



## 2024 Annual Physician Notice of Laboratory Compliance

To our Valued Healthcare Partners:

HealthTrackRx, Inc. ("HealthTrackRx"), 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, HealthTrackRx delivers annual provider information and education regarding laboratory compliance, billing and coding guidelines, and information to our provider clients on the responsibilities we share.

This physician annual notice specifies current Medicare/Medicaid program requirements and HealthTrackRx policies. HealthTrackRx also offers an anonymous hotline for reporting any compliance concerns and can be accessed using the following methods:

Toll Free Number: (833)255-7337

Website: <http://healthtrackrx.ethicspoint.com/>

HealthTrackRx must rely on you, our provider clients, for the following key compliance elements:

### Licensed Physicians and Non-Physician Practitioners (NPP)

A clinical laboratory may only bill Medicare and Medicaid for testing ordered by a licensed physician or NPP authorized by law to order laboratory tests. If your license has been revoked or suspended, please immediately notify the laboratory. Medicare requires individuals referring orders for laboratory services for Medicare beneficiaries to be registered in the Center for Medicare and Medicaid Services' Provider Enrollment, Chain and Ownership System (PECOS). Information on PECOS may be viewed at: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/InternetbasedPECOS.html>

### Medical Necessity

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. Criteria to establish medical necessity for testing must be based on patient-specific elements identified during the clinical assessment and documented by the clinician in the patient's medical record. Tests used for routine screening of patients without regard to individual need are not usually covered by the Medicare Program, and therefore are not reimbursed. As a participating provider in the Medicare Program, HealthTrackRx has a responsibility to make a good faith effort to ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations. *As the ordering physician or NPP, you are responsible for documenting medical necessity in the patient's medical record (including the intent to order or authorized ordering party signature) and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to HealthTrackRx. The Office of Inspector General takes the position that a physician or NPP who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.*

Recent policy changes and health plan actions, including increased use of post-payment audits, has encouraged HealthTrackRx to more aggressively enforce long-standing policies that patients' medical records must include documentation of medical necessity for ordering tests. Though this is specified in each HealthTrackRx *Practitioner Acknowledgement Form* that is signed by the provider and filed with HealthTrackRx we are also educating any provider that is currently using HealthTrackRx as the Reference Laboratory. Client Web Portal ("CWP") Personalized Menu Selection may be used if patient specific medical necessity is recorded clearly in the patient's medical records and reflected clearly on the Test Order Requisition.

It is important for you, as an ordering provider, to stay aware of medical coverage policy changes in regards to the HealthTrackRx testing that you order.

### Test Order Requisition

The HealthTrackRx test requisition is designed to encourage physicians or NPPs to order only those tests which are appropriate and medically necessary for the treatment and diagnosis of each patient. If HealthTrackRx receives a non-HealthTrackRx requisition form or an incomplete HealthTrackRx requisition form, processing of your test order may be delayed. As necessary, HealthTrackRx will contact physicians and NPPs to have them resubmit the test order on a HealthTrackRx test requisition form or otherwise clarify each specific test being ordered. To ensure accurate processing and testing, efficient patient identification, and timely reporting of laboratory results, valid laboratory orders must include the following:

- patient's full legal name,
- date of birth,
- reason for each test ordered,
- date and, if appropriate, time of collection,
- specimen source (when applicable),
- diagnosis code(s), and
- the licensed ordering physician's or NPP's name and address.

Handwritten orders must be signed and dated by the ordering physician or NPP. Signature stamps are NOT acceptable.

Although the physician or NPP signature is not required on laboratory requisitions, if signed, the requisition will serve as acceptable documentation of a physician's or NPP's intent to order the testing and so is strongly encouraged. 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 HealthTrackRx upon request, as needed. Documentation must accurately describe the individual tests ordered; it is not sufficient to state 'labs ordered.'

Upon request by HealthTrackRx or its payers/auditors, ordering providers are required to provide any/all chart documentation (including physician or NPP intent to order) that reflect the actual lab order and



supports the authenticity and medical necessity of the lab order(s) submitted. By signing and submitting a valid laboratory order, you agree to provide applicable medical records to HealthTrackRx upon request to support clinical review of claims as requested by Medicare or other health plans.

