accordance with program requirements and will also assess safeguards related to clinical trial claim processing requirements.

The costs Medicare will pay for include items or services:

- typically provided absent a clinical trial (for example, medically necessary conventional care)
- required solely for the provision of the investigational item or service (for example, administration of a noncovered chemotherapeutic agent)
- required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
- that are medically necessary for the diagnosis or treatment of complications arising from the provision of the investigational item or service

Costs not covered include:

- the investigational item or service itself
- items and services provided solely to satisfy data collection and analysis needs and not used in the direct clinical management of the patient (for example, monthly CT scans for a condition usually requiring only a single scan)
- items and services provided by the research sponsors free of charge for any enrollee in the trial

Additionally, to qualify for coverage the clinical trial must meet the following criteria:

- the subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (for example, physicians' service, durable medical equipment, diagnostic test), is not statutorily excluded from Medicare coverage (for example, cosmetic surgery, hearing aids), and is not the subject of a national noncoverage decision.
- the trial must have a therapeutic intent (in other words, it is not designed exclusively to test toxicity or disease pathophysiology).
- trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients to have a proper control group.

"Therapeutic intent" means that the trial must assess the effect of the intervention on patient outcome. Therefore, research studies that are investigating preventive services generally cannot be included in Medicare's national coverage policy on clinical trials.

If the Centers for Medicare and Medicaid Services (CMS, formerly HCFA) determines that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied, the beneficiaries enrolled in the trial could not be held liable for the costs, and fraud investigations of the billing providers and the investigator could be pursued.

How to Report Clinical Trial Services

For fiscal intermediaries and carriers to identify claims for clinical trial services providers must accurately report this information on the claim form. Clinical trial and non-clinical trial services should be reported as separate line items (in other words, they may not be commingled) when billing them on the same claim. More specific requirements appear below.[3]

HCFA-1500 or Electronic Equivalent

Effective for services furnished on or after January 1, 2002, procedure code modifier "QV" should be used to report routine care for Medicare-qualifying clinical trial services on the HCFA-1500 claim form. The description of this modifier is "item or service provided as routine care in a Medicare qualifying clinical trial."

Routine-care clinical trial services furnished on or after January 1, 2002, to healthy control group volunteers participating in Medicare-qualifying diagnostic clinical trials are to be reported with the QV modifier at the line-item level and ICD-9-CM code V70.7 (examination of participant in clinical trial) as the primary diagnosis for applicable line items. If code V70.7 is reported

as a secondary rather than a primary diagnosis, Medicare will not consider the service as having been furnished to a healthy, control group, diagnostic trial volunteer.

UB-92

Effective for inpatient discharges and all other intermediary and regional home health intermediary-processed services occurring on or after January 1, 2002, routine care for Medicare-qualifying clinical trial services must be identified on the UB-92 with ICD-9-CM code V70.7 as the second or subsequent diagnosis code. The principal diagnosis would be the diagnosis for which the patient is enrolled in the clinical trial.

Whenever claims are submitted for clinical trials, the provider should include information about the clinical trial (trial name, sponsor, and sponsor-assigned protocol number) in the beneficiary's medical record. This information should not be submitted with the claim, but should be provided if requested. A copy of routine items and services should also be made available if requested.

Notes

1. Department of Health and Human Services, Office of Inspector General. "Investigational Devices: Four Case Studies," April 1995. Available at OIG Web site at www.hhs.gov/oig.
2. Department of Health and Human Services, Office of Inspector General. "Institutional Review Boards: Their Role in Reviewing Approved Research," June 1998. Available at OIG Web site at www.hhs.gov/oig.
3. Medicare Transmittal AB-01-142, available at CMS Web site at www.hcfa.gov.

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