The Office of Inspector General (OIG) is part of the Department of Health and Human Services Department. It’s mission is to protect the integrity of the Department of Health and Human Services (HHS) programs as well as the health and welfare of the program beneficiaries.

1. **Written policies and procedures**, which should include:
   - Standards of Conduct
   - Medical Necessity
   - Billing
   - Reliance on Standing Orders
   - Compliance with Applicable HHS Fraud Alerts
   - Marketing
   - Prices Charged Physicians for Profiles
   - Retention of Records
   - Compliance as an Element of a Performance Plan

2. **Compliance officer and compliance committee**
   **The Compliance Officer:**
   - Oversees and monitors the implementation of the compliance program
   - Regularly reports to clinical laboratory’s governing body
   - Develops and distributes written policies and procedures to all affected employees
   - Revises the program based on necessary changes within the organization
   - Develops, coordinates and participates in educational and training programs on the elements of the compliance plan
   - Ensures physicians who order services from the clinical laboratory are informed of the compliance program standards
   - Assists the clinical laboratory’s financial management in coordinating internal compliance review and monitoring activities
   - Responds and investigate to all reports of compliance problems
   - Develops policies and programs that encourage employees to report suspected problems without fear of retaliation
   **Compliance Committee should be established to advise the compliance office and assist in the implementation of the compliance program**

3. **Training and education**
   - All affected employees should be required to attend specific training at first hire and periodically thereafter (i.e. yearly).
   - This should include training in Federal and State statutes, regulations, program requirements, the policies of private payers and ethics.
   - Targeted training for employees whose actions affect the accuracy of the claims submitted to the government and private payers.
4. **Lines of communication**

5. **Well-publicized disciplinary guidelines**
   This should include:
   - A discipline policy and actions for employees who have failed to comply with the clinical laboratory’s standards of conduct, policies and procedures or Federal and State Laws
   - A new employee policy that has a prudent background investigation including a reference check for each employee that may have discretionary authority to make decisions that involve compliance with the law or compliance oversight

6. **Auditing and monitoring**
   - Establish ongoing evaluation processes involving thorough monitoring and regular reporting to the clinical laboratory’s corporate officers.
   - Compliance audits by either internal or external auditors with experience in Federal and State health care statues, regulations and program requirements of private insurers is recommended.
   **Suggested techniques include:**
   - On-site visits
   - Interviews with personnel
   - Questionnaires
   - Review of requisition forms and other documents that support claims for reimbursement
   - Review of written materials and documentation produced by the lab and used by the physicians and other staff that order tests
   - Trend analysis looking for deviations in billing or ordering
   - Be independent of line management
   - Have access to existing audit resources and personnel
   - Present written reports on compliance activities
   - Identify areas for improvement

7. **Prompt response and corrective action**
   - This is important for the compliance office to promptly investigate deal with violations and take corrective actions if necessary.
   - Report the matter to the appropriate governmental authority within a reasonable period, but no more than 60 days after determining that there is a credible evidence of violation.