Overview of the NPL Compliance Program

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The Office of Inspector General (OIG) has developed guides to promote adherence to the regulatory requirements of federal and state health care programs and to prevent fraudulent activities. In February 1997, the OIG issued a "Model Compliance Plan for Clinical Laboratories" and then August 24, 1998, the OIG issued Compliance Program Guidance for Clinical Laboratories.

NPL is committed to the compliance process and has a Compliance Program in place that follows these guidelines.

The OIG lists 7 basic components to an effective compliance program.

# Implement written policies, procedures and standards of conduct.

* + Written procedures are developed to reduce the chance of coding and billing errors, filing of erroneous claims, and to deal with issues that have

been identified as possible risk areas.

* + NPL Compliance Manual is available electronically and in hard copy at the south location and north location.
  + These policies promote NPL's commitment to compliance and address specific areas such as:
    - Standards of conduct
    - Medical necessity-This includes policies on:
      * Test requisitions
        + Requisition must capture correct information
        + Must allow for an independent medical necessity decision (ordering of individual tests versus panels)
        + Include information on Medicare rules such as Medicare does not cover routine screening tests
      * Annual Notice to physicians include:

National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)-these are policies for specific tests that indicate which diagnosis codes are considered medically necessary. If a test is not considered medically necessary, Medicare will not pay for the test.

The notice instructs the physicians that panels will only be paid and will only be billed when all components are medically necessary.

It includes the reimbursement amounts paid by Medicare for laboratory tests.

* + - * Physician Acknowledgments - These documents request from specific physicians to-create panels (customized panels) or reflex testing rules specific to their needs.
      * Advance Beneficiary Notice of Non-coverage (ABN) - An ABN is a notice that is given to a beneficiary if there is reason to believe that Medicare will not pay for an ordered test. The notice must be in writing, must clearly identify the test, must give a reason for the belief that payment is likely to be denied, must include an estimate of the cost of the test and must be signed by the beneficiary. The ABN must be completed prior to specimen collection.
    - Billing - There are policies on:
  + CPT/HCPCS coding - CPT codes need to accurately describe the test or methodology.
  + Diagnosis coding - Only diagnosis information provided by physician or other authorized individual is acceptable.
  + Valid test orders - If ambiguous, orders need to be clarified by the physician or provider that ordered the test.
  + Billing of calculations is not allowed. Some results that are reported are calculated based on other tests that are performed. The calculated result is not billable.
  + Reflex testing
* Standing orders:
  + Must specify a time frame such as weekly, monthly, as needed.
  + Must be medically necessary. Appropriate diagnosis codes should be on the requisition.
  + After 1 year, a standing order expires and must be renewed.
* Compliance with Applicable Health & Human Services Fraud Alerts
* Marketing - Must only present honest, straightforward, informative marketing.
* Pricing - Pricing policies should ensure that laboratories are not providing any inducements to gain a physician’s business. The charge for a test must be greater than the cost to perform the test and must reflect fair market value.
* Documenting Compliance Activities -
  + Compliance policies and standards of conduct;
  + Employee education;
  + Anything reported via the disclosure hotline;
  + All disciplinary actions that are the result of non-compliance with laws, rules, regulations, or compliance program policy;
  + Compliance audits;
  + Investigations of any identified compliance issues such as misdirected PHI

# Designate a compliance officer and compliance committee.

The Chief Compliance Officer is Susan Kringlie

Members of the Compliance Committee are:

Robert Arndt

Shelbie Reimer

Dr. Elena Rodgers-Rieger

Paul Nelson

Patti Schmidt

Denise Semerad

# Conduct effective training and education,

NPL does training using newsletters, quizzes, etc.

# Develop effective lines of communication

Lines of communication are important for reporting compliance issues and also for asking questions.

Reporting options include:

* Talking to your Immediate Supervisor
* Report to the Compliance Officer or any member of Compliance Committee
* Report anonymously by calling the NPL hotline **701-530-5750.** This is a confidential voice mail system. The only person who has access to this system is the Compliance Officer. Questions and/or reporting can be done anonymously or if a response is desired, then a name and phone number would be included in the message to get a response back.
* Call the OIG Hotline at 1-800-447-8477

# Enforce standards through disciplinary guidelines

Employees at all levels must be accountable for the compliance requirements and subject to disciplinary action for non-compliance.

There must be appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or requirements of Federal, State or private health plans.

# 6.Conduct internal monitors and audits

Audits are used to monitor compliance and assist in the reduction of identified problem areas.

* + Utilization Audits- If a test's utilization grows more than 10% over the average growth of testing, then the laboratory should investigate the cause of such growth.
  + Focus review audits are audits that are done for specific areas of concern in areas such as billing, accessing PHI, etc. These audits can confirm that processes are functioning correctly, or a problem may be identified. If a problem in a process is identified, steps are taken to correct the problem. After some time has passed, the audit may be repeated to confirm that the resolution corrected the problem.
  + Review of all coding and pricing of all tests is done annually.
  + External audits are done annually by an outside vendor.

# Respond promptly to detected offenses and develop corrective action

Investigations are done to determine whether a violation of applicable law or the requirements of the compliance program has occurred. If a violation has occurred, steps must be taken to correct the problem.