



## **Laboratory Compliance – Annual Physician Notification Letter**

Dear Healthcare provider,

The Office of Inspector General (OIG) of the Department of Health and Human Services recommends in its Model Laboratory Compliance Plan that laboratories send an annual notice to physicians advising them of the elements of the laboratory's compliance program (available at <http://oig.hhs.gov/authorities/docs/cpglab.pdf>). This letter serves as the annual notice and provides helpful information regarding the ordering and processing of clinical laboratory tests.

Physicians can use multiple methods of ordering laboratory testing from TriHealth Laboratories, including EPIC and paper requisitions. Organ and disease related panels will only be billed to and paid by Medicare when all components are medically necessary. Tests ordered are screened against diagnoses provided by the physician according to the National Coverage Determinations ("NCDs") issued by the Centers for Medicare and Medicaid Services (CMS) and Local Coverage Determinations ("LCDs") issued by National Government Services (NGS) or Ohio's Medicare Administrative Contractor (MAC). NCDs and LCDs can be accessed from the CMS website at <http://www.cms.gov/center/clinical.asp>, under the heading "Coverage". If a particular test that is ordered for a Medicare patient does not meet the NCD or LCD medical necessity guidelines, or is frequently restricted, the patient will be provided with an Advance Beneficiary Notice ("ABN"), if one was not already assigned at the time of ordering the services. This informs the patient of their potential financial responsibility for the test if Medicare denies the service. If an ABN is provided to and signed by the patient, unless the patient waives billing Medicare, the tests will first be submitted to Medicare for an initial determination. If Medicare denies the test, the patient will then be billed for the test. Your patients will also be provided the opportunity to refuse the test if it is not likely to be covered by Medicare.

We encourage the completion of the hospital's Laboratory Requisition or a complete order information submitted electronically via an interface. However, our laboratory will accept requisitions and orders that contain the following information, which is required by federal regulations, CLIA requirements and/or is necessary to screen the tests in the Laboratory Information System:

1. Date
2. Patient's full legal name
3. Patient's date of birth
4. Patient's Gender
5. Test(s) to be performed
6. Signs/symptoms/diagnosis (indications as to why the test is being ordered)

### **Medical Directors, TriHealth Laboratories**

**Sajini Mathew MD**—Bethesda North Hospital, Good Samaritan Hospital, TriHealth Anderson, Good Samaritan Western Ridge, TriHealth Kenwood

**Megan Smith MD**—Bethesda Arrow Springs, Bethesda Butler Hospital, McCullough Hyde Memorial Hospital

7. Physician authorization of orders. Written or electronic signature via electronic order entry system is acceptable. Signature stamps are not acceptable.
8. Physician printed full name
9. Additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results as determined by the laboratory.

To provide the best possible service to your patients and to fully comply with federal regulations and third party payer billing requirements, the Laboratory will follow the TriHealth Lab policy on “Unclear or Missing Orders,” which requires the postponement of services when orders are not valid. If we receive an invalid order, we will make reasonable attempts to contact your office for the necessary information. If, however, attempts to retrieve the required but missing information fail, we will be required to postpone the requested service until the necessary information is provided. We appreciate your cooperation in submitting valid orders.

When outpatients present to one of our outpatient draw sites, the phlebotomist may draw the lab work within 30 days of the ‘expected date’ if indicated, through to the ‘expiration date’ without question. It is expected that the expiration of order should be indicated on the order. If the expiration date is not indicated on the order, the default expiration is 365 days from order date.

The American Medical Association has grouped certain tests into panels for coding purposes only. All AMA approved non-standard panels can be found in our test catalog (<https://www.testmenu.com/TriHealth>). All panels list each CPT code set billed for every panel. These panels may be ordered as a whole, rather than ordering each test individually, when each test is medically necessary. The catalog includes the name of the panel as it will appear on our requisition and the individual tests that make up the panel.

Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test or further testing is medically appropriate. Mandated testing criteria set by government or accrediting agencies, relevant practices in laboratory medicine, and avoidance of performing unnecessary testing help dictate which tests are subject to reflexive testing. TriHealth Laboratories will perform reflex testing upon results of an initial laboratory test as outlined in the policy “Reflex Testing.” This Medical Executive Committee approved list can be found online on the TriHealth Lab website <https://www.testmenu.com/TriHealth>. If you DO NOT want reflex testing for any of the tests indicated in the Reflex Testing list, please clearly communicate this request on the laboratory requisition and contact Laboratory Customer Support at 513.569.6345, option 2

The OIG’s Model Compliance Plan also suggests that we inform you that our laboratory is relying on the following when we perform tests that you order:

**Medical Directors, TriHealth Laboratories**

**Sajini Mathew MD**—Bethesda North Hospital, Good Samaritan Hospital, TriHealth Anderson, Good Samaritan Western Ridge, TriHealth Kenwood  
**Megan Smith MD**—Bethesda Arrow Springs, Bethesda Butler Hospital, McCullough Hyde Memorial Hospital



1. The information you submit on the order/requisition accurately reflects the medical reasons for requesting the specified tests.
2. The medical necessity and order for each of the individual tests submitted has been appropriately documented in the patient's medical record in your office.
3. Tests will only be ordered when each individual test is medically necessary for the diagnosis and/or treatment of the patient or the criteria in item #5 below are satisfied.
4. You are treating the patient in connection with the diagnoses, complaints or reasons listed on the order/requisition.
5. When ordering tests for screening purposes in asymptomatic patients, you acknowledge that Medicare generally does not cover screening tests. You also acknowledge that you or your staff have informed the patient of this coverage limitation, and that the test requisition clearly indicates the test is being ordered for screening purposes, even if reimbursement by the payer may not be available.
6. Upon request of the hospital or its payers, you agree to provide documentation from your office that reflects that the test ordered was medically necessary for the patient.

In accordance with the Model Compliance Plan, we are also providing you with the Medicare Clinical Laboratory Fee Schedule and informing you that Medicaid reimbursement for laboratory services may be equal to or less than the Medicare reimbursement amount. This information is intended to ensure transparency regarding the federal program reimbursement the hospital receives for the tests you order. You can access the Medicare fee schedule on the CMS website at <http://www.cms.hhs.gov/ClinicalLabFeeSched>.

If you have any questions or wish to discuss appropriate testing and/or ordering, please contact Laboratory Customer Support at 513.569.6345, option 2.

We greatly appreciate your support for our Laboratory Compliance Program. If you have any questions or comments regarding the Laboratory Compliance Program, please do not hesitate to contact one of us at the numbers listed below.

Sincerely,

Brittany Bedel, MHA, MLS (ASCP)<sup>CM</sup>  
System Director, TriHealth Laboratory Operations  
513.290.5234

Sajini Mathew, MD  
Medical Director, TriHealth Laboratories  
513.862.1604

**Medical Directors, TriHealth Laboratories**

**Sajini Mathew MD**—Bethesda North Hospital, Good Samaritan Hospital, TriHealth Anderson, Good Samaritan Western Ridge, TriHealth Kenwood  
**Megan Smith MD**—Bethesda Arrow Springs, Bethesda Butler Hospital, McCullough Hyde Memorial Hospital