

"A Guide to US Reimbursement for Drugs, Medical Devices, and Diagnostics"

Boston Healthcare Associates, 2006, 163 pages, D&MD Publications, \$795.00

Review by Norman M. Goldfarb

"A Guide to US Reimbursement for Drugs, Medical Devices, and Diagnostics" is a practical guide to obtaining public and private third-party payer reimbursement. The report is primarily designed for medical device, pharmaceutical and other medical product companies, but is useful for healthcare providers as well.

Reimbursement requires three elements:

- Coverage by third-party payers
- Codes for identifying reimbursable claims
- Payment systems for submitting and processing claims

Each of these elements has its own complexities. For example, Medicare issues only about 12 national coverage decisions (NCDs) per year, but, in the absence of an NCD, the 28 regional Medicare contractors can make their own coverage decisions. A medical products company can apply for national coverage, and take the risk of national rejection, or apply to each regional contractor. The implication for clinical research is that the regional contractors rely on local key opinion leaders, who should therefore be included in clinical trials.

FDA approves medical products based on efficacy and safety, generally without considering competitive products or cost vs. benefit. Coverage decisions, on the other hand, usually consider all of these factors. The implication for clinical research is that clinical trials should generate results that can be used for competitive comparisons of efficacy, safety, costs and benefits.

FDA approval is only half the battle in bringing a medical product to market. Somebody still has to agree to pay for it. Obtaining favorable coverage decisions and reimbursement codes can take years. The implication for clinical research, at least with medical devices, is that obtaining Medicare (and other third-party) reimbursement for use in clinical trials is a good start.

The report includes 9 chapters:

- The 2006 Reimbursement Guide
- Overview of Basic Reimbursement Concepts
- The Impact of Political and Regulatory Processes on Reimbursement
- HHS Agencies with the Greatest Impact on Reimbursement
- Public Sector Payers & Programs
- Private Sector Payers
- Health Economics and Reimbursement
- Tactical Reimbursement Support Tools
- The Timing of Reimbursement Actions and The Impact on Business Strategy

The report also includes a comprehensive glossary and other appendices.

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

Reviewer

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