



Sixth Annual National Congress on Health Care Compliance

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Compliance Risks for Clinical Laboratories

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On Corporate Integrity

“By complying with all applicable laws and regulations, and by adhering to LabCorp’s standards of business conduct, we earn the trust and respect of our fellow workers, customers, shareholders, government employees, elected officials, suppliers, neighbors, friends, the media, and the general public. Therefore, I believe that a strong commitment to corporate integrity is the key to our future success.”

Thomas P. Mac Mahon,
President and Chairman of the Board
Laboratory Corporation of America



OIG Model Compliance Program Guidance for Clinical Laboratories

▼ Medical Necessity

- Requisition Design
- Notices to Physicians
- Test Utilization Monitoring



OIG Model Compliance Program for Clinical Laboratories (cont.)

▼ Billing

- CPT/HCPCS Codes
- ICD-9 Diagnostic Codes
- Tests Covered by Claims for Reimbursement
- Billing of Automated Multichannel Chemistry tests
- Billing of Calculations



OIG Model Compliance Program for Clinical Laboratories (cont.)

- ▼ Standing Orders
- ▼ Marketing
- ▼ Physician Profile Pricing



Fraud Alerts

- ▼ In-office Phlebotomy
- ▼ Waivers of Co-pays, Coinsurance, and Deductibles
- ▼ Professional Courtesy
- ▼ Rental or Lease of Space from Physicians



Standard ABN

The Advance Beneficiary Notice (“ABN”) informs Medicare patients that their tests may not be covered by Medicare and that they may be liable for any charges for the test.

✓ Valid ABN’s must contain:

- Patient’s name
- Reasons why the test might not be covered
- A checked box indicating the patient’s intent
- Patient’s signature and date



2003 OIG Work Plan

- ✓ **Laboratory Proficiency Testing**
- ✓ **Clinical Laboratory Testing Outside Certified Specialties**
- ✓ **Part B Claims for Glucose Testing**



HIPAA Compliance

▼ Privacy

- Use of Protected Health Care Information (“PHI”)
- Provider Responsibility

▼ Security

- Access to Facilities
- Access to Information

