

**Health Care Regulatory
Due Diligence Checklist
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LICENSURE

- Governmental permits, licenses, certificates, or registrations held by or issued to target or its personnel

REIMBURSEMENT

- Participating provider agreements with Medicare, Medicaid, other third-party payers, and managed care companies
- Listing of items furnished per HCPCS and ICD-9 codes used
- Billing and documentation policies and procedures
- Information regarding any actual or threatened requests for refund of overpayments by any third-party payer received within the past 3 years
- Sample of claims submitted to Medicare and Medicaid and related records
- Files regarding pending reimbursement appeals
- All materials used by target for its reimbursement hotline

FRAUD AND ABUSE

- Corporate compliance plans and related policies
- Governmental citations, orders, decrees, reports, notices, and correspondences regarding regulatory compliance or noncompliance received during the past 3 years
- Governmental audit or inspection reports received within the past 3 years
- Information regarding any actual or threatened inquiries, investigations, or audits by any governmental agency received within the past 3 years
- Listing of pending governmental investigations, prosecutions, or judicial proceedings to which target is a party, subject, or target

- Agreements with hospitals, nursing homes, home health agencies, and other “providers”
- Agreements with physicians, non-physician practitioners, or other “suppliers”
- Agreements with sales representatives and distributors
- Agreements with management companies, billing agents, and medical directors
- Agreements with clinical trial sponsors, principal investigators, contract research organizations, and site management organizations
- Minutes or reports of quality assurance or control committee during the past 3 years
- Minutes or reports of compliance officer or committee during the past 3 years
- Reports or letters from consultants or auditors reviewing operations, financial performance, and quality of care
- Patient assistance program policies and procedures
- Sales and marketing policies and procedures
- Training materials used by sales and marketing representatives
- Records of any payments or other remuneration to referring physicians

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

- HIPAA policies and procedures
- HIPAA training materials and workforce certifications
- HIPAA Business Associate agreements
- HIPAA Notice of Privacy Practices