08/2021

RE: 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 are able to use multiple methods of ordering laboratory testing from Tampa General Hospital including *Epic, Community Connect and EpicCare Link* are all electronic means available and are all used to screen outpatient laboratory tests for medical necessity. 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 First Coast Service Options, Inc. (FCS), the hospital's Medicare Administrative Contractors. If a particular test that is ordered for a Medicare patient does not meet the NCD or LCD medical necessity guidelines, or is frequency 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 his/her potential financial responsibility for the tests 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 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)
    a. "R/O" and "verify" information is requested for provider communication, but *neither* are acceptable as sole diagnoses.
7. Physician authorization of orders. Written or electronic signature via electronic order entry system is acceptable. Signature stamps are not acceptable. The signature requirement applies only to the original order and not the requisition at the time of this communication.
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.

In order 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 Tampa General Hospital policy on Valid Written Orders, which requires the postponement of services when orders are not valid.

In the event that 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 any time 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.

These panels may be ordered as a whole rather than ordering each test individually when each test is medically necessary. This list includes the name of the panel as it will appear on our requisition and the individual tests that make up the panel. To the extent that you order one of these non-standard panels, the OIG has asked us to advise you of the following:

1. The Medicare program provides separate reimbursement to the laboratory for each individual component contained in the non-standard panel;
2. Ordering non-standard panels may result in the ordering of tests which are not covered, reasonable or necessary and those tests will not be billed to Medicare except for the purpose of receiving a denial; and
3. 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.

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 for accurate reporting of the ordered initial test.

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:

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 you order tests for purposes of screening for asymptomatic patients that you believe are appropriate even though the payor may not allow reimbursement, you acknowledge the fact that Medicare generally does not cover screening tests and that you or your staff have explained this to the patient and the order/requisition notes that the test is for screening purposes.
6. Upon request of the hospital or its payors, you agree to provide documentation from your office that reflects that the test ordered was medically necessary for the patient.

Lastly, the Model Compliance Plan also suggests that we provide you with a copy of the Medicare laboratory fee schedule and advise you that the Medicaid reimbursement amount may be equal to or less than the amount of Medicare reimbursement. This information is being provided to advise you of the federal program reimbursement that the hospital will receive on the tests you order. The Medicare fee schedule may be found on the CMS webpage at http://www.cms.hhs.gov/ClinicalLabFeeSched.
If you have any questions or wish to discuss appropriate testing and/or ordering, please contact the Laboratory Call Center at (813)844-7284.

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