



Nepenthe Laboratory Services, LLC  
1720 Willow Creek Circle, Ste. 5258  
Eugene, Oregon 97402

## **Annual Notice: Laboratory Compliance and Annual Physician Notice: January 2017**

Dear Valued Client:

This is your annual notification of our Laboratory Compliance Policies as required by the Office of the Inspector General (OIG). The Clinical Laboratory Compliance Program helps to ensure that current federal regulatory policies are appropriately implemented and enforced. As part of our commitment to compliance, we are sending you this annual letter which highlights those topics pertinent to the process of ordering laboratory tests used to diagnose and treat your patients as well as changes to coding and billing of laboratory services.

### **1. Authorized Ordering Provider**

If you order or refer items or service for Medicare beneficiaries, you must be enrolled in the Medicare and Medicaid programs. Effective, January 2014, the Centers for Medicare and Medicaid Services will deny Part B clinical laboratory claims that fail the ordering/referring provider edit.

Providers not enrolled must submit an enrollment application. Enrollment forms can be found at the Provider Enrollment Chain and Ownership System (PECOS) website:

<https://pecos.cms.hhs.gov/pecos/login.do#headingLv1> or by completing the [paper enrollment application \(CMS-8550\)](#).

### **2. Medical Necessity**

The Model Compliance Plan for Clinical Laboratories, drafted in 1997 by the OIG, advises that clinical laboratories must obtain documentation through laboratory requisitions confirming the medical necessity of tests performed as requested by the physician, since laboratories can neither treat nor determine medical necessity. Thus, physicians must establish the necessity of tests by providing diagnostic information to the laboratory by including the ICD-10 CM code(s) or a narrative reason/purpose for the order(s). Medicare will only pay for tests that they deem are reasonable and necessary for patient care.

Medical necessity guidance, documentation requirements and access to the OIG's Model Compliance Plan for Clinical Laboratories can be found by accessing the following links:

#### ***Medicare Contractor Local Coverage Determination***

[https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36393&ContrId=369&ver=10&ContrVer=1&CtrctrSelected=369\\*1&Ctrctr=369&LCntctr=All&DocType=Future&bc=AgACAAIAAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36393&ContrId=369&ver=10&ContrVer=1&CtrctrSelected=369*1&Ctrctr=369&LCntctr=All&DocType=Future&bc=AgACAAIAAAAAAA%3d%3d&)

#### ***Office of Inspector General – Model Compliance Plan Clinical Laboratories***

<http://oig.hhs.gov/authorities/docs/cpglab.pdf>

#### ***Documentation Requirements- CMS Learning Network***

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ProviderComplianceLabServices-Fact-Sheet-ICN909221.pdf>



### ***2017 Clinical Laboratory Fee Schedule- Centers of Medicaid and Medicare Services***

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html>

#### **3. Verbal Testing Orders**

Nepenthe Laboratory Services will not accept verbal testing orders. All testing orders will either be documented via the submitted requisition form, or on an affidavit that will be faxed to your office.

#### **4. Patient Billing and ABNs**

Increasingly, both commercial and government payers are scrutinizing the collection of patient responsibility for clinical laboratory testing services. In alignment with our commitment to compliant practices, we bill patients for balances that insurance providers determine are their responsibility. It is important to remember that this can be in the form of a co-payment, deductible, or co-insurance. We pursue collection of these balances and employ a collections department. We encourage you to have your patients call our collections department directly to answer questions they may have regarding the costs associated with the tests you order. The cost of each test will be provided to you on our fee schedule.

All patients must sign the Nepenthe Laboratory Services requisition form, acknowledging that the specimen is their own, authorizing payment to Nepenthe Laboratory Services, the release of the testing results to the ordering provider, as well as the patient's responsibility of payment when determined by their insurance carrier.

Multiple states have all recently passed legislation related to the billing of out of network service and the associated patient responsibility. Nepenthe Laboratory Services, at times, may be out of network, and ordering provider share in the responsibility of disclosing the use of an out of network laboratory to their patients.

#### **5. Privacy Policy**

As a healthcare provider and covered entity, Nepenthe Laboratory Services must comply with HIPAA privacy and security standards. Nepenthe Laboratory Services Notice of Privacy Practices is available on our website as well as through our client services team.

#### **6. Requisition Forms and Patient Demographic Information**

To coincide with changes implemented by Medicare Local Coverage Determinations and commercial payers, our requisition forms have had significant design changes. We will be including a how-to -guide with every shipment of requisition forms to assist you and your staff in the transition. As a reminder, to properly process specimens received from your office we need the following information completed on the requisition form:

- Name of physician or qualified healthcare professional ordering the test,
- Patient's name,
- Patient's date of birth,



- Patient's billing information (**copy of both sides of patient's insurance card**), as well as the Insurance ID, and Primary and Secondary Insurance Carriers,
- Tests ordered,
- Valid ICD-10CM diagnosis codes that are also listed in the progress note for the patient, and for workmen's compensation patient's the applicable compensable injury diagnosis code,
- Physician signature with date of the order with the completion of the medical necessity criteria section,
- Submission of any presumptive screening results either as an attachment or on the requisition.

The following information is needed to accurately process the specimen for payment and needs to be included with the requisition for for each date of service. This information can be printed directly from your electronic medical records, or we have a form available for your staff to use.

- Patient's name, address, city, state, and zip code
- Patient's date of birth, and social security number when possible,
- Name of Primary and Secondary Insurance with Address, Member ID, and Group ID
- Subscriber name, address, date of birth, Member ID

We require that the Nepenthe requisition forms are used when ordering lab tests. The requisition form lists current tests and can be preprinted with the provider's office information. Please note that specimens collected in the office should contain two pieces of identification: the patient's full name and the patient's date of birth. Please use the provided sticker on the requisition form.

## 7. Ordering and Reporting Guidelines

### A. Standing Orders, Customized Profiles and Laboratory Panels

Nepenthe will not accept requests for the establishment of standing orders, customized panels or offering laboratory-designed panels for ease of ordering. Current Medicare, Medicaid and commercial coverage policies are specific in their guidance that these panels encourage overutilization and are not individualized or specific enough to meet medical necessity criteria.

Each test for drug/drug class will need to be individually ordered for each patient, and we will also be requesting that each requisition form be signed by the ordering provider.

### B. Fee Schedule & Medical Records Requests

Nepenthe will publish the fee schedule for all drugs/drug classes contained on our laboratories test menu. The fee schedule will contain the applicable AMA CPT Code for the drug/drug class, the laboratory order code as well as our fee. There have been considerable changes in the coding and reimbursement of laboratory services for beneficiaries of the Centers for Medicaid and Medicare services for 2016 and these changes have been incorporated into the fee schedule for your review.

There has been a significant increase in medical records requests from both Medicare contractors and commercial payers. We ask that you and your staff comply with both direct requests from the payer and when our billing staff contacts your office for those records. The



medical necessity of each test ordered should be clearly documented in the patient's chart and both national and state guidelines recommend that each patient receiving chronic opioid therapy be screened for the risk of abuse and misuse of these agents, and that assessment should be documented in the chart.

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