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Annual Notice: Laboratory Compliance and Annual Physician Notice: 2017

Dear Valued Client:

Below please find the Stone Clinical Laboratories annual notification of 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, you are receiving this annual letter which highlights topics pertinent to the process of ordering laboratory tests utilized 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 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 code(s) or a narrative reason/purpose for the order(s). Medicare will only pay for tests they deem are reasonable and necessary for patient care. **The Office of Inspector General takes the position that a provider who orders medically unnecessary tests for which Medicare and Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.**

Stone Clinical Laboratories has gone to great length to provide requisition forms that allow for individualized testing choices, and in the case of drug of abuse testing has dedicated an area for you to provide documentation that supports the rationale for your testing order. Please note that this documentation does not replace what is required in the patient's chart.

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/indexes/lcd-list.aspx?Cntrctr=326&ContrVer=1&CntrctrSelected=326*1&s=23&DocType=All&LCDId=36393&ContrlD=369&ver=10&LCntrctr=All&bc=AggAAAAAAAAAAAA%3d%3d&#ResultsAnchor

Office of Inspector General – Model Compliance Plan Clinical Laboratories

<http://oig.hhs.gov/authorities/docs/cpqlab.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

Stone Clinical Laboratories will not accept verbal testing orders. All testing orders will either be documented via the Electronic Requisition format, a Stone Clinical Laboratories Requisition form, or a Test Request Form. All Test Clarification Forms will require the ordering provider's signature. All questions regarding test ordering procedures should be directed to our Client Services team. (clientservices@stoneclinicallaboratories.com or 1-844-STONECL)

4. Patient Billing and ABN's

Increased scrutiny by both commercial and government payers is occurring on the collection of patient responsibility for clinical laboratory testing services. Stone Clinical Laboratories in our commitment to compliance will bill patients for balances that their insurance provider has determined is their responsibility. This can either be in the form of a co-payment, deductible, or co-insurance. We will pursue collection of these balances, and have a collections policy. We encourage you to have your patients contact either our client services team or our billing department directly. To assist in the understanding of the cost associated with the testing ordered, you will be provided the cost of each test on our fee schedule.

Patients and Providers are asked to not involve or ask Stone Clinical Laboratories sales representatives to mediate situations that involve patient billing, testing results, or other scenarios that include protected health information. All patients must sign the Stone Clinical Laboratories requisition form, acknowledging that the specimen is their own, authorizing payment to Stone Clinical Laboratories, 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.

New York, California, and Georgia have all recently passed legislation related to the billing of out of network services and the associated patient responsibility. Stone Clinical Laboratories, at times, may be out of network, and ordering providers share in the responsibility of disclosing the use of an out of network laboratory. Providers who treat patients within these applicable state laws should review their responsibilities in patient education, choice, as well as additional documentation requirements.

5. Privacy Policy

As a healthcare provider and covered entity, Stone Clinical Laboratories must comply with the HIPAA privacy and security standards. Stone Clinical Laboratories Notice of Privacy Practices is available on our website as well as through our Client Services Department.

6. Requisition Forms, Physician Signatures and Patient Demographic Information

While the signature of the ordering provider is not required on a requisition form for CMS, multiple commercial and Medicaid plans do require the signature of the ordering provider. In the absence of a provider signature, documentation of the provider's intent of each specific test and/or drug must be included in the patient's record and made available upon request to Stone Clinical Laboratories. The following demographic information must be received from your office, in order to properly process a specimen:

- Name of physician or qualified healthcare professional ordering the test
- Address of physician or qualified healthcare professional ordering the test
- Phone number of physician or qualified healthcare professional ordering the test
- Patient's full legal name
- Patient's address
- Patient's date of birth, patient's sex, and preferably their social security number
- Patient's billing information (**copy of both sides of patient's insurance card**)
- Name of subscriber (if patient is not the subscriber)
- Subscriber information (date of birth, social security number, address)
- Tests ordered
- Diagnosis, sign, or symptom
- Physician signature with Date of the Order
- Date of specimen collection

We require that Stone Clinical Laboratory requisition forms or the electronic ordering system be used when ordering lab tests. The requisition 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. Specimens received without proper identification will not be processed, without an attestation of identification signed by the ordering provider.

7. Ordering and Reporting Guidelines

A. Standing Orders, Customized Profiles and Laboratory Panels

Stone Clinical Laboratories encourages providers to only order tests that are medically necessary for the treatment and diagnosis of a patient's condition. Current Medicare, Medicaid, and Commercial coverage policies are specific in their guidance that the use of standing orders and blanket panels encourages over utilization, and are not individualized or specific enough to meet medical necessity criteria.

Stone Clinical Laboratories blood testing menu does contain the AMA published Disease and Organ panels as well as Stone Clinical Laboratory panels. Each test included in the panels, is also available to order individually and providers should only order those specific tests that are medically necessary for that patient.

For client's that would like to establish custom panels specific to their practice, the provider may contact our Client Services department and work with our laboratory director on the establishment of the requested testing.

B. Fee Schedule & Medical Records Requests

Stone Clinical Laboratories will publish the fee schedule for all tests contained on our laboratories test menu. The fee schedule will contain the applicable AMA CPT Code for the test, the laboratory order code, as well as our fee.

There has been a significant increase in medical records requests from both Medicare contractors, as well as commercial payers. We ask that you and your staff comply with both direct requests from the payer, as well as Stone Clinical Laboratories record requests. 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. All patient assessments should be documented in the chart and be made available to both Stone Clinical Laboratories, CMS/MAC Contractors, and private payers upon request.