

ENFORCEMENT AND PREVENTION POLICY

It is the policy of LabPharm, LLC (hereinafter referred to in this policy as the “Practice”) to respond to reports by independent contractors or others that a business unit or individuals employed by a business unit are engaging in activity which may be contrary to applicable Medicare and Medicaid laws or regulations or that such persons or business units may be submitting claims in a manner which does not meet the Medicare or commercial healthcare program requirements, as applicable. This policy is intended to reflect the requirements set forth in Comments 3.(k)(6) and 3.(k)(7) to Section 8A1. of the Federal Sentencing Guidelines.

I. INVESTIGATION

A. Purpose of Investigation

The purpose of the investigation shall be to identify those situations in which the laws, rules and standards of the Medicare and commercial healthcare programs may not have been followed; to identify individuals who may have knowingly or inadvertently caused claims to be submitted or processed in a manner which violated payer policies; to facilitate the correction of any practices not in compliance with the appropriate laws, rules, standards and payer policies; to implement those procedures necessary to insure future compliance; to protect the Practice in the event of civil or criminal enforcement actions, and to preserve and protect the Practice’s assets.

B. Control of Investigations

The compliance officer will conduct an investigation as to any complaint received and will confer with legal counsel. The compliance officer, with the assistance of legal counsel shall prepare a Compliance Report Form. The compliance officer will be responsible for directing the investigation of the alleged problem or incident. In undertaking this investigation, the compliance officer may solicit the support of internal audit, external counsel and auditors, and internal and external resources with knowledge of the applicable laws and regulations and required policies, procedures or standards that relate to the specific problem in question.

These persons shall function under the direction of the compliance officer and shall be required to submit relevant evidence, notes, findings, and conclusions to legal counsel.

C. Investigative Process

Upon receipt of an independent contractor complaint or other information (including audit results) which suggests the existence of a serious pattern of conduct in violation of compliance policies or applicable laws or regulations, an investigation under the direction and control of the compliance officer with the assistance of the legal counsel shall be commenced. Steps to be followed in undertaking the investigation shall include, at a minimum:

1. Notification of Management of the nature of the complaint and obtaining a memorandum from management authorizing an investigation.
2. The investigation shall be commenced as soon as reasonably possible but in no event more than thirty (30) days following the receipt of the complaint or report. The investigation shall include, as applicable, but need not be limited to:
 - a. An interview of the complainant and other persons who may have knowledge of the alleged problem or process and a review of the applicable laws and regulations which might be relevant to or provide guidance with respect to the appropriateness or inappropriateness of the activity in question, to determine whether or not a problem actually exists.

If the review results in conclusions or findings that the complained of conduct is permitted under applicable laws, regulations, or policy or that the complained of act did not occur as alleged or that it does not otherwise appear to be a problem, the investigation shall be closed.

If the initial investigation concludes that there is improper billing occurring, that practices are occurring which are contrary to applicable law, that inaccurate claims are being submitted, or that additional evidence is necessary, the investigation shall proceed to the next step.

- b. The identification and review of representative bills or claims submitted to the Medicare / Medicaid or other third party payors to determine the nature of the problem, the scope of the problem, the frequency of the problem, the duration of the problem, and the potential financial magnitude of the problem.
- c. Interviews of the person or persons in the departments who appeared to play a role in the process in which the problem exists. The purpose of the interview will be to determine the facts related to the complained of activity, and may include, but shall not be limited to:
 - i. Individual understanding of the Medicare and Medicaid laws, rules and regulations, as they are the standard by which the Practice models its compliance;
 - ii. the identification of persons with supervisory or managerial responsibility in the process;
 - iii. the adequacy of the training of the individuals performing the functions within the process;

- iv. the extent to which any person knowingly or with reckless disregard or intentional indifference acted contrary to the compliance program of the Practice in its efforts to comport with the Medicare or Medicaid laws, rules or regulations;
- v. the nature and extent of potential civil or criminal liability of individuals or Total Care; and
- vi. preparation of a summary report which (1) defines the nature of the problem, (2) summarizes the investigation process, (3) identifies any person whom the investigator believes to have either acted deliberately or with reckless disregard or intentional indifference toward the Compliance Program as it follows the Medicare/Medicaid laws, rules and policies, (4) if possible, estimates the nature and extent of the resulting overpayment by the government or other third party payor, if any.

II. ORGANIZATIONAL RESPONSE

A. Possible Criminal Activity

In the event the Practice uncovers what appears to be criminal activity on the part of any independent contractor or business unit, it shall undertake the following steps.

1. It shall immediately stop all billing related to the problem in the department(s) where the problem exists until such time as the offending practices are corrected.
2. It shall initiate appropriate disciplinary action against the person or persons whose conduct appears to have been intentional, willfully indifferent, or with reckless disregard for the Practice Compliance Program as it follows the Medicare and Medicaid laws. Appropriate disciplinary action shall include, at a minimum, the removal of the person from any position with oversight for or impact upon the claims submission or billing process and may include, in addition, suspension, demotion, and discharge.
3. Where only Medicaid is involved, the appropriate state agency and/or the Georgia Medicaid Fraud Unit shall be notified. In the event that Medicare and Medicaid claims are involved, the Practice shall notify the programs through the local United States Attorney's Office or the local office of the United States Department of Health and Human Services Office of the Inspector General Division, as counsel for the Practice deems appropriate. The Practice, through its counsel, shall attempt to negotiate a voluntary disclosure agreement prior to the disclosure.

B. Other Non-Compliance

In the event the investigation reveals billing or other problems which do not appear to be the result of conduct which is intentional, willfully indifferent, or with reckless disregard

for the Practice Compliance Program or Medicare and Medicaid laws, the Practice shall nevertheless undertake the following steps.

- 1. Improper Payments.** In the event the problem results in duplicate payments by Medicare or Medicaid, or another third-party payor, or payments for services not rendered or provided other than as claimed, it shall:
 - a. Correct the defective practice or procedure as quickly as possible;
 - b. Calculate and repay to the appropriate governmental entity or third party payor duplicate payments or improper payments resulting from the act or omission;
 - c. Initiate such disciplinary action, if any, as may be appropriate given the facts and circumstances. Appropriate disciplinary action may include, but is not limited to, reprimand, demotion, suspension and discharge.
 - d. Promptly undertake a program of education at the appropriate business unit to prevent future similar problems.

- 2. No Improper Payment.** In the event the problem has or does not result in an overpayment by the Medicare or Medicaid program, or some other third party payor, the Practice shall:
 - a. Correct the defective practice or procedure as quickly as possible.
 - b. Initiate such disciplinary action, if any, as may be appropriate given the facts and circumstances. Appropriate disciplinary action may include, but is not limited to, reprimand, demotion, suspension and discharge.
 - c. Promptly undertake a program of education at the appropriate business unit to prevent future similar problems.

III. DISCIPLINE

Independent contractors may be subject to discipline for failing to participate in organizational compliance efforts, including, but not limited to:

1. The failure of an independent contractor to perform any obligation required of the independent contractor relating to compliance with the program or applicable laws or regulations;
2. The failure to report suspected violations of the Practice Compliance Program or applicable laws or regulations to an appropriate person; and
3. The failure on the part of a supervisory or managerial independent contractor to implement and maintain policies and procedures reasonably necessary to ensure compliance with the terms of the program or applicable laws and regulations.

Discipline should follow the Practice existing independent contractor discipline policies and procedures.

I hereby certify that I have received, read, understand, and shall abide by this and Prevention Policy.

SIGNATURE

PRINTED NAME

DATE