### Verbal Test Orders

Medicare regulations require that all orders for laboratory tests be in writing. If a physician, NPP, or his/her authorized representative orders a test by telephone or wishes to add a test to an existing order, a written order is required to support the verbal order. In these cases, HealthTrackRx will send a confirmation of the verbal order request to the ordering physician or NPP, requesting it to be signed and sent back to the laboratory for its records. Testing will not be performed until the signed confirmation or a properly completed HealthTrackRx requisition form is returned to the laboratory.

### ABN

If a physician or NPP requests a test for a Medicare beneficiary and reports a 'non-covered' diagnosis, the patient must be notified prior to specimen collection and given the opportunity to sign the Advance Beneficiary Notice (ABN). The ABN must be completed for any Medicare patient where claim denial is anticipated based on medical necessity, frequency limitations or other Medicare policy. Medicare does not cover most routine screening tests. The signed, original ABN must be attached to the original lab order prior to submission. Per Medicare rules, routine provision of the ABN on all Medicare beneficiaries is considered an unacceptable practice. Please use ABN Form CMS-R-131 and check the expiration date located in the lower left-hand corner of the ABN, to assure the most current version of the form is being utilized when an ABN is necessary for a Medicare beneficiary.

Information about ABNs may be viewed at:

<https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN>

### Patient Privacy (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), HealthTrackRx is a health care provider and a covered entity. It is our policy to comply with the letter and intent of the HIPAA privacy and security standards. Our privacy policy is available at <https://www.healthtrackrx.com/privacy-statement/>.

### Prohibited Referrals & Inducements

It is the policy of HealthTrackRx to comply with all aspects of the Physician Self-Referral Law (Stark) and the federal Anti-kickback Statute. The Stark Law's self-referral ban states that if a financial relationship exists between a physician (or an immediate family member) and a laboratory and the relationship does not fit into one of the law's exceptions, then (a) the physician may not refer Medicare patients to the laboratory and (b) the laboratory may not bill Medicare for services referred by the physician. A financial relationship is construed very broadly to mean all remuneration from a lab to a physician, including in-kind compensation.

The Anti-kickback Statute prohibits offering or paying remuneration-meaning anything of value- to induce the referral of tests that are covered by Medicaid, Medicare or other federal health care programs. Any form of kickback, payment or other remuneration that is intended to secure the referral of federal health care program testing business is strictly prohibited. Any concerns about compliance with these laws should be reported to the HealthTrackRx Compliance Hotline by calling 844-990-0002. Additional information on these laws can be found on the Office of Inspector General's Physician Education website: <https://oig.hhs.gov/compliance/physician-education/>

### Clinical Consultants

Physicians and NPPs have access to the services of clinical consultants available to answer questions and provide guidance on proper test ordering. They may be reached at 940-435-0242.

### To ensure compliance with applicable coverage and reimbursement laws, please be sure to:

1. Order only those tests necessary for diagnosis or treatment of a specific patient. Each component of a testing panel must be medically necessary in order for the panel to qualify for Medicare reimbursement.
2. Provide a diagnosis, sign or symptom for each test ordered
3. Document this information in the patient's medical record followed by the ordering physician's signature
4. Obtain an ABN from Medicare patients when tests do not meet the medical necessity or other coverage criteria.
5. Provide medical records to HealthTrackRx upon request for Medicare or health plan review of claims

### Medicare National and Local Coverage Determinations

The Medicare Program publishes National Coverage Determinations (NCDs) and local Medicare contractors publish Local Coverage Determinations (LCDs) for certain tests. These policies identify the conditions or other circumstances, including diagnosis codes, for which the included tests are or are not covered or reimbursed by Medicare. Further information can be found at the following website:

<https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>

### CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury. Code of Federal Regulations (CFR) Title 42 § 410.32 indicates that diagnostic tests may only be ordered by the treating physician (or NPP acting within the scope of his or her license and Medicare requirements) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician or NPP who is treating the beneficiary are not reasonable and necessary (see 42 CFR § 411.15(k)(1)). Except where authorized by statute, Medicare does not cover diagnostic testing used for



routine screening or surveillance. Medicare's Clinical Laboratory Fee Schedule (CLFS), including all CPT codes, can be found at:

<https://www.cms.gov/medicare/medicare-fee-for-service-payment/clinlabfeesched/clinical-laboratory-fee-schedule-files>

Thank you for your attention to and collaboration on these important compliance topics. If you have any questions, please feel free to contact our Compliance Department at 866-287-3218 or [compliance@healthtrackrx.com](mailto:compliance@healthtrackrx.com).