



April 21, 2021

RE: Physician Annual Notice of Laboratory Compliance

Dear Provider or Client,

The Office of Inspector General (OIG) and the Centers for Medicare/ Medicaid Services (CMS) recommends clinical laboratories educate physicians about medical necessity and billing compliance each year. This letter serves as our annual notice and provides helpful information regarding the ordering and processing of clinical laboratory tests.

### **Medical Necessity**

Health care providers have the right to order any tests believed to be appropriate in the treatment of their patients. However, many insurers will only reimburse for the service if it is “covered, reasonable, and necessary” as defined by their payer-specific criteria which is based on ICD-10 codes supplied for each test ordered. This requires that lab tests ordered must be documented in the patient’s medical record, along with the ICD-10 code submitted on the lab order, and signed by the ordering physician.

If our laboratory receives an order that is missing this essential information, or if we are not able to bill for the test because the ICD-10 codes supplied do not meet medical necessity definitions, we will contact your office to obtain additional coding information. Our lab cannot assign ICD-10 codes to the lab order. All lab tests can only be ordered by a licensed medical provider. If ordering lab tests for Medicare/Medicaid patients, the provider must be eligible to order such testing by their provider type guidelines.

Lab orders must include the following information:

1. The patient’s name or other unique identifier
2. The patient’s insurance information
3. The name and phone number or other suitable identifiers of the physician (or other authorized individual) ordering the test and, if applicable the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the report of imminent life-threatening laboratory results or panic value.
4. The name and/or CPT code of the tests(s) to be performed
5. The patient’s current ICD-10 code(s)
6. The date and time of specimen collection
7. The specimen source
8. The signature of the physician (or other authorized individual) ordering the test

Should we receive a lab order that does not contain all the necessary information list above, we will contact your office and/or send the form back to your office for completion. Without appropriate documentation, the patient may be required to pay for services that otherwise would be covered as part of their insurance plan.



## Specimen Collection

Please reference the specimen collection instructions at [www.assurancescientificlabs.com/manual/](http://www.assurancescientificlabs.com/manual/) for guidance in proper collection and shipping to ensure the specimen is viable when it arrives at our lab. Should you have questions, please contact your representative or [ClientServices@AssuranceScientific.com](mailto:ClientServices@AssuranceScientific.com).

## Other Important Information

Providers have the option of ordering a panel or individual pathogens, depending on the medical necessity. Certain lab tests may require pre-authorization according to the patient's insurance provider's guidelines. Any required pre-authorization paperwork should be completed by the ordering provider's office before the lab test order is submitted. Please include the pre-authorization paperwork with the lab requisition form, when applicable, along with any related documentation. If the laboratory determines that pre-authorization is needed, and there is not enough information included on the patient paperwork to obtain it, we will contact the ordering physician's office before testing and request more clinical information for this purpose.

Assurance complies with federal law prohibiting our lab from offering or paying anything of value to induce the referral of tests that are covered by Medicare, Medicaid, or any other federal health care program. Any form of payment or kickback that is intended to secure business for federal health care testing referrals is strictly prohibited.

Medicaid reimbursement must be less than or equal to the Medicare reimbursement for all laboratory tests. Medicare's Clinical Laboratory Fee Schedule (CLFS), including all CPT codes, can be found at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>. The OIG states that any individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal, and administrative law. Assurance will not knowingly bill Medicare for testing that is non-covered, unreasonable, and/or unnecessary.

Thank you for the trust you put in Assurance Scientific Laboratories. We appreciate our partnership. Should you have any questions about the information contained in this letter, please contact us at [ClientServices@AssuranceScientific.com](mailto:ClientServices@AssuranceScientific.com) or call 1.855.319.4459.

Sincerely,

A handwritten signature in black ink, appearing to read "Shawn A. Hood".

Shawn A. Hood, CEO  
Assurance Scientific Laboratories