

"Clinical Trial Billing: Third-Party Reimbursement"

FDAnews, October 2006, 61 pages, \$335.00

Review by Norman M. Goldfarb

"Clinical Trial Billing: Third-Party Reimbursement" explains the issues, laws, regulations and best practices relating to billing Medicare/Medicaid and other third-party payors for clinical research costs. The report is a paragon of clear writing about an unbelievably confusing topic. If your job requires you to understand this topic, you've already made one mistake; don't make another by ignoring this report.

About half of the report consists of explanations and recommendations; the balance consists of the Medicare National Coverage Decision, a CMS "clarification" document, and a state-by-state list of required health plan coverage for cancer trials.

I won't even try to elucidate how the rules work. Suffice it to say that Medicare has three sets of rules – the original Medicare rules (pre-1995), device regulations (1995), and the National Coverage Decision (2000) – all of which may or may not apply in a specific circumstance. Oh, did I forget to mention that Medicaid has its own rules and pricing standards?

If you do not have a billing department that can bury the costs in overhead, figuring out what you can bill, applying for permission to bill, reviewing the bills, submitting the bills, resubmitting the bills, and following-up on problems could be a formidable expense that the study sponsor may not care to cover.

Sites ask for trouble if they:

- Start a trial without a clear plan and trained personnel for billing third-party payors.
- Do not know in advance who is going to cover expenses that third-party payors decline to pay (in full).
- Accept a study budget that lumps together visit activities that are billable to a third-party payor with those paid by the sponsor; it becomes impossible to sort out questions of double-billing.
- Double-bill the sponsor, third-party payor, and/or subject.

Sponsors ask for trouble if they:

- State in the informed consent form or clinical trial agreement that they will be the secondary payor behind Medicare/Medicaid. Medicare/Medicaid is ALWAYS the secondary payor.
- Offer to pay the subject's Medicare/Medicaid copay, which constitutes an illegal inducement to use government services.

The report is available at <http://www.fdanews.com/>

Reviewer

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