Fictional Diagnostic Laboratories
Procedure for Investigating Hotline Complaints & Potential Compliance Violations

1. Policy

In accordance with its Laboratory Compliance Plan, Fictional Diagnostic Laboratories (FDL) is committed to complying with all billing, coding, reimbursement, clinical quality and other requirements related to its participation in federal health care programs. To the extent violations and wrongdoing cannot be prevented, FDL is committed to identifying, correcting and reporting them to the appropriate authorities and parties.

2. Purpose

FDL has adopted this Procedure is to ensure that internal complaints, reports and other indications of potential violations and wrongdoing are immediately, thoroughly and appropriately investigated to ascertain their validity and, where necessary, initiate timely corrective and notification actions.

3. Initial Assessment

The FDL [*insert title, e.g., Compliance Officer/Lab Manager*] will conduct an initial review of allegations and indications of wrongdoing received via the FDL hotline, other internal complaints or communications, audit findings and otherwise to determine the type of investigation required and whether there is a need to involve legal counsel and notify senior management.

4. Investigation

The Compliance Officer or, where necessary, legal counsel will promptly investigate the allegation, which may include, among other things:

a. Review of billing and other records to determine what happened in the circumstances addressed in the allegation;
b. Review of statistical records to identify trends or tendencies affecting other cases not covered in the allegation;
c. Review of applicable FDL policies and procedures;
d. Interviews of witnesses; and
e. Review of any other records or material relevant to the case.

5. Investigation Report and Recommendations

When the investigation is complete, the Compliance Officer will create a report summarizing the steps of the investigations, its findings and any recommended actions to be taken in response. Such actions may include but are not limited to one or more of the following:

a. Revising current policies, procedures and systems to correct technical or procedural errors;
b. Conducting wider review of current policies, procedures and system that may be affected by the allegations;
c. Providing additional or improved education and training on current procedures;
d. Disciplining lab employees;
e. Notifying the CMS Office of Inspector General or other government authorities;
f. Repaying overpayments; and/or
g. Requesting payment of underpayments.

6. Documentation of Investigation

In addition to the information stipulated in Section 5 above, the final report will list:

- The time and date of the allegation or indication of wrongdoing;
- The form of the allegation, e.g., hotline report;
- A description of the facts alleged;
- A description of the steps taken during the investigation process, including the names of witnesses interviewed;

Supporting materials including but not limited to interview logs and notes.