BRONSON

Notification Date: March 2, 2022

Laboratory

RE: Laboratory Compliance – OIG Annual Notification

Bronson Healthcare System maintains an active compliance program that reflects our commitment to conduct business in compliance with all federal, state and local laws. As a participant in federally funded healthcare programs, Bronson Lab delivers annual practitioner information and education regarding laboratory compliance, billing and coding guidelines, and to inform our practitioner clients on the responsibilities we share together. This letter serves as the annual notice to provide helpful information regarding compliant ordering and processing of clinical laboratory tests for our shared patient per Medicare/Medicaid program requirements and Bronson Compliance policies.

Medical Necessity

As the practitioner, you are responsible for documenting medical necessity in the patient's medical record, including your signature, and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to Bronson. The Office of Inspector General (OIG) takes the position that a practitioner who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act. Please follow long-standing federal and Bronson policy that patients' medical records must include a valid laboratory order or your signed documentation of medical necessity for ordering tests.

Medicare will only pay for tests that meet the Medicare coverage criteria and are medically necessary for the diagnosis or treatment of the individual patient. Tests used for routine screening of patients without regard to their individual need are not usually covered by the Medicare Program, and therefore are not reimbursed. We expect that you or your staff have explained this to the patient and the order/requisition notes will reflect that the test is for screening purposes.

Valid Lab Orders - Test Order Requisition

To ensure accurate processing and testing, efficient patient identification and timely reporting of laboratory results, **valid laboratory orders** include the following:

- Patient's full legal name, date of birth, ICD-10 or diagnostic narrative for tests ordered, collection date and time, source (when applicable), and the licensed ordering practitioner's name and signature.
- Although the practitioner signature is not currently required on laboratory requisitions, when signed, the requisition will serve as acceptable documentation of a practitioner order for the testing.
- In the absence of a signed requisition, documentation of your intent to order each laboratory test must be included in the patient's medical record and available to Bronson upon request. (Signature stamps are NOT acceptable).
- Custom and/ Reflex custom Profiles may be used if patient specific medical necessity is recorded in the patient's medical records and clearly marked on the Test Order Requisition.
- Documentation must accurately describe the individual tests ordered; it is not sufficient to state 'labs ordered'.

The test order requisition – electronic or printed - is the tool used to communicate your valid order to the laboratory but is NOT considered the 'valid order' as defined by Medicare. Upon request by Bronson or its payers/auditors, ordering practitioners are required to provide any/all chart documentation, including practitioner signature that reflects the actual lab order and supports the authenticity and medical necessity of the lab order(s) submitted. **Please complete the test order requisition each time with the required information as detailed above.**

If Bronson receives an incomplete order requisition form, the processing of your test order may be delayed. To meet mandated valid order data requirements, Bronson will contact practitioner to clarify or provide missing elements.

Custom Panels
The American Medical Association has grouped certain tests into panels for coding purposes only. In addition to those approved panels, Bronson Laboratory offers a set of non-standard diagnostic panels approved by our Medical Executive Committee. The list of both panels, AMA approved and non-standard, can be found at the end of this correspondence and also online in the Bronson Lab Catalog under Laboratory Compliance: Annual Practitioner Notification, http://bronsonlab.testcatalog.org/.

These panels may be ordered as a whole rather than ordering each test individually as long as each test is medically necessary. 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;
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
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. A list of Bronson Laboratory reflex tests can be found at the end of this correspondence under "Additional Panels Offered at Bronson Laboratory" or online within the Bronson Lab Catalog under Laboratory Compliance: Annual Practitioner Notification, http://bronsonlab.testcatalog.org/.

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 federal program reimbursement the hospital will receive on tests you order. The Medicare fee schedule may be found on the CMS webpage at http://www.cms.hhs.gov/ClinicalLabFeeSched.

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.

Sincerely,

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