

June 16, 2020

Re: Physician Annual Notice of Laboratory Compliance

Dear Provider:

The United States Department of Health and Human Services, Office of Inspector General (OIG) recommends in its laboratory compliance guidance that laboratories send an annual notice to physicians and other providers advising them of the elements of the laboratory's compliance program. This letter is informational only requiring no action, it serves as Broward Health's annual notice and provides helpful information regarding the ordering and processing of laboratory tests.

Medical Necessity

Broward Health utilizes Pathway Compliance Advisor to screen outpatient laboratory tests for medical necessity. The program screens tests ordered against the diagnoses provided by the provider according to the National Coverage Determinations (NCDs) issued by the Centers for Medicare & Medicaid Services (CMS) and Local Coverage Determinations (LCDs) issued by First Coast Service Options Inc., Broward Health's Medicare Administrative Contractor (MAC). If a particular test does not meet the NCD or LCD medical necessity guidelines, the patient will be provided with an Advance Beneficiary Notice (ABN) which informs the patient of his/her potential financial responsibility for the test if Medicare denies the claim. If the patient decides to receive the service and signs the agreement to pay on the ABN, the claim will first be submitted to Medicare for an initial determination. If Medicare denies the claim, the patient will 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. NCDs and LCDs can be accessed from the CMS webpage, <http://www.cms.gov/center/clinical.asp> under the heading "Coverage".

Laboratory Requisition

To simplify the processing of tests in Pathway Compliance Advisor, we encourage the completion of the hospital's laboratory requisition. However, our laboratories will accept any laboratory requisition or prescription that contains the following information, which is required by Clinical Laboratory Improvement Amendments (CLIA) regulations and/or necessary to screen tests in Pathway Compliance Advisor:

1. The patient's name or other identifier.
2. The name and telephone number or other suitable identifiers of the physician (or other person authorized under state law) 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 reporting of imminent life threatening laboratory test results or critical value.
3. The name and/or CPT code of the test(s) to be performed including the CPT code for each component of any panels ordered. **Broward Health prefers to have both the name and the CPT code.**
4. All of the patient's current ICD-10-CM codes or narrative diagnoses.
5. The date of specimen collection (for pap smears, the date of the last menstrual period, age or date of birth and indication of whether the patient had a previous abnormal result, treatment or biopsy).
6. Additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results as determined by Broward Health. This information should include if appropriate, the source of the specimen and time of collection.
7. The signature of the physician or other person authorized to directly order clinical laboratory tests under state law.

Non-Standard Diagnostic Panels

If a non-standard panel is ordered, the OIG recommends we advise you of the following:

- The Medicare program provides separate reimbursement to the laboratory for each individual component contained in the non-standard panel;
- Ordering non-standard panels may result in the ordering of tests which are not covered, reasonable or necessary and the tests will not be billed except for the purpose of receiving a denial;
- Any individual who knowingly causes a false claim to be submitted may be subject to sanction or remediation available under civil, criminal and administrative law;
- Organ or disease related panels will only be billed and paid when all components are medically necessary.

Reflex tests will be performed as indicated by the results of the initial lab test unless you specifically opt out of the reflex test by noting this on the original order or requisition.

Broward Health's laboratories rely on the following information when we perform tests that you order:

- The information you submit on the requisition or order accurately reflects the medical reasons for ordering the specified tests;
- The medical necessity and order for each of the individual tests have been appropriately documented in the patient's medical record in your office;
- Tests will only be ordered when each individual test is medically necessary for the diagnosis and treatment of the patient;
- You are treating the patient in connection with the diagnosis, complaints or reasons listed on the requisition or order;
- When you order tests for purposes of screening for asymptomatic patients that you believe are appropriate even though the payor may not allow reimbursement, the fact that Medicare generally does not cover screening tests has been explained to the patient and the requisition or order notes that the test is for screening purposes; and
- Upon request of Broward Health or its payors, you agree to provide documentation from your office that reflects that the test was ordered and medically necessary for the patient.

Medicare Fee Schedule

The Medicare Clinical Laboratory Fee Schedule is found on the CMS webpage at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>. Medicaid reimbursement is usually equal to or less than the amount of Medicare reimbursement.

For your convenience, you may contact the Laboratory Clinical Consultant/Laboratory Medical Director at your specific hospital or if you would like additional information on ordering appropriate laboratory tests please contact: Ronald Giffler, M.D., Broward Health Laboratory Medical Director, at 954.977.6977.

Fred W. Reineke, M.D.
Laboratory Medical Director
Broward Health Medical Center
954.355.5594

Marjan Mirzabeigi, M.D.
Laboratory Medical Director
Broward Health North
954.786.7370

Fred W. Reineke, M.D.
Laboratory Medical Director
Broward Health Imperial Point
954.776.8771

Elena Vrotsos, D.O.
Laboratory Medical Director
Broward Health Coral Springs
954-344-3051

We greatly appreciate your support for our laboratory compliance program.

Sincerely,



Brian W. Kozik, CHC, CCEP, CHPC
Senior Vice President
Chief Compliance and Privacy Officer
Broward Health Corporate Compliance



Ronald Giffler, M.D.
Laboratory Medical Director,
Broward Health